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Viewpoint

Exploring the Use of Activity Trackers to Support Physical Activity and Reduce Sedentary Behavior in Adults Diagnosed With Type 2 Diabetes: Qualitative Interview Study Using the RE-AIM Framework

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Abstract

Background: The prevalence of type 2 diabetes in adults worldwide is increasing. Low levels of physical activity and sedentary behavior are major risk factors for developing the disease. Physical activity interventions incorporating activity trackers can reduce blood glucose levels in adults diagnosed with type 2 diabetes. The My Diabetes My Way website is a support and educational platform for people diagnosed with diabetes and health care professionals. Users of the My Diabetes My Way website can upload their Fitbit (Google Inc) activity data into the system but this is not presently being analyzed and used routinely within clinical care. Developers of the My Diabetes My Way system are planning to allow different makes of activity trackers to be integrated with the platform.

Objective: This qualitative study aimed to explore (through the RE-AIM [reach, effectiveness, adoption, implementation, and maintenance] framework) views from adults diagnosed with type 2 diabetes and health care professionals on the integration of activity trackers into type 2 diabetes care.

Methods: Overall, 12 adults diagnosed with type 2 diabetes and 9 health care professionals (4 general practitioners, 1 consultant, 2 diabetes nurses, 1 practice nurse, and 1 physical activity advisor) were recruited through social media and professional contacts. Semistructured one-to-one interviews were conducted. Abductive thematic analysis was undertaken, and main themes and subthemes were identified. The RE-AIM framework was used to evaluate the themes with respect to the wider use of activity trackers and the My Diabetes My Way platform within type 2 diabetes clinical care.

Results: Overall, 6 main themes (awareness, access, cost, promotion, support, and technology and data) and 20 subthemes were identified. Evaluation using the 5 RE-AIM dimensions found that reach could be improved by raising awareness of the My Diabetes My Way platform and the ability to upload activity tracker data into the system. Effectiveness could be improved by implementing appropriate personalized measures of health benefits and providing appropriate support for patients and health care staff. Adoption could be improved by better promotion of the intervention among stakeholders and the development of joint procedures. Implementation could be improved through the development of an agreed protocol, staff training, and introducing measurements of costs. Maintenance could be improved by supporting all patients for long-term engagement and measuring improvements to patients' health.

Conclusions: Through this study, we identified how the reach, effectiveness, adoption, implementation, and maintenance of integrating activity trackers into adult type 2 diabetes care could be improved.

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KEYWORDS

type 2 diabetes; physical activity; sedentary behavior; Fitbit; activity tracker; My Diabetes My Way; RE-AIM framework; diabetes care; clinical care; thematic analysis; health promotion

Introduction

Type 2 diabetes mellitus is a noncommunicable disease. Worldwide it is estimated that 483 million adults (20 - 79 years of age) are living with type 2 diabetes [1]. By 2045, this number is estimated to rise to 705 million [1]. Annually 6 million adults die, prematurely due to type 2 diabetes [1]. In the United Kingdom, 5 million adults have been diagnosed with type 2 diabetes and the care costs for the National Health Service (NHS) are approximately £12 billion (US $15 billion) each year [2]. Major risk factors for developing type 2 diabetes include low levels of physical activity and sedentary behavior [2]. Adults diagnosed with type 2 diabetes have been found to be less physically active and spend more time engaged in sedentary behavior than those without the disease [3]. Physical activity even at low levels of intensity and reducing sedentary behavior can improve blood glucose levels in adults diagnosed with type 2 diabetes [4-7].

Physical activity interventions involving the use of activity trackers have been shown to increase physical activity and reduce sedentary behavior in adults diagnosed with type 2 diabetes [8]. Activity trackers are technological devices designed to measure the users' steps, distance moved, physical activity intensity, and sedentary behavior [9]. Fitbit (Google Inc) consumer activity trackers are a valid and reliable method of measuring physical activity (steps, distance walked, energy expenditure, physical activity intensity, and sedentary behavior). When compared with laboratory-based tests of physical activity, Fitbit activity trackers have been shown to have large significant correlation coefficients of between 96.5 and 99.1 [10]. Recent discussions have suggested that national physical activity guidelines should be formulated around activity tracker measured physical activity rather than self-reported data, which tends to over or underestimate the users' activities [11].

My Diabetes My Way is a web-based support and educational platform for diabetes patients and their health care professionals. The website allows users to access their patient records including prescribed medication and blood glucose measurements. The My Diabetes My Way website includes basic physical activity advice for patients though this element of the system is used less than other content [12]. Since 2019, patients have been able to upload their Fitbit activity data into the My Diabetes My Way platform. The developers of this platform state that there is an appetite for the linking of further makes of activity trackers, mobile apps, and web-based tools [13]. Users of My Diabetes My Way have shown a desire for uploading physical activity data into the system from alternative commercial activity trackers and mobile apps [13]. However, very little is known about if and how patients and health care professionals use the activity trackers in combination with web-based systems like the My Diabetes My Way platform to support the patients' physical activity and reduce their sedentary behavior. Increasing our understanding of potential barriers and facilitators to the use of activity trackers and technology such as the My Diabetes My Way platform from both patients and health professionals will enable future improvement and development of digital health platforms and technologies to improve the clinical care of adults diagnosed with type 2 diabetes.

One way to evaluate the use of activity trackers is by using the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework. RE-AIM is a planning and evaluation framework used to improve the adoption and sustainable implementation of a wide range of evidence-based interventions including health-related interventions. The main RE-AIM dimensions are reach, effectiveness, adoption, implementation, and maintenance [14]. Reach is defined as the absolute number, proportion, and representativeness of individuals participating in a given initiative. Effectiveness is the impact of an intervention on outcomes, including potential negative effects, quality of life, and health components. Adoption is the proportion, representativeness, and absolute number of organizational agents involved in the intervention. Implementation is set at an organizational level and how the program was delivered by staff. Maintenance is defined as the extent to which a program or policy becomes embedded in routine practice. At an individual level, maintenance is a measure of the long-term impact of an intervention over 6-months [15].

This qualitative study aimed to explore (through the RE-AIM framework) views from adults diagnosed with type 2 diabetes and health care professionals on the integration of activity trackers into type 2 diabetes care. This study highlights how the integration of activity trackers into the My Diabetes My Way platform and general type 2 diabetes clinical care can be improved.

Methods

Ethical Considerations

Ethical approval for this qualitative interview study was obtained from the ethics committee of the University of Strathclyde (approval number 2021). For the study, both adults diagnosed with type 2 diabetes and health care professionals were provided with web-based participant information sheets. Informed consent was demonstrated by the digital signing of a consent form. Participants electronically selected individual items in the digital form, corresponding to the paper consent form, in order to confirm they had read and agreed with each item. Their electronic signature was achieved by entering their allocated 4-digit identification number. The research team undertook a number of steps to ensure the security of the information collected. To ensure anonymity each participant was allocated a unique 4-digit identification number and all data were stored under this number. Any information stored by the research team was stored within the university-approved, password-protected encrypted storage sites. Participants involved in this study received no form of compensation for taking part.

Participants

Adults Diagnosed With Type 2 Diabetes

Participants (n=12) were recruited through social media posts (via Facebook and Twitter). Recruitment inclusion criteria included adults aged 18+ years, diagnosed with type 2 diabetes, residing in the United Kingdom, and able to read and write in English. Exclusion criteria included any other type of disease not listed in the inclusion criteria and any people aged out with

the defined age bracket. The study participant information sheet and consent form were uploaded into the secure Qualtrics survey system. A link to this form was emailed to participants and their consent was recorded by indicating "yes" on the Qualtrics consent form. Once consent was received, participants were emailed a link to a baseline questionnaire on the Qualtrics system. This questionnaire gathered demographics, educational level, activity tracker use, and who if anyone provides physical activity advice within the person's clinical care.

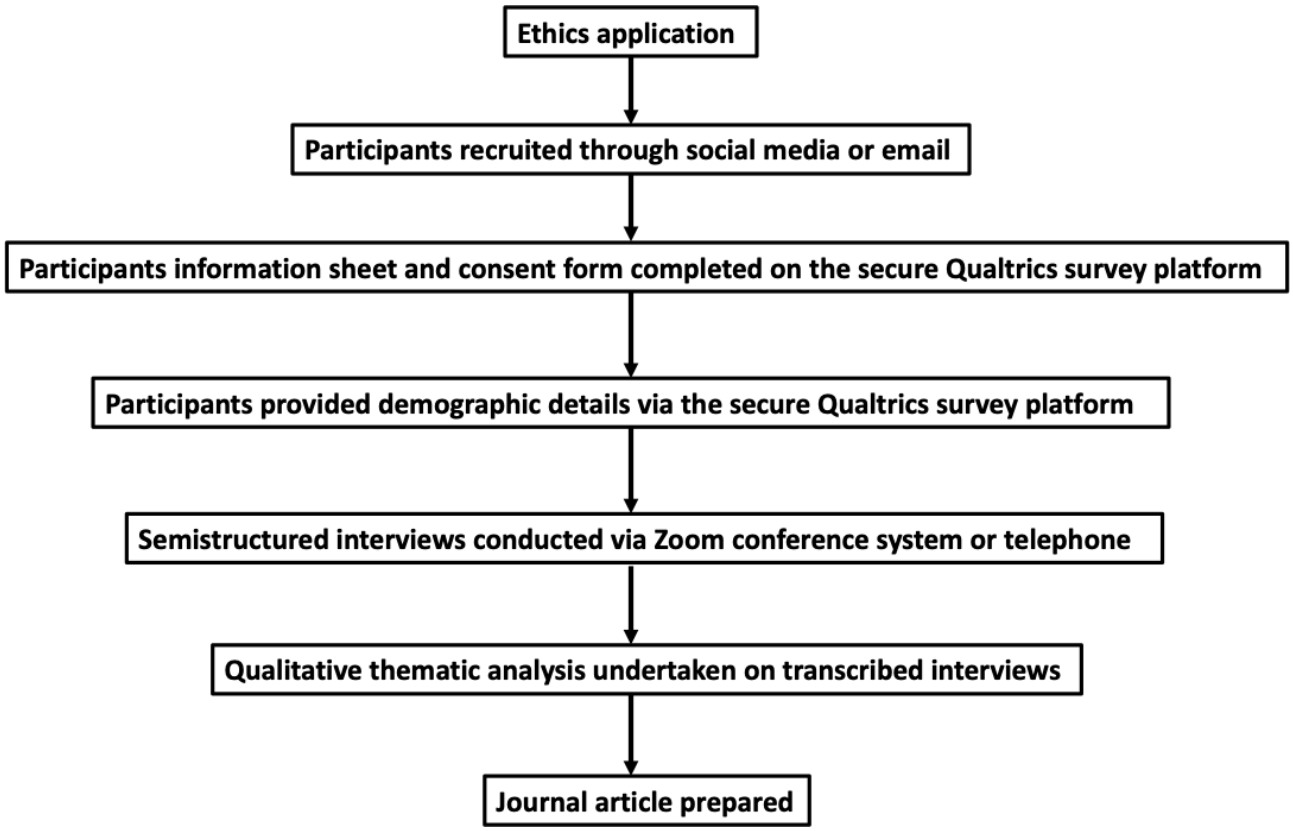
Health Care Professionals

Participants (n=9) were recruited through university contacts (via email) and social media posts (via Facebook and "X"). Recruitment criteria included adults aged 18+ years, residing in the United Kingdom, and experience of type 2 diabetes health care or physical activity for health. The study participant information sheet and consent form were uploaded into the secure Qualtrics survey system. A link to this form was emailed to participants and their consent was recorded. Once consent was received, a link to a questionnaire on the Qualtrics survey system to collect information on demographic and job role characteristics was emailed to participants.

Procedure

A summary of the study procedures are provided in Figure 1.

Figure 1. Flow diagram of study procedures.



Data Saturation

Initially, participant numbers were set at 15 for each group (type 2 diabetes participants and health care professionals). Data saturation was undertaken using the "stopping criterion" [15]. Participant interview saturation was reached when no new codes were identified [16]. All consented participants were retained with none dropping out.

Semistructured Interviews

One-to-one interviews were conducted with all participants. A semistructured interview schedule was prepared to focus on the 5 RE-AIM dimensions of reach, effectiveness, adoption, implementation, and maintenance. Interviews were conducted either over the telephone or via the secure Zoom conferencing platform. Each interview was recorded via a secure encrypted dictaphone. An abductive interview technique was used which started with the main RE-AIM dimension and worked down into the participants' lived experiences in more detail [17]. Each interview was later transcribed verbatim from the dictaphone recording.

Analysis

NVivo 12 (Lumivero) software was used to manage the data and support the thematic analysis. All transcribed interviews were uploaded into this platform. A thematic analysis plan was developed which incorporated the 6-stage process recommended by Braun and Clarke [18]. The 6-stages are data familiarization (repeated reading of the transcripts), initial coding (identification of words or sentences connected to the analysis), initial development of themes (combining of codes into themes), review of identified themes, naming, and finalization of themes and preparation of the final journal article. The thematic analysis was conducted by the lead author (WH) and cross-checked by the 3 coauthors (AK, ML, and XJ). Differences in thematic and code names or meanings were resolved via discussion between these 3 researchers and the lead author.

Results

Participant Demographics

Participant demographics are displayed in Table 1.

Table . Participant demographics.

		Adults diagnosed with type 2 diabetes (n=12)	Health care professionals (n=9)
Gender, n			
	Female	8	5
	Male	4	4
Age (years), mean (SD)		53.17 (11.18)	52.57 (7.59)
Diagnosed with type 2 diabetes (years), mean (SD)		8.42 (6.76)	—[a]
Education, n			
	Degree	5	8
	Higher education	5	1
	School qualifications	2	0
Ethnicity, n			
	White	10	8
	Black	2	0
	Asian	0	1
Country of residence, n			
	Scotland	10	8
	England	2	1
Home setting, n			
	Rural	2	4
	Urban	10	5
Used an activity tracker before the study, n			
	Fitbit	3	—
	None	9	—
Physical activity advice in clinical care, n			
	General practitioner	2	—
	Diabetes nurse	5	—
	Practice nurse	1	—
	Diabetes consultant	1	—
	Cancer nurse	1	—
	None	2	—
Role in clinical care, n			
	General practitioner	—	4
	Consultant	—	1
	Diabetes nurse	—	2
	Practice nurse	—	1
	Physical activity advisor	—	1

[a]Not applicable.

Findings

Abductive thematic analysis of interviews with adults with type 2 diabetes and health care professionals identified 6 main themes and 20 subthemes. These are displayed in Table 2 and discussed in more detail below.

Table . Thematic analysis of main themes and subthemes.

Main themes (n=6)	Subthemes (n=20)
Awareness	• My Diabetes My Way • Benefits of activity tracking • Benefits to health
Access	• Activity trackers • Digital literacy barriers
Cost	• Activity trackers • Internet access • Digital technology • Health care staff
Promotion	• Signposting • Knowledge and credibility
Support	• Advice • Gym referrals • Data interpretation • Educational packages
Technology and data	• Feedback • Personalization • Motivation • Data management • Fitbit functions

Awareness

My Diabetes My Way

The majority of adults diagnosed with type 2 diabetes stated that they were not aware of the My Diabetes My Way platform and that it had not been discussed during consultations with a health care professional. For those registered on the platform, only one was aware of the ability to upload the Fitbit data into the system.

> *I am not aware of this website…* [Male, 61 years of age]
>
> *I am registered but did not know you could upload your Fitbit activities.* [Female, 44 years of age]

Health care professionals discussed awareness of the My Diabetes My Way platform and the ability to upload Fitbit data into the system. The majority of health care professionals were aware of the platform but none knew that users could upload the Fitbit data.

> *I have limited knowledge of My Diabetes My Way and certainly did not know you could upload Fitbit data. This needs to be addressed by making staff aware.* [Female, 57 years of age]
>
> *I would say not aware. I have been using this system for a while and was not aware that Fitbit data could be uploaded.* [Female, 61 years of age]

Benefits of Activity Tracking

Awareness of the benefits of tracking physical activity through activity trackers was discussed. Adults diagnosed with type 2 diabetes suggested that these devices would provide the user and health care professionals with an accurate indication of an individual's physical activity.

> *… monitoring a patients levels of activity. If these are low then they could be directed towards information on exercise or local classes.* [Male, 37 years of age]

Health care professionals discussed the benefits of using activity trackers in clinical care. The ability to monitor a patient's physical activity and provide appropriate advice and support was identified as the main benefit.

> *The first would be to see how active a patient is. After that advice can be given on appropriate exercise activities which can then be further monitored.* [Male, 52 years of age]
>
> *The activity tracker could form part of a physical activity intervention which would include advice and attending exercise classes.* [Male, 43 years of age]

Benefits to Health

Awareness of the benefits of using activity trackers to improve the health of users was explored. Adults diagnosed with type 2 diabetes stated that these devices could increase user's physical activity and reduce sedentary behavior which would improve the health of the individual.

> *It would give me a better understanding of how active I am and this may motivate me to do more physical activity and improve my overall health.* [Female, 46 years of age]

Health care professionals discussed the benefits to a patient's health if activity trackers were used in the clinical care of adults diagnosed with type 2 diabetes. Improved health was highlighted as the main benefit which would reduce the need for medical treatment.

> *Long term this would benefit the patient's health with less reliance on medication and treatment for related health conditions.* [Male, 52 years of age]

Access

Activity Trackers

Adults diagnosed with type 2 diabetes discussed how clinical care providers could gain access to activity trackers. It was suggested that these devices could be prescribed by the health care provider and used as part of a patient's treatment plan.

> *The tracker could be prescribed on the NHS especially for those on low incomes.* [Female, 57 years of age]

Health care professionals discussed how patients could access an activity tracker as part of their clinical care. It was suggested that these devices could be prescribed by a health care professional.

> *Prescribing an activity tracker could help motivate a patient to be more active.* [Female, 61 years of age]

Digital Literacy Barriers

Access to the My Diabetes My Way platform was discussed during interviews with adults diagnosed with type 2 diabetes. It was suggested that accessibility could be improved by a health care professional providing clear guidance and instructions on how to register for this service, especially for people with limited information technology skills.

> *I am not confident using computers and would need my GP or the practice nurse to provide me with support so I can register for this website.* [Male, 61 years of age]

Health care professionals discussed the digital literacy barriers that may prevent a patient from accessing and using information technology as part of their clinical care. It was suggested that those with limited digital skills and confidence in using technology would need support and training.

> *Some of my patients are uncomfortable using technology and would need support.* [Male, 43 years of age]

Cost

Activity Trackers

Adults diagnosed with type 2 diabetes discussed the costs with respect to purchasing an activity tracker. The majority of those interviewed said they would pay for a device if it was to form part of their type 2 diabetes care. If prescribed by a health care professional, the cost would be covered by the NHS though some suggested that with stretched budgets this may not be possible.

> *I would be happy to pay for the activity tracker though not everyone can afford them.* [Female, 72 years of age]
>
> *Cuts in funding may prevent the NHS from giving these devices to patients.* [Female, 46 years of age]

Health care professionals discussed the cost of purchasing an activity tracker. It was suggested that those who can afford the device should pay for it. If bought by the health care provider in bulk, the cost could be reduced for the patient. For those on a limited budget, the activity tracker could be prescribed.

> *Our resources are stretched and those who can afford a Fitbit should pay for it. We could prescribe the Fitbit if the patient is on a low income.* [Male, 43 years of age]

Internet Access

Adults diagnosed with type 2 diabetes discussed the costs associated with internet access. Those interviewed stated that they had to pay an internet provider for home access and that would be required to access their activity tracker data and the My Diabetes My Way platform. It was suggested that those on low incomes may need financial support to access the internet at home.

> *Costs could also include accessing the internet.* [Male, 61 years of age]
>
> *Not everyone can afford internet access so they may need help to pay for this.* [Female, 44 years of age]

Health care professionals discussed the cost implications of accessing the internet. It was suggested that those on limited incomes may need support with the costs. Poor internet coverage in rural areas could also increase access costs and make it difficult for people in these locations to use technology in clinical care.

> *Not all of my patients can afford internet access.* [Male, 43 years of age]
>
> *Basic internet access is poor on the island. More efficient systems are expensive.* [Female, 57 years of age]

Digital Technology

Adults diagnosed with type 2 diabetes discussed the costs associated with purchasing digital technology. They indicated that either a smartphone or computer would be needed to access activity tracker data and the My Diabetes My Way website. For those on low incomes, such devices could be prescribed by the NHS.

> *Another cost would be buying a mobile phone or laptop. I already have these but some may struggle to afford them.* [Female, 41 years of age]

Health care professionals discussed the costs associated with purchasing digital technology. It was highlighted that for patients to upload activity tracker data into the My Diabetes My Way platform they would need to have either a smartphone or

computer. Patients on lower incomes may need support with the cost of these items.

> *In addition to the activity tracker users would have to have a mobile phone or PC. Not all of my patients can afford these items.* [Female, 61 years of age]

Health Care Staff

Adults diagnosed with type 2 diabetes discussed the cost implications with respect to health care staff if activity trackers are used as part of type 2 diabetes treatment. The main costs identified included staff training and staff time.

> *This will be their time and training on how to use the activity tracker.* [Female, 72 years of age]

Health care professionals discussed the costs associated with being health care professionals. The main costs identified were staff time and training.

> *The main costs for our practice would be our time and any training to improve or knowledge and understanding.* [Male, 53 years of age]

Promotion

Signposting

Adults diagnosed with type 2 diabetes discussed the promotion of the My Diabetes My Way platform and how this could be signposted. Awareness of the system was low and it was indicated that better signposting by health care professionals was required. Suggested methods of communication were face-to-face consultations, posters in health service clinics, leaflets, SMS text messages, telephone calls, and emails.

> *During a face-to-face consultation with a medical practitioner.* [Female, 57 years of age]
>
> *Other methods of promotion could be a telephone call from my diabetes nurse or an information leaflet when I attend the clinic.* [Female, 41 years of age]

Health care professionals discussed the promotion of My Diabetes My Way and the ability to upload activity tracker data into the system. It was suggested that signposting should be the responsibility of the health care provider and make all staff aware. Promotion should be undertaken during face-to-face consultations between the patient and health care professional. Staff could be made aware during team meetings and work emails.

> *I would prefer to promote these during my consultation with the patient.* [Male, 42 years of age]
>
> *I would make all our practice staff aware during team meetings or email.* [Female, 57 years of age]

Knowledge and Credibility

Adults diagnosed with type 2 diabetes discussed the importance of the knowledge and credibility of health care staff when promoting the use of technology in clinical care. In recommending such technology, the health care staff should understand how it works, the benefits, and the ability to fully support the patient.

> *The health care professional promoting should fully understand how the technology works.* [Male, 37 years of age]
>
> *The doctor or nurse should highlight the benefits of the technology during consultations with the patient.* [Female, 47 years of age]

Health care professionals discussed the importance of health care professionals being credible and knowledgeable of any technology promoted. It was suggested that health care staff would need appropriate training to gain a full understanding before discussing and promoting information technology to a patient.

> *I would need to ensure that we all had necessary training before discussing with a patient.* [Male, 42 years of age]

Support

Advice

Adults diagnosed with type 2 diabetes discussed the advice and support patients may require when using an activity tracker or the My Diabetes My Way platform. The main advice focused on individuals who possess low information technology skills and confidence in using such systems. Further advice in relation to exercise and physical activity was suggested.

> *I am not confident using computers and would need plenty of advice on how to use them.* [Female, 72 years of age]
>
> *More advice on exercise and weight which I have not received during my treatment.* [Female, 57 years of age]

Health care professionals discussed the advice patients may require to support them when using an activity tracker and the My Diabetes My Way platform as part of their type 2 diabetes treatment. The suggested advice included how best to access and use the technology.

> *Probably like my gym work sitting down with the patient and talking them through the process, identifying their needs and encouraging them.* [Male, 43 years of age]
>
> *Many of my elderly patients would need advice to support them using these systems.* [Female, 62 years of age]

Gym Referrals

Adults diagnosed with type 2 diabetes discussed the additional support they would need to compliment the use of activity trackers as part of their type 2 diabetes care. The majority stated that being prescribed a gym referral would motivate them to be more physically active.

> *It would be nice to get directed to specific exercise classes for those diagnosed with type 2 diabetes.* [Female, 46 years of age]

Health care professionals discussed the prescription of gym referrals to support the use of activity trackers in clinical care. The majority of health care professionals stated that prescribed

gym referrals were already used to support adults diagnosed with type 2 diabetes. Some suggested that the gym referral through an exercise professional should incorporate an input about activity trackers.

> *I already refer patients to the local gym. The fitness advisor would be the best person to show the patient how to use the activity tracker.* [Female, 61 years of age]

Data Interpretation

Adults diagnosed with type 2 diabetes discussed the support patients may need to interpret the data collected on an activity tracker. It was suggested that health care professionals with knowledge of exercise and activity trackers should conduct the interpretation and communicate this to the patient.

> *I would suggest a dedicated member of staff with knowledge of activity trackers and exercise. At the moment activity advice is limited and only occasionally discussed. The main focus is on medication and diet.* [Female, 56 years of age]

Health care professionals discussed the support patients would need to interpret the data collected from the activity tracker. It was suggested that this support would be best delivered by a qualified health care professional with knowledge of physical activity and exercise.

> *Ideally our health authority would employ fitness instructors.* [Male, 53 years of age]

Educational Packages

Adults diagnosed with type 2 diabetes discussed the support in the form of educational packages that could be developed and deployed to assist patients to use activity trackers and the My Diabetes My Way platform effectively. It was suggested that the packages could be delivered online or booklet or face-to-face educational class.

> *Some type of educational support package would assist patients to use technology in an effective manner.* [Male, 37 years of age]

Health care professionals discussed patient support in the form of educational packages. It was suggested that these packages could be self-read or delivered in a classroom setting.

> *Additional support packages could be produced or we could run special classes to support the patient.* [Female, 61 years of age]

Technology and Data

Feedback

Adults diagnosed with type 2 diabetes discussed how feedback from activity tracker data could be communicated and by who. The majority suggested the feedback should be delivered during a face-to-face consultation with a health care professional. Some proposed that when activity data was uploaded into the My Diabetes My Way platform the system interpreted the information and provided immediate feedback and advice.

> *I would prefer my GP or the practice nurse to give me feedback from my activity data.* [Female, 57 years of age]

> *I have uploaded my Fitbit data onto MY Diabetes My Way. It would be great if the system would give me advice when I do this.* [Female, 41 years of age]

Health care professionals discussed how best feedback from technology can be communicated to the patient. It was suggested that in the majority of cases this would be best served during face-to-face consultations. With respect to the My Diabetes My Way platform, participants proposed that the system analyzes the uploaded Fitbit data and provides feedback directly to the patient.

> *Most patients would prefer feedback delivered by a health care professional.* [Female, 62 years of age]

> *Would it be possible for the website to feedback on the Fitbit information.* [Male, 43 years of age]

Personalization

Adults diagnosed with type 2 diabetes discussed how data collected from an activity tracker and interpreted should be personalized for the user during the feedback process. This should take into account the patients' medical history and understanding of physical activity.

> *I would like any feedback to be personalised for my needs.* [Female, 44 years of age]

Health care professionals discussed the personalization of data obtained through technology. It was suggested that as each patient has differing needs and goals the collected data should be personalized for the individual.

> *After analysis I would personalise the feedback for the patient.* [Female, 61 years of age]

Motivation

Adults diagnosed with type 2 diabetes discussed the motivational aspect of using data from technology in clinical care. Some suggested that activity trackers could motivate users to be more physically active. Before there, use participants said that users must be motivated to engage with the technology.

> *My Fitbit has certainly motivated me to be more active.* [Female, 41 years of age]

> *Before using an activity the user must be motivated to engage with it.* [Male, 61 years of age]

Health care professionals discussed how activity trackers could act as a motivational tool for patients. For this to be effective, it was highlighted that the patient would need to engage with the intervention for this to be successful.

> *I can see these devices motivate some people to be more active. Saying that the patient always need to engage with any treatment plan.* [Male, 52 years of age]

Data Management

Adults diagnosed with type 2 diabetes discussed who should manage the data obtained from activity trackers and stored on

the My Diabetes My Way platform. All suggested that a health care professional such as the patient's doctor, practice nurse, and diabetes nurse should have responsibility for managing the storage and use of the data.

> *This would be my GP or the practice nurse.* [Male, 37 years of age]

Health care professionals discussed the management of any data collected from patients. It was suggested that this must follow national guidelines and policies for health care organizations. Such data should be managed by the local health authority.

> *Any data collected from patients must be stored and managed as per NHS policy.* [Female, 61 years of age]

Fitbit Management

Adults diagnosed with type 2 diabetes discussed the available activity tracker functions. For those with knowledge of these devices, the preferred functions were daily steps, distance moved, challenges, and sleep.

> *For me it is daily steps and distance travelled. Sleep is also interesting though I don't bother too much about it unless I have a poor night's sleep.* [Female, 61 years of age]

> *I enjoy the challenges as these motivate me to keep going. I can do these with friends and family.* [Female, 57 years of age]

Health care professionals discussed the main activity tracker functions that could be used to support patients. The main functions identified were steps, physical activity intensity, distance walked, and stairs climbed.

> *As a gym instructor I am aware of the useful functions. These would be steps taken, the level of physical activity, the distance moved and the height climbed.* [Male, 42 years of age]

Discussion

Overview

This qualitative study aimed to explore (through the RE-AIM framework) views from adults diagnosed with type 2 diabetes and health care professionals on the integration of activity trackers into type 2 diabetes care. The study themes are discussed in alignment with the 5 main RE-AIM dimensions (reach, effectiveness, adoption, implementation, and maintenance) [14]. Some of the identified themes cross over more than one dimension. This evaluation seeks to identify how activity trackers can be implemented and effectively used by health care organizations to support the long-term maintenance of active lifestyles within type 2 diabetes care.

Reach

In Scotland, 267,615 adults are diagnosed with type 2 diabetes, yet only 32,000 (12%) are presently active users of the My Diabetes My Way platform [19,20]. As reach is a measure of the proportion and representativeness of a health intervention the combined use of activity trackers together with the My Diabetes My Way platform should be made more visible and available to all adults diagnosed with type 2 diabetes [19]. This study has shown, for example, that awareness of the My Diabetes My Way platform was low among the adults diagnosed with type 2 diabetes though the majority of health care professionals did have knowledge of the system. We have also shown that there is low uptake and a lack of awareness of the ability to upload activity tracker data into the My Diabetes My Way platform. Reach could be significantly improved through better promotion of the platform and what it does and what the benefits are if people upload their tracking data. Previous research has shown that the implementation of web-based physical activity interventions for adults at risk of developing type 2 diabetes has only reached a small proportion of eligible patients and was not representative of the target population. Improved engagement strategies have been recommended by others to increase the level of awareness [21] and this study has shown this to be the case for both patients and professionals.

Effectiveness

Effectiveness is a measure of the impact an intervention will have on important outcomes [14]. Previous research has shown that individuals who have uploaded their Fitbit data in the My Diabetes My Way platform have lower blood glucose readings, are less likely to develop diabetes foot problems, and are less likely to have experienced a myocardial infraction [21]. When the use of activity trackers is added as part of a type 2 diabetes physical activity intervention, HbA_{1c} levels have been shown to reduce, as have BMI and sedentary behavior [22]. This study has shown that people are interested in and motivated by the perceived and actual benefits of activity tracking. It would be extremely beneficial, therefore, to create better ways to link activity tracker data to recorded health outcomes and to physical activity guidelines on platforms such as My Diabetes My Way and make these features and their benefits much clearer to both patients and health care professionals [23].

Previous research has shown that personalized feedback via device-informed technology can increase levels of physical activity and reduce sedentary behavior in adults [24]. Our study also confirmed that physical activity feedback should be personalized for the individual patient. Our findings also indicate that to improve the effectiveness of these interventions further we would recommend that additional support should be made available to patients including advice, data interpretation, and educational packages. This level of personalization with supporting educational packages to the user will help overcome individual barriers such as digital literacy and also improve understanding of physical activity and sedentary behavior patterns to make interventions more inclusive and effective to a wider audience.

Adoption

Adoption is the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program [14]. Our research identified that the integration of activity tracker data into the My Diabetes My Way platform and its use within type 2 diabetes clinical care was not being routinely adopted by health care providers. Research has shown that adoption can be enhanced through stakeholders working in close

partnership [25]. We identified the main stakeholders as the My Diabetes My Way website developer, the NHS, regional health boards, local diabetes clinics, and local medical practices. In an effort to improve the adoption of activity trackers into type 2 diabetes clinical care, we recommend that stakeholders identify the added value of activity tracker use in terms of improved patient health and improve awareness for both patients and health care professionals. Furthermore, there is a need to develop and manage the organizational capacity by providing training to improve health care professional knowledge and understanding of implementing activity tracking into clinical care.

Implementation

Implementation refers to the various stakeholders' commitment to all aspects of an intervention's protocol, including delivery consistency and the time and cost of the program [14]. At an individual level, implementation requires an understanding of how patients use the intervention [14]. Our research found that a protocol should be developed focusing on the implementation of activity tracker data into type 2 diabetes clinical care. We recommend that a protocol be produced which pays particular attention to organizational implementation and the development of health care staff promoting and delivering an activity tracker program. During the development of this protocol, intervention testing should be undertaken through the use of pilot studies [26].

Results in this study also show that health care providers are presently working with limited financial budgets. When implementing an activity tracker intervention health care organizations need to balance the costs against the health benefits. Our analysis identified costs such as the purchase of activity trackers, internet access, digital technology, and health care staff training. Research has shown that providing adult patients with a free-of-cost wearable activity tracker in combination with supporting technology can increase levels of physical activity and reduce sedentary behavior [27]. It would be useful to explore partnerships with commercial organizations and the opportunity to provide activity trackers at reduced or no cost. We also recommend further research and evaluation to understand how patients and health care professionals use activity trackers, the impact on health in the short and long terms, and further work to explore cost savings by comparing the intervention costs against any reduced health care costs.

Maintenance

Maintenance is the extent to which a program or policy becomes routine practice within stakeholder organizations. At an individual level, the measure of maintenance is a patient's engagement with the intervention for 6 or more months [14]. Research has shown that adults diagnosed with type 2 diabetes require long-term support and monitoring to maintain an active lifestyle after taking part in a physical activity intervention [28]. Personalized feedback and peer support have been shown to improve patient engagement, physical activity levels, and cardiorespiratory fitness of adults diagnosed with type 2 diabetes [29]. Many studies fail to address and assess the RE-AIM dimension of maintenance and as such few interventions last more than 6 months and fail to become routine clinical care [30]. Our study identified support factors to maintain patient engagement in an activity tracker intervention with the aim of becoming routine type 2 diabetes care. It is recommended that support factors such as prescribed gym referrals, patient assistance in interpreting activity tracker data, personalized data interpretation, and development of a personalized physical activity educational program be routinely incorporated into patient care.

Table 3 provides a summary of the main recommendations under each of the 5 main RE-AIM dimensions.

Table . Summary of main recommendations under the 5 main RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) dimensions.

RE-AIM dimension	Main recommendations
Reach	• Better promotion be undertaken through improved signposting • Increase the knowledge and awareness of health care professionals
Effectiveness	• Personalize physical activity feedback for the individual patient • Additional support should be made available to patients including advice, data interpretation, and educational packages
Adoption	• Stakeholders should identify the added value of activity tracker use (improved health), improving awareness (patients and health care professionals), and organizational capacity (health care professional knowledge and potential training) • Development of joint procedures between stakeholders
Implementation	• Development of an agreed protocol • Development of a staff training program • Introduce measurements of costs
Maintenance	• Support all patients for long-term engagement • Develop measures of improvements to patients' health

Strengths and Limitations

Through abductive thematic analysis, detailed main themes and subthemes were identified. Further evaluation of the results through the RE-AIM framework helped develop a better understanding of how the intervention could be improved and become routine practice within type 2 diabetes care. The sample size for this study was relatively small with 12 adults diagnosed with type 2 diabetes and 9 health care professionals though it was apparent that data saturation had been reached with similar responses suggested by participants within each group.

In conclusion, this study set out to explore through qualitative analysis the use of activity trackers to support physical activity and reduce sedentary behavior in adults with type 2 diabetes. Both adults with type 2 diabetes and health care professionals suggested that with amendments the use of activity tracker data could help support physical activity and reduce sedentary behavior in adults diagnosed with type 2 diabetes and this study has concluded with recommendations aligned to the RE-AIM framework on how to improve current implementation within both the My Diabetes My Way platform and general diabetes clinical care.

Conflicts of Interest

None declared.

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Abbreviations

NHS: National Health Service
RE-AIM: reach, effectiveness, adoption, implementation, and maintenance

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Impact of a Text Messaging Intervention as an In-Between Support to Diabetes Group Visits in Federally Qualified Health Centers: Cluster Randomized Controlled Study

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Abstract

Background: In the United States, 1 in 11 people receive primary care from a federally qualified health center (FQHC). Text messaging interventions (TMIs) are accessible ways to deliver health information, engage patients, and improve health outcomes in the health center setting.

Objective: We aimed to evaluate the impact of a TMI implemented with a group visit (GV) intervention among patients with type 2 diabetes mellitus (T2DM) at FQHCs on patient-reported outcomes and clinical outcomes based on patient TMI engagement.

Methods: A TMI was implemented for 11 health centers participating in a cluster randomized study of diabetes GVs in Midwestern FQHCs targeting adults with T2DM. FQHC patients participated in 6 monthly GVs either in person or online and a concurrent 25-week TMI. Outcome measures included clinical markers such as glycated hemoglobin A_{1c} and patient-reported diabetes distress, diabetes self-care, diabetes self-efficacy, diabetes care knowledge, diabetes quality of life, diabetes social support, and TMI use and satisfaction. TMI response rate was calculated as responses to an SMS text message requesting a response divided by total messages requesting a response sent. Patients were grouped as high responders if their response rate was greater than or equal to the median response rate and low responders if their response rate was below the median. We conducted linear mixed models to compare high and low responders and within a group, adjusting for age, gender, GV attendance, and depression/anxiety at baseline.

Results: In total, 101 of 124 GV patients (81.5%) enrolled in the TMI. The average age of the population in the TMI was 53 years. Of the 101 respondents, 61 (60%) were racial or ethnic minorities, while 42 of 82 respondents (51%) had a high school diploma/General Education Development or less, and 56 of 80 respondents (71%) reported an annual income less than US $30,000. In addition, 70 of 81 respondents (86%) owned a smartphone and 74 of 80 respondents (93%) had an unlimited texting plan. The median response rate was 41% and the mean response rate was 41.6%. Adjusted models showed significantly improved diabetes knowledge (P<.001), foot care (P<.001), and exercise (P=.002) in high responders (n=34) compared to low responders (n=23) at 6 months. No group difference was found in glycated hemoglobin A_{1c}. Within high responders, diabetes distress (P=.001), social support (P<.001), quality of life (P<.001), diabetes knowledge (P<.001), foot care (P<.001), and diet (P=.003) improved from baseline to 6 months. Low responders only improved in diabetes quality of life (P=.003) from baseline to 6 months.

Conclusions: In a FQHC safety net population participating in a combined TMI and GV intervention, our study showed improved diabetes distress, social support, knowledge, self-care, self-efficacy, and quality of life among patients highly engaged in the SMS text messaging program.

Trial Registration: ClinicalTrials.gov NCT03487692; https://clinicaltrials.gov/study/NCT03487692

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KEYWORDS

diabetes; diabetes mellitus; type 2 diabetes; mHealth; mobile health; digital health; digital technology; digital intervention; text messaging intervention; text message; text messaging; texting; federally qualified health center; FQHC; mobile phone

Introduction

In the United States, 1 in 11 people receive primary care from a federally qualified health center (FQHC). FQHCs represent a population disproportionately comprised of people with lower socioeconomic status, racial and ethnic minorities, and those with a higher disease burden of uncontrolled diabetes [1]. Text messaging interventions (TMIs) have been identified as a promising method to improve clinical outcomes and health behaviors among patients with diabetes [2-8]. Many studies have found that TMIs have the potential to improve patient understanding of diabetes, self-efficacy, self-management behaviors, and clinical outcomes such as glycated hemoglobin A_{1c} (HbA_{1c}) among adults with diabetes. TMIs have been understudied in vulnerable populations and FQHC patients, which share a disproportionate burden of diabetes [3,6,9]. A literature review conducted between January 2012 and February 2019 identified only 9 original articles studying T2DM TMIs in US adults that provided some participant demographics on race, income, or education [9]. Of these articles, only 4 of 9 reported English-speaking status and 2 of 9 reported income or education [9]. Today, though cellphone ownership is similar across racial groups, education levels, and income levels, disparities still exist with smartphone ownership and home broadband access [10,11]. With the increasing accessibility and broad use of cellphones and SMS text messaging among vulnerable populations, the barriers to TMIs are continuously decreasing, yet research focusing on vulnerable groups remains sparse [9].

TMIs are one of the most widely used mobile health tools and can be used for a wide variety of purposes including medication reminders, provider-patient communication, patient education, patient motivation, and data collection [2]. However, to date, very few studies have evaluated the usage of TMIs integrated with other clinic- and community-based interventions such as group visits (GVs). One prior study combined an interactive and tailored TMI with monthly phone coaching found significant treatment effects on HbA_{1c} at 3 months and 6 months that were not sustained at later follow-up [12]. GVs are a model of care that combines individual medical care with group education and social support. GVs have been found to be powerful tools in addressing health care inequalities, especially for vulnerable patients with chronic conditions such as diabetes [13,14]. The application of TMIs in addition to other interventions may be an effective approach to improve outcomes and serve to continue care and contact between patients and providers between visits.

The study of mobile health interventions in vulnerable populations represents both an emerging field of research and opportunity to utilize a powerful tool to serve disadvantaged patient populations that are disproportionately affected by diabetes [6,9]. Combining a TMI with an FQHC GV intervention is a novel approach to addressing diabetes and diabetes disparities. In this study, a combined diabetes GV and TMI was implemented at 11 Midwestern FQHCs with a diverse population of patients with diabetes with suboptimal glycemic control randomized into either a standard in-person cohort or an online GV cohort. The aim of this study was to assess how engagement with an SMS text messaging program correlated with clinical and patient-reported outcomes when implemented in the setting of a concurrent GV program.

Methods

A cluster randomized controlled study was implemented, where FQHC staff conducted a 6-month GV and TMI at their site or online.

Ethical Considerations

The University of Chicago Institutional Review Board (IRB 17-1385) approved all study procedures. The study was registered at ClinicalTrials.gov (NCT03487692) on April 4, 2018. Patients enrolled study provided informed consent. Patient data was shared by clinics with the University of Chicago as limited datasets and were saved on password protected, secure servers. Clinics engaged in the study received a stipend for their participation and could use the funds to offset any costs.

Health Center Recruitment

The research team sent messages through the Midwest Clinicians' Network (MWCN) listserv, set up a webinar through the MWCN, advertised in the quarterly MWCN e-newsletter, and mailed a letter and brochures about the study to the directors of all MWCN member health centers. Health centers were randomized to either the 2018 in-person intervention arm or the 2020 delayed intervention arm. The 2020 cohort was eventually adapted to an online format due to the onset of the COVID-19 pandemic. Initially, 16 health centers were enrolled and 5 withdrew. Of the remaining 11 health centers, 6 health centers with 7 clinical sites were randomized to the intervention cohort, and 5 health centers with 6 clinical sites were randomized to the 2020 delayed intervention. Health centers represented 7 Midwestern states including Indiana, Minnesota, Iowa, Wisconsin, Nebraska, Missouri, and Illinois. Specific cities represented both rural and urban settings. Due to a technical error, patients from 1 enrolled health center were not enrolled in the SMS text messaging program.

Patient Recruitment

Eligible patients had to be at least 18 years of age, English- or Spanish-speaking, have a diagnosis of T2DM, and a most recently documented HbA_{1c} result in the last 6 months equal to or greater than 8.0%. Patients must have attended at least 2 appointments at the FQHC within the past year, with at least 1 of them being from the past 6 months to ensure that enrolled patients were actively engaged at the FQHC for care. Patients must have owned a cellphone with SMS text messaging capabilities and have had the ability to send and receive SMS text messages. Patients who were pregnant or planning to become pregnant or who had an uncontrolled psychiatric problem, dementia, another cognitive impairment, hearing difficulties, or a severe physical disability that would have excluded them from participation or benefiting from a GV were excluded. FQHC staff invited patients from a randomly ordered list until 15 patients met the eligibility criteria and agreed to participate. For the online 2020 cohort, FQHCs enrolled up to 12 patients due to the online format. Trained community health center (CHC) staff obtained written informed consent from all

intervention participants prior to enrollment. Patients who consented and enrolled in the GV program were then offered the opportunity to also enroll in the SMS text messaging program, which was to run concurrently with the GV program. A total of 124 patients were enrolled in the GV program. There were 75 patients enrolled in the 2018 in person cohort and 49 patients enrolled in the 2020 online cohort.

GV Intervention

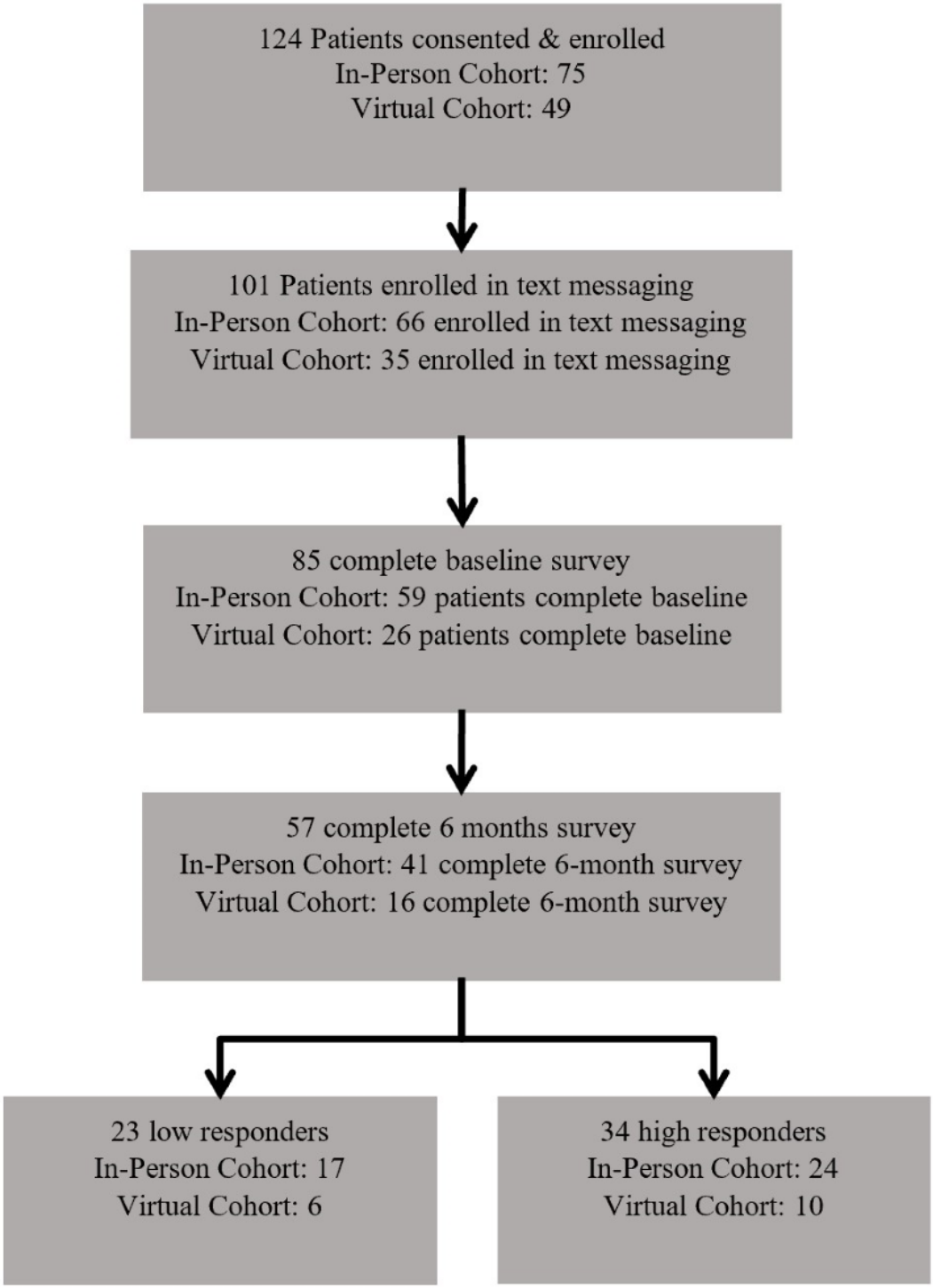
The in-person FQHCs were asked to implement 6 monthly GVs lasting 2-3 hours at their care sites based on a previous, successful pilot study [13]. Participants in the online cohort were asked to implement 6 monthly group video visits lasting 1-2 hours. Due to the COVID-19 pandemic, the 2020 cohort had video-based GVs. The intervention was designed based on a review of the literature and input from staff and providers with experience implementing GVs in health center settings. The GVs contained several core components: (1) an individual medical visit with a provider, (2) group diabetes education, (3) group social support, and (4) goal setting.

Both in-person and online GVs included diabetes education led by a staff member or a guest speaker and a facilitator-led discussion to encourage peer support and goal setting. Due to the diversity of the CHCs and patients served, CHCs were able to use their own diabetes education curricula or curriculum resources provided during the training. The CHC staff and providers were encouraged to provide medication refills, provide referrals, order vaccinations and laboratory testing, and complete other process of care based on the American Diabetes Association Standards of Care during the GVs.

TMI Implemented in the Study

CareMessage is a nonprofit health care patient engagement platform that serves clinical sites with underserved patient populations including FQHCs, free clinics, and other safety net care settings. It has an automated 25-week interactive T2DM SMS-based program focused on self-management and disease education based on national guidelines and supported by medical literature. Their program contains both unidirectional and bidirectional messages that ask for patient responses, including yes/no, true/false, and multiple-choice questions. Patients received 3 - 5 text messages per week. Messages were available in both English and Spanish, written below a sixth-grade reading level, and culturally tailored for Black and Hispanic patients, with content designed to be practical and applicable for low-income patients. CareMessage provided training and worked with the FQHCs to implement the SMS text messaging platform within the clinic's existing infrastructure and workflow. Of the 124 patients enrolled in the GV program, 104 patients enrolled in the SMS text messaging program, of which a total of 101 patients successfully received SMS text messages in the program. Full enrollment data are presented in Figure 1.

Figure 1. Enrollment and inclusion flowchart of in-person and online (virtual) cohorts.



Measures

Patients in both the in-person 2018 cohort and the online 2020 cohort completed surveys at baseline and 6 months, after the last GV. Patient surveys were administered by health center teams; there were multiple options for survey completion including on paper, by phone, or online. The patient surveys collected demographic data and data on patients' access, comfort, and prior usage of technology such as texting. Surveys also assessed diabetes knowledge [15] via the Diabetes Knowledge Questionnaire (DKQ), diabetes self-management via the Summary of Diabetes Self-Care Activities (SDSCA) scale [16], SDSCA self-efficacy, diabetes-related distress via the Diabetes Distress Scale (DDS-2) [17], diabetes-related quality of life via the Diabetes Quality of Life (DQOL) Brief Clinical Inventory [18], and diabetes-related social support via the Diabetes Social Support Questionnaire (DSSQ) [18]. The SDSCA is divided into 5 sections: foot care, exercise, blood sugar testing, general diet, and specific diet. SDSCA self-efficacy is a survey we developed based on the SDSCA,

which surveyed patients' confidence in performing those activities. FQHC staff conducted chart reviews to collect patients' clinical outcomes such as HbA_{1c}. Chart data also contained some basic demographic data. Patient surveys also contained free-text portions regarding their experiences with CareMessage.

The CareMessage platform collected data on patient engagement, including the number of texts sent and received, response rates, and retention rates. FQHC teams sent these data reports with deidentified patient information to the University of Chicago team.

Postintervention, trained research team members from the University of Chicago team conducted 20- to 45-minute telephone interviews with FQHC staff. The interview questions were based on an interview guide designed to assess staff characteristics and involvement; barriers and facilitators to implementing and maintaining a diabetes GV intervention; characteristics of the GV intervention as implemented and adapted to their site; desire and ability to sustain the GV intervention; and patient and staff perceptions of the SMS text messaging program. Interviews were audio recorded then transcribed by a professional transcription company.

Analysis

The baseline demographic information, diabetes-related health history, and patients' access to, prior usage, and familiarity with SMS text messaging were described for each cohort separately and across both cohorts for patients that were enrolled in the TMI.

Response rate was calculated as the number of SMS text messages a patient replied to that were categorized as SMS text messages requesting a response, divided by the total number of SMS text messages that were categorized as ones requiring a response. To grade intervention engagement, patients were classified as high responders if their response rate was equal to or above the median response rate and low responders if their response rate was below the median response rate. Sensitivity analyses were also performed to evaluate response rate as a continuous variable. We defined the median response rate as the median response rate of all patients from both cohorts combined that enrolled in the SMS text messaging program.

All patient demographics and quantitative outcomes were summarized with descriptive statistics. Linear mixed models (for continuous variables) or generalized estimating equations (for categorical/binary variables) were used to adjust for within health center association. Each linear mixed model/generalized estimating equation was also used to examine TMI effects over time by testing the effects of the TMI and time and their interaction on each of the patient-reported outcomes and HbA_{1c}. To consider any potential confounding effects, age, gender, number of GVs attended, and/or depression or anxiety at baseline were adjusted in these models. Through these models, we also conducted within-group comparison. Furthermore, we examined any cohort effect in each outcome and did not find any evidence to show significance. The interaction term between TMI responder status and GV attendance in a linear mixed model was not significant and was removed from the model. GV attendance was also not significant in the models and thus was not included. A 2-sided test with $P<.05$ was considered statistically significant.

To analyze patient free-text responses, 2 investigators used a modified template approach to text analysis to create an initial codebook [19]. Each member coded the free-text responses independently then met with the other to reach a consensus.

Results

Baseline Patient Characteristics

Table 1 describes the demographics and baseline characteristics of patients who enrolled in the SMS text messaging program (N=101). Their mean age was 53 (SD 12) years, 71% (72/101) were female, 60% (60/101) identified as racial or ethnic minorities, 20.7% (17/82) worked full-time, 51.2% (42/82) had completed high school, General Education Development, or less, and 73% (74/101) had public health insurance. Chart data were abstracted for every patient enrolled. Only some patients completed baseline surveys.

Table . Baseline characteristics of high and low responders (N=101).

Demographics	High responders		Low responders		All		*P* value
	Values	Participants, n	Values	Participants, n	Values	Participants, n	
Age, mean (SD)	51.1 (11.3)	50	55.0 (12.9)	51	53 (12.3)	101	.12
Female, n (%)	37 (74)	50	35 (69)	51	72 (71)	101	.62
Race/ethnicity, n (%)							.88
Hispanic or Latino	13 (26)	50	7 (14)	51	20 (20)	101	
Non-Hispanic Native American	3 (6)	50	5 (9.8)	51	8 (7.9)	101	
Non-Hispanic Asian	1 (2)	50	0	51	1 (1)	101	
Non-Hispanic Black	9 (18)	50	22 (43)	51	31 (31)	101	
Non-Hispanic White	23 (46)	50	17 (33)	51	40 (40)	101	
Other	1 (2)	50	0	51	1 (1)	101	
Income, n (%)							.94
Less than US $30,000	28 (68.3)	41	28 (71.8)	39	56 (70)	80	
US $30,000 to US $80,000	12 (29.3)	41	10 (25.6)	39	22 (27.5)	80	
Greater than US $80,000	1 (2.6)	41	1 (2.6)	39	2 (2.5)	80	
Employment status, n (%)							.35
Working full-time	12 (27.3)	44	5 (13.16)	38	17 (20.7)	82	
Working part-time	5 (11.4)	44	7 (18.4)	38	12 (14.6)	82	
Homemaker	5 (11.4)	44	3 (7.9)	38	8 (9.8)	82	
Retired	2 (4.6)	44	7 (18.4)	38	9 (11)	82	
Disabled	15 (34.1)	44	11 (29)	38	26 (31.7)	82	
Unemployed	4 (9.1)	44	5 (13.2)	38	9 (11)	82	
Education, n (%)							.26
High school, General Education Development, or less	20 (45.4)	44	22 (57.9)	38	42 (51.2)	82	
Some college or more	24 (54.6)	44	16 (42.1)	16	40 (48.8)	82	
Insurance, n (%)							.04
Private	9 (18)	50	2 (3.9)	51	11 (11)	101	
Public	31 (62)	50	43 (84)	51	74 (73)	101	
Self/uninsured	10 (20)	50	6 (12)	51	16 (16)	101	
Preferred language, n (%)							.97
English	42 (84)	50	47 (92)	51	89 (88)	101	
Spanish	8 (16)	50	4 (7.8)	51	12 (12)	101	
Clinical characteristics							

Demographics	High responders		Low responders		All		*P* value
	Values	Participants, n	Values	Participants, n	Values	Participants, n	
Age at diagnosis with diabetes, mean (SD)	39 (11)	45	41 (15)	38	39.9 (12.9)	83	.57
Duration of diabetes, mean (SD)	11.6 (7.8)	45	13.6 (11.1)	38	12.5 (9.5)	83	.33
Family history of diabetes, n (%)	41 (89.1)	46	34 (89.5)	38	75 (89.3)	84	.96
Glycated hemoglobin A_{1c}, mean (SD)	9.02 (1.36)	50	9.60 (1.51)	51	9.31 (1.46)	101	.03
Smoking, n (%)							.85
Current smoker	10 (20)	50	11 (22)	51	21 (21)	101	
Former smoker	9 (18)	50	13 (25)	51	22 (22)	101	
Never smoker	31 (62)	50	27 (53)	51	58 (57)	101	
Depression, n (%)							
Patient Health Questionnaire positive (score ≥3)	9 (20)	45	16 (42.1)	38	25 (30.1)	83	.03
Patient-reported medication use, n (%)							
Uses insulin	31 (67.4)	46	32 (84.2)	38	63 (75)	84	.08
Uses other diabetes medications	40 (87)	46	33 (86.8)	38	73 (86.9)	84	.99
Texting access, usage, and comfort							
How comfortable are you with text messaging on your phone? (1=very comfortable to 4=very uncomfortable), mean (SD)	1.22 (0.60)	44	1.5 (0.81)	36	1.35 (0.71)	80	.09
Very comfortable, n (%)	37 (84.1)	44	24 (66.7)	36	61 (76.2)	80	
Somewhat comfortable, n (%)	5 (11.4)	44	7 (19.4)	36	12 (15)	80	
Somewhat uncomfortable, n (%)	1 (2.3)	44	4 (11.1)	36	5 (6.2)	80	
Very uncomfortable, n (%)	1 (2.3)	44	1 (2.8)	36	2 (2.5)	80	
Sends text messages on their phone at least once per day, n (%)	40 (90.9)	44	24 (64.9)	37	64 (79)	81	.004

Demographics	High responders		Low responders		All		*P* value
	Values	Participants, n	Values	Participants, n	Values	Participants, n	
Receives text messages on their phone at least once per day, n (%)	41 (93.2)	44	27 (73)	37	68 (84)	81	.01
Owns a smartphone, n (%)	40 (90.9)	44	30 (81.1)	37	70 (86.4)	81	.20
Has an unlimited texting plan, n (%)	43 (97.7)	44	31 (86.1)	36	74 (92.5)	80	.05
Has received SMS text messages from a health care provider or clinic, n (%)	29 (64.4)	45	18 (52.9)	34	47 (59.5)	79	.30
Has sent SMS text messages to a health care provider or clinic, n (%)	13 (28.9)	45	8 (23.5)	34	21 (26.6)	79	.69
Has used a smartphone app to communicate with a health care provider or clinic, n (%)	16 (35.6)	45	8 (24.2)	33	24 (30.8)	78	.29
Has used a smartphone app to help them with self-care for their diabetes, n (%)	9 (20.5)	44	2 (6.3)	32	14 (15.1)	76	.08

Engagement With the TMI

Among those enrolled in the SMS text messaging program, the mean response rate was 41% (SD 37%). Of the 101 participants, 71 (70%) responded to at least 1 message. The mean number of SMS text messages sent was 89.7 (SD 23.8) and the mean number of SMS text messages requiring a response was 20.3 (SD 6.6). The mean number of days participants remained in the program was 157.5 (SD 42.2), ranging from 2 to 172 days. The median number of days in the program was 172. Among those that started the SMS text messaging program, 91 of 101 (90.1%) completed the program. Among those successfully enrolled in the SMS text messaging program, 51 patients were identified as low responders and 50 were identified as high responders. Of patients both enrolled in the SMS text messaging program and surveyed at baseline and 6 months successfully, 34 patients were classified as high responders and 23 were low responders. Sensitivity analyses were performed with response rate added as a continuous variable and the primary analysis results remained robust.

High and low responders differed in insurance status at baseline. Among high responders, 9 of 50 (18%) had private insurance, 31 of 50 (62%) had public insurance, and 10 of 50 (20%) were self-insured or uninsured. Among low responders, 2 of 51 (3.9%) had private insurance, 43 of 51 (84%) had public insurance, and 6 of 51 (12%) were self-insured or uninsured. High and low responders also differed significantly in GV attendance (*P*=.008). On average, high responders had an attendance of 3.58 (SD 1.99) GVs, while low responders had an average of 2.33 (2.03) GVs. High and low responders demonstrated differences in baseline HbA_{1c}. High responders had a mean HbA_{1c} of 9.02% (1.36) and low responders had a mean HbA_{1c} of 9.6% (1.51*; P*=.03). High responders and low responders did not differ by race, age, gender, smoking status, diabetes family history, depression or anxiety, or preferred language at baseline.

Patient SMS Text Messaging Usage and History

At baseline, 73 of 81 (91%) participants indicated they were “very comfortable” or “somewhat comfortable” with SMS text messaging on their phone. In addition, 64 of 81 (79%) participants sent SMS text messages on their phone at least once per day and 68 of 81 (84%) received texts at least once per day. Additionally, 70 of 81 (76%) participants had a smartphone and 74 of 81 (93%) had an unlimited texting plan. A total of 47 of

79 (60%) participants had received SMS text messages from a health care provider or clinic; most had never sent SMS text messages to a health care provider or clinic, used a smartphone app to communicate with a health care provider or clinic, or used a smartphone app to help with their diabetes self-care (Table 1).

Patient-Reported Outcomes

DDS-2, DQOL, and DSSQ are noted in Figure 2. At baseline, there were no statistically significant differences between high and low responders on DDS-2, DQOL, or DSSQ scores. Within high responders, diabetes distress (P=.001), diabetes quality of life (P<.001), and diabetes support improved significantly (P<.001). Among low responders, diabetes distress (P>.05) and diabetes support (P>.05) did not improve significantly. Diabetes quality of life did improve significantly among low responders (P=.003). Between groups, changes in diabetes distress, diabetes quality of life, and diabetes support between high responders and low responders were not significant.

Diabetes self-care and self-care self-efficacy are noted in Table 2. At baseline, there were no statistically significant differences between high and low responders. Overall, diabetes self-care self-efficacy did not improve significantly for either high (P=.06) or low responders (P=.94). Changes between groups were also not significant (P=.16). Among high responders, diabetes self-care activities improved for foot care (P<.001) and general diet practices (P=.003). Changes in foot care practices were also significantly different between high and low responders (P<.001). For low responders, exercise worsened significantly from baseline to 6 months (P=.01) and the change in exercise was significantly different between high and low responder groups (P=.002), although high responders did not improve significantly within-group from baseline to 6 months (P=.21).

Diabetes care (DKQ) knowledge differences are noted in Figure 2. At baseline, there were no statistically significant differences between high and low responder scores for any DKQ knowledge item. Among high responders, DKQ knowledge improved significantly from baseline to 6 months (P<.001). DKQ knowledge did not improve in low responders (P=.11). The improvement in DKQ knowledge for high responders was significantly higher than that for low responders in the between-group analysis (P<.001).

Figure 2. Diabetes social support (upper left, scored 1 - 5) [18], diabetes quality of life (upper right, scored 1 - 5) [18], diabetes distress (bottom left, scored 1 - 6) [17], and diabetes knowledge (bottom right, scored 0 - 4) [15] scores from baseline to 6 months in low responders and high responders. Bars represent standard errors.

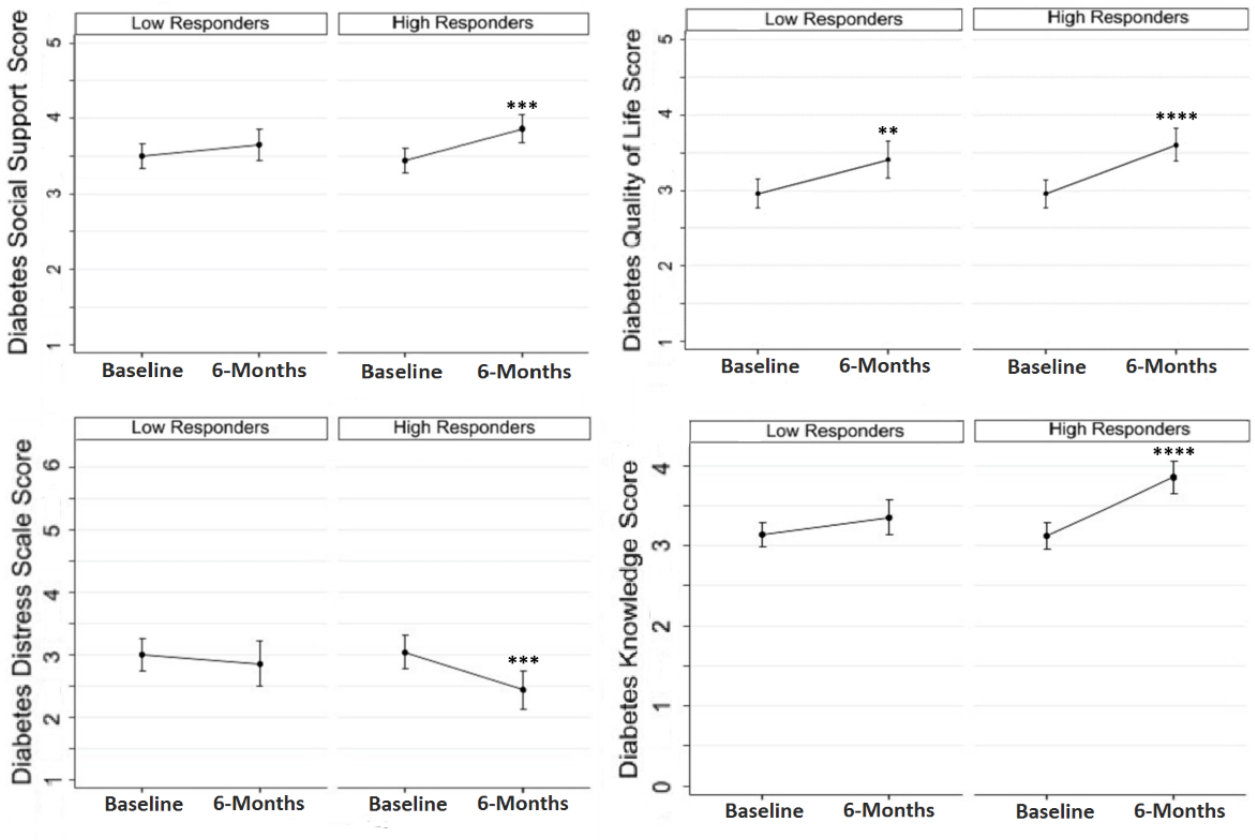


Table . Change in glycated hemoglobin A_{1c} and diabetes self-care activities measured by SMS text message engagement status.

	High responder (n=50)				Low responder (n=51)				Between groups at 6 months
	Baseline, mean (SD)	6 months, mean (SD)	*P* value	Total participants	Baseline, mean (SD)	6 months, mean (SD)	*P* value	Total participants	*P* value
Glycated hemoglobin A_{1c} (%)	9.02 (1.36)	8.74 (1.54)	.17	46	9.60 (1.51)	9.22 (1.72)	.27	43	.81
Summary of Diabetes Self-Care Activities measure self-efficacy	3.80 (0.69)	4.08 (0.64)	.06	33	4.08 (0.81)	4.09 (0.79)	.94	23	.16
Foot care	2.64 (2.41)	3.78 (2.43)	<.001	34	3.89 (2.90)	3.37 (2.76)	.28	23	<.001
Exercise	2.30 (1.96)	2.76 (2.08)	.21	34	2.67 (2.56)	2.13 (2.00)	.01	23	.002
Blood sugar testing	4.62 (2.58)	4.72 (2.36)	.68	34	5.46 (1.95)	5.18 (2.34)	.29	23	.50
General diet	3.39 (2.25)	4.21 (1.94)	.003	34	3.86 (2.61)	4.09 (2.41)	.06	23	.69
Specific diet	3.17 (1.67)	3.93 (1.54)	.09	34	4.12 (1.5)	4.00 (1.45)	0.34	23	.87

Clinical Outcomes

When comparing high responders to low responders at 6 months, there was no significant difference in HbA_{1c}. A within-group analysis of high responders and low responders also showed no significant change in HbA_{1c} from baseline to 6 months.

Satisfaction With the TMI

Overall, 49 of 54 (91%) respondents reported being "very satisfied" (38/54; 70%) or "moderately satisfied" (10/54; 19%) with the SMS text messaging program. Satisfaction was higher among high responders than low responders. Of the high responders, 31 of 34 respondents (91%) reported being "very satisfied" (25/34; 74%) or "moderately satisfied" (6/34; 18%) with the SMS text messaging program. Of the low responders, 15 of 20 respondents (75%) reported being "very satisfied" (10/20; 50%) or "moderately satisfied" (5/20; 25%) with the SMS text messaging program.

Of the 71 patients who answered the free-text questions at the 6-month survey, 23 respondents mentioning they liked the information provided through the SMS text messages. One participant shared that the texts "were very informative with helpful hints and facts about dealing with [their] diabetes." In addition, 18 mentioned liking logistic functions of the SMS text messaging program, such as the texts acting as reminders and the quiz functions. For example, participants shared that the texts helped with "remembering that [they] need to take care of [themselves]" and that "it was just a nice little reminder a few times a week." Furthermore, 10 mentioned feeling supported or finding opportunities for reflection through the SMS text messages. Participants shared that the texts "reminded [them] that someone cares," that they liked "just staying in touch," that it "[helped them] understand that [they] could do this," and that the texts "really showed up at times [they] needed a lift."

When asked what aspects they would change about the SMS text messaging program, 29 of 43 (67%) patients reported that they would change nothing, 6 (14%) wanted more information or content, 5 (12%) wanted the ability to respond to more SMS text messages, and 3 (7%) wanted to change the timing of the messages.

Staff also answered survey free-text questions about the SMS text messaging program and noted both highlights and challenges. Staff noted that the SMS text messaging program was "helpful," "quick," and "encouraging" for patients. Several staff also commented on the utility of the SMS text messaging program for patients who may not have been as engaged in GVs:

> *Although many of our participants didn't show to every visit, they were still actively participating in the CareMessage program. They liked being able to receive quick, relative information about diabetes in a short text. Many of our patients have very busy lives, so this was an effective way to communicate educational pieces to them.*

> *Patients seemed to be really engaged with the material, even when they weren't attending the group visits.*

Staff also remarked on the challenges of the SMS text messaging program, in particular technological challenges for patients including problems updating patients' phone numbers that had changed over the course of the program and delivery errors where patients were not getting texts that the program reported were sent. Some staff also wanted more personalization and echoed patients' wishes regarding being able to respond to additional messages, not only the quizzes:

> *From my end, there were features I wish it had, like personalized messaging. This way we could have more consistent contact with the participants.*

…it would've been nicer if patients could've responded, a lot of patients wanted to respond but weren't able to.

Discussion

Principal Findings

In this study, we evaluated a 6-month TMI combined with a diabetes GV program in 13 Midwestern FQHC sites serving a diverse population of adults with diabetes. SMS text messaging as a supplement to GV interventions is a novel approach to diabetes interventions. Our study found patients who were more engaged in the SMS text messaging program had significantly higher diabetes care knowledge, had better foot care practices, and exercised more than patients who were less engaged. Highly engaged patients also significantly improved in nearly all patient-reported outcomes including diabetes distress, social support, and quality of life and most self-care practices at 6 months, while low responders did not have any significant changes. Many patients noted feeling supported and encouraged by the SMS text messages. Information was noted as the most helpful aspect of the SMS text messaging program across the cohorts. Unfortunately, these improvements did not translate to clinical improvement in HbA_{1c}, unlike what has been seen in prior research. However, the usage of TMIs in vulnerable populations and care sites that serve safety net populations is still emerging. SMS text messaging programs can be a low-burden and effective resource in improving patient-reported outcomes for vulnerable patient populations like those often served by FQHCs, though it may take additional resources to transform improvements in patient-reported outcomes into changes in clinical outcomes.

Though improvements were seen in exercise and foot care, changes in other measured self-care practices were not significantly different between more highly engaged and less engaged patients. These findings may have been due to a high preintervention level of practice or higher barriers to change. Overall, patients already had high frequencies of blood sugar testing at baseline relative to other self-care practices at approximately 5 of 7 days per week and improvements in self-testing were marginal. The improvements seen in foot care may be due to the relatively low barrier of changing foot care behavior compared to other self-care practices. For practices like exercise and diet, behavior change is more resource intensive, requiring patients to have access to and time for healthier eating and exercise, though we did see some improvements. The ability to change diet and exercise practices can be dependent on numerous other factors that cannot be fully addressed by access to information, motivating messages, or self-care reminders.

Unlike considerable prior research, our study did not find significant changes in HbA_{1c} between high and low responders. Generally, systematic analysis and reviews have found that TMIs have a small to moderate effect of reduction of HbA_{1c} in adults with T2DM, though results were variable [4,20,21]. They found that those with a shorter duration of T2DM (<7 years) and a lower HbA_{1c} at baseline had the greatest treatment effects [20]. In our study, the average duration of T2DM was 12.5 years, with an average baseline HbA_{1c} of 9.31%, which may have contributed to the lack of statistically significant improvement in HbA_{1c} despite improvement in patient-reported outcomes. Asian countries and countries of low-to-middle income had greater effects compared to the United States and high-income countries. Other factors evaluated including TMI length, bidirectionality versus unidirectionality, and content and medium of technology were nonsignificant or had conflicting impact among the reviewed analyses [20]. Additional support, resources, and time may be necessary to transform improvements in patient-reported outcomes into improved clinical outcomes, especially in patient populations with long durations of disease and higher baseline HbA_{1c}. Several recent studies have similarly not found significant improvements in HbA_{1c} but have found improvements in other outcomes such as patient health engagement and self-empowerment, as well as finding that SMS text messaging programs are generally well-received [7,22].

On average, high responders attended 1 additional GV session than low responders. The difference in GV attendance between high and low responders may be indicative of patient engagement or other willingness or ability to participate in health interventions. To assess for potential confounding between GV attendance and engagement, our models showed that neither GV attendance nor the interaction between GV attendance and SMS text message engagement was significant. Enrollment from the general study population in the TMI was high, as was completion of the program, but survey attrition was also high from baseline to 6 months, especially among low responders. There were few significant differences between high and low responders at baseline. At baseline, there was a statistically significant difference in HbA_{1c} between high and low responders. However, the difference between 9% in high responders and 9.6% in low responders is not a clinically significant difference as both still represent uncontrolled diabetes.

TMIs can provide valuable knowledge for patients by introducing new information and reinforcing previous education. We hypothesized that the TMI served as a continuous source of information that patients received and could access between their diabetes GVs and any individual medical appointments. TMIs can function similarly as being a source of reminders, check-ins, and suggestions for self-care practices in between check-ins with a provider or clinic. Given that many FQHCs can be underresourced and overburdened, TMIs present a largely automated way for patients to receive continuous education, reminders, and suggestions between visits that do not require intensive staff management or clinical appointment time. Although cellphone ownership and SMS text messaging are nearly ubiquitous across socioeconomic statuses, the same cannot be said for smartphone ownership, home broadband access, and comfort with technology. This makes delivery of education and reminders via SMS text messaging (as opposed to smartphone apps or patient portals) extremely important and a catalyst for reducing the digital divide [3]. The TMI was well-received by patients, with both satisfaction and completion being high and patient free-text responses indicating that they

liked the content, liked the quizzes, and felt supported. However, both patients and staff had commented on wanting to be able to respond to and engage with additional messages, not only during quizzes. As evident in the literature, it is challenging to discern what features make a TMI and its implementation most effective, though patient satisfaction is usually high [3,20,21]. In an optimized setting, a bidirectional TMI with higher personalization of education and feedback may be most effective and must be considered in the context of lower-resourced clinical settings such as FQHCs [4,20,23].

Limitations

There are several limitations to this study. The study sites were FQHCs in the Midwest and thus the study may not be generalizable to all FQHC patients**,** though our study population was diverse across many demographics including race, income, and education level. Patient survey responses had considerable attrition at 6-month follow-up, limiting our sample sizes. Patients who were most engaged in care may have been more likely to complete the follow-up survey, thus not representing the total patient sample. Attrition was higher in the online cohort, which is consistent with other research showing survey nonresponse increased during the COVID-19 pandemic [24]. Future studies may consider utilizing additional ways to reach patients for survey completion, such as SMS text messaging or patient portals, to increase response rates. Additionally, due to the COVID-19 pandemic, the delayed cohort ultimately went forward with online GVs, resulting in a different context for their intervention than the original in-person cohort, though the SMS text messaging program remained the same. Analysis comparing the in-person 2018 cohort and the online 2020 cohort was attempted; however, this was limited by the small sample size of the 2020 cohort. Furthermore, there were some technological issues with the implementation of the SMS text messaging program, including having no patients enrolled from 1 site and some patients being unable to receive program texts after changing phone numbers at others.

Conclusions

This randomized cohort study examined the impact of a TMI combined with a GV intervention in patients with T2DM receiving primary care at FQHCs. Patients with higher TMI engagement had greater improvements in patient-reported outcomes than patients with low engagement; however, clinical improvement was not seen in either group. Further research should examine the part TMIs play in improving patient-reported outcomes and patient clinical outcomes, as well as the relationship between improving them. Additional explorations should investigate what other groups of patients benefit most from TMIs and elucidate which aspects of TMIs best support patients in the FQHC setting. Finally, the integration of TMIs with other health interventions should similarly investigate which patients may benefit the most, what TMI and intervention characteristics are most effective, and how or even if a combined intervention compares to standard approaches.

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Conflicts of Interest

None declared.

Checklist 1
CONSORT E-HEALTH Checklist (V 1.6.1)
[PDF File, 1330 KB - diabetes_v9i1e55473_app1.pdf]

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Abbreviations

CHC: community health center
DDS-2: Diabetes Distress Scale
DKQ: Diabetes Knowledge Questionnaire
DQOL: Diabetes Quality of Life
DSSQ: Diabetes Social Support Questionnaire
FQHC: federally qualified health center
GV: group visit
HbA_{1c}: glycated hemoglobin A_{1c}
MWCN: Midwest Clinicians' Network
SDSCA: Summary of Diabetes Self-Care Activities
T2DM: type 2 diabetes mellitus
TMI: text messaging intervention

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Original Paper

Effects of Digitization of Self-Monitoring of Blood Glucose Records Using a Mobile App and the Cloud System on Outpatient Management of Diabetes: Single-Armed Prospective Study

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Abstract

Background: In recent years, technologies promoting the digitization of self-monitoring of blood glucose (SMBG) records including app-cloud cooperation systems have emerged. Studies combining these technological interventions with support from remote health care professionals have reported improvements in glycemic control.

Objective: To assess the use of an app-cloud cooperation system linked with SMBG devices in clinical settings, we evaluated its effects on outpatient management of diabetes without remote health care professional support.

Methods: In this multicenter, open-label, and single-armed prospective study, 48 patients with diabetes (including type 1 and type 2) at 3 hospitals in Japan treated with insulin or glucagon-like peptide 1 receptor agonists and performing SMBG used the app-cloud cooperation system for 24 weeks. The SMBG data were automatically uploaded to the cloud via the app. The patients could check their data, and their attending physicians reviewed the data through the cloud prior to the patients' regular visits. The primary outcome was changes in glycated hemoglobin (HbA_{1c}) levels.

Results: Although HbA_{1c} levels did not significantly change in all patients, the frequency of daily SMBG following applying the system was significantly increased before induction at 12 (0.60 per day, 95% CI 0.19-1.00; *P*=.002) and 24 weeks (0.43 per day, 95% CI 0.02-0.84; *P*=.04). In the subset of 21 patients whose antidiabetic medication had not been adjusted during the intervention period, a decrease in HbA_{1c} level was observed at 12 weeks (*P*=.02); however, this significant change disappeared at 24 weeks (*P*=.49). The Diabetes Treatment Satisfaction Questionnaire total score and "Q4: convenience" and "Q5: flexibility" scores significantly improved after using the system (all *P*<.05), and 72% (33/46) patients and 76% (35/46) physicians reported that the app-cloud cooperation system helped them adjust insulin doses.

Conclusions: The digitization of SMBG records and sharing of the data by patients and attending physicians during face-to-face visits improved self-management in patients with diabetes.

Trial Registration: Japan Registry of Clinical Trials (jRCT) jRCTs042190057; https://jrct.niph.go.jp/en-latest-detail/jRCTs042190057

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KEYWORDS

app; diabetes care; diabetes; digital intervention; digital therapeutics; glycemic control; mobile app; mHealth

Introduction

Patients with diabetes treated with insulin or the glucagon-like peptide 1 receptor agonist (GLP-1RA) are recommended to perform self-monitoring of blood glucose (SMBG), which is covered by health insurance in Japan, to achieve and maintain blood glucose within the normal range as much as possible [1-5]. SMBG data can be useful not only in confirming hypoglycemia or hyperglycemia in real time but also in the long-term management of diabetes (adjusting insulin, diet, and exercise). On the other hand, entering SMBG data into handwritten logbooks can be time-consuming, and transcription errors (or intentional misreporting) may occur [6,7]. It is also difficult for the attending physicians to accurately assess lifestyle or therapeutic problems from the patient's SMBG record during consultation at outpatient clinics.

With the prevalent use of the internet and smartphones, increasing evidence suggests that interventions with information and communication technology effectively enhance diabetes management [8-10]. Continuous glucose monitoring devices, which have become increasingly popular in recent years, allow patients to visualize the information on glucose levels and trends in real time on a portable receiver or a smartphone app and share these data with health care professionals (HCPs) [11-13]. Although not as common as continuous glucose monitoring, SMBG devices are becoming capable of digitizing and using data. Previous studies on SMBG have reported that self-monitoring systems with glucose meters connected wirelessly to mobile apps and web-based monitoring systems have shown improved glycemic control [14-26] and have helped patients with diabetes achieve target glycemic control with less hypoglycemia [20,21]. In these studies, information and communication technology–based self-monitoring systems provided personalized medical advice, including lifestyle-related advice from HCPs by web-based messaging [14,15,17-19,21,23-26] or telephone [16,26]. However, routine clinical practice differs from these research settings in that support from remote HCPs is limited. Furthermore, several of these studies have included participants who had never performed SMBG [17,18,20-22,25], suggesting that the effects are partly attributed to the introduction of SMBG. To apply SMBG digitization in real-world clinical practices, it is necessary to investigate its effect without remote HCP support on patients who are already performing SMBG. However, no such study has yet been conducted to date.

In recent years, several app-cloud cooperation systems that use cloud-computing services and mobile apps linked to SMBG devices have been used by patients with diabetes in Japan [27-29]. The apps used in these systems support patients' lifestyles by digitization of SMBG records and visualization of blood glucose levels. These apps are also linked to cloud-computing services, which allow the sharing of information registered in the app with HCPs via the internet. HCPs can easily see a patient's recent progress and trends in blood glucose variability by referring to simple graphs and summaries. Thus, the app-cloud cooperation systems allow HCPs to monitor and analyze patients' trends in blood glucose levels and lifestyle problems at any time. These features of the app-cloud cooperation system would be beneficial if attending physicians could analyze the data before every visit of patients, as consultation time is limited in most clinical settings. These commercially available app-cloud cooperation systems are already in use among certain patients and medical institutions in Japan, and similar systems are gaining worldwide popularity. However, prospective data validating their effectiveness are lacking.

Therefore, in this study, we used a commercially available app-cloud cooperation system that is widely used in Japan and is linked to SMBG devices and evaluated its effects on glycemic control, self-management, behavioral change, or treatment satisfaction with only feedback from the attending physician during face-to-face visits in patients with diabetes (including type 1 and type 2) treated with insulin or GLP-1RA and already performing SMBG.

Methods

Study Design

This was a 24-week, multicenter, open-label, and single-armed prospective study conducted at 3 participating hospitals in Japan (Nagoya University Hospital, Japan Red Cross Medical Center Nagoya Daini Hospital, and Tosei General Hospital). The trial is registered in the Japan Registry of Clinical Trials (jRCTs042190057).

Ethical Considerations

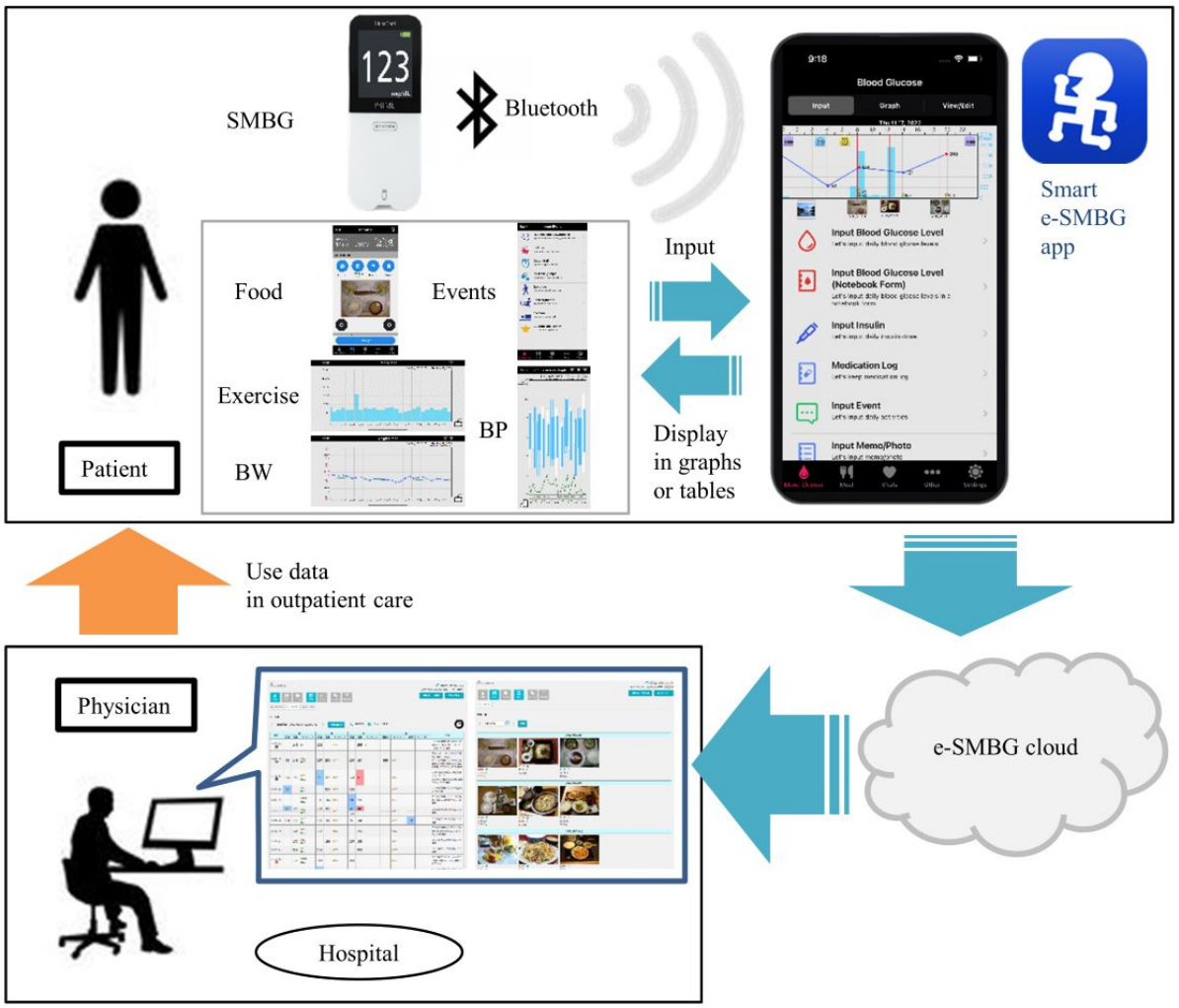
The study protocol was approved by the ethics committee of Nagoya University Graduate School of Medicine (2019-0142) and performed in accordance with the ethical principles of the Declaration of Helsinki. All enrolled patients provided written consent to participate after they were informed of the study purpose and the potential risks and benefits. Our study guarantees the protection of privacy and confidentiality of participants by ensuring that the study data are anonymized. Participants were not provided any compensation for study participation.

Smart e-SMBG System

The Smart e-SMBG system (ARKRAY, Inc) is one of the commercially available app-cloud cooperation systems for the management of diabetes using the cloud-computing service "e-SMBG Cloud" and the "Smart e-SMBG app" (for Android and iOS) linked to several SMBG devices. By linking the patient's blood glucose meter with the Smart e-SMBG app using Bluetooth or near-field communication, the measured glucose value can be automatically transferred into the app when the patient performs an SMBG measurement. Patients can also enter

health-related data such as blood pressure, weight, and step counts, as well as dietary records, treatment records, and event records, such as hypoglycemia, into this app. The entered glucose values and these data are transmitted to an e-SMBG cloud server via a wireless network. Attending physicians can review each patient's report on the e-SMBG cloud from their office computers to use the data in outpatient care. Thus, the Smart e-SMBG system is characterized by its ability to collaborate with medical institutions and physicians. An overview of the Smart e-SMBG app and e-SMBG cloud is shown in Figure 1.

Figure 1. Overview of the Smart e-SMBG app and e-SMBG cloud. BP: blood pressure; BW: body weight; SMBG: self-monitoring of blood glucose.



Screenshots of what the patient can see in the Smart e-SMBG app are shown in Figures S1-S4 in Multimedia Appendix 1. Specifically, patients can view the blood glucose record, including the blood glucose logbook and blood glucose variability graph (Figure S2 in Multimedia Appendix 1). Patients can also view the events, dietary and insulin records (Figure S3 in Multimedia Appendix 1), and activity and weight records (Figure S4 in Multimedia Appendix 1). Physicians can view data, such as the weekly summary, list of dietary records, and blood glucose variability graph, on the e-SMBG cloud (Figure S5 in Multimedia Appendix 1).

Patients

Outpatients with diabetes from 3 participating hospitals were recruited. Diabetes was diagnosed based on the diagnostic criteria of the Japan Diabetes Society [30]. The inclusion and exclusion criteria for the study are detailed in Textbox 1. To accurately evaluate the effectiveness of the intervention by the app-cloud cooperation system linked to SMBG devices, we included patients who were currently performing SMBG but had no history of using a system similar to the Smart e-SMBG app and required improved glycemic control.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Glycated hemoglobin ≥7% and <8.9% within the previous 2 months
- Patients who are currently performing self-monitoring of blood glucose
- Patients who have a smartphone or tablet for using the Smart e-SMBG app
- Patients who have not previously used the Smart e-SMBG and similar apps
- Patients who are currently using a blood glucose meter that can be linked to the Smart e-SMBG app: Glucocard G Black (GT-1830 ARKRAY, Inc), Glucocard Plus Care (GT-1840 ARKRAY, Inc), Glucotest Aqua (GT-7510 Sanwa Kagaku Kenkyusho Co, Ltd), Glucocard Prime (GT-7510 ARKRAY Inc), or Glucotest Neo Alpha (GT-1830 Sanwa Kagaku Kenkyusho Co, Ltd)
- Aged ≥20 years

Exclusion criteria

- Patients who cannot properly operate the devices
- Those who are judged unsuitable by their physicians for participation in the study

Registration

Participants who qualified the above criteria and visited 1 of the 3 participating hospitals between June 24, 2019, and March 31, 2021, were eligible for recruitment.

Intervention

After informed consent was obtained, the patients downloaded the Smart e-SMBG mobile app on iOS or Android. The patients were then instructed on how to use the app and used it in conjunction with their blood glucose meter for 24 weeks. The patients were also encouraged to enter health-related data, such as blood pressure, weight, and step counts, as well as dietary records, treatment records, and event records. The attending physician could view their patients' data on the e-SMBG cloud and were provided with reports of blood glucose lists, a weekly summary, lists of dietary records, and blood glucose variability graphs at each regular patient regular monthly visit. The attending physician could check these reports before every visit of the patient and review them with the patient to adjust treatment and guidance.

Information on patients' age, sex, BMI, type of diabetes, complications, and medical history were collected from electronic medical records upon enrollment. Type 1 diabetes was diagnosed based on the diagnostic criteria of the Japan Diabetes Society [31,32], whereas type 2, pancreatic, and steroid diabetes were diagnosed based on clinical data. Laboratory data, SMBG data for the past 2 weeks, and changes in diabetes medication were collected at enrollment, 12 weeks, and 24 weeks. The Diabetes Treatment Satisfaction Questionnaire (DTSQ) was used to assess patient satisfaction with the diabetes treatment [33], and the Japanese version of the DTSQ [34] was answered at enrollment, 12 weeks, and 24 weeks. The following were the items of the DTSQ: Q1="satisfaction with current treatment," Q2="frequency of hyperglycemia," Q3="frequency of hypoglycemia," Q4="convenience," Q5="flexibility," Q6="understanding of diabetes," Q7="recommend treatment to others," and Q8="willingness to continue the current treatment." Each item was assessed using a 7-point Likert scale, with scores from 0 (very dissatisfied) to 6 (very satisfied). Furthermore, a questionnaire for patients and physicians was administered at the end of the intervention.

Outcomes

The primary outcome was the change in glycated hemoglobin (HbA_{1c}) level. Secondary outcomes included changes in insulin dose, frequency of daily SMBG, DTSQ score, parameters for glycemic variability, and hypoglycemia. The parameters for glycemic variability included the SD of glucose and mean amplitude of glycemic excursions (MAGE) [35-37]. The parameters for hypoglycemia included low blood glucose index (LBGI) [38]. Treatment intensification was defined as an addition or dose increase of hypoglycemic agents, including insulin or GLP-1RA. Treatment reduction was defined as a discontinuation or dose reduction of these agents.

Sample Size

Based on the results of a previous clinical trial [39,40], the geometric SD of the change in HbA_{1c} at the last observation period was assumed to be 0.7%. We estimated that ≥46 patients were required to confer a power of 90% to detect a 0.5% significant difference in the change from baseline at the end of the intervention. We thus planned to recruit 50 patients with consideration for potential discontinuation or dropout of the enrolled patients during the study period.

Statistical Analysis

Continuous variables are expressed as the mean (SD), and nominal variables are expressed as frequency (%) unless stated otherwise. A linear mixed model, including the treatment period as a fixed effect, was used to compare changes in the HbA_{1c} level, insulin dose, frequency of daily SMBG, DTSQ score, mean glucose, SD of glucose, MAGE, and LBGI from baseline at 12 and 24 weeks. Effect sizes for continuous variables were calculated using the paired 2-tailed *t* test and quantified using Cohen *d*. For ordinal variables, the Wilcoxon signed-rank test was used, with the effect size represented by $r=Z/\sqrt{n}$. Analyses were conducted using 2-sided tests at a significance level of .05. SAS 9.4 software and JMP Pro 15.1.0 software (SAS Institute Inc) and Stata (version 17.0; StataCorp LLC) were used for all statistical analyses.

Results

Figure 2 shows the CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study. In the participating hospitals, 165 candidates were assessed for eligibility for this study. Of the 165 patients, 92 did not meet the eligibility criteria and 25 patients refused to enroll in the study. The following were the reasons for the exclusion of the 92 participants: inability to properly operate the devices (n=85), anticipated difficulty in participation due to the intervals between hospital visits (n=1), poor compliance (n=2), psychiatric illness or dementia (n=3), and poor general health due to comorbidities (n=1). Therefore, 48 patients were recruited into the study. As 1 patient withdrew owing to an app installation error, 47 completed the study.

Figure 2. Flowchart of the study.

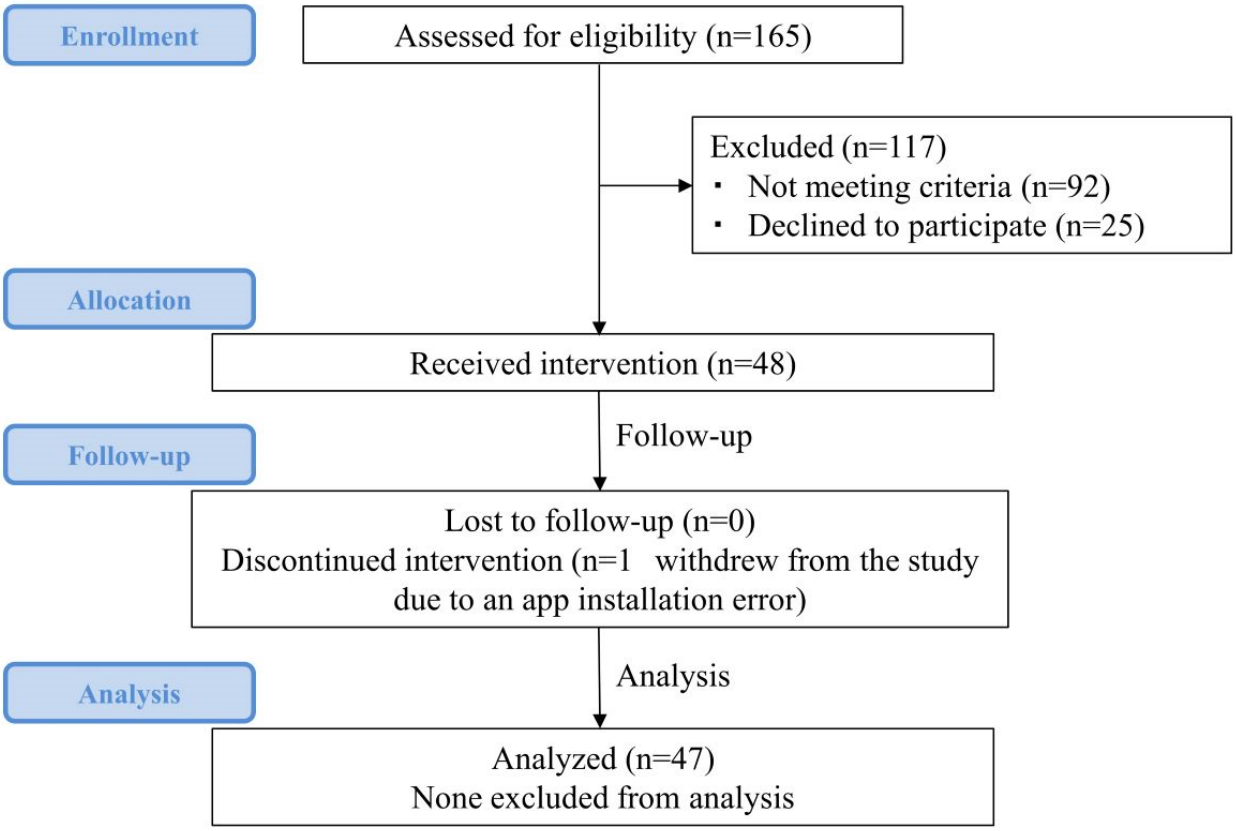


Table 1 shows the baseline characteristics of the patients. Overall, 34 patients were male and 14 were female, with a mean age of 59.8 (SD 11.9) years and a mean BMI of 25.2 (SD 4.8) kg/m^2. The mean HbA_{1c} was 7.7% (SD 0.6%), and the mean duration of diabetes was 18.2 (SD 10.8) years. Regarding the type of diabetes, of the 48 patients, 4 (8%) had type 1 diabetes, 40 (83%) had type 2 diabetes, 3 (6%) had pancreatic diabetes, and 1 (2%) had steroid diabetes. Moreover, 31 (65%), 7 (15%), and 10 (21%) were treated with insulin only, GLP-1RA only, and both treatments, respectively.

Table 1. Baseline characteristics of the study patients (n=48).

Characteristic	Value
Age (years), mean (SD)	59.8 (11.9)
Sex, n (%)	
Male	34 (71)
Female	14 (29)
BMI (kg/m^2), mean (SD)	25.2 (4.8)
HbA_{1c}[a], mean (SD)	7.7 (0.6)
Duration of diabetes (years), mean (SD)	18.2 (10.8)
Type of diabetes, n (%)	
Type 1	4 (8)
Type 2	40 (83)
Pancreatic	3 (6)
Steroid	1 (2)
Type of disease, n (%)	
Retinopathy	22 (46)
Nephropathy	26 (54)
Neuropathy	19 (40)
Cardiovascular disease	6 (13)
Cerebrovascular disease	2 (4)
Insulin treatment, n (%)	
Use of insulin	31 (65)
Use of GLP-1RA[b]	7 (15)
Use of both insulin and GLP-1RA	10 (21)
Insulin dose (n=41; units per day), mean (SD)	32.8 (22.4)
Frequency of daily SMBG[c], mean (SD)	
Total (n=47)	2.3 (0.9)
MDI[d] (n=35)	2.3 (1.0)
Others (n=12)	2.4 (0.9)

[a]HbA1c: glycated hemoglobin.

[b]GLP1RA: glucagon-like peptide 1 receptor agonist.

[c]SMBG: self-monitoring of blood glucose.

[d]MDI: multiple daily injection.

Table 2 shows the changes in glycemic outcomes and questionnaire scores in patients. Compared to the baseline values, HbA_{1c} decreased by –0.13% at 12 weeks (*P*=.15) and –0.06% at 24 weeks (*P*=.53), but the difference was not statistically significant. The frequency of daily SMBG was significantly increased at 12 weeks (0.66 per day, 95% CI 0.25-1.07; *P*=.002) and 24 weeks (0.43 per day, 95% CI 0.02-0.84; *P*=.04). In patients on multiple daily injections, the frequency of daily SMBGs increased by 0.76 per day at 12 weeks (95% CI 0.29-1.23; *P*=.002) and 0.50 per day at 24 weeks (95% CI 0.03-0.97; *P*=.04). The MAGE (*P*=.39) and LBGI (*P*=.23) values showed a trend toward an increase after 12 weeks; however, it was not statistically significant, which may be caused by the increase in the frequency of daily SMBG. The DTSQ total score and "Q4: convenience" and "Q5: flexibility" scores were significantly improved after the use of the Smart e-SMBG app (all *P*<.05). Effect sizes for each outcome are presented in Table S1 in Multimedia Appendix 1. The average number of face-to-face visits with patients or physicians during the intervention was 4.7 (SD 1.0), and the attending physician reviewed the cloud data at every visit. No significant correlation was observed between the number of visits and HbA_{1c} change or SMBG frequency change (Table S2 in Multimedia Appendix 1).

Table 2. Changes in glycemic outcomes and questionnaire scores in total patients (n=47).

Parameter	Change at 12 weeks (95% CI)	*P* value	Change at 24 weeks (95% CI)	*P* value
HbA_{1c}[a] (%)	–0.13 (–0.31 to 0.05)	.15	–0.06 (–0.24 to 0.13)	.53
Insulin dose (units per day)	–1.02 (–2.53 to 0.49)	.18	–1.34 (–2.85 to 0.17)	.08
Glycemic outcome				
SD of glucose (mg/dL)	3.46 (–1.80 to 8.71)	.19	0.37 (–4.93 to 5.67)	.89
MAGE[b] (mg/dL)	5.37 (–7.17 to 17.92)	.39	–3.04 (−15.69 to 9.62)	.63
LBGI[c]	0.73 (–0.48 to 1.94)	.23	0.41 (–0.81 to 1.64)	.50
Frequency of daily SMBG[d]				
Total (n=46)	0.66 (0.25 to 1.07)	*.002* [e]	0.43 (0.02 to 0.84)	*.04*
MDI[f] (n=35)	0.76 (0.29 to 1.23)	*.002*	0.50 (0.03 to 0.97)	*.04*
Others (n=11)	0.33 (–0.63 to 1.29)	.46	0.20 (–0.76 to 1.16)	.65
DTSQ[g] score				
Total score	1.74 (0.10 to 3.39)	*.04*	2.23 (0.59 to 3.87)	*.01*
Q1: Current treatment	0.06 (–0.21 to 0.34)	.65	0.21 (–0.07 to 0.49)	.13
Q2: Frequency of hyperglycemia	–0.13 (–0.65 to 0.39)	.62	–0.06 (–0.58 to 0.46)	.81
Q3: Frequency of hypoglycemia	–0.13 (–0.62 to 0.36)	.60	–0.17 (–0.66 to 0.32)	.49
Q4: Convenience	0.60 (0.10 to 1.09)	*.02*	0.74 (0.25 to 1.24)	*.004*
Q5: Flexibility	0.49 (0.09 to 0.89)	*.02*	0.70 (0.30 to 1.10)	*.001*
Q6: Understanding	0.32 (–0.01 to 0.65)	.06	0.32 (–0.01 to 0.65)	.06
Q7: Recommend	0.11 (−0.38 to 0.60)	.66	0.13 (−0.36 to 0.62)	.60
Q8: Continue	0.17 (–0.10 to 0.44)	.22	0.13 (−0.15 to 0.40)	.35

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

[b]MAGE: mean amplitude of glycemic excursion.

[c]LBGI: low blood glucose index.

[d]SMBG: self-monitoring of blood glucose.

[e]Italic formatting indicates *P* values <.05.

[f]MDI: multiple daily injection.

[g]DTSQ: Diabetes Treatment Satisfaction Questionnaire.

During the intervention period, the changes in the overall diabetes medications (insulin, GLP-1RA, and oral hypoglycemic agents) were observed as follows: at 12 weeks, treatment was continued in 28 (60%) out of 47 patients, reduced in 10 (21%), and intensified in 9 (19%); at 24 weeks, treatment was continued in 21 (45%) patients, reduced in 15 (32%), and intensified in 11 (23%).

Based on the observed medication changes in several patients, it appears that those experiencing worsening control underwent treatment intensification, whereas those showing improvement underwent treatment reduction. Therefore, to assess the effect of the intervention, post hoc subgroup analyses were performed, considering the presence or absence of treatment changes. Table 3 shows changes in glycemic outcomes and questionnaire scores in 21 patients whose antidiabetic medication has not been adjusted by the 24-week time point. HbA_{1c} decreased significantly at 12 weeks (–0.26%, 95% CI –0.47 to –0.05; *P*=.02); however, this significant change disappeared at 24 weeks. The DTSQ total score and scores for "Q1: convenience," "Q2: convenience," "Q4: convenience," and "Q5: flexibility" were significantly improved after the use of the Smart e-SMBG system (all *P*<.05). The results of the subgroup analysis for patients whose treatment was either intensified or reduced are presented in Tables S3 and S4 in Multimedia Appendix 1. In the subgroup with intensified treatment, a significant increase in insulin dose (*P*=.003) and MAGE (*P*=.02) at 24 weeks was noted. Conversely, the subgroup with reduced treatment showed a decrease in insulin dose (*P*=.002) and MAGE (*P*=.04) at 24 weeks. In both groups, a significant increase in the frequency of daily SMBG at 12 weeks was observed (intensified: *P*=.01; reduced: *P*=.048), whereas no significant changes in HbA_{1c} levels were noted (both *P*>.05). The effect sizes for each outcome within each subgroup are presented in Tables S5-S7 in Multimedia Appendix 1.

Table 3. Changes in glycemic outcomes and questionnaire scores in patients whose antidiabetic medication had not been adjusted during the study (n=21).

Parameter	Change at 12 weeks (95% CI)	*P* value	Change at 24 weeks (95% CI)	*P* value
HbA_{1c}[a] (%)	–0.26 (–0.47 to –0.05)	*.02*[b]	–0.07 (–0.28 to 0.14)	.49
Glycemic outcome				
SD of glucose (mg/dL)	0.54 (–7.44 to 8.52)	.89	0.64 (–7.34 to 8.61)	.87
MAGE[c] (mg/dL)	4.33 (–12.43 to 21.08)	.60	–0.31 (–17.06 to 16.45)	.97
LBGI[d]	0.49 (–0.47 to 1.46)	.30	–0.25 (–1.21 to 0.72)	.60
Frequency of daily SMBG[e]	0.31 (–0.34 to 0.97)	.33	0.25 (–0.41 to 0.91)	.44
DTSQ[f] score				
Total score	2.33 (0.06 to 4.61)	*.04*	3.19 (0.91 to 5.47)	*.01*
Q1: Current treatment	0.14 (–0.26 to 0.55)	.47	0.48 (0.07 to 0.88)	*.02*
Q2: Frequency of hyperglycemia	0.43 (–0.20 to 1.08)	.19	0.67 (0.02 to 1.32)	*.04*
Q3: Frequency of hypoglycemia	–0.38 (–1.06 to 0.29)	.25	–0.52 (–1.20 to 0.15)	.12
Q4: Convenience	0.52 (–0.13 to 1.18)	.11	0.71 (0.06 to 1.37)	*.04*
Q5: Flexibility	0.33 (–0.15 to 0.82)	.17	0.67 (0.18 to 1.15)	*.01*
Q6: Understanding	0.24 (–0.21 to 0.69)	.28	0.19 (–0.26 to 0.64)	.39
Q7: Recommend	0.71 (–0.16 to 1.59)	.10	0.76 (–0.11 to 1.64)	.09
Q8: Continue	0.38 (–0.01 to 0.77)	.06	0.38 (–0.01 to 0.77)	.06

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

[b]Italic formatting indicates *P* values <.05.

[c]MAGE: mean amplitude of glycemic excursion.

[d]LBGI: low blood glucose index.

[e]SMBG: self-monitoring of blood glucose.

[f]DTSQ: Diabetes Treatment Satisfaction Questionnaire.

Table 4 presents the results of the questionnaire administered to the patients and physicians after the intervention. More than 90% of the patients (44/47, 94%) and physicians (44/47, 94%) responded that the blood glucose monitoring chart (as a logbook in the SMBG format) was helpful. For the diurnal variability graphs of blood glucose, 89% (42/47) of the patients and 94% (44/47) of the physicians found them helpful. Additionally, 83% (39/47) of the patients and 77% (36/47) of the physicians reported that the Smart e-SMBG system helped motivate the patients to improve their lifestyle, and 72% (33/46) of the patients and 76% (35/46) of the physicians reported that the Smart e-SMBG system helped them with insulin dose adjustment. Furthermore, 83% (39/47) of the patients and 91% (43/47) of the physicians reported that the Smart e-SMBG system aided their diabetes treatment. In addition, 44 (96%) out of 46 patients and 45 (96%) out of 47 physicians who participated in the study indicated that they would like to continue using the Smart e-SMBG system for their diabetes care.

Table 4. Results of the questionnaire for patients and physicians after the intervention.

Question and response	Patients, n (%)	Physicians, n (%)
Was the use of this e-SMBG app useful for motivating you to improve your lifestyle? (patients: n=47; physicians: n=47)		
Very useful	8 (17)	15 (32)
Useful	31 (66)	21 (45)
Not very useful	6 (13)	10 (21)
Not useful at all	2 (4)	1 (2)
Was the use of this e-SMBG app useful for adjusting the insulin dose? (patients: n=46; physicians: n=46)		
Very useful	8 (17)	18 (39)
Useful	25 (54)	17 (37)
Not very useful	8 (17)	11 (24)
Not useful at all	5 (11)	0 (0)
Was the use of this e-SMBG app useful for diabetes treatment? (patients: n=47; physicians: n=47)		
Very useful	7 (15)	17 (36)
Useful	32 (68)	26 (55)
Not very useful	6 (13)	4 (9)
Not useful at all	2 (4)	0 (0)
Do you want to continue to use this e-SMBG app for diabetes treatment? (patients: n=46; physicians: n=47)		
Yes	44 (96)	45 (96)
No	2 (4)	2 (4)
Did you find the following app items useful?		
Blood glucose logbook (patients: n=47; physicians: n=47)		
Very useful	21 (45)	19 (40)
Useful	23 (49)	25 (53)
Not very useful	0 (0)	3 (6)
Not useful at all	3 (6)	0 (0)
Blood glucose variability graph (patients: n=47; physicians: n=47)		
Very useful	18 (38)	20 (43)
Useful	24 (51)	24 (51)
Not very useful	4 (9)	3 (6)
Not useful at all	1 (2)	0 (0)
Weekly summary (patients: n=46; physicians: n=45)		
Very useful	7 (15)	16 (36)
Useful	18 (39)	18 (40)
Not very useful	14 (30)	10 (22)
Not useful at all	7 (15)	1 (2)
Event record (patients: n=42; physicians: n=46)		
Very useful	5 (12)	14 (30)
Useful	7 (17)	11 (24)
Not very useful	20 (48)	15 (33)
Not useful at all	10 (24)	6 (13)
Dietary record (patients: n=43; physicians: n=45)		
Very useful	4 (9)	16 (36)
Useful	9 (21)	10 (22)

Question and response	Patients, n (%)	Physicians, n (%)
Not very useful	18 (42)	11 (24)
Not useful at all	12 (28)	8 (18)
Blood pressure, activity, and weight records (patients: n=43; physicians: n=45)		
Very useful	6 (14)	16 (36)
Useful	11 (26)	16 (36)
Not very useful	15 (35)	7 (16)
Not useful at all	11 (26)	6 (13)

Discussion

Principal Findings

Using the "Smart e-SMBG System," an app-cloud cooperation system that supports digitization and sharing of SMBG and other health data between patients and attending physicians without special support such as remote HCP, there was a significant increase in the frequencies of SMBG and improved treatment satisfaction among patients with diabetes who performed SMBG, and there was a temporary but significant decrease in the HbA_{1c} level in the patients for whom the treatment was not changed during the study.

In this study, the digitization of SMBG records resulted in an increase in the SMBG frequency. It is possible that patients recording their blood glucose on the app and sharing their blood glucose trends with attending physicians at follow-up visits may have increased their interest in blood glucose levels. This increased attention to blood glucose levels may lead to a better understanding of specific lifestyle issues and self-improvement and improved their self-management by changing their behavior, resulting in better glycemic control. Previous studies have shown that a higher frequency of daily SMBG corresponds with better glycemic control regardless of the type of diabetes, patient's age, or type of treatment received [16,17,20,21,41-43].

In addition to a significant increase in the total DTSQ score, there was a significant increase in the convenience and flexibility scores on the DTSQ. Using the "Smart e-SMBG system," patients simply performed the SMBG measurement as per their usual procedure, allowing the measured data to be automatically transmitted from the blood glucose meter to the smartphone, thus reducing the need for patients to enter blood glucose data into handwritten logbooks each time. The system also offers unique features, such as weekly summaries and blood glucose level variation graphs. These features help patients manage their diabetes care more easily and flexibly, potentially contributing to both improved patient satisfaction and the low rate of dropout observed in this study. Improvement in treatment satisfaction has been shown to improve patient's treatment compliance and promote lifestyle modifications [44]. Furthermore, attending physicians appreciated the reporting features, including a weekly summary with good visibility, with 76% (34/45) of them noting their usefulness. Such features, emphasizing convenience and simplicity, may have contributed to sustained patient-clinician interactions during the study.

Although no significant changes in HbA_{1c} levels were noted among all patients in this study, it is important to note that treatment was not fixed. This flexibility allowed the SMBG results and reports on the cloud to be used for treatment adjustments. As a result, drug therapy was intensified or decreased in some patients during the study, which may be related to the finding that there were no significant changes in HbA_{1c} in all patients. On the other hand, 72% (33/46) of the patients and 76% (35/46) of the attending physicians responded on the questionnaire that the system was useful in adjusting insulin doses, suggesting that the app-cloud cooperation system is useful for the adjustment of drug therapy. Although this is a post hoc subgroup analysis, the observed improvement in glycemic control at 12 weeks after intervention in patients in whom the treatment did not change during the study suggested that the digitization of SMBG records using the app-cloud cooperation system improved glycemic control through effects other than intensified therapy with insulin, GLP-1RA, and oral hypoglycemic agents. As indicated by the increase in the SMBG frequency, this is presumably an improvement via behavioral change. However, as no significant changes in HbA_{1c} levels were observed at 24 weeks, along with the degree of increase in the SMBG frequency attenuated at 24 weeks compared with that at 12 weeks, the long-term effects of promoting behavioral change may require further testing.

This study has demonstrated for the first time that digitization and sharing of SMBG data between patients already performing SMBG and their attending physician were useful for improving glycemic control and enhancing diabetes self-management not only for patients in limited settings with sufficient time and resources, such as research or telemedicine, but also in routine outpatient management of diabetes. The findings underscore the benefit of promoting SMBG digitization, suggesting it as a practical approach to improve self-management and treatment outcomes in diverse clinical settings for diabetes care.

Limitations

Our study had several limitations that should be considered. First, this study had a single-armed design without a control and cannot rule out potential biases, including the Hawthorne effect, or influences from other concurrent events, including the COVID-19 pandemic. Additionally, we excluded patients who did not use smartphones or had difficulty operating the apps, which may have influenced the age and socioeconomic status of the participants. Our study group primarily consisted of participants from a specific region of Japan, which may limit

the broader generalization of our findings. Furthermore, although we included patients with various diabetes types, it remains possible that there was a difference in the impact on their lifestyle modifications due to the system between patients with type 1 and type 2 diabetes. The observed improvement in HbA_{1c} levels was obtained from the post hoc subgroup analysis focusing on patients who did not change medications, and an additional evaluation of whether the behavioral changes brought about by this system led to improved glycemic control is needed with outcomes that also consider changes in medication. As the observation period of our study was limited to 24 weeks, further studies are needed to clarify whether the interaction between patients or physicians and this system continues over a long term.

Conclusions

In conclusion, this study demonstrated that digitization of SMBG records and sharing of SMBG and other health data between patients and attending physicians and supporting the regular face-to-face visits by using the app-cloud cooperation system improved the SMBG frequency and treatment satisfaction in patients with diabetes performing SMBG. The significant outcomes achieved without the need for specialized support such as remote HCP involvement suggest the system's potential for widespread adoption in real-world clinical practices.

Acknowledgments

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Conflicts of Interest

HA reports having received speaker honoraria and scholarship grants from Sanwakagaku Kenkyusyo. TO reports having received speaker honoraria from ARKRAY, Inc and Sanwakagaku Kenkyusyo. All the other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Screenshots of the Smart e-SMBG app and additional data on effect sizes, correlation analysis, and subgroup analysis.
[PDF File (Adobe PDF File), 2483 KB - diabetes_v9i1e48019_app1.pdf]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trial
DTSQ: Diabetes Treatment Satisfaction Questionnaire
GLP-1RA: glucagon-like peptide 1 receptor agonist
HbA1c: glycated hemoglobin
HCP: health care professional
LBGI: low blood glucose index
MAGE: mean amplitude of glycemic excursion
SMBG: self-monitoring of blood glucose

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Original Paper

The Potential of a Digital Weight Management Program to Support Specialist Weight Management Services in the UK National Health Service: Retrospective Analysis

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Abstract

Background: Digital weight management interventions (DWMIs) have the potential to support existing specialist weight management services (SWMS) in the National Health Service (NHS) to increase access to treatment for people living with obesity and type 2 diabetes. At present, there is limited real-world evidence and long-term outcomes on the potential effectiveness of DWMIs to support such services.

Objective: This study aimed to examine real-world data to evaluate the impact of Second Nature's 12-month DWMI for patients living with obesity with or without type 2 diabetes, referred from NHS primary care services, on sustained weight loss over a 2-year period.

Methods: Retrospective data were extracted in August 2023 for participants who participated in the program between January 1, 2017, and January 8, 2021. Eligible participants were adults with a BMI ≥35 kg/m^2, with or without type 2 diabetes. The primary outcomes were weight change in kilograms and percentage weight change at 2 years. Secondary outcomes were weight loss at 1 year, program engagement, and the proportion of participants who achieved ≥5% and ≥10% weight loss. Differences in weight loss between baseline and the 1- and 2-year follow-up points were compared using paired 2-tailed *t* tests. Linear regression models were used to examine whether participants' ethnicity, indices of multiple deprivation, presence of type 2 diabetes, or program engagement were associated with weight loss at 1 year or 2 years.

Results: A total of 1130 participants with a mean baseline BMI of 46.3 (SD 31.6) kg/m^2 were included in the analysis. Of these participants, 65% (740/1130) were female (mean age 49.9, SD 12.0 years), 18.1% (205/339) were from Black, Asian, mixed, or other ethnicities, and 78.2% (884/1130) had type 2 diabetes. A total of 281 (24.9%) participants recorded weight readings at 2 years from baseline, with a mean weight loss of 13.8 kg (SD 14.2 kg; P<.001) or 11.8% (SD 10.9%; P<.001). A total of 204 (18.1%) participants achieved ≥5% weight loss, and 130 (11.5%) participants reached ≥10% weight loss. Weight loss did not significantly differ by ethnicity, indices of multiple deprivation, presence of type 2 diabetes, or engagement in the program.

Conclusions: The findings suggested that Second Nature's DWMI has the potential to support people living with obesity and type 2 diabetes remotely to achieve clinically significant and sustained weight loss at 2 years from baseline. Further research is needed to compare the intervention to standard care and assess integration with multidisciplinary clinical teams and pharmacotherapy in order to support this study's findings.

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KEYWORDS

digital health intervention; smartphone; diabetes management; obesity management; mobile phone; management; obesity; digital health; diabetes; weight; manage; support; weight management; retrospective analysis; treatment; type 2 diabetes; effectiveness; primary care; weight loss; clinical; primary care service

Introduction

Background

Most adults in the United Kingdom (UK) (around 65%) are affected by overweight or obesity, with the prevalence continuing to rise [1-4]. Due to the complex and chronic nature of obesity and its associated conditions, such as type 2 diabetes [5-7], the annual cost to UK society is estimated to be US $68.6 billion, roughly equivalent to 2-3% of gross domestic product [8].

Treatment for overweight and obesity in the UK broadly consists of 4 tiers of weight management service [9]. Tier 1 includes population-wide, universal, prevention interventions that reinforce messages of healthy eating and physical activity. Tier 2 includes community-setting lifestyle interventions delivered by a health coach, sometimes as part of a multicomponent weight management service, which may include pharmacotherapy. Tiers 3 and 4 are described as "specialist weight management services" (SWMSs) for people living with obesity, and they provide specialist assessment, monitoring, and comprehensive tailored treatment by a clinician-led, multidisciplinary team (MDT). An MDT typically includes a doctor, nurse, dietitian, psychologist, and a physiotherapist or exercise therapist, each with a specialist interest in obesity. Treatment in tier 3 may include pharmacotherapy and support from a dietitian, psychologist, and physiotherapist or exercise therapist where required. Treatment in tier 4 includes preoperative assessment for, and delivery of, bariatric surgery, further supported by an MDT.

While evidence for SWMSs in the UK is limited, short-term data suggest that they can be an effective obesity treatment [10]. For example, a systematic review of 19 studies of SWMSs in the UK reported positive effects on weight (specifically, 43.4% and 29.4% achieved ≥5% and 10% weight loss, respectively), BMI, glycemic control, blood pressure, and physical activity at 12 months [10]. While treatment duration varies between 6 and 24 months, to our knowledge, there are no published data on long-term outcomes following discharge from SWMSs [10,11].

Unlike tier 2, the provision of, and access to, SWMSs across the UK remains limited and varies geographically due to a lack of funding [12]. Similarly, due to the high costs associated with delivering these specialist services, existing services face increasing problems such as long waiting lists, understaffing, and a lack of treatment flexibility, and therefore, treatment often varies between services [11-13]. These barriers can result in treatment delays and adversely affect patient outcomes [11]. As a result, in June 2023, a US $50.9 million 2-year pilot program was announced by the UK government that aims to increase access to newly approved weight loss medication, semaglutide, outside of hospital settings, by using commercial digital weight management providers [14,15]. Furthermore, in August 2023, the National Institute for Health and Care Excellence announced an early value assessment of semaglutide treatment provided by commercial digital weight management providers [16].

Digital weight management interventions (DWMIs) offer a promising addition or alternative to traditional SWMSs that historically have been provided in person [10,17,18]. Potential benefits of DWMIs include increased access to services for some people, increased convenience, more frequent care, resource- and cost-savings, and the potential scalability to help manage the increasing prevalence of obesity and related conditions [16,18]. Previous systematic reviews have shown that DWMIs can be as effective as in-person interventions for weight loss and related outcomes for people with obesity [19-21], and the COVID-19 pandemic provided further evidence that existing intensive, in-person programs could be effectively transformed to deliver care remotely and effectively using technology [22-24]. Furthermore, 2 studies have shown that remote delivery of a weight management program in the UK can be as effective as usual face-to-face support in a tier 3 weight management service [18,25]. For example, a dietetic weight loss app program was found to be as effective and feasible when delivered remotely from a hospital-based SWMS to their usual face-to-face care [25]. However, real-world evidence of the potential for digital intervention to support SWMS in the UK National Health Service (NHS) remains limited [26].

This Study

To build on this growing evidence base, this study aimed to explore the potential of Second Nature's [27] DWMI to expand SWMSs outside of hospital settings for NHS-referred patients. It also aimed to contribute real-world evidence of DWMIs and longer-term outcomes following discharge from a weight management service. This retrospective analysis examined real-world data for patients living with obesity with or without type 2 diabetes, referred from NHS primary care services. The impact of Second Nature's 12-month program on weight change at 2 years from baseline was evaluated. This program was delivered via a smartphone or web-based app and has been found to be an effective weight management intervention and diabetes-related weight management intervention for patients with overweight, obesity, and type 2 diabetes referred by the NHS [28,29]. Previous research has found that DWMIs typically require a high amount of personal agency to be effective, given that making such changes to health behaviors requires time, resources, and education [30,31]. Consequently, such interventions risk exacerbating health inequalities and may be inequitable [30,31]. For this reason, this study also examined whether weight loss differs by ethnicity, socioeconomic status, type 2 diabetes status, and program engagement.

Methods

Ethical Considerations

This study did not require institutional review board approval, as it was a service evaluation and did not include personally identifiable information. As per General Data Protection Regulations, participants could request to have their information deleted at any time.

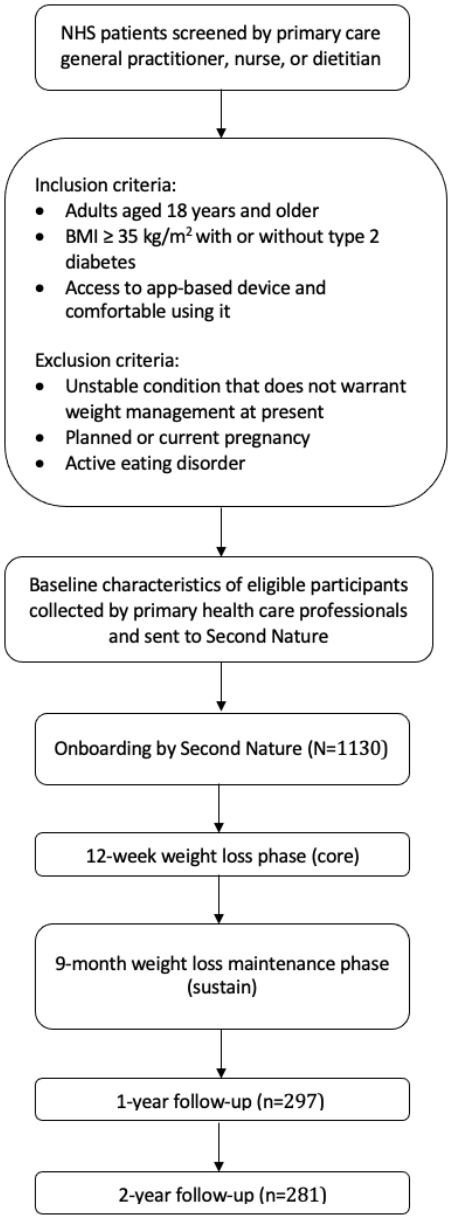
Participants

For participants who met our eligibility criteria, retrospective data were extracted directly from Second Nature's database in November 2023, deidentified, and pseudonymized using

identification numbers. To be referred to the Second Nature program, participants were required to consent for their anonymized data to be collected for research purposes, including analysis and publication. When registering for the program, participants were asked to agree to a privacy policy that reminded them of their consent. Participants included in this analysis participated in the Second Nature weight management program between January 1, 2017, and January 8, 2021. No major changes were made to the program content during this time.

Participants included in this analysis were screened and referred via secure NHS email to Second Nature by their NHS primary care general practitioner, nurse, or dietitian for weight management support (plus structured diabetes education for participants with obesity and type 2 diabetes). Eligible participants were adults (aged 18 years and older) with a BMI ≥35 kg/m^2, with or without type 2 diabetes. Participants were required to have access to a smartphone or tablet device and to be comfortable using technology to participate in the Second Nature program. Participants were referred to Second Nature if they were deemed clinically suitable for the program by the referrer, in relation to our inclusion and exclusion criteria. Exclusion criteria included an unstable condition that does not warrant weight management at present, planned or current pregnancy, and an active diagnosis of an eating disorder. Figure 1 presents the participant flowchart.

Figure 1. Participant flowchart. NHS: National Health Service.



Intervention Description

Second Nature's digital weight management program is a 12-month program, accessed by smartphone or web-based app, and consists of 2 phases: an initial 12-week phase that focuses on weight loss (called "core") followed by 9 months focusing on maintenance of weight loss (called "sustain"). Participants were encouraged to engage with this program for at least 12 months; however, they retained access to the program and

resources indefinitely. The program is available in 10 different languages.

Prior to starting the program, each participant received a recipe book, an instructional handbook, and wireless weighing scales. Throughout each of the phases, participants were given access to educational material on a variety of health and wellness topics such as nutrition guidelines, increasing physical activity, stress management, and improving mental well-being. Participants with type 2 diabetes also received additional structured education modules on managing their condition (accredited by an independent body, Quality Institute for Self Management Education and Training), including the role of insulin and managing their nutritional needs. The program was developed by an MDT of medical doctors, psychologists, dietitians, nutritionists, and behavioral scientists in line with relevant National Institute for Health and Care Excellence guidance for obesity and type 2 diabetes management and behavior change [32-37]. Behavior change techniques and insights were also adopted from the NHS Diabetes Prevention Programme guidelines [38] and the "behaviour change wheel" [39], with new behaviors encouraged through self-monitoring, goal setting, social rewards, and education from credible sources.

Features of the program include daily educational papers and goals; weight, steps, and sleep tracker; and a toolbox of resources (educational materials, recipes and meal planner, journal and food diary, and guided exercise videos). Each participant is assigned a health coach, who provides one-to-one tailored guidance through private text-based communication available during normal working hours, Monday to Friday. Additionally, participants had access to a group chat feature for peer support. The group chat was supervised by a health coach. Engagement with the app was monitored automatically, and health coaches were alerted when a participant showed low engagement (defined as <10 interactions) to indicate the risk of disengaging. Alerts prompted coaches to provide additional support for these participants in the form of messages. Support from their health coach ended following the completion of the 12-week "core" weight loss phase. Health coaches were dietitians (registered with the Health and Care Professions Council) or nutritionists (registered with the Association for Nutrition). Where a participant was coached by a nutritionist, supervision was provided by a dietitian.

Second Nature's health coaches and participants' primary care team communicated when necessary throughout the program to ensure safe, effective, and joined-up care. Communication took place through ad hoc phone calls and secure NHS email exchanges. Health information was shared when relevant to discuss and review participants' progress and challenges. Using this MDT approach ensured continuous monitoring of clinical measures and adjustments to medications, where needed. For example, if participants with type 2 diabetes were using a hypoglycemia-inducing medication, medication was adjusted based on weight loss progress.

Data Collection

Baseline characteristics (weight, height, age, gender, type 2 diabetes diagnosis, and ethnicity) and contact details were collected by the participant's primary care referrer and emailed to Second Nature. These data were entered into Second Nature's referral management system, and participants were sent an email link to complete a series of onboarding questions about their mobility, physical barriers to exercise, motivation, eating behaviors, and diabetes medication. Postcode data were also collected during onboarding to calculate socioeconomic deprivation based on the index of multiple deprivation (IMD) [40].

Participants were sent wireless weighing scales so that they could transfer their weight data to Second Nature. Instructions accompanying the scales advised placement on a firm, flat surface, weighing first thing in the morning after using the restroom, and on the same day at the same time each week to ensure accurate and consistent measurements. After use, the scales automatically transmitted readings to Second Nature's central database. A weight validation algorithm was used to ensure accuracy, accepting only measurements within a predicted range, considering the last recorded weight and the time since. Any irregular readings prompted an email alert to the participant to explain the reading would not be saved; however, if this was a mistake, then participants could contact their health coach or email the support team. This method aimed to filter out anomalous readings (such as readings from another member of a household), ensuring reliable data for analysis.

Weight readings at baseline, 1 year, and 2 years from the participant's start date of the program were extracted for the database. The lowest valid weight reading and the closest reading, after 1 year and 2 years, were used for analysis.

Engagement data were continuously collected as users engaged with the program and stored in Second Nature's secure analytics database. Engagement was defined as the total number of interactions with the app or web-based platforms and only analyzed during the first 3 months of the "core" active intervention phase of the program. Activity was only monitored during this active intervention phase as the intensity of the intervention decreased after 12 weeks, and participation was encouraged less frequently during the maintenance phase.

Statistical Analysis

The primary outcomes were weight change in kilograms and percentage weight change at 2 years. Secondary outcomes were weight loss after 1 year, program engagement, and the proportion of participants who achieved ≥5% and ≥10% weight loss.

Descriptive statistics were used to examine baseline characteristics of the study population, weight loss (percentage and kilograms), and engagement with the program. Continuous values are presented as mean (SD), and categorical data as n (%), unless otherwise stated.

For the primary analysis, differences in weight between the baseline and the 1- and 2-year follow-up points were compared using paired 2-tailed *t* tests. For each observation, we only compared those with available weight readings at each time point. Data were also analyzed on an intention-to-treat basis, using the baseline weight observation carried forward (BOCF) method when a final weight was not available [41] and using completers only (ie, participants with complete data at all time

points), to confirm the validity of the findings and illustrate the pattern of weight change in the same individuals over time.

A series of linear regression models were used to examine the association between baseline characteristics (ethnicity, IMDs, and presence of type 2 diabetes) and weight loss at 1 year and 2 years. Each characteristic was added as an independent variable into separate models to test for factors independently associated with weight loss. In each model, weight loss at either 1 year or 2 years was the dependent variable, and baseline weight was included as a covariate.

A further linear regression model was used to examine the association between program engagement and weight loss at 1 year and 2 years. Engagement was included as the independent variable, the dependent variable was weight loss, and baseline weight was included as a covariate.

All statistical analyses were performed using the R open-source statistical language through the RStudio interface (R Foundation for Statistical Computing), and the criterion for statistical significance was $P<.05$.

Results

Baseline Characteristics

A total of 1130 participants were included in this analysis. Of these participants, 740 (65%) were female. The mean age was 49.9 (SD 12.0) years, and the mean baseline BMI was 46.3 (SD 31.6) kg/m^2. In total, 78.2% (n=884) of participants included in the sample had type 2 diabetes.

In total, 30% (339/1130) of participants had ethnicity data, with 18.1% (205/339) from Black, Asian, mixed, or other ethnicities. All participants had IMD data available, with 30.8% (n=348) falling into the lower tertile, 34.3% (n=388) falling into the middle tertile, and 34.9% (n=394) falling into the upper least deprived tertile. A full breakdown of baseline characteristics can be found in Table 1.

Table 1. Baseline characteristics of program participants (N=1130).

Characteristic	Values
Age (years), mean (SD)	49.9 (12.0)
Female sex, n (%)	740 (65.4)
BMI (kg/m^2), mean (SD)	46.3 (31.6)
Weight (kg), mean (SD)	115.7 (21.7)
IMD[a] tertile, n (%)	1130 (100)
1-3	348 (30.8)
4-6	388 (34.3)
7-10	394 (34.9)
Ethnicity, n (%)	339 (30)
Black, Asian, mixed, or others	205 (18.1)
White	127 (11.2)
Missing or prefer not to say	798 (70.6)
Presence of type 2 diabetes, n (%)	884 (78.2)

[a]IMD: index of multiple deprivation.

Weight Change

Of the 1130 participants, 297 (26.2%) recorded weight readings at 1 year from baseline, and 281 (24.9%) recorded weight readings at 2 years from baseline. At the 1-year follow-up, the mean weight loss for those with recorded weights was 10.7 kg (SD 12.3 kg; $P<.001$), equating to a mean percentage weight loss of 9.1% (SD 9.6%; $P<.001$) from baseline. A total of 191 (17%) participants had ≥5% weight loss from baseline, while 107 (9.5%) participants had ≥10% weight loss (Table 2).

Table 2. Weight loss outcomes at the 1- and 2-year follow-ups for all participants with recorded weights, all with baseline observation carried forward, and complete cases only.

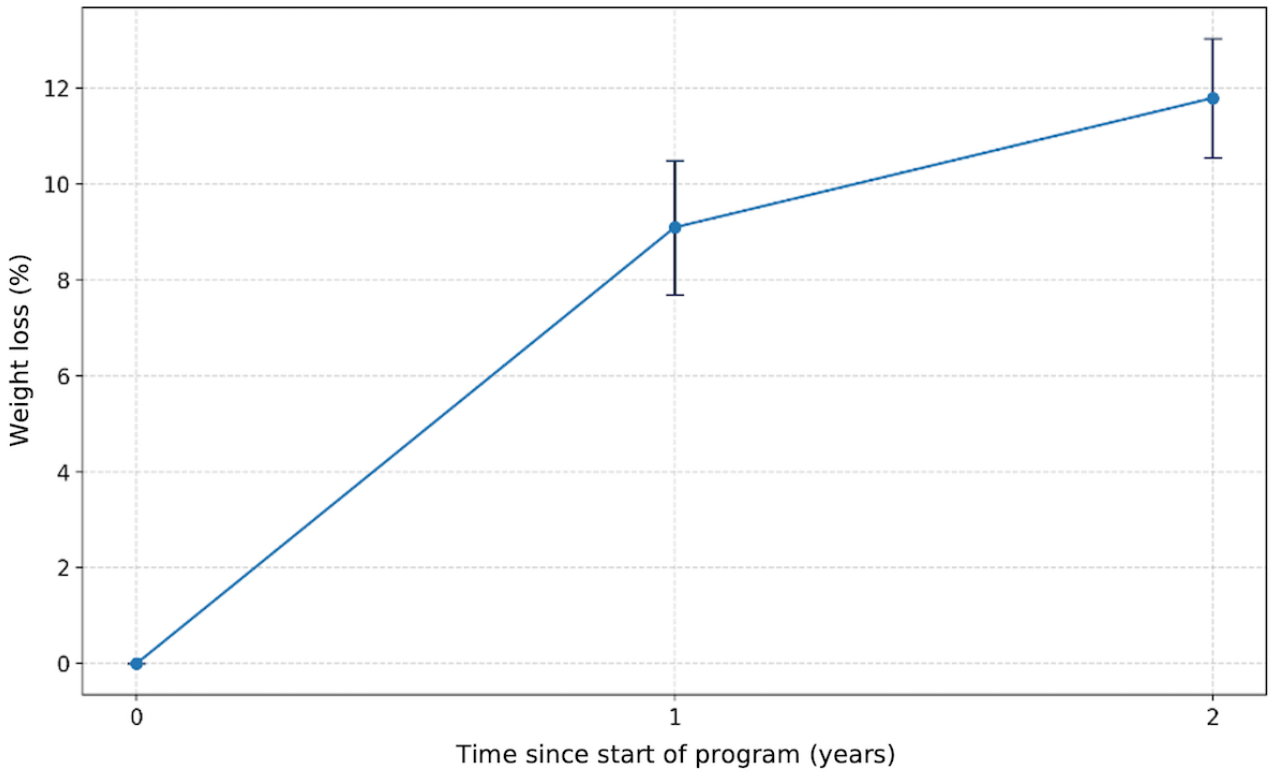
	At 1-year follow-up	At 2-year follow-up
All with weight recorded, n (%)	297 (26.2)	281 (24.9)
Weight loss (kg), mean (SD)	10.7 (12.3)[a]	13.8 (14.2)[a]
Weight loss from baseline (%), mean (SD)	9.1 (9.6)[a]	11.8 (10.9)[a]
≥5% Weight loss from baseline, n (%)	191 (17)	204 (18.1)
≥10% Weight loss from baseline, n (%)	107 (9.5)	130 (11.5)
Baseline observation carried forward, n (%)	1130 (100)	1130 (100)
Weight loss (kg), mean (SD)	2.8 (7.8)[a]	3.4 (9.2)[a]
Weight change from baseline (%), mean (SD)	2.4 (6.4)[a]	2.8 (7.3)[a]
≥5% Weight loss from baseline, n (%)	191 (17)	197 (17.4)
≥10% Weight loss from baseline, n (%)	107 (9.5)	127 (11.2)
Complete cases,[b] n (%)	207 (18.3)	207 (18.3)
Weight loss (kg), mean (SD)	10.1 (12.3)[a]	14.7 (14.0)[a]
Weight change from baseline (%), mean (SD)	9.1 (9.6)[a]	12.5 (10.8)[a]
≥5% Weight loss from baseline, n (%)	131 (11.6)	156 (13.8)
≥10% Weight loss from baseline, n (%)	73 (6.5)	105 (9.3)

[a]*P*<.001.

[b]The complete case analyses included participants who had weight readings at both the 1- and 2-year follow-ups.

The 2-year data also indicated a significant mean weight loss of 13.8 kg (SD 14.2 kg; *P*<.001), which translated to a mean weight loss of 11.8% (SD 10.9%; *P*<.001) from baseline (Figure 2). A total of 204 (18.1%) participants had ≥5% weight loss from baseline, and 130 (11.5%) participants had ≥10% weight loss.

Figure 2. Mean weight loss (%) after 1 year and 2 years. Error bars represent 95% CIs.



Applying the BOCF method to account for participants who did not record weight readings, the mean weight loss at 1 year was 2.8 kg (SD 7.8 kg; *P*<.001), and at 2 years, it was 3.4 kg (SD 9.2 kg; *P*<.001).

Among completers, those who recorded weights at both 1 year and 2 years, the mean weight loss was 10.1 kg (SD 12.3 kg; *P*<.001) at 1 year and 14.7 kg (SD 14.0 kg; *P*<.001) at 2 years.

Association Between Baseline Characteristics and Weight Loss

There was no evidence that weight loss at 1 year differed by ethnicity (Black, Asian, mixed, or others vs White) or type 2 diabetes diagnosis. Similarly, at 2 years, there was no evidence that weight loss differed by ethnicity (Black, Asian, mixed, or others vs White) or type 2 diabetes diagnosis, as shown in Table 3.

Table 3. Association between baseline participant characteristics and weight loss in kilograms at 1 year and 2 years.

Baseline characteristic	Weight loss from baseline to 1 year[a]		Weight loss from baseline to 2 years[a]	
	β (95% CI)	*P* value	β (95% CI)	*P* value
Ethnicity (reference=Black, Asian, mixed, or other ethnicities)				
White	.77 (–3.8 to 5.3)	.74	.68 (–4.4 to 5.7)	.79
Prefer not to say	–3.79 (–17.9 to 10.3)	.60	–12.78 (–39.5 to 14.0)	.35
IMD[b] tertile (reference=1-3)				
4-6	–1.58 (–4.8 to 1.67)	.34	.40 (–3.4 to 4.2)	.84
7-10	–1.60 (–4.9 to 1.7)	.34	1.46 (–2.5 to 5.4)	.47
Type 2 diabetes (reference=no)				
Yes	1.05 (–2.4 to 4.5)	.55	.24 (–3.8 to 4.3)	.91

[a]All models were adjusted for baseline weight. Separate analyses were run for each baseline characteristic.

[b]IMD: index of multiple deprivation.

Association Between Engagement and Weight Loss

The mean number of engagements in month 1 was 325 (SD 351.2), rising to 447 (SD 494.7) in month 2, before falling to 313 (SD 313.2) in month 3. There was no evidence that engagement during the "core" phase of the active intervention was associated with weight loss at either 1 year (β=.0007; 95% CI –0.0056 to 0.0071; *P*=.82) or 2 years (β=.0055; 95% CI –0.0026 to 0.0136; *P*=.18). These models were adjusted for baseline weight.

Discussion

Principal Results

In this study, we explored the effectiveness of Second Nature's 12-month DWMI to support adults with obesity, with or without type 2 diabetes, outside of hospital settings to help expand SWMSs for NHS patients. Furthermore, we aimed to contribute to the real-world evidence base on DWMIs and longer-term outcomes of such interventions. Participants demonstrated a statistically significant mean weight loss of 10.7 (SD 12.3) kg, equating to a mean percentage weight loss of 9.1% (SD 9.6%), at 1 year and 13.8 (SD 14.2) kg, which translated to a mean weight loss of 11.8% (SD 10.9%), at 2 years. When analyzed using BOCF, we found a statistically significant mean weight loss of 3.4 (SD 9.2) kg and a mean weight change of 2.8% (SD 7.3%) at 2 years. Weight loss did not significantly differ by ethnicity, IMDs, type 2 diabetes status, or engagement in the program. Overall, these results suggest that Second Nature's DWMI has the potential to be an effective and equitable DWMI for a diverse NHS patient population living with obesity and comorbid type 2 diabetes and therefore support increased access to SWMS in the NHS.

Limitations

There were notable limitations within our study. Due to the retrospective, real-world nature of this study, there was no control group, which means the findings must be interpreted carefully. However, a similar study of a commercial DWMI with a larger sample size also found that users lost a significant amount of weight using this type of program [42]. Due to the observational nature of the study, a significant number of participants did not submit weight readings within the specified data collection period, despite regular reminders and encouragement from health coaches. Capturing long-term, real-world data for DWMIs is challenging. Additionally, one-to-one support from health coaches ceased after 3 months of the total program period, which likely contributed to difficulties in capturing longer-term weight data. For the weight and engagement data collected, a self-selection bias is possible, as those participants who weighed themselves more frequently may have been more motivated and engaged and therefore experienced more weight loss.

Participants were referred to Second Nature from tier 2 weight management pathways or as part of routine type 2 diabetes care and not from a SWMS. Nevertheless, patients with obesity are eligible for treatment within SWMS in the NHS at BMI ≥35 kg/m^2. The average BMI of participants in this study was 46.3 (SD 31.6) kg/m^2; therefore, many participants would be eligible to access a SWMS. Furthermore, while this program was not initially developed to be a specific "tier 3" program, a distinguishing feature of tier 3 services is an MDT approach.

In this study, we worked effectively with the patients' primary care teams using such an approach, reflecting a similar protocol to existing tier 3 services. Similarly, while we did not have input from an existing tier 3 service, the program was developed by an MDT from Second Nature that consisted of medical doctors, psychologists, dietitians, nutritionists, and behavioral scientists. As such, this study was able to assess the *potential* of a DWMI to support existing SWMS in the NHS.

Due to the retrospective and real-world nature of this analysis, it was not possible to extract and analyze other relevant data such as medication usage, side effects, clinical outcomes (eg, hemoglobin A_{1c}, blood pressure, and lipid profile), and psychological and quality of life-related outcomes. Further research is needed to determine the impact of our program on these health outcomes and wider economic impact. Finally, the data used for this study were collected by employees of Second Nature and were not checked by an independent party or NHS organization.

Comparison With Prior Work

The effectiveness of Second Nature's DWMI has previously been explored in self-paying consumers and patients with type 2 diabetes; however, these studies included populations with lower average baseline BMIs of 33.7 and 35.9 kg/m^2, measured shorter-term outcomes at 6 and 12 months [28,43]. This study builds on this earlier work by exploring longer-term outcomes with a population similar to that seen in SWMS [32]. Importantly, an observational study, which assessed the uptake of a commercial DWMI among patients awaiting their first appointment with a SWMS, similarly found their app to be feasible [44]. This study similarly provides preliminary evidence that DWMIs may be a viable way to expand NHS SWMS [19-21]. Remotely delivered interventions have the potential to increase access to treatment for people with busy schedules, limited mobility, and those living in remote areas.

Previous research has found that DWMIs typically require a high amount of personal agency to be effective, given that making such changes to health behaviors requires time, resources, and education [30,31]. Consequently, such interventions risk exacerbating health inequalities and may be inequitable [30,31,45]. In this study, there was no evidence that weight loss differed by ethnicity, IMD, or type 2 diabetes status at follow-up. Similarly, we did not find an association between engagement in the first 12 weeks and weight loss at follow-up. A recent systematic review of 13 studies investigated differences in the uptake of, engagement with, and effectiveness of mobile interventions for weight-related by age, gender, race and ethnicity, and socioeconomic status [46]. Given the limited number of studies and inconsistent findings, the authors stated that current evidence of the presence of a digital divide in mobile interventions targeting weight-related behaviors is inconclusive [46]. However, further research, such as a randomized controlled trial with a larger sample size, is warranted to support the findings of this study.

To continue building the evidence base on DWMIs, it would also be beneficial to explore the impact of the collaboration of a DWMI and MDT including dietitians, doctors, psychologists, and exercise specialists on outcomes for people living with obesity and related conditions with the view to increase safety and accountability and optimize treatment outcomes. Additionally, an evaluation of the integration of pharmacotherapeutic interventions embedded in DWMIs for SWMSs is also needed.

Conclusions

This study suggests that Second Nature's DWMI has the potential to support people living with obesity and type 2 diabetes remotely to achieve clinically significant and sustained weight loss at 2 years from starting an intervention. DWMIs could help to expand existing SWMS outside of hospital settings to increase access to treatment and reduce pressure on hospitals. Further research is needed to compare such interventions to standard care as well as assess the integration of DWMIs with multidisciplinary clinical teams and pharmacotherapy to support this study's findings.

Conflicts of Interest

RR and MW are employees of Second Nature Healthy Habits Ltd. Second Nature is the industrial partner on GMW's Medical Research Council Industrial Collaborative Awards in Science and Engineering studentship.

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Abbreviations

BOCF: baseline weight observation carried forward
DWMI: digital weight management intervention
IMD: index of multiple deprivation
MDT: multidisciplinary team
NHS: National Health Service
SWMS: specialist weight management service

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Original Paper

Acceptability of Mobile App–Based Motivational Interviewing and Preferences for App Features to Support Self-Management in Patients With Type 2 Diabetes: Qualitative Study

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Abstract

Background: Patients with type 2 diabetes mellitus (T2DM) experience multiple barriers to improving self-management. Evidence suggests that motivational interviewing (MI), a patient-centered communication method, can address patient barriers and promote healthy behavior. Despite the value of MI, existing MI studies predominantly used face-to-face or phone-based interventions. With the growing adoption of smartphones, automated MI techniques powered by artificial intelligence on mobile devices may offer effective motivational support to patients with T2DM.

Objective: This study aimed to explore the perspectives of patients with T2DM on the acceptability of app-based MI in routine health care and collect their feedback on specific MI module features to inform our future intervention.

Methods: We conducted semistructured interviews with patients with T2DM, recruited from public primary care clinics. All interviews were audio recorded and transcribed verbatim. Thematic analysis was conducted using NVivo.

Results: In total, 33 patients with T2DM participated in the study. Participants saw MI as a mental reminder to increase motivation and a complementary care model conducive to self-reflection and behavior change. Yet, there was a sense of reluctance, mainly stemming from potential compromise of autonomy in self-care by the introduction of MI. Some participants felt confident in their ability to manage conditions independently, while others reported already making changes and preferred self-management at their own pace. Compared with in-person MI, app-based MI was viewed as offering a more relaxed atmosphere for open sharing without being judged by health care providers. However, participants questioned the lack of human touch, which could potentially undermine a patient-provider therapeutic relationship. To sustain motivation, participants suggested more features of an ongoing supportive nature such as the visualization of milestones, gamified challenges and incremental rewards according to achievements, tailored multimedia resources based on goals, and conversational tools that are interactive and empathic.

Conclusions: Our findings suggest the need for a hybrid model of intervention involving both app-based automated MI and human coaching. Patient feedback on specific app features will be incorporated into the module development and tested in a randomized controlled trial.

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KEYWORDS

mobile health; motivational interviewing; diabetes; self-management; health coaching; acceptability; application; management; type 2 diabetes; communication; patient barrier; healthy behavior; feedback; visualization; hybrid model

Introduction

Type 2 diabetes mellitus (T2DM) is a leading cause of mortality and disability. Globally, 537 million adults have diabetes, and it is projected to increase to 783 million by 2045 [1]. In Singapore, 1 in 3 adults are at risk of developing diabetes in their lifetime [2]. The prevalence of T2DM will increase from 14.2% in 2022 to 25% in 2050, highlighting the urgent need for developing effective management strategies for patients with T2DM [3].

Self-management has been found to be effective in enhancing clinical and behavioral outcomes of patients with T2DM [4]. However, research indicates that self-management in patients with T2DM is inadequate due to the lack of adherence to healthy behavior and medications [5]. This is concerning because poorly controlled T2DM results in increased incidence of life-threatening complications such as neuropathy, retinopathy, amputation, and cardiovascular disease [6-8]. Patients' knowledge deficit, lack of motivation toward behavior change, and inadequate self-discipline have been identified as main patient-related barriers to effective self-management [9-11].

Motivational interviewing (MI) is a patient-centered and goal-oriented communication method that can address patient barriers and promote positive health behavior changes [12]. Central to MI is assisting a patient to resolve inner state of ambivalence by expressing empathy, avoiding argumentation, developing discrepancy, and supporting self-efficacy [13,14]. Evidence suggests that MI holds promise for improving self-management of T2DM [15]. Several systematic reviews and meta-analysis of randomized controlled trials (RCTs) have found that MI-based interventions contributed to not only a reduction in hemoglobin A_{1c} value but also improvements in self-management skills, dietary behaviors, and emotional well-being, albeit some of these positive results were not sustained long term [12,16,17].

Although existing literature provides important insight, the vast majority of studies used face-to-face or telephone-based MI interventions [18,19]. With the growing adoption and penetration of smartphones, automated MI techniques powered by artificial intelligence (AI) on mobile devices may offer effective motivational support to patients, complementing the traditional model of in-person counseling. In addition, the delivery of MI using AI could allow more sustainable scaling up and implementation of MI in clinical practice [20]. However, there is little evidence supporting the use of mobile app–based MI in improving health outcomes of patients with T2DM. Furthermore, no study explored the acceptability of app-based MI among patients with T2DM as end users [21]. Incorporating end-user feedback into the design of MI would be essential to improving the effectiveness of the MI intervention for patients with T2DM.

We have developed a mobile app EMPOWER that performs remote monitoring and education of patients with T2DM through AI-powered personalized nudges. The clinical effectiveness of the EMPOWER app is being tested through an ongoing RCT [22]. The addition of an MI module into the EMPOWER app has been planned for improved T2DM management as a follow-on intervention. This study aimed to explore the perspectives of patients with T2DM on the acceptability of app-based MI in routine health care and collect patient feedback on MI module features to inform future interventions.

Methods

Study Design

The study adopted a qualitative research method involving semistructured interviews.

Participant Recruitment

Eligibility criteria included patients who had a diagnosis of T2DM, aged 40 years and older, and had no cognitive impairment that prohibits normal conversation. Patients with gestational diabetes or serious diabetes-related complications were excluded. Eligible patients were recruited from polyclinics, which provide subsidized comprehensive and integrated public primary care services in Singapore. Patients were purposively recruited in terms of age (40-49, 50-59, and 60-69 years old) and educational attainment (university and above, diploma, secondary school, and primary and below) to ensure a diversity of opinions from July 2022 to November 2022. Previous studies have demonstrated that age and education levels influence app use [23-26].

Data Collection

A semistructured interview guide was developed based on the review of relevant literature and pilot-tested with 3 participants (data included). Topics included current diabetes management, confidence and importance of behavior changes, acceptability of MI in general and app-based MI in combination or the absence of health coaches, preferences for the mode of MI delivery, and usefulness of MI module features. In this study, app-based MI includes delivery of MI through rule-based techniques and machine learning techniques, without the involvement of humans. To assess participants' confidence and importance of behavior changes, we used the 0-10 ruler (numerical rating scale), which is recommended by Miller and Rollnick [13,14]. These rulers have been validated for tobacco cessation [27]. To facilitate specific feedback from participants, we used a mock-up app wireframe similar to the appearance of a proposed module wireframe built on a transtheoretical model [28] and self-determination theory [29]. The wireframe included features such as rulers of importance and confidence, self-reflection and change talk with goal setting, tracking of progress and nudging, backup plan writings, educational resources, and gamification and rewards, along with a summary page of goals and achievements that may be shared with health care providers. The wireframe focused on 3 areas to promote diabetes self-management: diet, physical activity, and

medication adherence. These module features had been iterated over time as the interview progressed. All interviews were conducted via videoconferencing in English and Mandarin by interviewers trained in qualitative research. The interviews lasted approximately 60 minutes in duration. Field notes were taken during the interviews.

Data Analysis

All interviews were audio recorded and transcribed verbatim. Transcripts were thematically analyzed [30]. Coding categories were developed based on the following steps: familiarizing data by reading transcripts line by line, developing a coding frame to apply to the whole data set, attributing data to individual codes, collating codes into themes, and interpreting them through meaning and connections. Each transcript was coded by 3 coders (HT, CW, JL). Agreement regarding the coding frame and category refinement was achieved via discussions and reflexive reviews of the previous codes and emergence of new themes. The code categories and themes were subsequently reviewed by the study team to ensure that the codes reflect the major themes that emerge from the data. The NVivo 12 software (Lumivero) was used for analysis. Data collection and analysis were conducted in an iterative manner until thematic saturation was accomplished. To ensure transparency, rigor, and trustworthiness, we used a detailed audit trail, member checking, and reflexivity at each step [31]. Participant feedback was not sought due to difficulty in recontacting patients.

Ethical Considerations

The study was approved by the SingHealth Centralized Institutional Review Board (CIRB 2022/2031). Participants provided verbal informed consent prior to study commencement. The study team maintained data confidentiality by redacting personally identifiable information from interview transcripts and generating unique study identifiers, which were linked to participant identifiable information through a password-protected file. Participants were reimbursed SGD $50 to defray the cost of their participation in this research.

Results

Characteristics of Participants

A total of 33 patients participated. Data saturation was achieved with 30 interviews. The mean age of the participants was 56 years. Approximately 70% (23/33) were male and 85% were Chinese. The majority were working full-time (20/33, 61%), and more than half (28/33, 85%) of the participants attained secondary education and above. Participants had comorbid health conditions such as hypertension and hyperlipidemia. Median motivational ruler ratings of importance and confidence were 8.5 and 7, respectively (Table 1).

Findings were presented by 3 major areas: perceptions of MI as part of routine health care, receptivity toward app-based MI, and feedback on app-based MI module features.

Table 1. Participant characteristics (N=33).

Participant characteristic	Value
Age (years), mean (range)	56 (42-66)
Sex, n (%)	
Male	23 (70)
Female	10 (30)
Ethnicity, n (%)	
Chinese	28 (85)
Non-Chinese (Malay, Indian, others)	5 (15)
Employment status, n (%)	
Full-time	20 (61)
Part-time	7 (21)
Retired or unemployed	6 (18)
Education, n (%)	
University and above	9 (27)
Diploma	11 (33)
Secondary school	8 (24)
Primary and below	5 (15)
Medical condition[a], n (%)	
Type 2 diabetes mellitus	33 (100)
Hypertension	21 (64)
Hyperlipidemia	17 (52)
Importance to change (1-10), median (range)	8.5 (5-10)
Confidence to change (1-10), median (range)	7.0 (1.5-10)

[a]Participants may have multiple conditions.

Perceptions of MI as Part of Routine Health Care

MI Serving as a Mental Reminder to Build Confidence and Motivation

By and large, participants were open to the idea of MI. They stated that something would have to be done to improve their current state of self-management. This is because their motivation to maintain healthy behaviors was often attenuated by a host of challenges. Participants believed that MI could offer them the encouragement and mindset required to overcome the "mental barriers," which are psychological challenges that hinder their consistent engagement in healthy behavior, such as a lack of self-discipline and motivation.

> *MI would be good to overcome mental barriers. MI can serve as a check-in mechanism to remind me of my progress and how to improve [my behavior]. So even when I am tired, I will still make an effort to exercise.* [Participant #31, male]

Other participants noted that additional assistance from MI would enable them to learn new knowledge and build confidence to improve self-management skills.

> *I would like to have somebody that I can talk to because he or she will understand what I could eat or what I could do, that will help lower my cholesterol or improve diabetes.* [Participant #19, male]

MI as a Complementary Care Model to Existing Health Care Services

Participants felt that MI would be a useful tool to address problems they experienced in busy primary care clinics. Many expressed issues of care discontinuity at length. For example, being unable to consistently see the same provider undermined their interest in listening to advice. Frustrations related to receiving conflicting health advice from different providers seemed to further compound trusting relationship and willingness to change health behaviors. Hence, they saw MI as a care model that would complement the existing services.

> *Let's just say that most of the time, doctors just throw you a chunk of information and then you're supposed to go home and digest it. Then, digestion or indigestion is another issue…so I am open to it [MI]. It's something that will benefit me.* [Participant #22, female]

Perceived Behavioral Control Leading to Reluctance to MI

Despite many being interested in trying the MI, some patients expressed a strong desire to self-manage their conditions and change behaviors. Some felt confident in their ability to manage conditions, while others reported already making changes and preferred self-management at their own pace.

> *Actually, I'm very independent, doing things on my own. I don't really listen to any counsellor. I know the direction that I wanted to head to...So, I got to do it on my own. I prefer to do it on my own.* [Participant #03, female]

Time Constraints and Competing Demands Diminishing Interest in MI

A host of competing demands was mentioned by several participants as something that would diminish their interest in MI-based coaching sessions. MI was characterized as useful, but engaging in MI was considered a physical and cognitive burden over many more important responsibilities related to family and employment that may take priority.

> *If a counsellor wants to motivate me, if I got the time [to listen] and if it's what I want, I will do. Though I am very open, my time is really not enough so I don't think I will participate [in-person].* [Participant #08, male]

Receptivity Toward App-Based MI Using AI for Self-Management

Perceived Convenience for Access

By and large, participants agreed that mobile app–based MI would be convenient compared with in-person sessions given greater flexibility in terms of access and scheduling. Those who expressed unwillingness to try MI due to competing priorities welcomed the potential of app-based MI as an ideal alternative to face-to-face MI.

> *Well, for my case, I would prefer an app [based MI] because I can do this like, anywhere. During my lunchtime, I can do it while I am at my work.* [Participant #32, male]

Enabling Person-Centered Advice

Some participants expressed a preference for app-based MI over in-person MI where they often received health advice that was less individualized and potentially difficult to adopt. They felt that the app-based MI's ability to tailor individual needs and circumstances in an ongoing self-management journey would help foster motivation through timely and pertinent guidance.

> *Diet wise, I would prefer more app-based MI because it can be individualized. I have been advised not to eat this and that [from healthcare professionals]. I get frustrated because it's like someone keeps telling me to avoid certain food, which then becomes my own problem…I'd like to get advice through app on what I can eat or why I can't eat.* [Participant #11, female]

Appreciation of Anonymity

Participants in favor of app-based MI expressed their feeling of discomfort about in-person consultation for fear of being judged or being told off. They felt that they would be more guarded and less relaxed when they were asked to share their lifestyle behaviors and self-management.

> *Because sometimes face-to-face you want to say something, but you cannot articulate. That's something I am worried about, like offending someone. So, this [app] is better. If I am not happy with what I will say, I don't have to mention immediately in the app.* [Participant #10, male]

Concerns About the Lack of Human Touch

Participants at the same time expressed concerns about lack of authentic human contact and insufficient social connections between the app and the users. A few participants highlighted the importance of verbal and nonverbal gestures and cues in social conversation that could play an important role in engaging and motivating patients. They were worried that the app-based MI may not be able to build a relational foundation that in-person session could offer.

> *I mean the kind of personal touch in MI must be done face-to-face. And even in counselling, I believe sometimes tapping on the shoulder, saying something softly, could change the mood as well.* [Participant #18, male]

Limited Digital Literacy to Adopt App-Based MI

Some older participants who were less receptive to app-based MI raised issues about the navigation of various features. They were worried that the app-based MI would not be easily learned and adopted due to technical complexity.

> *I'm not so into this because different apps are always giving me problems. I have to find the code and speak to people [to learn how to use it]. It's quite frustrating for some of us older folks who are not IT savvy.* [Participant #14, female]

Participant Feedback on App-Based MI Module Features

Overall Module Design and Interface

Simplicity and Ease of Navigation

Participants suggested that the module interface should be easy to navigate to ensure that users with limited digital experience could follow the instructions. On average, participants were willing to use the MI module for 10 minutes with the flexibility of responding to 3 or more MI-related questions. The suggested interval between using the MI module ranged from once a week to once every 6 months. They would like the motivational prompts to be concise and relevant to positive behaviors based on completed tasks.

> *I will say that for the design, you might want to make it simple for beginners. You can ask people 10 questions but for others who are not tech-savvy, you can just ask three questions. If someone has a lot of*

things to tell you, you can ask like 20 questions. [Participant #05, male]

More Visualization Tools to Foster Motivation

The necessity for additional visuals, beyond graphics, was stressed by many participants. Participants expressed that clear visualization would enable them to closely monitor their progress, make necessary adjustments, and change behavior, which ultimately fosters their motivation.

> *I would prefer seeing, you know, some charts to indicate where I am, so after a certain period, I will know whether I am on the right track. So, a graph or whatever chart will help me. I like more direct outcomes and I want to see them soon.* [Participant #01, male]

Inclusion of a Human Health Coach as Opposed to Being Solely Automated

It was commonly viewed that competent health coaches should be accessible through the app, although they may not be required frequently. The health coach would support the patient's ongoing efforts to achieve their goals, especially when dealing with complex matters that cannot be addressed by the app alone. This is particularly crucial during the initial stage of using the app, as users may encounter challenges that require immediate guidance and assistance from health coaches.

> *I would like the health coach to be available on the app. The app may be more for daily tracking, right? Then if the health coach, face-to-face, maybe once a month, can talk to me about what my progress is, to give more professional advice, I think that will help me.* [Participant #31, male]

Specific Module Features

Goal Setting and Change Talk

The initial wireframe included a goal setting (allowing users to set right-sized and attainable goals), diary (prompting users to reflect on reasons for change), rulers of importance and confidence (user's level of motivation and self-efficacy), and goal countdown (enabling users to determine a start date) to encourage the patient's self-reflection and autonomy. While participants appreciated the ability to set personal goals for behavior change, they suggested the goal setting function to be more specific and direct with some examples (eg, take the stairs and take 0% sugar drinks). Importantly, many desired to receive more guidance to ensure the attainment of those goals (Figures 1 and 2).

Figure 1. Goal setting and Change Talk. The goal setting feature includes Change Talk, importance and confidence rulers, reasons for change and goal countdown to foster self-reflection on capabilities, intrinsic motivation, and relatedness.

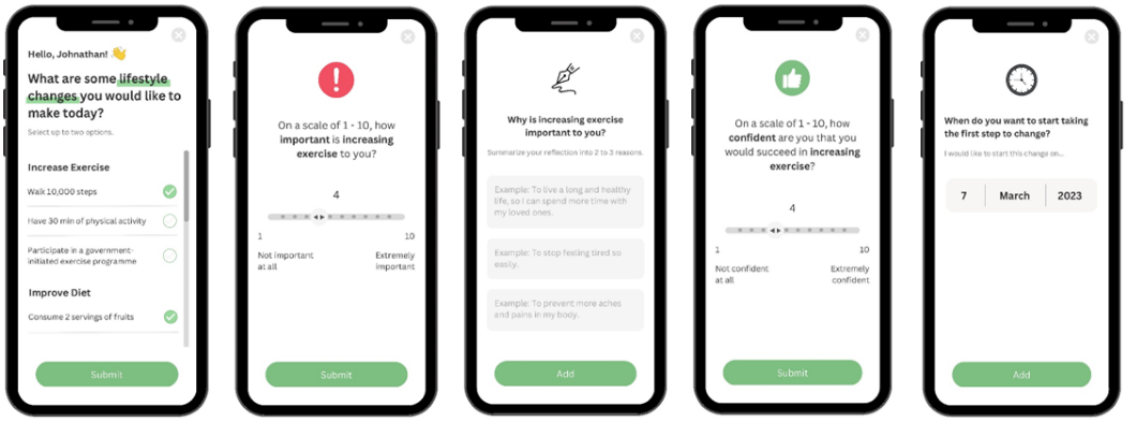
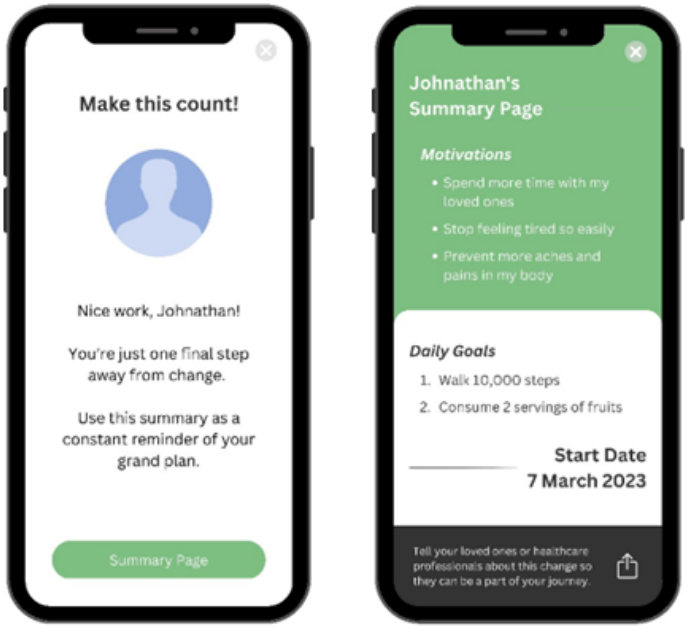


Figure 2. Summary of motivations and goals. The summary page serves to reinforce the patient's autonomy and intrinsic motivation. It can be shared with a human health coach remotely to improve a sense of relatedness.



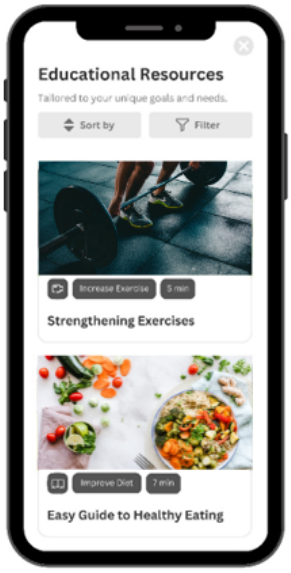
The goal setting will help me achieve what I want to achieve, by giving me better vision and future target, so once I have achieved that target, I can move on to the next target. As I move on, I achieve certain milestones, then from there, it sort of motivates me to continue. [Participant #16, male]

Personally, the best solution for me is, daily when I open the app, it can tell me what I need to do instead of writing so many journals in this app. Better ask me what I want to change and tell me what I can do to improve. I just need a very straightforward instruction. [Participant #31, male]

Educational Resources

Health education materials were designed to improve autonomous motivation by providing tailored educational resources and guidance. Participants wished to have more multimedia resources that they found easier to understand compared with textual information. Participants would like to receive specific health information based on personal goals and needs (eg, definition of refined carbohydrates; Figure 3).

Figure 3. Educational resources. Tailored educational resources based on goals increase patient competence and intrinsic motivation.



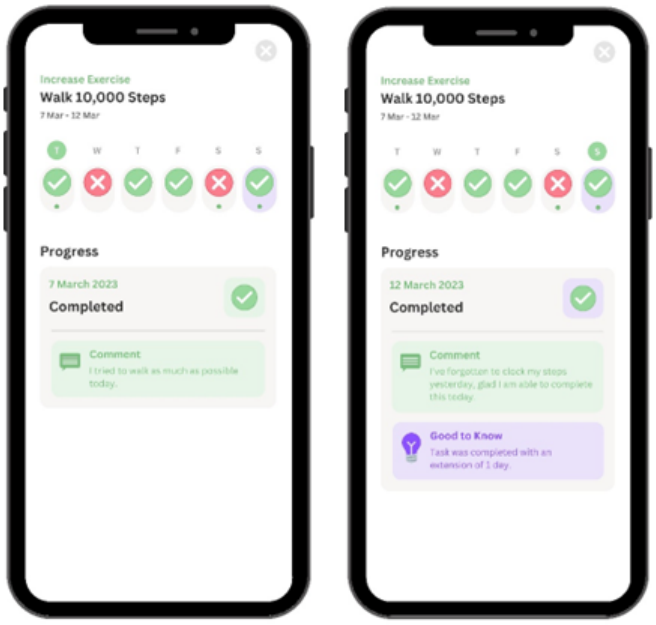
I would like to see more live ones. I don't like to read a lot of words or look at cartoons. Sometimes, those things are really misleading, and you don't understand what they are talking about, like some exercises I saw in graphic forms. [Participant #04, female]

Tracking and Nudges Adaptable to Behavioral Data

The wireframe presented algorithm-based notifications that support patient competence and self-efficacy to continue engaging in health behavior. Participants liked the idea of nudging to help motivate the app users and felt that daily

prompts would be an important reminder. In addition to daily prompts, they would like to review weekly and monthly health tasks. Participants desired a 2-way conversational feature where the prompts can be interactive and empathic with different types or tones of encouragement (Figure 4).

Figure 4. Progress tracking and nudging. Progress tracking and nudging (reminders) with multiple measures of success improve patient competence and self-efficacy for sustained engagement.



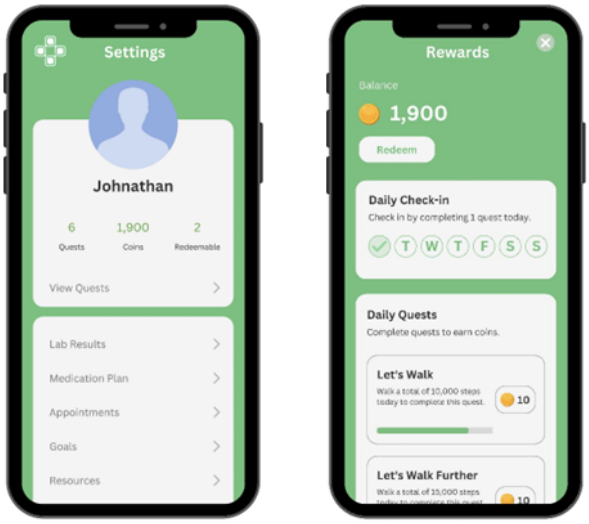
Reminders will help pay attention to your diabetes management, because you might forget and go back to old ways of eating sweet things. But if someone tells me that you must cut your sugar intake, then maybe it will remind me that I shouldn't be taking so much sugar. It's like having someone to remind you of…a motivating force. [Participant #015, male]

I like the motivational prompts to be like a two-way communication. So instead of simply telling me 'Today, you have zero hours of walking', the reminder can say 'have you done this already today? Why was it not done yet? Why are you so busy?' A gentle reminder. Just like talking to your friend who understands me. [Participant #01, male]

Gamification and Rewards

Features of gamified challenges and rewards were included in the wireframe to increase patient competence and intrinsic motivation. Participants suggested incremental incentives for cumulative days engaged or the number of health tasks completed to make sure that individuals could stay motivated (Figure 5).

Figure 5. Gamification and rewards. Gamified challenges and rewards enhance patient competence and autonomous motivation through fun activity.



…Rewarding will encourage people to change behaviors. If you can exchange points for a voucher, that's a very good idea, and in addition to step counts, if there are other tasks to increase your points, such as healthy eating, that will motivate people. [Participant #25, male]

Lastly, participants acknowledged that MI via a mobile app may not be as effective in addressing their personal concerns as receiving MI from human coaches. However, they expected the MI module to offer advice that would be as clear and pertinent as the one provided by health care providers.

> *I understand the MI through app cannot replace a human, but I'm hoping that it will be better than a chatbot and as human as possible… Just like when you go to a doctor, they give their direct opinions. Certain predefined answers on chatbots at times are not relevant to my concerns.* [Participant #30, male]

Discussion

Principal Findings and Comparison With Prior Work

This study sought to explore the perspectives of patients with T2DM on the acceptability of MI and app-based MI as part of routine health care and their preferences on MI module features. Most technology-delivered adaptations of MI relied on texting or web-based interventions [32]. To the best of our knowledge, 2 studies used mobile apps for MI, focusing on encouraging behavior change [21] and reducing risky alcohol use [33]. Therefore, our study offers unique perspectives on app-based and AI-enabled MI for T2DM self-management.

In our study, participants in general saw MI as a mental reminder to increase motivation and a potentially complementary care model that allows more opportunities to reflect on and alter their management of T2DM. Despite general openness to MI as part of routine health care, our findings indicate that there was a desire to manage their own condition and behaviors by some participants without having life choices being interfered with by the introduction of MI. This sense of reluctance to MI could stem from the lack of understanding of the principles and core strategies of MI given that none of the participants experienced MI. Literature shows that patients with T2DM preferred to have the autonomy to make decisions about their own management of condition based on personal values, and to avoid external pressures that may influence their decision-making process [34,35]. Recent studies on AI-powered chatbot for brief MI also revealed that there were common perceptions of MI chatbots as less intrusive and less threatening to autonomy compared with their human counterparts [36,37]. Therefore, when implementing an MI intervention in routine clinical care, more efforts should be made on patient education to ensure that patients are adequately informed of the concept, main techniques and benefits of MI, and the difference between MI and a traditional consult model. In addition, the interaction model of MI should provide patients with a sense of independence and autonomy, create ample opportunities to express themselves, and establish reciprocal feedback to empower patients to exercise their self-determination [38].

While the idea of incorporating technology into the delivery of MI was novel, participants were generally receptive to the app-based MI given that app-based MI can be accessed remotely. Notably, app-based MI was seen by many as providing a more relaxed atmosphere for open sharing without having the fear of being judged by their health care providers. This finding echoes prior research that individuals receiving technology-enabled MI appreciated nonjudgmental interaction with a simulated counselor, underscoring the significance of patient-centered reflections and guiding for a change [18,39]. However, participants also expressed reservations regarding the lack of human touch with the app, which could potentially undermine the therapeutic relationship between the provider and the patient. Systematic reviews indicate that MI interventions using technology tended to pay less attention to relational and interpersonal components of MI despite technology-delivered MI's marked advantages to face-to-face counseling [19,39]. In addition to the limited relational contact, technology can bring its own set of challenges to some patients due to the lack of digital literacy as shown in our study. To foster relational emphasis of MI, our app development will adopt a hybrid model that will consist of automated MI delivered through an app supplemented by human health coaching (which can be through an app, texting, or telephone call). A summary page of goals and achievements can be tracked by a human health coach for further discussion with patients who require additional MI support in a time-efficient manner. Improving digital literacy of patients would be imperative to increasing eventual uptake of technology-enabled MI.

In line with existing literature [21,40,41], participants valued tailored goal setting features that support individual autonomy and choice. At the same time, there were concerns about the ability to reach the goal and longer-term engagement. To sustain motivation via a mobile app, participants requested for features of flexible and ongoing supportive nature such as the visualization of milestones, use of multimedia tailored to their specific needs, and communication tools that are interactive and empathic. Indeed, studies suggest that technology-powered MI interventions involving imagery, carefully designed chatbots and embodied conversational agents as a companion in decision-making and branching algorithms customized to individual motivations could be potentially effective in changing target behaviors [36,42,43]. These efforts will be considered in the current or future version of our MI intervention to improve user experience and patient outcomes. Another important input from participants was the provision of incremental rewards based on goals and gamified challenges for motivation-enhancing activity. Although gamification features are found to increase user engagement and experience of competence [21,44], evidence is sparse regarding its impact on cognitive engagement in behavioral changes. Future research is warranted to assess the effectiveness of digital gamification vis-à-vis nongame mechanism on behavior change in MI interventions for patients with T2DM.

Strengths and Limitations

The strength of this study lies in its emphasis on cocreation of app-based MI and its optimal implementation with purposively sampled patients with T2DM, which provided a diversity and richness of end users' perspectives.

This study has a few limitations. Participants were recruited from public primary care clinics, and hence their responses may not represent the range of health care services used by patients with T2DM. With the high median rating of importance to change (8.5) and high median rating of confidence to change

(7.0) among the participants in this study, it is possible that the voluntary nature of participation might have introduced a selection bias, with patients who were motivated to change behaviors being more prone to participate. Although we sought to recruit a balanced sample, there was limited representation of female and Indian or Malay participants in our multiethnic population. In addition, previous studies have shown that MI may increase the self-efficacy of participants [45-47]. However, we did not assess the self-efficacy of participants in this qualitative interview as there is no conclusive evidence regarding the sustained effect of MI delivery on self-efficacy. Lastly, because we used a mock-up wireframe of MI features, participant feedback may have been limited to the features presented during the interviews.

Conclusions

This study examined the acceptability of app-based MI and user preferences on MI module features through qualitative interviews with patients with T2DM to inform the development of module content and optimal implementation of app-based interventions. Our findings revealed general openness to app-based MI. Yet, concerns were raised regarding potential compromise of patient autonomy in self-care and lack of meaningful human engagement. To address these concerns, more consideration should be given to patient education on the core principles and benefits of MI and a hybrid model of intervention involving both automated MI and human health coaching. Specific participant feedback will be incorporated into the app and tested through a pragmatic RCT.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
MI: motivational interviewing
RCT: randomized controlled trial
T2DM: type 2 diabetes mellitus

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Original Paper

Development of a Novel Mobile Health App to Empower Young People With Type 1 Diabetes to Exercise Safely: Co-Design Approach

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Abstract

Background: Blood glucose management around exercise is challenging for youth with type 1 diabetes (T1D). Previous research has indicated interventions including decision-support aids to better support youth to effectively contextualize blood glucose results and take appropriate action to optimize glucose levels during and after exercise. Mobile health (mHealth) apps help deliver health behavior interventions to youth with T1D, given the use of technology for glucose monitoring, insulin dosing, and carbohydrate counting.

Objective: We aimed to develop a novel prototype mHealth app to support exercise management among youth with T1D, detail the application of a co-design process and design thinking principles to inform app design and development, and identify app content and functionality that youth with T1D need to meet their physical activity goals.

Methods: A co-design approach with a user-centered design thinking framework was used to develop a prototype mHealth app "acT1ve" during the 18-month design process (March 2018 to September 2019). To better understand and respond to the challenges among youth with diabetes when physically active, 10 focus groups were conducted with youth aged 13-25 years with T1D and parents of youth with T1D. Thereafter, we conducted participatory design workshops with youth to identify key app features that would support individual needs when physically active. These features were incorporated into a wireframe, which was critically reviewed by participants. A beta version of "acT1ve" was built in iOS and android operating systems, which underwent critical review by end users, clinicians, researchers, experts in exercise and T1D, and app designers.

Results: Sixty youth with T1D, 14 parents, 6 researchers, and 10 clinicians were engaged in the development of "acT1ve." acT1ve included key features identified by youth, which would support their individual needs when physically active. It provided advice on carbohydrates and insulin during exercise, information on hypoglycemia treatment, pre- and postexercise advice, and an educational food guide regarding exercise management. "acT1ve" contained an exercise advisor algorithm comprising 240 pathways developed by experts in diabetes and exercise research. Based on participant input during exercise, acT1ve provided personalized insulin and carbohydrate advice for exercise lasting up to 60 minutes. It also contains other features including an activity log, which displays a complete record of the end users' activities and associated exercise advice provided by the app's algorithm for later reference, and regular reminder notifications for end users to check or monitor their glucose levels.

Conclusions: The co-design approach and the practical application of the user-centered design thinking framework were successfully applied in developing "acT1ve." The design thinking processes allowed youth with T1D to identify app features that would support them to be physically active, and particularly enabled the delivery of individualized advice. Furthermore, app development has been described in detail to help guide others embarking on a similar project.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12619001414101; https://tinyurl.com/mu9jvn2d

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KEYWORDS

Mobile health application; Exercise; fitness; physical activity; design; co-design; focus group; focus groups; acT1ve; Type 1 diabetes; Young people; Blood glucose level; diabetic; diabetes; young; youth; type 1; prototype; develop; development; mHealth; mobile health; app; apps; applications; applications; user-centered design; mobile phone

Introduction

Background

Physical activity has many physical and psychological benefits for young people living with type 1 Diabetes (T1D) [1]. In addition to the cardiovascular benefits, weight loss, and physical conditioning benefits, physical activity is associated with positive mental well-being, improved self-esteem, and quality of life [2-4]. However, the challenges experienced by young people living with T1D like fear of hypoglycemia can prevent them from being physically active [5-7]. Maintaining stable blood glucose levels (BGLs) before, during, and after exercise is affected by many factors and may not be predictable on repeated exercise occasions [8]. In addition, young people with T1D show significant decline in treatment adherence as they move through adolescence [9].

Several interventions have been developed to help young people with T1D effectively manage their physical activity [10]. However, few randomized controlled trials have explored the efficacy of these interventions [11]. Furthermore, most T1D interventions are educational, despite evidence that educational components alone, while necessary, are not sufficient in supporting adolescents when they are physically active [12]. Adding behavioral elements to an intervention, such as monitoring, goal setting, and linking medication taking with established routines, may enhance outcomes [12]. The use of mobile health (mHealth) technologies has become more common practice for diabetes self-management in middle- and high-income countries [13,14] enabling small to moderate improvements in glycemic stability, life satisfaction, and concern about diabetes and mental health [15-19].

Apps and T1D

Apps to manage diabetes have become widespread and diverse in their functionality and purpose [18]. The recent consensus report from the joint European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group highlights the potential value of digital apps for diabetes self-management [20]. An exercise advisor app for those living with TID has recently been designed [21], and there are an increasing number of apps that give guidance to people living with T1D during exercise [22].

Apps that target specific age groups are needed to help in the management of physical activity and T1D [23]. Adolescents living with T1D have specific health and developmental needs related to the many physical, psychological, and neurodevelopmental changes they are undergoing. They are not only becoming focused on peer relationships but are also developing a need for autonomy and have unique challenges adhering to T1D management regimes [24]. Therefore, apps for this age group need to be specifically tailored.

Bant (Centre for Global eHealth Innovation from University Health Network Toronto), an app designed for young people with T1D collects information on physical activity with no specific design aspect for exercise [12]. While the app T1D Exercise focuses on exercise management strategies, it is only designed for adults [22]. Previous formative research by our team provided anecdotal evidence that young people living with T1D would use an app, if suited to their needs, to help them manage their BGLs before, during, and after physical activity [25]. Until recently, there were no apps that specifically support diabetes self-management and provide individualized information around exercise in young people living with T1D. Diactive-1 App has been recently developed by a team of researchers from University of Turin, Italy. This app which is not commercially available is being tested to explore the effect of this app intervention on insulin dose requirements in children and adolescents with T1D [26].

User-Centered Design

User-centered design (UCD) of mHealth apps recognizes that all innovation starts with a deep and comprehensive understanding of the end user, such as their current behaviors, motivations, their feelings and emotions, intentions, what technology they depend on, who is important to them, and their self-image [27]. In UCD, the needs, abilities, and desires of the end user drive the design at each stage of the process [28]. Design thinking is a UCD process that encourages iterative exploration of solutions, continual refinement of the problem, and increased understanding of user needs [29]. This approach in app development may ensure the necessary relevance and robustness of the app. This is important given that with high drop-out rates of mHealth app use [30], more effort is needed to incorporate the needs, experiences, and expectations of end users in app development [31,32]. A recent integrative review questioned whether mHealth was indeed being used to address the target audiences' needs [33].

UCD and co-design can be used together to maximize app relevance. A co-design approach to designing and developing

mHealth apps allows people who are the end users of the app, providers who are the health care professionals, and researchers to contribute their collaborative insights [34]. Co-design (also referred to as participatory design) is a key research methodology that enables the perspectives and preferences of the target end user population to influence subsequent development of the mHealth app. Ideally, it involves a process of shared decision-making, which is characterized by health care professionals and end users collaborating to make decisions about the mHealth app, with a balanced focus on both hard-clinical evidence as well as the end user's priorities and values [35]. This suggests the necessity of engaging both end users and health care professionals in co-design to design and develop the technology they will use together [36]. Although the number of available mHealth apps is increasing rapidly, there is a need to create a rigorous design thinking process for their development [29] and guidance that ensures the sustainability of the apps [37,38].

Emerging apps do provide exercise support. However, none of the currently available apps exclusively provide tailored advice on exercise for young people with T1D. Hence, the aim of the study was to apply a co-design process and design thinking principles to build a novel app for young people living with T1D that delivers individualized diabetes management advice to support physical activity. The objectives of the study were to (1) detail the application of a co-design process and design thinking principles to inform the design and development of the app and (2) identify the content and functionality that young people living with T1D need in the app to meet their physical activity goals.

Methods

Recruitment

Adolescents and young adults aged 13-25 years with a diagnosis of T1D for more than 6 months and competent in speaking English were eligible to participate. Multiple recruitment strategies were used to provide broad representation. Eligible participants were identified through the Western Australian Children's Diabetes Database, a state-wide, population-based, longitudinal diabetes registry. Participants were provided with participation information sheets via email, or when approached by researchers at diabetes clinics at Perth Children's Hospital. The studies were also advertised on local diabetes organization websites and social media. Recruitment of focus group participants continued until data saturation was attained. In the subsequent phases, recruitment concluded when all recruitment methods were exhausted.

Ethical Considerations

Participants provided consent in accordance with the Child and Adolescent Health Service Human Research Ethics Committee, registered with the National Health and Medical Research Council's Australian Health Ethics Committee. Parental consents were also obtained for participants younger than 18 years. Ethical approval of this project (RGS0000000743) from the Child and Adolescent Health Service Human Research Ethics Committee was valid from January 4, 2018, to January 4, 2021, subject to compliance with conditions of Ethics Approval for a Research Project.

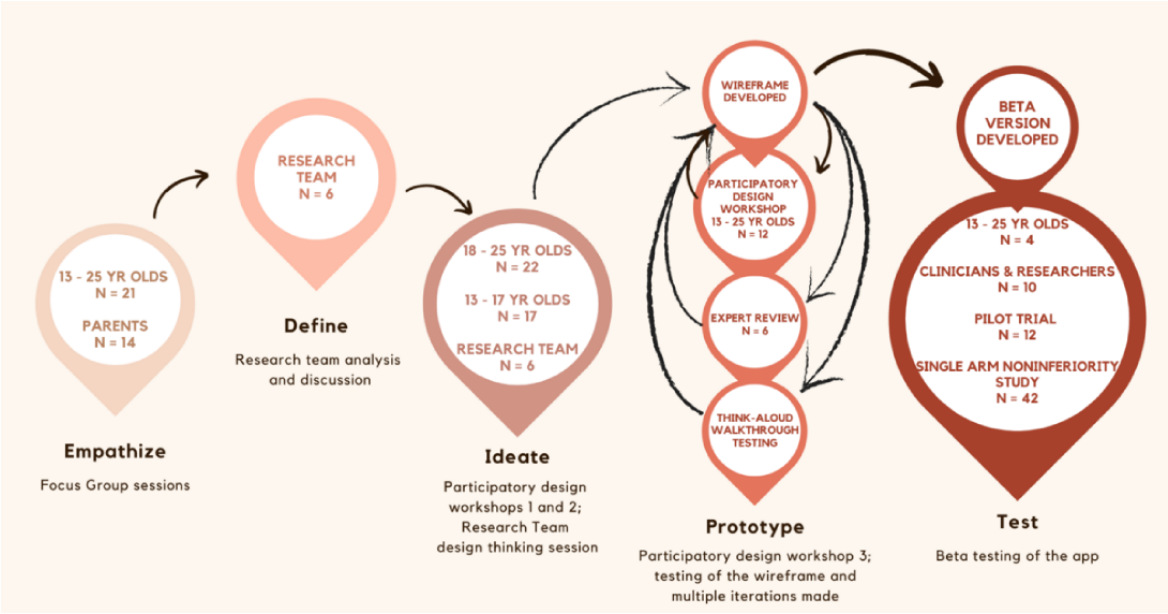
Study Design

Overview

A co-design approach and design thinking framework (Figure 1) were used, supported by UCD methodology to understand the requirements of the end users and to iteratively design the app. The user-centered mixed methods included focus groups, participatory design workshops, and acceptability and usability evaluation methods. These methods were iteratively applied during the 18-month design process from March 2018 to September 2019.

A UCD framework based on the Stanford Design Thinking 5-stage (Empathize, Define, Ideate, Prototype, and Test) methodology [39] was used to develop the app (Figure 1).

Figure 1. The 5-stage design thinking process.



Empathize

The Empathize stage in design thinking is to provide greater insight into the identified problem and gain a deep understanding of the end user's needs, emotions, and experiences.

In the Empathize stage, focus groups were conducted with young people with T1D with ongoing input from the research team, to better understand end users' perspectives of diabetes management around exercise, especially the challenges they faced while being physically active. Participants were asked questions such as: *What are the main difficulties you have when physically active? What works for you when you are physically active?* Thematic analysis was undertaken to synthesize the feedback from the focus group.

Define

The purpose of the Define stage is to use the findings from the Empathize stage to more precisely define the problem statement to guide the subsequent stages of the design process. In the Define stage, a series of structured and unstructured discussions were undertaken by the research team using the thematic analysis of data collected to (1) define the problem statement, (2) confirm details of the target audience, (3) outline the needs of the target audience, and (4) determine how these needs were to be met.

Ideate

In the Ideate phase, generation of a wide range of creative ideas and concepts is the main goal. Judgement and evaluation are deferred to encourage the target audience to develop a broad range of possible solutions. In the ideate stage, 2 participatory design workshops were conducted to identify features of an app that support the target group to be physically active, and to translate existing clinical guidelines into an exercise advisor algorithm providing targeted and individualized recommendations in the app. Participants were organized into mixed-sex groups, each with a cofacilitator.

A total of 22 young adults aged 18-25 years and 17 adolescents aged 13-17 years with T1D participated in the first and second participatory design workshop, respectively. The research team facilitated and recorded the process. The questions and activities were tailored to the age groups and included individual responses and affinity paired or small-group discussions. Data were collected primarily using a nominal group process whereby participants generated and recorded their ideas individually, and then discussed and voted on these ideas as a group.

In the first workshop, participants were asked questions (Multimedia Appendix 1) about what technology motivates them during physical activity, the challenges faced during physical activity, specific roadblocks they experienced trying to solve the challenges, the source of the help or information they received to address the challenges, and what they would want from an exercise app if they were to design one. They were then presented with a physical activity "tree" (or commonly called a "user journey flow" in design thinking methodology), that outlines the steps, interactions, and touch points an end user goes through while engaging with a product, service, or experience, providing a holistic understanding of their overall experience. Participants were instructed to map their own physical activity routines and diabetes management plans and share it with a partner, then with the group. Participants gave feedback on the flow and identified priority areas where they needed help and where an app could support them. Activities included brainstorming and designing paper prototypes for the app.

The second workshop followed the same format as the first, with different questions (Multimedia Appendix 1) and tasks. A "scenario approach" was used where participants were instructed to draw a flowchart of their last physical activity, describe the steps taken to manage their glucose levels, and identify and address any roadblocks encountered. Features of an app that might help them to be physically active, manage T1D, and solve roadblocks were recorded individually and then shared with the group. At the end of the group discussions, comments were presented to the whole workshop.

The Ideate stage also included a design thinking session with a digital health officer and a subgroup of the research team (n=6) using a brainstorming process that considered requirements and constraints to identify ways of developing the app. In addition to discussing the structure of the exercise advisory algorithm to be incorporated in the app, this process considered the major themes that arose from the participatory design workshops, considering how young people would use technology to make decisions about diabetes management around exercise and to determine features that could be included.

Prototype

The Prototype phase is an experimental phase, designed to identify the best possible solutions to address the problems. The aim was to use the findings from the Ideate stage to rapidly build and test low-fidelity prototypes to explore potential solutions and gather feedback for further iteration. In the Prototype stage, a wireframe prototype (simple mock-up version) and beta versions of the app ("beta" means the app is under development) were developed based on the input from the participatory design workshops. This phase aligns with one of the principles of design thinking—*The tangibility rule*: Making ideas tangible in the form of prototypes to enable designers to communicate more effectively with the target audience [40]. UCD methods commonly used in contemporary design were used. These entailed the iterative involvement of the end user in the design process by eliciting formal feedback on reference and prototype versions of the app and formative usability testing of the system. Participants from the initial 2 workshops were invited back to participate in a third participatory design workshop (n=12) to provide this feedback.

Test

The prototype stage was followed by developing a fully functional app in the Test stage that could be downloaded, tested, and iterations made based on feedback. The beta version of the app was developed and tested in the final fourth workshop by 10 clinical and research staff and 4 young people with T1D who had attended the previous 3 workshops. The app was modified based on the feedback from beta testing. The final app was then tested in a pilot trial.

The app was piloted in a free-living setting to assess its acceptability, functionality, and gather feedback on the user experience. The trial participants were 10 adolescents and young adults (aged 12-25 years) living with T1D who had not attended any of the participatory design workshops. They tested the app in a free-living setting and were asked to use the app to guide their exercise management for 6 weeks. At the end of 6 weeks, all participants completed both a semistructured interview and the user Mobile Application Rating Scale (uMARS) [41]. All semistructured interviews were transcribed. Thematic analysis was conducted whereby interview transcripts were independently analyzed by 2 researchers to uncover relevant themes. The uMARS was scored for the 6 quality subscales (engagement, functionality, aesthetics, information, perceived impact, and subjective quality). All scores have a maximal possible value of 5, and were presented as medians, IQRs, and ranges [42].

An important aspect of this study design was the ongoing engagement of young people as co-designers in the design, implementation, and evaluation of the wireframe and then fully functional app. The process moved from generating insights about end users to idea generation and testing [43].

Results

Empathize: End User Focus Groups

To identify the challenges faced by young people living with T1D when physically active, 6 focus groups were conducted with a total of 14 adolescents and 7 young adults with T1D. Four focus groups were also conducted with 14 parents of the adolescents. Thematic analysis of focus group data suggested many challenges experienced by young people living with T1D when physically active and the results are reported elsewhere [25]. Briefly, these included, managing food and equipment, managing glucose levels with changing environment conditions, and psychosocial challenges. Parents also experienced their own challenges when their adolescents were physically active, including supporting them to be autonomous. These challenges were revisited in later phases of the design process to inform the presentation and support for the physical activity guidelines.

Define: Research Team Discussions

Clinicians and researchers were involved in this stage (n=6). Analysis of the discussion data were used to define the following:

1. Problem statement: young people living with T1D are challenged by the unpredictability of their BGLs before, during, and after physical activity. This unpredictability is caused by various physical, environmental, and psychosocial factors. To manage this unpredictability, young people need guidelines and support to implement these guidelines. The research problem involves finding the best means of presenting young people with personalized guidance on insulin dosing and carbohydrate intake strategies for facilitating diabetes management around exercise.
2. Target audience: young people living with T1D aged between 13 and 25 years who are, or who would like to be, physically active.
3. Needs of the target audience: to maintain stable BGLs before, during, and after physical activity by building their understanding of their blood glucose response patterns to varying types, duration, times, and intensities of physical activity.
4. How their needs were to be met: deciding the best way to meet the identified needs was through the development of an app to deliver individualized advice on insulin dosing and carbohydrate intake during and after physical activity.

Ideate: Participatory Design Workshops

Workshop duration was approximately 90 minutes for each. In total, 22 young adults aged 18-25 years (mean age 20.4 years) with a diagnosis of T1D participated in the first participatory design workshop, and 17 adolescents aged 13-17 years (mean age 14.5 years) with a diagnosis of T1D participated in the second workshop.

The research team reviewed the individual and group responses as well as the facilitator notes from the participatory design workshops and developed a list of desirable app features that participants indicated they needed to overcome the challenges experienced when physically active (Table 1). The team then selected the features rated the highest by the participants to incorporate into the first version of the app.

Table 1. Desirable app features from Ideation phase.

Desirable app features	Examples
Support music	• Can receive advice for different activities • Can search for answers to questions • Listen to music while tracking blood glucose levels
Diet tracker	• Counts carbs and suggests foods
Blood glucose levels	• Measures effects of different types of exercise on blood glucose and tracks patterns
Communication	• Communicates with CGM[a] and Fitbit

[a]CGM: Continuous glucose monitor.

In the software development process, an exercise advisory algorithm with 240 pathways was created based on the decision tree from the published international consensus guidelines [44-46]. The algorithm expanded from a skeletal exercise activity mapping tree to separate decision trees for 4 different types of exercise: mild, moderate, mixed-intermittent intensity, and resistance exercise of up to 60 minutes in duration. Personalized insulin dose and carbohydrate advice is generated by the decision tree algorithm based on the end user's weight, type, intensity and duration of physical activity, the duration since the last insulin bolus, and the participant's glucose levels at the start of activity. In addition, more information on hypoglycemia treatment, pre- and postexercise insulin and carbohydrate advice, and an educational food guide which highlights the importance of low and high–glycemic index foods in the context of exercise was developed to be incorporated into the app.

Prototype

Developing the Wireframe

With the knowledge generated from the workshops and input from the research team, the digital health officer developed a "wireframe" of the app. A wireframe is a simplified visual representation or blueprint that outlines the basic structure, layout, and content placement of a web page or application, focusing on functionality and information hierarchy rather than visual design. End users reviewed a set of images displaying the functional elements of the app on their smartphones. The end users included participants from the initial 2 workshops who were invited back to participate in a third participatory design workshop (n=12) and researchers (n=6) through individual and group feedback processes. The wireframe was refined after each group's review.

The objective of this third workshop was for the participants to assess the wireframe tool on an iOS device and to determine whether it was appropriate for further development and testing as a smartphone app. A total of 12 adolescents and young adults with T1D aged 13-25 years (8 females), attended a 2-hour workshop, and were asked to test the wireframe on an iOS device (iPhone or iPad). Participants were given time to explore the wireframe individually and then discussed their impressions in small nominal groups (mean group size=4). Figure 2 shows an example of a feature presented in the wireframe. The screenshots show an example of the exercise advice provided at the start of exercise and the activity log feature where all the information of the activity undertaken by the end user is recorded and available for future reference (Figure 2).

Figure 2. Wireframes of the app showing exercise advice and Activity log.

Participants were then asked to respond to more targeted questions about each of the functions integrated into the wireframe including the Activity Log, Quick Advice, Music, What Worked, Profile, Notifications, and Quick View, provide comments on what they liked or did not like and what functions could be improved. Individual, group, and facilitator notes were collated and analyzed to inform wireframe version 2.0 of the prototype. These findings are shown in Table 2. Research team members, pediatric endocrinologists, and a digital health officer independently reviewed wireframe version 2.0 over a week and then met to discuss the flow, content, and aesthetics of the app. A list of suggestions to improve the app was generated and aligned with the aim of the project.

Table 2. Feedback from the third participatory design workshop.

Feature	Liked	Did not like	Suggestions for improvement
Activity log	Clearly set up and easy to follow	Do not understand the facial expressions of exercise intensity	Could include a regular activity profile—a typical week
Music	Being able to set the duration of the music	The general aesthetics	Link to your own music library
Quick advice	How you click on previous activity and get advice	It took a bit of time to get the advice	A different look including different icons
Notifications	The inspirational quote	The design of the buttons	Include a change in quotes and pictures
Profile	The ability to set goals		Include time frame to achieve goals
What worked	Clearly showed important information about the activity	7 days and 30 days could be changed to a week and a month	Should be able to record BGLs[a] and information about what worked in relation to advice given
Quick view	Very helpful	Information too squashed	Needs more pages

[a]BGLs: blood glucose levels.

App Development

Following the involvement of the researchers and end users in the iterative design process by eliciting formal feedback on reference and the wireframe of the app, the app scope was developed. Feedback collected through testing the wireframe was synthesized and used to inform the development of the app. Insights gained from the end users and researcher feedback were organized into functional components, informing requirements of the app's design in a product roadmap. The research team met with several app development companies to ensure the scope and functional requirements of the app were fully understood during the tender process. Following the tender process, the digital health company "Curve Tomorrow" developed the beta version of the app. The software development process involved the app developers actively engaging with the endocrinologist and researchers weekly for 4 months to understand and develop the different elements of the complex exercise advisory algorithm in a functional way in the app and to ensure they understood the needs of the end users. The process was an ongoing 2-way communication until the app was fully functional.

The end users and the research team provided a list of desired features and functionality for development, but when these features were investigated in more detail by a business analyst, it was discovered that the feature requests were more detailed, complex, and likely to require additional funding to develop. The features were prioritized by the team based on the highest end user engagement and needs analysis, denoted as must-have requirements for the pilot trial such as additional information for each exercise, against nice-to-have functionality such as adding decision-making support through artificial intelligence. Even during this refinement process, further investigation, and analysis to understand the complex functional requirements was needed. This iterative process required collaboration from end users, researchers, and the app development team. During this refinement process, the aim was to ensure the end users felt their needs were met while considering budgetary constraints. After confirmation, the nice-to-have features which were not viable for the pilot trial were reserved for future additions. Following the 4-month period of software development, a further process to prioritize the features based on cost or benefit was applied, a preliminary list of features was agreed to, and the process proceeded toward beta development.

Test

Beta Testing of App

In the final workshop, the beta version of the app was tested by 4 participants from the initial 2 workshops and 10 clinical and research staff. All test participants were given the beta version of the app to explore and then respond to the "think-aloud" process, which involves observing and recording an individual's thought processes and verbalizations as they interact with the app or perform a task to provide insights into their cognitive processes and end user experience. When participants expressed emotion, the researcher would ask, for example, "Why is that frustrating you? What did you expect to happen?" or "What would you prefer instead?" or "How would you make it better?" All feedback and suggestions for improvement were collated into 1 spreadsheet and summarized.

The research team then presented the feedback suggested by the majority of the app testers to the app developer. Feedback presented was quite minor with adjustments such as content changes, amendments to questions in the profile set up, some visual amendments (buttons being larger), and renaming menu

names. These modifications were made to the app to enable pilot-testing. Following feedback from end users, researchers, and clinicians, the app was named "acT1ve."

Pilot Trial

In total, 10 individuals (8 females and 2 males) were enrolled in this study and had a mean age of 17.7 (SD 4.2) years, T1D duration of 7.2 (SD 4.8) years, and hemoglobin A_{1c} of 54 (5.5 mmol/mol) (7.1 ± 0.5%) and engaged in physical activity for 4.5 ± 2.9 hours per week. All 10 participants had acT1ve installed on an Apple iPhone. No participants stopped using the app before the end of the 6-week period.

The qualitative and quantitative analysis of this study provided an important insight into the perspectives of participants in relation to the functionality and usability of the app. The information provided by the app was found to be relevant, appropriate, and clear, with a simple and easy flow of presentation. Participants felt they received adequate information to guide their diabetes management and enable them to maintain stable BGLs during physical activity. This reduced their worry about their glucose levels and provided them with trusted information and confidence to be more physically active. The participants liked the design of the app and found it acceptable and useful. They indicated that they would continue to use it long term and recommend it to friends and other people with T1D. The suggestions provided by the participants for improvement of the app were: a help section on how to use the app for those who may need extra guidance, added information for longer duration of exercise of more than 60 minutes of activity, minimization, and simplification of some of the information, suggestions for data sharing and social interaction features, and improving aesthetics.

The uMARS scores for acT1ve were high (out of 5) for its total quality 4.3 (4.2-4.6), engagement 3.9 (3.6-4.2), functionality 4.8 (4.5-4.8), information 4.6 (4.5-4.8), aesthetics 4.3 (4.0-4.7), subjective quality 4.0 (3.8-4.2), and perceived impact 4.3 (3.6-4.5). The pilot results showed that the acT1ve app is functional and acceptable with high user satisfaction. Details of this pilot study are published in a separate paper [42].

acT1ve was amended following the feedback from the pilot study participants. The amended app has been tested for safety and efficacy in a larger clinical trial (single arm noninferiority study) with 42 adolescents and young adults (aged 12-25 years) living with T1D in free-living environment. Once safety is established, regulatory approvals will be obtained prior to introducing the app to regular clinical practice.

Discussion

Principal Findings

This paper describes the co-design approach and the practical application of the *5-stage design framework* in developing an app to support young people living with T1D to be physically active. The process enabled the development of a unique exercise app that provides individualized insulin and carbohydrate advice and builds a record of "what works" for various activities, potentially facilitating a greater level of end user confidence when physically active. It is intended that just prior to exercise, youth living with T1D would answer questions about the exercise they are about to complete, and their diabetes management at that point in time, and would be provided with personalized insulin dose and carbohydrate advice for exercise. As the relationship between exercise and T1D is very complex, it is expected that end users would engage with the app for each exercise session, especially when commencing a new form of exercise.

Young people with T1D identified desirable features of the app and provided suggestions to improve the individual advice given, including linking it to their own continuous glucose monitor (CGM) and Fitbit, and the recording of responses to advice to build a better understanding of the individualized way their body responds to physical activity. They also wanted the app to count carbohydrates and suggest foods to eat before, during, and after exercise and to provide a search function so users can ask a range of questions. Additionally, they identified the desire to personalize the appearance of the app where possible and to be able to listen to music while using the app.

Project Contribution

This project and the acT1ve app are unique for 4 reasons: the app focuses solely on exercise management for young people with T1D, a "state of the art" design thinking process was used in the development of the app, individualized advice is provided to end users and a pilot testing phase was included. In a recent study of m-health apps for people with a chronic condition only a small number included a pilot testing phase [31]. There are apps on the market that involve young people at each stage of the participatory design process [47] such as the *Bant* app for T1D [12]. However, unlike our project, the effects of involvement on acceptability were not examined for this app.

The failure of health information technology interventions in the past has been largely due to poor design that did not meet the requirements of the users of the technology [28]. In this co-design project end-user's needs drove the app development, including their input at each stage of the process. To strengthen the robustness of the app, each stage of this project was informed by the previous stage and design iterations were undertaken to refine the app to meet the needs of young people with T1D. The continual synthesis of end user's feedback with health professional's advice has enabled the development of a potentially usable and useful app, with high end user satisfaction, as confirmed in the pilot trial [42].

The Design Process and Adolescents

The importance of the participatory design process is highly relevant for the adolescent T1D population. The blood glucose response to physical activity can be highly individualized for young people living with T1D [48], hence the need to involve a group of adolescents and young adults with T1D of different ages and gender in the process of developing the app. Involving adolescents with T1D in a participatory design process enhances their empowerment and addresses their need for autonomy. Feelings of empowerment and autonomy are associated with improved psychological outcomes for young people with T1D [49]. Novel approaches as used in the initial workshops, that is,

a “scenario” approach—are also suited to young people who particularly like real-world and relevant activities [50].

Limitations

Several cofacilitators were needed to conduct the participatory design workshops which contributed to different levels of participant engagement. At times, the participatory design workshops were dominated by more vocal participants, often the older participants, and it is possible that less vocal participants were not able to fully express their viewpoints. This is a well-documented limitation of focus groups that can be offset by experienced facilitators [51]. There was also, in one of the participatory design workshops, a discrepancy in the power relations between adults and young people, with a considerable number of adults present. Adult numbers need to be minimal in participatory design processes with young people to encourage a sense of equality among the participants [52].

Designing an application to display complicated information is challenging. The additional barrier of presenting digestible information for the younger audience on a mobile format required omissions to what could be displayed, such as necessary language to be used being unable to fit the character limits of mobile devices. Additional challenges involved in using mobile devices included limiting the number of devices to be tested on and compatibility issues with operating software updates. Due to limited budget and certain logistic issues, certain features which could increase user engagement (ie, nice-to-haves) like integration with real-time CGM, activity tracker, and data sharing options were deprioritized for future modifications.

Conclusions

This paper describes a co-design approach using design thinking processes undertaken to develop an mHealth app to support young people with T1D when they are physically active. The design thinking processes allowed young people with T1D to identify app features that would support them to be physically active, and particularly that enabled the delivery of individualized advice. In addition, the process of app development has been described in detail to help provide guidance to others embarking on a similar project. Use of the design thinking process has the potential to create highly usable mHealth apps that can improve health behaviors in various populations of young people, especially those who need to self-manage chronic conditions such as diabetes while increasing the relevance of the content and empowering those involved in the process.

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Authors' Contributions

VBS, LF, HCR, RN, AO, MJ, DC, WHKS, and ED contributed to the conception and design of the study. VBS, RN, and HCR contributed to the conduction and co-ordination of the whole study.VBS, LF, RN, and HCR contributed to the acquisition, analysis, and interpretation of data. VBS, HCR, and LF contributed to the thematic analysis of the interviews. VBS, LF, and JF drafted the manuscript, and all authors revised it critically for important intellectual content. All authors approved the final version of the manuscript. ED is responsible for the integrity of this work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questions from participatory design workshops.
[DOCX File , 15 KB - diabetes_v9i1e51491_app1.docx]

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Abbreviations

BGL: Blood glucose levels
CGM: Continuous glucose monitor
mHealth: Mobile health
T1D: Type 1 diabetes
UCD: User-centered design
uMARS: User mobile applications rating scale

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Original Paper

A Culturally Sensitive Mobile App (DiaFriend) to Improve Self-Care in Patients With Type 2 Diabetes: Development Study

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Abstract

Background: Mobile apps designed with cultural sensitivity have demonstrated higher user acceptability and greater effectiveness in enhancing self-care skills. However, a significant gap exists in developing such apps for specific populations, such as Portuguese Americans living in southern Massachusetts, home to the second-largest Portuguese community in the United States. This group possesses unique cultural traditions, particularly in dietary practices, including a tendency toward high carbohydrate intake. Tailoring diabetes self-care apps to address these specific cultural requirements could substantially improve diabetes management within this population.

Objective: The aim of this app development project was to develop a prototype diabetes management app for Portuguese Americans with type 2 diabetes mellitus using the design thinking methodology, incorporating user-centered design principles and cultural sensitivity. This paper describes the phase-2 results, focusing on app design and development.

Methods: Phase 2 of this app development project adhered to the design thinking methodology delineated by the Hasso Plattner Institute of Design at Stanford University, focusing on 2 critical steps: ideation and prototyping. This phase started in March 2022 and continued until April 2024. The project was driven by a multidisciplinary team consisting of 2 nurse educators; an app development specialist; and 2 graduate research assistants from the university's Computer and Information Sciences Department, both well-versed in mobile app development. Data collected during phase 1, which will be published separately, informed the app design and development process.

Results: The prototype of the DiaFriend app (version 1) was designed and developed. The app comprises five features: (1) blood glucose monitoring, (2) weight tracking, (3) carbohydrate tracking, (4) exercise log, and (5) medication reminder. The carbohydrate tracking feature was explicitly tailored to correspond to Portuguese food culture. This paper presents the front-end interface flowchart, demonstrating how the user navigates through each screen. It also discusses the challenges faced during the backend development, such as data not being able to be stored and retrieved.

Conclusions: The DiaFriend app (version 1) distinguishes itself from conventional diabetes self-care apps through its emphasis on cultural sensitivity. The development of this app underscores the importance of cultural considerations in health informatics. It establishes a foundation for future research in developing and evaluating culturally sensitive mobile health apps. The adaptation of such technologies has the potential to enhance self-care practices among Portuguese Americans with type 2 diabetes mellitus, with improved glycated hemoglobin levels as a potential outcome. The last step of the design thinking methodology, testing the app, will be conducted in phase 3 and the results will be published elsewhere.

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KEYWORDS

cultural sensitivity; design thinking; mobile app; self-care; type 2 diabetes; mobile phone; app; design; diabetes; development; prototype; effectiveness; user engagement; blood glucose; glucose; weight; carbohydrate; exercise; Portuguese Americans; ethnic group

Introduction

The number of adults aged 18 years or older with diabetes in the United States reached 38.4 million, or 11.6% of all US adults in 2021 [1]. Between 2002 and 2018, the overall incidence of diabetes significantly increased, with approximately 16.8 million adults aged 18 years or older with diabetes visiting the emergency department, including 267,000 for hyperglycemic crisis (11.4 per 1000 adults) and 202,000 for hypoglycemia (8.6 per 1000 adults) [2].

Approximately 1.5 million people of Portuguese descent live in the United States, with over 265,000 residing in Massachusetts, which has the second-highest concentration of Portuguese Americans [3]. Despite being one of the largest ethnic groups in Massachusetts and several other states, the health status, issues, and disparity among the Portuguese American population are not well documented [4]. However, statistical data indicate a significantly higher prevalence of diabetes among numerous racial and ethnic minority populations in the United States relative to non-Hispanic White Americans [3]. In Massachusetts, 14.7% of people aged from 45 to 64 have diabetes [5]. In the South Coast region of Massachusetts, particularly in New Bedford and Fall River, cities with substantial Portuguese American populations, the prevalence of diabetes among adults aged 18 and older exceeds the national average [6]. Moreover, diabetes ranks among the sixth leading causes of death in this area, with mortality rates showing an annual increase [6].

Portuguese Americans face unique challenges in managing type 2 diabetes mellitus (T2DM) and preventing its complications due to their cultural traditions, particularly dietary practices. The carbohydrate-rich, fatty, and sugary nature of many traditional Portuguese dishes, desserts, and pastries may increase the risk of developing diabetes. These dietary traditions pose significant obstacles for Portuguese Americans in adopting and maintaining the self-care behaviors necessary for effective diabetes management.

Self-care is considered essential in chronic illness management. Riegel et al [7] defined self-care as a process of maintaining health through health promotion practice and managing illness. T2DM is a complex chronic condition that requires ongoing self-care behavior modification, with patients assuming an active role in making daily decisions that impact their health and well-being. Effective diabetes management requires substantial lifestyle modifications with physical and psychological adaptation to maintain healthy behaviors. Mobile apps have provided support for diabetes self-care in patients with T2DM, leading to enhanced glycemic control [8-11]. Mobile apps offer significant potential to enhance diabetes self-management by providing patients with multifaceted support. These digital tools facilitate convenient blood glucose monitoring, carbohydrate tracking, physical activity promotion, access to educational resources, and personalized guidance. However, many existing apps lack user-friendly interfaces and personalization of features, fail to accommodate diverse cultural perspectives, and do not offer experiences tailored to individual needs and preferences [12-14].

In total, 2 studies have addressed the importance of culturally sensitive apps for diabetes management to improve blood glucose in Asian people with diabetes [14,15]. They identified the gap in culturally tailored content and features that address specific dietary habits, lifestyle practices, and health beliefs of diverse ethnic populations. In the first study, the Welltang app, a smartphone-based diabetes management app tailored to Chinese culture, demonstrated significant positive outcomes among its users, including reductions in glycated hemoglobin (HbA_{1c}) levels and blood glucose concentrations, alongside increased satisfaction with the app's functionality [15].

The second study used qualitative methodologies to design a prototype app aimed at enhancing diabetes self-care behaviors and self-management outcomes [14]. The researchers identified a significant gap in culturally sensitive diabetes apps tailored to Asian populations. Consequently, they conducted a qualitative study involving patients and health care experts in app development. However, the results of this study have not yet been published, and this study, highlighting the need for culturally tailored weight control apps for Hispanic and Brazilian Americans, provides compelling evidence for the importance of culturally sensitive apps in improving self-care. This research is particularly relevant to diabetes management, as it addresses health-promoting behaviors such as healthy eating and physical activity, which are crucial components of diabetes self-care. The study's findings underscore the potential impact of culturally adapted digital tools in enhancing self-management practices across various health domains.

In addition to a lack of cultural sensitivity, other obstacles to using diabetes apps include time-consuming multistep tasks, repetitive data-entry processes, and complicated system navigation, all of which require technological skills. These factors could pose significant barriers for people with T2DM to adopt and integrate apps into their daily lives. To compound these challenges, individuals who are not technologically savvy or who face socioeconomic disadvantages, as well as those from diverse racial and ethnic backgrounds, may find these apps to be obstacles rather than aids in improving self-care behaviors and supporting self-management of T2DM [8,16-19].

While mobile apps have the potential to provide significant benefits for diabetes self-management, current research reveals critical limitations. Many existing apps lack cultural sensitivity specific to users' ethnic backgrounds, and their features often require advanced technological skills. These factors may significantly diminish the effectiveness and adoption rates of apps. Despite recognizing these issues, a significant gap remains in the literature regarding developing culturally tailored diabetes

management apps for diverse populations. Portuguese Americans with T2DM have distinct preferences that influence their behavior and expectations regarding technology; therefore, they require a user-centered app customized and sensitive to their culture.

The design thinking methodology, a user-centered approach that prioritizes cultural sensitivity, has recently gained popularity in mobile app development to enhance user engagement and improve self-management outcomes [9,20,21]. This methodology involves users developing an app that better meets their needs and expectations. To date, there are no culturally tailored apps for diabetes self-care among Portuguese Americans with T2DM. This app development project aimed to develop a prototype app for Portuguese Americans with T2DM using the design thinking approach.

Methods

App Development Design

The multidisciplinary research team consisted of 2 nurse educators, an app development expert, and 2 graduate research assistants with mobile app development knowledge from the university's Computer and Information Sciences Department. The design thinking methodology developed by the Hasso Plattner Institute of Design at Stanford University (Stanford Design School) [20,21] was used to develop the DiaFriend app (Version 1) for Portuguese Americans with T2DM.

This paper describes phase 2 of the 3-phase app development, focusing on the design and development of the DiaFriend app prototype. This phase started in March 2022 and continued until April 2024. In the context of design thinking methodology, this phase encompasses 2 critical steps: ideate and prototype [22-24]. The app design and development process in this phase was informed by findings from phase 1, wherein 22 participants were interviewed to ascertain desired app features and functionalities. These insights from phase 1, which will be published separately, provided crucial direction for the prototype development in phase 2. The subsequent section delineates the app development process in detail.

Ethical Considerations

Ethical approval for this app development project was obtained from the University of Massachusetts Dartmouth institutional review board (22.030).

Results

The DiaFriend prototype app was designed and developed using the 2 steps of phase 2 of the design thinking methodology (ideate and prototype). During the ideating step, the multidisciplinary research team met multiple times to brainstorm and discuss ideas for the DiaFriend app framework, programming language, features, and app functions. Due to the funding of this project coinciding with the COVID-19 pandemic, the research team's institution prohibited in-person interactions with app development participants. As a result, the information gathered during the ideation phase about the app design originated exclusively from the research team members.

Flowcharts were used to illustrate the step-by-step process of navigating the app, which is the flow of the screens the user will interact with to perform specific tasks while using the app. Throughout the iterative design process, the flowcharts underwent multiple revisions. During this process, the research team acknowledged that no idea should be dismissed as inherently wrong and that not every idea represents the optimal solution. This approach fostered a creative and open-minded environment, encouraging the exploration of diverse possibilities. Upon the culmination of this iterative design phase, the team used a consensus-driven approach to determine the optimal design framework explicitly tailored for Portuguese Americans with diabetes, our target user population.

Based on the participants' recommendations collected during phase 1 of the app development published elsewhere, the researchers prioritized and selected 5 essential features to be incorporated into the initial version of the DiaFriend app. These features include blood glucose monitoring, weight tracking, carbohydrate tracking, exercise logging, and medication reminders. For weight tracking, the basal metabolic index was used. While more than 5 features were suggested, the research team first focused on implementing these 5 essential functionalities, intending to add more features in future iterations based on user feedback in the project's next phase (phase 3).

Because the DiaFriend app does not collect and store sensitive user information, a log-in process involving a username and password was not required. This design will reduce the burden on users by eliminating the need to create and memorize a password, thereby providing a more seamless and accessible user experience. Figure 1 illustrates the tree model of the final flowchart. The flowchart begins with the entry point to the app (home page screen) and ends with the exit point, where the user completes tasks of each function.

In the prototype step, the prototype app development stage, the 5 features (blood glucose monitoring, weight tracking, carbohydrate tracking, exercise logging, and medication reminders) were built into the app. Flutter Software (version 2.2; Google), a single codebase, was used to build the DiaFriend prototype app; therefore, the app can run on both Android and iOS smartphones. In adherence to intellectual property rights, the research team designed and created the app logo and graphic symbols for each feature (Figure 2).

The glucose monitoring feature, which included a customizable list of testing times, enabled users to select the times recommended by their physicians and track their blood sugar levels in real time. As suggested in phase 1 of the app development, the input can be presented as a comprehensive list of all the results in numerical format or as a visual graph (Figure 3).

The carbohydrate tracking feature included food databases tailored to Portuguese food culture, incorporating Portuguese American cultural dietary choices such as various types of Portuguese bread, beans, sausages, pastries, and desserts. The database provided nutritional information (eg, calories, carbohydrates, etc) for each food item, enabling users to make informed decisions about their dietary intake. To enhance the user experience and make food selection more accessible, the

app displayed pictures alongside the food names, offering visual cues that facilitate quicker recognition and choice compared with a text-only list (Figure 4). Moreover, fresh and dried figs, which are not commonly used in American cuisine but are staples in Portuguese dishes, were added to the food database to make it easier for users to track their calorie intake. The DiaFriend app incorporates various images to enhance user experience and engagement. However, due to copyright restrictions, the images used in the app cannot be reproduced or displayed in this paper.

For the exercise feature, walking was prominently featured on the exercise screen because most participants interviewed in phase 1 indicated that walking was their primary form of exercise. The research team intended to create a visually appealing and easily recognizable image design that displayed estimated calorie expenditure per mile, enabling users to make informed choices.

At this stage, the medication tracking feature permitted users to input their medication name, dosage, and time and establish reminder times. To enhance usability, the researchers plan to incorporate a prepopulated list of diabetes medications, allowing patients to select their medications without the need for manual input.

The current stage of the diabetes prototype app's development includes a functional frontend interface that incorporates the 5 selected features. The front-end user interface was established during the initial development of the DiaFriend app; however, improvement was still necessary to ensure consistency in feature nomenclature and component design. The backend infrastructure and application programming interface still need to be developed to ensure full functionality and data management. Due to the specialized nature of backend development, the research team acknowledges the need for collaboration with experts in this field to complete the prototype. Future steps will involve partnering with experienced backend developers to design and implement the necessary backend components, such as databases, server-side logic, and communication interfaces between the front end and backend.

Figure 1. DiaFriend app flowchart.

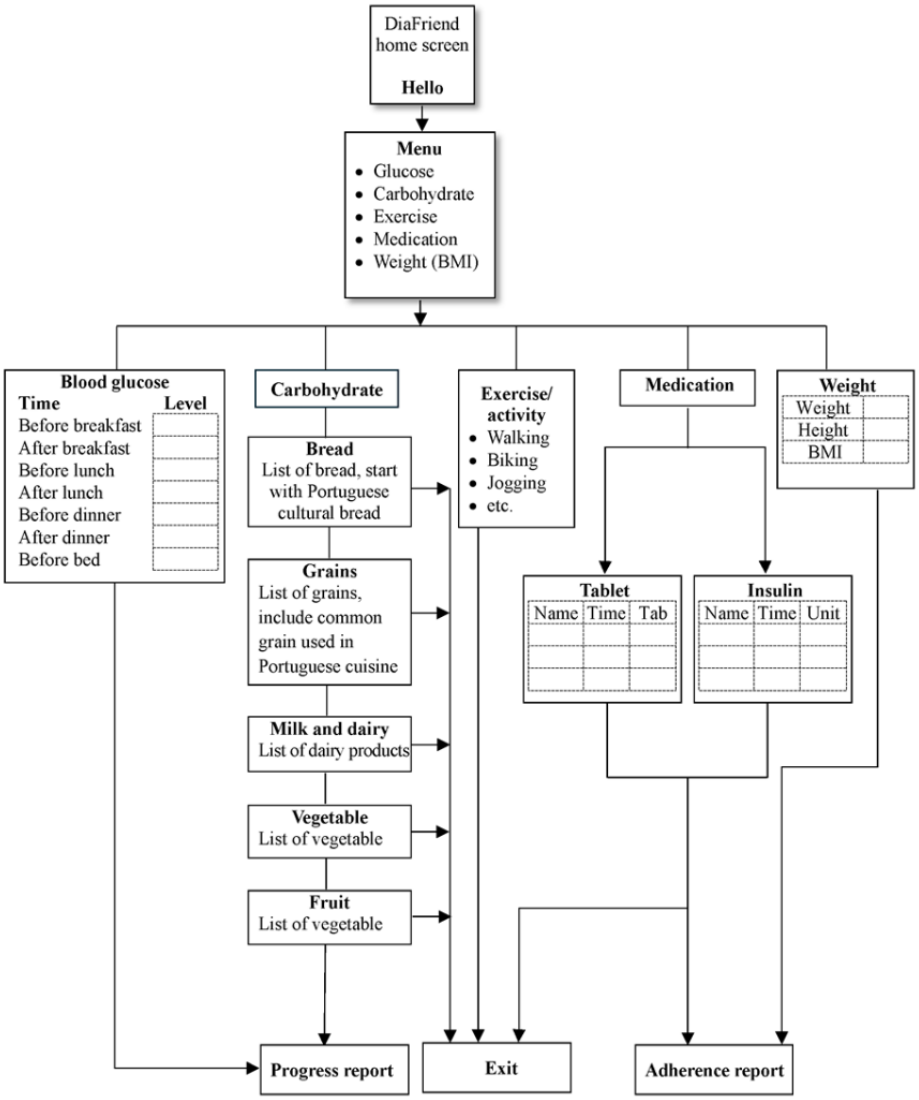


Figure 2. Home screen and feature screen.

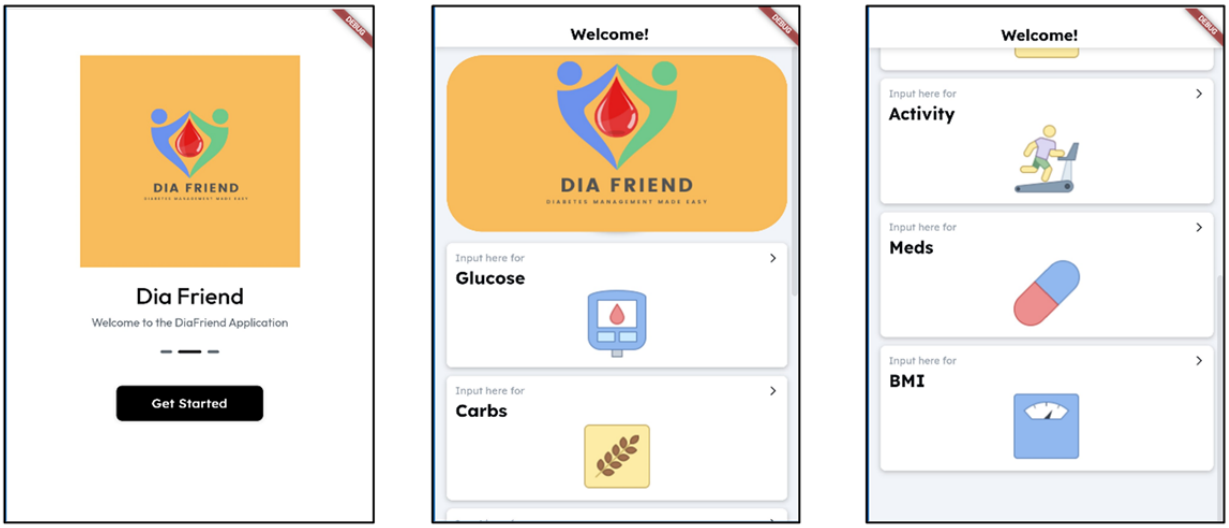


Figure 3. Glucose monitoring feature screen.

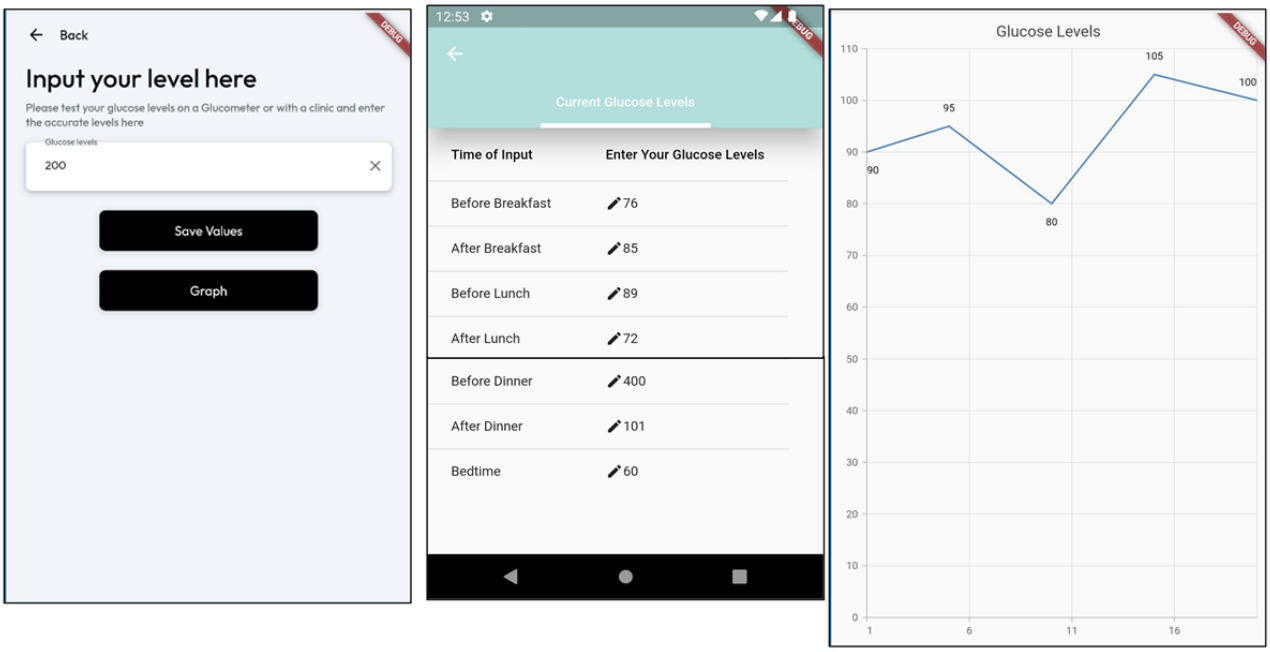
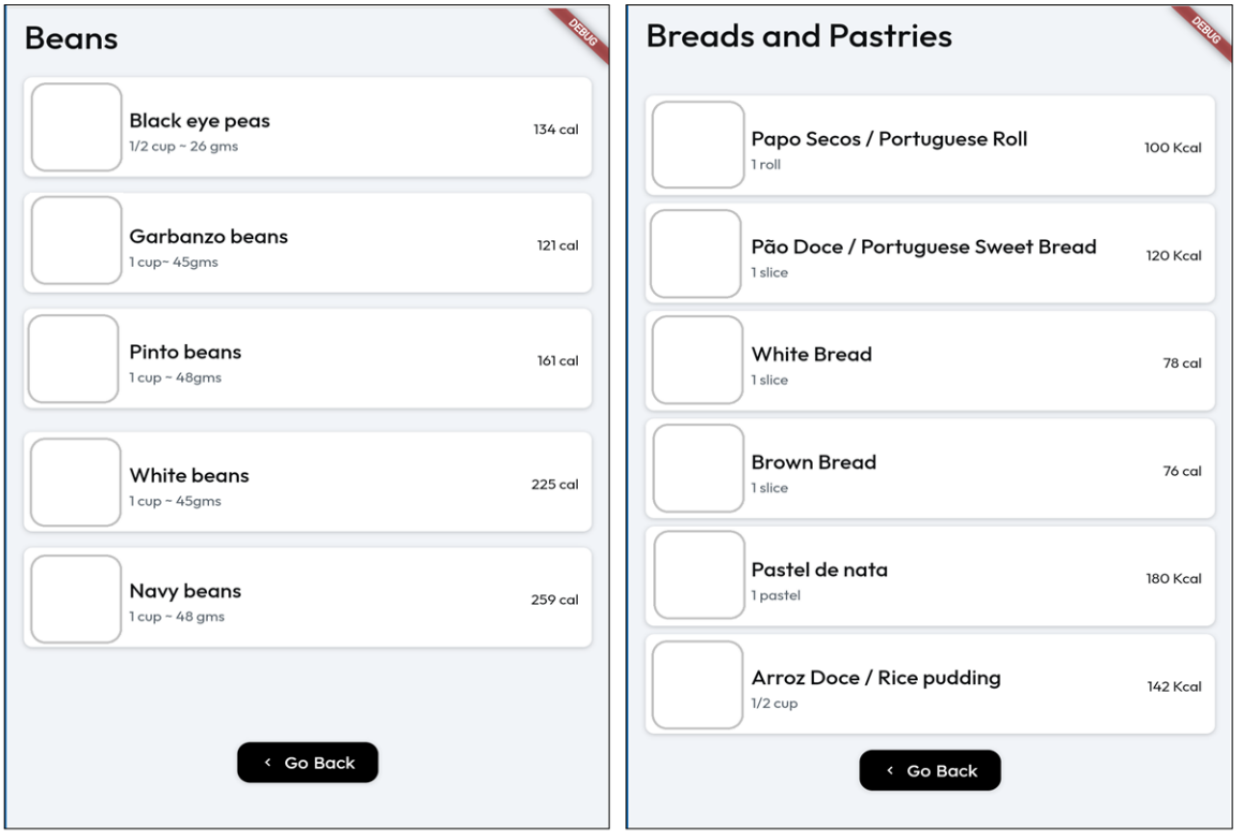


Figure 4. Food choice.



Discussion

Principal Findings

Mobile apps can effectively support self-care practices among individuals with T2DM. However, many apps lack cultural relevance, which may negatively impact user engagement, particularly within specific ethnic populations. Portuguese Americans, for instance, seem to be an underrepresented group in this context. Using 2 steps of the design thinking methodology (ideate and prototype), the research team developed the DiaFriend app, a culturally sensitive app designed to facilitate diabetes self-management among Portuguese Americans with T2DM. The DiaFriend app incorporates 5 core features: blood glucose monitoring, weight tracking, carbohydrate tracking, exercise logging, and medication reminders. As a diabetes self-care app, these features are essential for supporting effective diabetes self-management [14,19,25,26]. One of the key strengths of the DiaFriend app is its ability to integrate blood sugar management, carbohydrate tracking, and exercise monitoring into a single, user-friendly platform. Unlike existing apps that built these aspects of diabetes management separately, often requiring patients to use multiple apps to track their progress, DiaFriend consolidates all these functions into one single, user-friendly platform. Therefore, streamlining the self-care monitoring behaviors necessary for diabetes self-management into a single app should enhance user engagement and adherence by providing a solution for diabetes management [26].

Moreover, the carbohydrate tracking feature of the DiaFriend app, which incorporates Portuguese American cultural dietary choices and food images alongside the food names, is another strength of the app. T2DM is a chronic disease that requires lifelong self-care behavior modification, including dietary changes and regular exercise, often influenced by an individual's cultural background and ethnicity. Previous studies have indicated the need for culturally sensitive and personalized apps to support self-care for specific cultural and ethnic populations [9]. Culturally tailored apps are likely to increase users' motivation to engage in behaviors, such as caloric restriction, healthy eating, and physical activity; be perceived as personally relevant; and lead to a greater likelihood of behavior change [27]. Moreover, a dietary tracking feature should incorporate culturally relevant food databases in features with visual aids to facilitate effective monitoring of calorie intake [13]. DiaFriend app provides a carbohydrate tracking feature tailored to Portuguese food culture to ensure cultural sensitivity. Portuguese American cuisine has its specialty dishes, such as a soup made by soaking country bread in a broth; some stew containing tripe, beans, linguiça sausages, cured ham, chicken, and vegetables; and typical desserts and confections, such as flan (a baked custard topped with a caramelized sugar sauce) and pastel de nata (Portuguese custard tarts), which may be served as dessert or used as icing on a cake [28]. Therefore, the food database in the DiaFriend app includes Portuguese American cultural dietary choices from which users can select the food they consume. Furthermore, insights from phase-1 interviews revealed that walking was the most common form of physical activity among participants. Therefore, walking has been prioritized and listed first in the exercise feature, allowing users to access it immediately without scrolling down the screen.

In addition, the DiaFriend app's user-centered design, which considers the preferences and habits of its target population, Portuguese Americans with T2DM, further distinguishes it from other apps. Previous studies indicate that a more user-friendly app is desirable; users expect less effort in learning, tracking data, and understanding the app [17]. Ease to use is one of the characteristics of diabetes self-care apps that affect patient intention to use and engage with the app, especially for participants with limited exposure to technology [12,14,16,17]. Previous studies have reported that many diabetes apps are confusing, complex, and stressful to set up and use, often resulting in a physically burdensome experience for users [13,26]. In contrast, apps tailored to individual technological skill levels are perceived as easy to use and associated with engagement and successful usability [12]. When designing the DiaFriend app, the research team adhered to the characteristics of an easy-to-use app described by Portuguese Americans with T2DM. The user interface screens were simple and easy to navigate, and a log-in process involving a username and password was bypassed. The app displays large picture icons and a sizable font size that provides easy visualization. This simplicity characteristic of the app should reduce time constraints and be less burdensome to Portuguese Americans who may not be familiar with the technology.

Finally, according to the design thinking methodology, the final step of the design thinking methodology is required to complete the app development process. Diabetes apps tailored to the user culture demonstrated significant positive outcomes among their users, including reductions in HbA_{1c} levels and blood glucose concentrations, alongside increased satisfaction with the app's functionality [15]. Previous app development highlighted the need for culturally tailored apps for diverse ethnic groups, underscoring the importance of culturally sensitive apps in diabetes management [14,15,26,27]. The development of the DiaFriend app underscores the importance of cultural considerations in health informatics. It establishes a foundation for future research in developing and evaluating culturally sensitive mobile health apps. The research team plans to address backend issues and examine the usability and acceptability of the app with Portuguese Americans with T2DM. Further details on the testing process will be provided in subsequent reports. The adaptation of such technologies has the potential to enhance self-care practices among Portuguese Americans with T2DM.

Limitations

While the researchers successfully developed a user-centered, culturally sensitive prototype app, the current version of the DiaFriend app has several limitations due to funding and development time constraints. First, advanced functions such as real-time feedback and notifications based on users' inputs have not been incorporated into this iteration of the app. These features could provide timely reminders to users. Timely prompts can encourage regular blood sugar monitoring, consistent carbohydrate and exercise tracking, and improved medication adherence.

Second, the app's backend infrastructure, which requires expert development skills, has not been fully developed. This limitation hinders the app's ability to store, process, and analyze user data securely and efficiently. Therefore, future versions of the DiaFriend app should prioritize the development of these critical backend components and integrate real-time feedback and notification features to offer a more comprehensive and user-centric diabetes self-care tool.

Third, as the research team members are not Portuguese speakers, the current version of the DiaFriend app is available only in English. This language barrier may limit the app's accessibility and usability for Portuguese American users who prefer their native language. Previous studies highlight the need for culturally tailored apps for non-English speakers to enhance healthy eating, promote exercise, and weight control [27]. Future versions of the DiaFriend app should be translated appropriately into Portuguese to address this limitation.

Finally, the research team recognized the significance of user collaboration with designers throughout every stage of app development to ensure that the app effectively fulfills their needs. However, the COVID-19 pandemic posed challenges, limiting the ability to conduct face-to-face research with participants. Due to institutional guidelines, the research team was not permitted in-person contact with app development participants. Thus, the information about the app design derived during the ideate step was solely from the research team, which had experience caring for patients with T2DM who have limited health literacy and technological skills. Moreover, specialists such as clinical diabetes educators and endocrinologists were not included in the design and development. Thus, some valuable user and expert perspectives might have been overlooked.

The DiaFriend app version 1, which is the result of phase 2 of this app development project, will be used to revise and develop the DiaFriend app version 2. To address the limitations and enhance the functionality and usability of the DiaFriend app, the research team plans to recruit Portuguese Americans with T2DM to be involved in the remaining stages of front-end development and backend creation. Furthermore, the team plans to collaborate with a multidisciplinary health care team and experienced backend developers. This collaboration will focus on designing necessary personalized features, such as real-time feedback and notifications based on the users' inputs, and completing the backend functionality, including data computing, analysis, and storage, before progressing to the app testing step in the design thinking methodology.

Conclusions

As a result of phase 2 of this app development project, the prototype DiaFriend app for Portuguese Americans with T2DM was developed. In total, 2 steps in the design thinking methodology (ideate and prototype) were used to ensure the user-friendliness and cultural sensitivity characteristics of the app. The DiaFriend app version 1 comprises five features: (1) blood glucose monitoring, (2) weight tracking, (3) carbohydrate tracking, (4) exercise log, and (5) medication reminder. The carbohydrate tracking feature was explicitly tailored to correspond to Portuguese food culture. This feature includes food databases tailored to Portuguese food culture and dietary choices. The app features displayed large picture icons and a sizable font size that provides easy visualization, and the

data-entry steps are easy to navigate, which should reduce time constraints and be less burdensome to Portuguese Americans who may not be familiar with the technology. Therefore, by incorporating these characteristics into the app's design, the DiaFriend app should promote app engagement and adherence to self-management among Portuguese Americans with T2DM. The findings for this phase will serve as the basis for updating and refining the DiaFriend app, leading to the development of version 2. The usability of the app will be tested in phase 3 of this app development project, which uses the final step (test) of the design thinking methodology. The DiaFriend app lays the groundwork for subsequent studies focused on creating and assessing mobile health tools tailored to specific cultural contexts. The adoption of the DiaFriend app may significantly improve their ability to manage their condition independently. Future research could involve a randomized controlled trial comparing the use of the DiaFriend app to standard care among Portuguese Americans with T2DM, measuring outcomes such as HbA_{1c} levels and adherence to self-care behaviors. In addition, a longitudinal app development could be conducted to evaluate the long-term impact of the DiaFriend app on diabetes management and quality of life, potentially incorporating qualitative interviews to gain insights into user experiences and cultural acceptability.

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Conflicts of Interest

None declared.

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Abbreviations

HbA_{1c}: glycated hemoglobin
T2DM: type 2 diabetes mellitus

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Original Paper

Association of Blood Glucose Data With Physiological and Nutritional Data From Dietary Surveys and Wearable Devices: Database Analysis

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Abstract

Background: Wearable devices can simultaneously collect data on multiple items in real time and are used for disease detection, prediction, diagnosis, and treatment decision-making. Several factors, such as diet and exercise, influence blood glucose levels; however, the relationship between blood glucose and these factors has yet to be evaluated in real practice.

Objective: This study aims to investigate the association of blood glucose data with various physiological index and nutritional values using wearable devices and dietary survey data from PhysioNet, a public database.

Methods: Three analytical methods were used. First, the correlation of each physiological index was calculated and examined to determine whether their mean values or SDs affected the mean value or SD of blood glucose. To investigate the impact of each physiological indicator on blood glucose before and after the time of collection of blood glucose data, lag data were collected, and the correlation coefficient between blood glucose and each physiological indicator was calculated for each physiological index. Second, to examine the relationship between postprandial blood glucose rise and fall and physiological and dietary nutritional assessment indices, multiple regression analysis was performed on the relationship between the slope before and after the peak in postprandial glucose over time and physiological and dietary nutritional indices. Finally, as a supplementary analysis to the multiple regression analysis, a 1-way ANOVA was performed to compare the relationship between the upward and downward slopes of blood glucose and the groups above and below the median for each indicator.

Results: The analysis revealed several indicators of interest: First, the correlation analysis of blood glucose and physiological indices indicated meaningful relationships: acceleration SD (r=–0.190 for lag data at –15-minute values), heart rate SD (r=–0.121 for lag data at –15-minute values), skin temperature SD (r=–0.121), and electrodermal activity SD (r=–0.237) for lag data at –15-minute values. Second, in multiple regression analysis, physiological indices (temperature mean: t=2.52, P=.01; acceleration SD: t=–2.06, P=.04; heart rate_30 SD: t=–2.12, P=.04; electrodermal activity_90 SD: t=1.97, P=.049) and nutritional indices (mean carbohydrate: t=6.53, P<.001; mean dietary fiber: t=–2.51, P=.01; mean sugar: t=–3.72, P<.001) were significant predictors. Finally, the results of the 1-way ANOVA corroborated the findings from the multiple regression analysis.

Conclusions: Similar results were obtained from the 3 analyses, consistent with previous findings, and the relationship between blood glucose, diet, and physiological indices in the real world was examined. Data sharing facilitates the accessibility of wearable data and enables statistical analyses from various angles. This type of research is expected to be more common in the future.

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KEYWORDS

PhysioNet; Empatica; Dexcom; acceleration; heart rate; temperature; electrodermal activity

Introduction

Global Prevalence of Diabetes and Hyperlipidemia

The global prevalence of diabetes in 2021 among individuals aged between 20 and 79 years was estimated to be 10.5% (536.6 million people), with this figure expected to rise to 12.2% (783.2 million) by 2045. Global diabetes-related health expenditures were estimated at US $966 billion in 2021 and are projected to reach US $1054 billion by 2045 [1]. In 2020, approximately 38.1 million adults aged ≥18 years, or 14.7% of all adults in the United States, had diabetes [2]. The global prevalence of hyperlipidemia in adults is 39% (37% in men and 40% in women), and as of 2020, approximately 10% (about 25 million people) of adults aged ≥20 years in the United States had total cholesterol levels of ≥240 mg/dL and 33% (about 86 million people) had total cholesterol levels of ≥200 mg/dL [3]. Several primary hyperlipidemias (eg, familial combined hyperlipidemia, familial hypertriglyceridemia, and abnormal β lipoproteinemia) have been reported to be associated with an increased risk of type 2 diabetes [4].

The Role of Wearable Devices and Real-World Data

Wearable devices are becoming increasingly capable of measuring a range of physiological data. Real-world data, which collect and analyze activity and physiological measurements from participants in clinical studies, can provide more sensitive measures of disease activity than traditional scales, thereby enabling faster and more objective readings in clinical trials [5]. Wearable devices can continuously collect measures of multiple physiological functions in real-time. Depending on the size and complexity of the raw data obtained from the device, data preprocessing, feature extraction, and selection are performed through data processing, such as data mining, and are applied toward abnormality detection, prediction, diagnosis, and decision-making [6]. Conversely, data repositories have advanced in recent years, making large, open databases available for wearable devices. Data mining techniques have advanced significantly in the last few years, and with the availability of these open data, opportunities emerged to devise algorithms suitable for wearable sensors [6].

Use of Open Datasets and Research Progress

Table S1 in Multimedia Appendix 1 depicts studies that applied existing open datasets. Several studies were conducted to establish algorithms and prediction models based on machine learning from sensor data [7-24].

Open datasets are available on the following websites: (1) IEEE Data Port, a research data platform designed to store research data and provide global access to research data across various fields [25]; (2) the Open Wearables Initiative, which aims to promote the effective use of high-quality sensor-generated health measurements in clinical research by openly sharing algorithms and datasets [26]; (3) PhysioNet, a searchable database containing a collection of cardiopulmonary, neurological, and other biomedical signals from healthy individuals and patients with several serious health conditions, including congestive heart failure, epilepsy, gait disturbance, and sleep apnea [27].

Development of Prediction Models for Blood Glucose Indicators

The BIG IDEAs Lab Glycemic Variability and Wearable Device Data (version 1.1.1) by Cho et al [28,29], a wearable database containing blood glucose–related indicators from PhysioNet, was selected for the study. Two previous studies have used the same database [30,31]. The first study demonstrated the feasibility of predicting blood glucose changes by continuously detecting individualized blood glucose deviations and determining the contribution of each variable to interstitial glucose prediction. The LOPOCV random forest regression model was used to examine the importance of the characteristics, resulting in the extraction of *diet*, *circadian rhythm*, *stress*, *activity*, *body temperature*, *heart rate*, *electrodermal activity*, *biological sex*, and *HbA$_{1c}$* [30]. The second study evaluated methods for detecting prediabetes and estimating glycated hemoglobin (HbA_{1c}) and glucose variability using digital biomarkers from wearables [31]. The relationships between features extracted from wearables and blood glucose variability and HbA_{1c} were investigated, and the results showed that glucose variability indices and HbA_{1c} could be estimated with high accuracy. The HbA_{1c} estimation model developed from a noninvasive wrist-worn wearable was as accurate as the invasive continuous glucose monitor (CGM)–based estimated A_{1c} (as recommended by the American Diabetes Association). Notably, all the sensors used in this study (triaxial accelerometer-derived acceleration [ACC], heart rate [HR], electrodermal activity [EDA], and skin temperature [TEMP]) were important for estimating glucose variability indices and HbA_{1c}, although EDA and TEMP were the most important indicators when estimating HbA_{1c} [31]. Similar to the other studies based on existing open datasets (Table S1 in Multimedia Appendix 1), these 2 studies were conducted to establish a prediction model for blood glucose-related indicators using machine learning and used the random forest regression model for analysis. This analysis can be difficult to interpret in a specific clinical context.

Factors Influencing Blood Glucose Levels and Real-World Evaluation

Several factors influence blood glucose levels, including diet [32], physical activity, exercise [33], stress [34], circadian rhythm [35], and HR [36]. For example, regarding diet, following the dietary approaches to stop hypertension (DASH) diets [37], low carbohydrate diets [38,39], and high consumption of phytochemicals and polyphenols [40,41] prevent type 2 diabetes. However, although some factors associated with blood glucose variability, such as HR [36], body temperature [42], and autonomic functions [43], including sweating motor response [44], have been reported [30], these factors have not been evaluated in real-world setting. Therefore, we conducted an exploratory study of the association between blood glucose and each physiological and nutritional index, using existing data from PhysioNet as well as simple analytical methods, such as correlation and multiple regression analyses. These analysis methods were used for their simplicity compared to the random forest model and may increase the explanatory potential as the contribution of each variable is clarified.

Methods

Database Selection and Dataset Creation

A database search was conducted using the word "wearable" from PhysioNet, which yielded 11 hits. Among these, we focused on wristband-type wearable devices and searched the relevant databases because the major market share is dominated by wristband- and watch-type devices [45]. The search resulted in 7 (64%) of 11 studies with wristband-type wearable devices (Empatica [Empatica Inc]: n=5, 45%; Apple watch [Apple Inc]: n=2, 18%; Fitbit [Fitbit, Inc]: n=2, 18%; Garmin [Garmin Ltd]: n=1, 9%; Samsung Galaxy watch [Samsung, Inc]: n=1, 9%; Xiaomi [Xiaomi Corp]: n=1, 9%; and Biovotion Everion [Biofourmis Inc]: n=1, 9% study; Table S2 in Multimedia Appendix 1).

We selected 1 study that investigated Empatica E4, the most commonly used wristband-type wearable device. The dataset, BIG IDEAs Lab Glycemic Variability and Wearable Device Data (version 1.1.1) by Cho et al [28,29] was selected to examine the correlation between each physiological index and blood glucose as well as conduct multiple regression analysis and 1-way ANOVA of the slope in postprandial glucose over time with each physiological index and nutrient value. The main eligibility criteria in the study included men and postmenopausal women aged 35-65 years, with point-of-care HbA_{1c} measurements between 5.2% and 6.4%.

A total of 16 patients (n=7, 44% men and n=9, 56% women) with HbA_{1c} in the high normal and prediabetic range (5.3%-6.4%, mean 5.73%, SD 0.28%) were included and monitored for 8-10 days using the Dexcom G6 CGM and Empatica E4 wrist-worn wearable-type device [28].

The demographic characteristics of the participants are listed in Table 1.

Table 1. Demographic characteristics of the participants in the database.

ID	Sex	HbA_{1c}[a] (%)
a01	Female	5.5
a02	Male	5.6
a03	Female	5.9
a04	Female	6.4
a05	Female	5.7
a06	Female	5.8
a07	Female	5.3
a08	Female	5.6
a09	Male	6.1
a10	Female	6.0
a11	Male	6.0
a12	Male	5.6
a13	Male	5.7
a14	Male	5.5
a15	Female	5.5
a16	Male	5.5

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

Notably, all data were time-shifted (by date) to prevent reidentification; the Dexcom G6 measured interstitial glucose concentration (mg/dL) every 5 minutes using a CGM, and the Empatica E4 measured photoelectric volumetric pulse wave, electrical activity: EDA, TEMP, and ACC, for 7 functions. The photoelectric volumetric pulse wave was sampled at 64 Hz, and HR and blood volume pulse (BVP) signals were obtained every second, from which the interbeat interval (IBI) data were calculated. Of these, EDA is known as a psychological factor and a measure of sympathetic activation related to stress [46,47]. In addition, HR variability, a related index of HR and IBI, was used as a psychological stress indicator [47,48]. EDA and TEMP were sampled at 4 Hz, whereas accelerometry was sampled at 32 Hz. For ACC, triaxial data were calculated using the Euclidean norm as a measure of average motion in the 3 axes using the following formula [49]:

Each physiological index (ACC, HR, TEMP, EDA, BVP, and IBI) collected using Empatica was also extracted at 5-minute intervals to match blood glucose, which had the longest measurement interval (5 minutes).

In addition, when the Cho et al [28] dataset was updated from version 1.0.0 to version 1.1.0 on March 6, 2023, the results of nutrient value calculations from the dietary survey records were added to the analysis dataset. The parameters of the calculated

nutritional values were calories, total carbohydrate (carbon), dietary fiber, sugar, protein, and total fat. The values of these nutritional assessment indices at each time point were summed.

Correlation Analyses Between Blood Glucose and Each Physiological Index

The correlation of each physiological index (ACC, HR, TEMP, EDA, BVP, and IBI) was calculated and examined to determine whether their mean values or SDs affected the mean value or SD of blood glucose. Mean values and SDs were calculated for blood glucose and each physiological index at three 5-minute points in the same individual (10 minutes in total), and their correlation coefficients were calculated. To examine the impact of each physiological indicator on blood glucose before and after the time of collection of blood glucose data, lag data (data on physiological indicators before glucose data collection at 8 points [120, 105, 90, 75, 60, 45, 30, and 15 minutes] and after blood glucose data collection at 8 points [15, 30, 45, 60, 75, 90, 105, and 120 minutes]) were collected, and the correlation coefficient between blood glucose and each physiological indicator was calculated for each physiological index.

Lag data for physiological indicators before glucose data collection were created by time-shifting each physiological indicator every 15 minutes until 120 minutes (Figure S1 in Multimedia Appendix 1). Lag data for physiological index data after blood glucose data collection were time-shifted by 15 minutes for each glucose reading to 120 minutes (Figure S2 in Multimedia Appendix 1). The purpose of creating lag data was to calculate the correlation between glucose levels and ACC (ACC values at 15, 30, 45, 60, 75, 90, 105, and 120 minutes) before and after measurement. The correlation coefficient was calculated using Spearman correlation.

Multiple Regression Analysis of Postprandial Blood Glucose Over Time and Each Physiological Index and Nutrient Value

To examine the relationship between postprandial blood glucose rise and fall and physiological and dietary nutritional assessment indices, multiple regression analysis was performed on the relationship between the slope before and after the peak in postprandial glucose over time and physiological and dietary nutritional indices. Multiple regression analysis was performed using objective and explanatory variables.

Objective Variables

The objective variables included the slope of the tangent line to the postprandial blood glucose curve, which includes the slope of the rise in postprandial glucose from the lowest point before the rise to the peak and the slope of postprandial blood glucose from the peak to the lowest point.

The following formula was used to calculate the slope:

where x indicates time (min) and y indicates blood glucose (mg/dL).

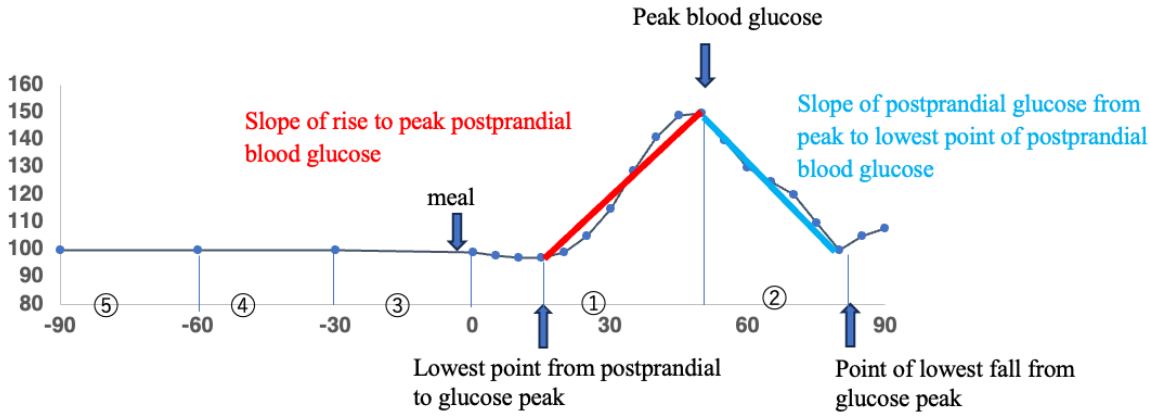
Explanatory Variables

The explanatory variables comprised the calculated nutritional value of the diet (carbon, protein, calories, sugar, dietary fiber, protein, and total fat) and the means and SDs of physiological indices (ACC, HR, TEMP, EDA, BVP, and IBI) at the following time points (Figure 1):

1. Time from the most recent postprandial glucose to peak glucose level. The variables are ACC, HR, TEMP, EDA, BVP, and IBI.
2. Time from peak glucose to the lowest glucose level (excluded from the analysis of the slope of peak ascent owing to limited data). The variables are ACC_af, HR_af, TEMP_af, EDA_af, BVP_af, and IBI_af.
3. Time from the most recent postprandial glucose peak to 30 minutes before the most recent postprandial glucose. The variables are ACC_30, HR_30, TEMP_30, EDA_30, BVP_30, and IBI_30.
4. Time from 30 minutes before the most recent postprandial glucose to 60 minutes before. Variables are ACC_60, HR_60, TEMP_60, EDA_60, BVP_60, and IBI_60.
5. Time from 60 minutes before the most recent postprandial glucose to 90 minutes before. Variables are ACC_90, HR_90, TEMP_90, EDA_90, BVP_90, and IBI_90.

Multiple regression analysis was performed using the variable reduction method, and the significance level used as the criterion for the backward elimination method [50,51] was P=.20.

Figure 1. Collection times for the objective (blood glucose slope) and explanatory (physiological indexes) variables used in the multiple regression analysis.



One-Way ANOVA for Postprandial Blood Glucose and Groups Above and Below Each Physiological Indicator and the Median Dietary Nutrient Value

As a supplementary analysis to the multiple regression analysis, a 1-way ANOVA was performed to compare the relationship between the upward and downward slopes of blood glucose and the groups above and below the median for each indicator. The groups below the median were used as comparison controls. The following variables were used in the 1-way ANOVA.

Objective Variables

The same variables were used for analysis as those in the multiple regression analysis.

Explanatory Variables

For the following indices, variables were created through patterns of group combinations using the physiological index mean and dietary nutrient value, with groups above and below the median for each index as 1 and 0, respectively. Group combinations that contained missing measures or extremely low group combinations were not included in the analysis population. The mean values of physiological indices (ACC, HR, TEMP, and EDA) at three 5-minute intervals (10 minutes in total) in the same participant at the following times and the nutritional value of the diet (carbon, protein, calories, sugar, and dietary fiber) were assessed.

The results of the multiple regression analysis showed that the physiological indicators associated with the slope of the rise and fall of blood glucose were TEMP, ACC, HR, and EDA, and the nutritional value indicators were carbon, protein, calories, sugar, and dietary fiber. Therefore, we focused on the following time indicators:

1. Time from the most recent postprandial glucose to peak glucose level.
2. Time from peak glucose to lowest glucose level (excluded from this analysis).
3. Time from the most recent postprandial glucose to 30 minutes before.
4. Time from 30 minutes before the most recent postprandial glucose to 60 minutes before.
5. Time from 60 minutes before the most recent postprandial glucose to 90 minutes before.

Patterned combination of groups by physiological indicator mean and dietary nutrient value are given in Textbox 1.

All analyses were performed using JMP Pro (version 16.10; SAS Institute Inc), SAS (version 9.4; SAS Institute Inc), and Microsoft Excel for Mac (version 16; Microsoft Corp).

Textbox 1. Patterned combination of groups.

Combination patterns of physiological index mean groups. Combination pattern of temperature (TEMP), acceleration (ACC), heart rate (HR), and electrodermal activity (EDA); for example,

- Combination pattern for groups with TEMP, ACC, HR, and EDA below the median (used as a comparison). TEMP: ACC:HR:EDA=0000.
- Combination pattern for groups with TEMP, ACC, HR, and EDA above the median. TEMP: ACC:HR:EDA=1111.
- Combination pattern for groups where TEMP and EDA were above the median and all other values were below the median. TEMP:ACC:HR:EDA=1001.

Combination patterns for dietary nutrient value groups; for example,

- Combination pattern for all indicators of dietary nutritional value (used as comparisons and controls) below the median. Calories:carbon:dietary fiber:sugar:protein=00000.
- Combination pattern for all indicators of dietary nutritional value above the median. Calories:carbon:dietary fiber:sugar:protein=11111.
- Combinations pattern for carbon and sugar above the median and all other indicators of dietary nutritional value below the median. Calories:carbon:dietary fiber:sugar:protein=01010.

Ethical Considerations

No ethical approval was required since this study was exclusively based on published literature.

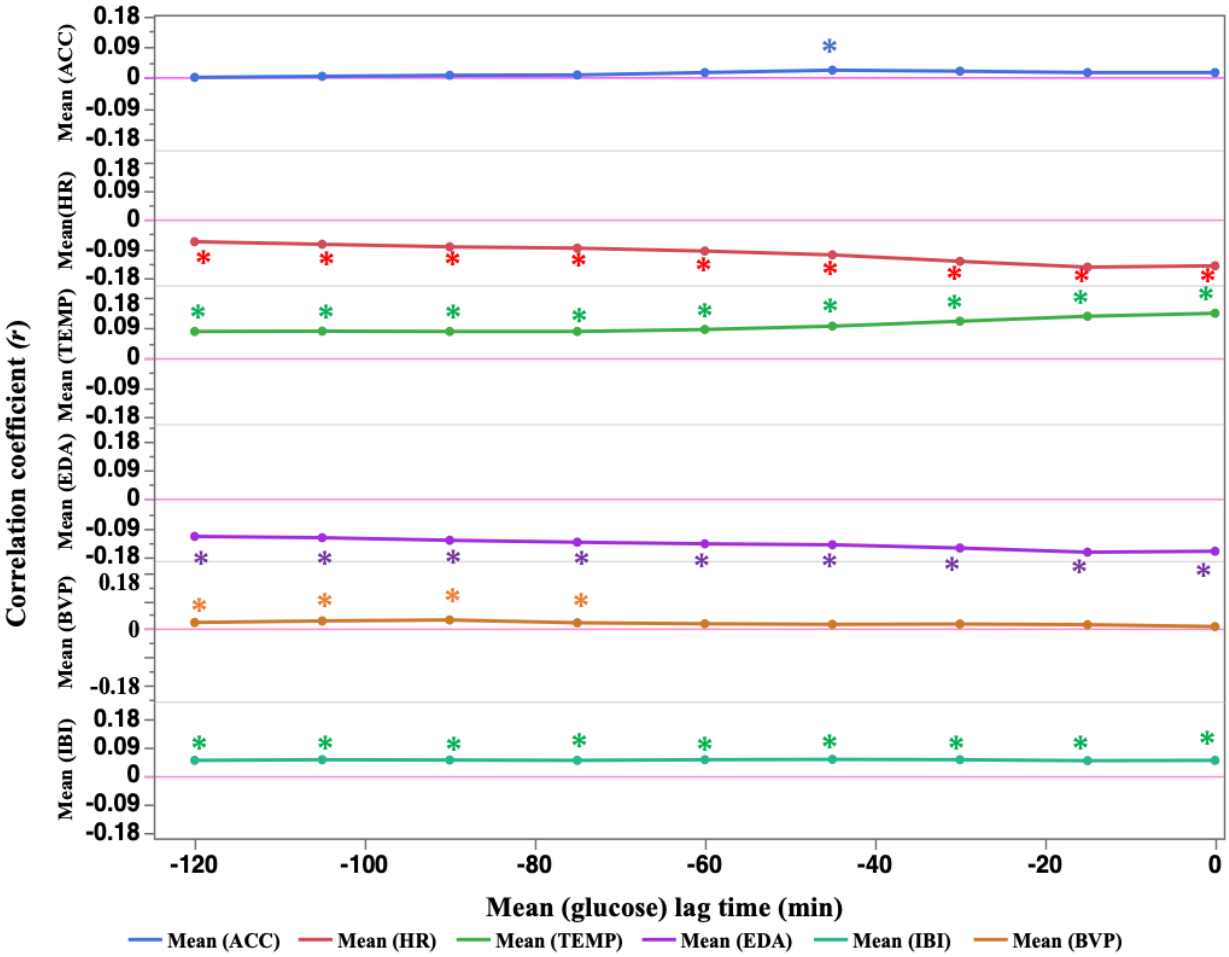
Results

Correlation Coefficients Between Blood Glucose Mean and the Mean of Lag Data for Each Physiological Indicator

Lag Data for Each Physiological Indicator Before Blood Glucose Data Collection

Figure 2 and Table S3 in Multimedia Appendix 1 illustrate the evolution of the correlation coefficients of the lag data (–120, –105, –90, –75, –60, –45, –30, and –15 min) between the mean values of blood glucose and physiological indices. For HR, the correlation remained negative, peaking at the –15-minute value of lag data (r=–0.147). For TEMP, the correlation remained positive, with a peak at the 0-minute value (r=0.135). For EDA, the correlation remained negative, peaking at the –15-minute value of lag data (r=–0.164).

Figure 2. Trends in correlations between mean blood glucose and the mean of lag data for each physiological indicator (lag data for physiological indicators before blood glucose data collection). ACC: triaxial accelerometer–derived acceleration; BVP: blood volume pulse; EDA: electrodermal activity; HR: heart rate; IBI: interbeat interval; TEMP: skin temperature. *P value of correlation coefficient P<.05.



Lag Data for Each Physiological Indicator After Blood Glucose Data Collection

Figure S3 and Table S4 in Multimedia Appendix 1 illustrate the evolution of the correlation coefficients of the lag data (15, 30, 45, 60, 75, 90, 105, and 120 min) for the mean values of glucose and physiological indices.

For HR, the correlation remained negative and peaked at the 45-minute value of lag data (r=–0.147). For TEMP, the correlation remained positive, peaking at the 60-minute value of lag data (r=0.161). For EDA, the correlation remained negative, with a peak at 0 minutes (r=–0.161). For IBI, the correlation remained positive, peaking at the 120-minute value of lag data (r=0.120).

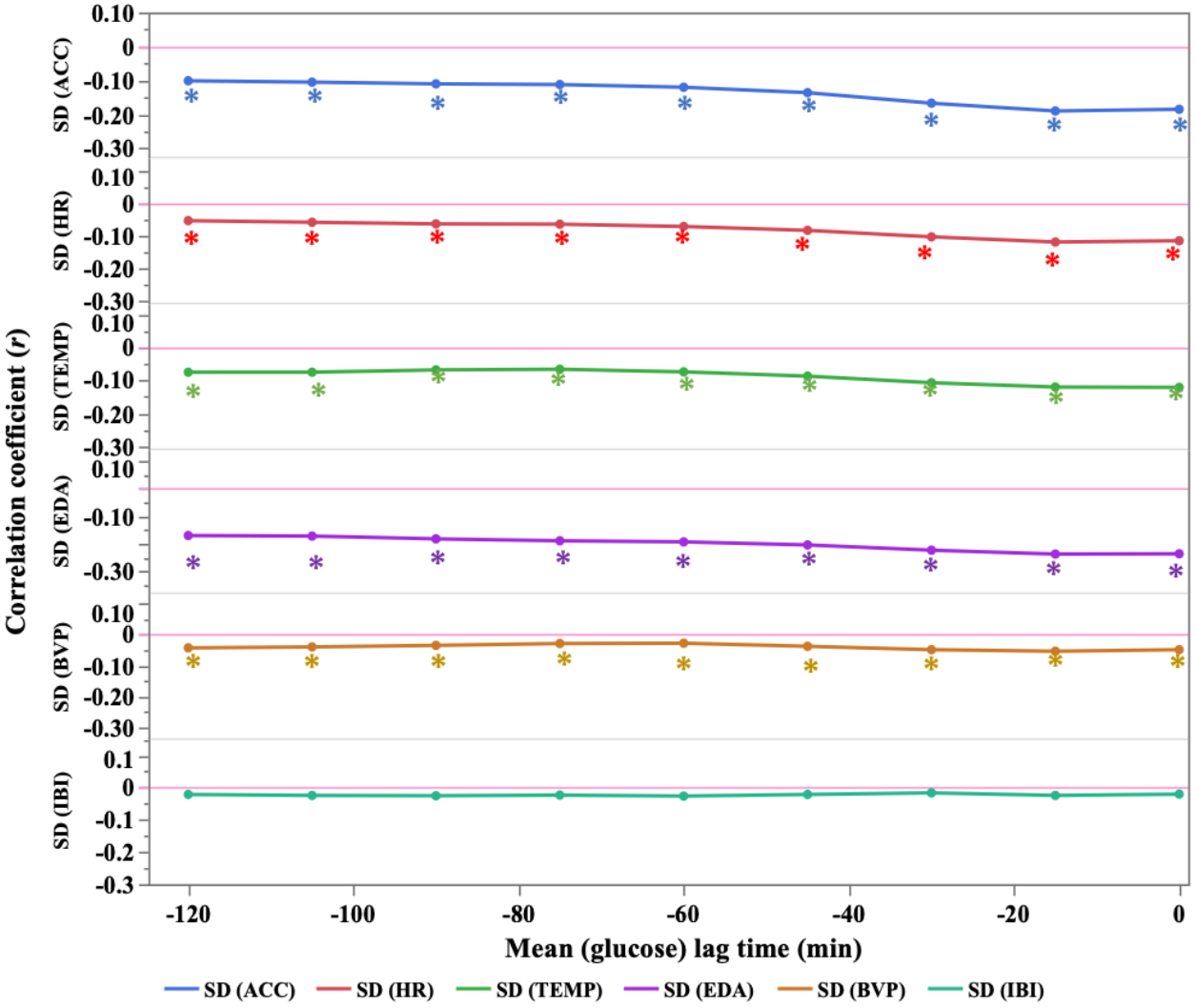
Correlation Coefficients Between Blood Glucose Mean and SD of Lag Data for Each Physiological Indicator

Lag Data for Each Physiological Indicator Before Blood Glucose Data Collection

Figure 3 and Table S5 in Multimedia Appendix 1 illustrate the evolution of the correlation coefficients of the lag data (–120, –105, –90, –75, –60, –45, –30, and –15 min) of the mean blood glucose values and SDs of physiological indices.

Regarding the evolution of the correlation coefficient of the lag data, which are the data at and after the time of blood glucose measurement, the correlation remained negative and peaked at the 15-minute value of lag data (r=–0.190) for ACC. For HR, the correlation remained negative, peaking at the 15-minute value of lag data (r=–0.121). For TEMP, the correlation remained negative, with a peak at the 0-minute value (r=–0.121). For EDA, the correlation remained negative, peaking at the 15-minute value of lag data (r=–0.237).

Figure 3. Trends in correlations between mean blood glucose values and SD of lag data for each physiological indicator (lag data for physiological indicators before blood glucose data collection). ACC: triaxial accelerometer derived acceleration; BVP: blood volume pulse; EDA: electrodermal activity; HR: heart rate; IBI: interbeat interval; TEMP: skin temperature. *P value of correlation coefficient P<.05.



Lag Data for Each Physiological Indicator After Blood Glucose Data Collection

Figure S4 and Table S6 in Multimedia Appendix 1 illustrate the evolution of the correlation coefficients of the lag data (15, 30, 45, 60, 75, 90, 105, and 120 min) for the mean blood glucose values and SDs of physiological indices.

Regarding the evolution of the correlation coefficients of the lag data, which are the data at and after the time when blood glucose was measured, the correlation remained negative and peaked at the 0-minute value (r=–0.185) for ACC. For HR, the correlation remained negative, peaking at the 45-minute value of lag data (r=–0.127). For TEMP, the correlation remained negative, with a peak at 0-minute value (r=–0.121). For EDA, the correlation remained negative, with a peak at the 0-minute value (r=–0.236).

Correlation Coefficients Between SD of Blood Glucose and SD of Lag Data for Each Physiological Indicator

Lag Data for Each Physiological Indicator Before Blood Glucose Data Collection

Figure S5 and Table S7 in Multimedia Appendix 1 illustrate the evolution of the correlation coefficients of the lag data (–120, –105, –90, –75, –60, –45, –30, and –15 min) for the SD of blood glucose and physiological indices.

Regarding the evolution of the correlation coefficients of the lag data, which are the data at and after the time of glucose measurement, the correlation remained positive, with a peak at the 0-minute value for ACC, HR, and TEMP (r=0.157, r=0.142, and r=0.127, respectively).

Lag Data for Each Physiological Indicator After Blood Glucose Data Collection

Figure S6 and Table S8 in Multimedia Appendix 1 illustrate the evolution of the correlation coefficients of the lag data (15, 30, 45, 60, 75, 90, 105, and 120 min) for the SD of glucose and physiological indices.

For the transition of the correlation coefficients for the lag data, which are the data at and after the time of glucose measurement, the correlation remained positive and peaked at the 0-minute value (r=0.157) for ACC. For HR, the correlation remained positive, with a peak at the 0-minute lag data (r=0.142). For TEMP, the correlation remained positive, with a peak at the 0-minute value (r=0.127).

Results of Regression Analysis of Postprandial Glucose Over Time and Each Physiological Index and Nutrient Value

Results of Multiple Regression Analysis Between the Slope of the Peak of Blood Glucose Rise and the Mean Values of Physiological and Nutritional Assessment Indices

The results of multiple regression analysis between the slopes of the elevated blood glucose peak and the mean values of physiological and nutritional assessment indices are shown in Table S9 and S10 in Multimedia Appendix 1.

The physiological index (TEMP: t=2.52, P=.01) and nutritional assessment indexes (calorie: t=–3.98, P<.001, carbon: t=6.53; P<.001, dietary fiber: t=–2.51, P=.01, and protein: t=3. 82, P<.001) suggest that the mean values of these nutritional measures were significantly associated with the slope of the peak blood glucose elevation.

Results of Multiple Regression Analysis Between the Slope of the Descending Peak of Blood Glucose and the Mean Values of Physiological and Nutritional Assessment Indexes

The results of multiple regression analysis between the slope of the blood glucose descending peak and the mean values of physiological and nutritional assessment indices are shown in Table S11 and S12 in Multimedia Appendix 1.

The physiological indices (ACC: t=2.67, P=.008, HR_af: t=3.86; P<.001, and HR_90: t=2.27, P=.02), and nutritional assessment index (sugar: t=–3.72, P<.001) suggest that the mean values of these physiological and nutritional assessment measures were significantly associated with the slope of the descending peak of blood glucose.

Results of Multiple Regression Analysis Between the Slope of the Peak of Blood Glucose Rise and SD of Physiological and Nutritional Assessment Indexes

The results of multiple regression analysis between the slope of the peak of elevated blood glucose and the SD of physiological indices are shown in Tables S13 and S14 in Multimedia Appendix 1.

The physiological indices (ACC: t=–2.06, P=.04, HR_30: t=–2.12, P=.03, and EDA_90: t=1.97, P=.049) suggest that the SD of these physiological indicators was significantly associated with the slope of the peak glucose rise.

Results of Multiple Regression Analysis Between the Slope of the Descending Peak of Blood Glucose and SD of Physiological and Nutritional Assessment Indexes

The results of multiple regression analysis between the slope of the blood glucose descending peak and SD of physiological and nutritional assessment indices are shown in Tables S15 and S16 in Multimedia Appendix 1.

None of the physiological indices showed a significant association between the SD of the physiological index and the slope of the blood glucose elevation peak.

Age [52], weight, BMI, blood lipid levels, blood pressure [53,54] and sex [55] affect blood glucose levels. However, since we obtained data from a public database, background information other than sex could not be obtained. When sex was added to the multiple regression analysis as an adjustment factor, the results were largely consistent with the unadjusted results (Tables S17-S24 in Multimedia Appendix 1).

Results of the 1-Way ANOVA of Postprandial Blood Glucose Over Time and Groups Above and Below Each Physiological Indicator and the Median Dietary Nutrient Value

Results of the 1-Way ANOVA of the Slope of Elevated Postprandial Blood Glucose and the Combined Pattern for Groups Above and Below the Median of the Mean of Each Physiological Index (TEMP, ACC, HR, and EDA)

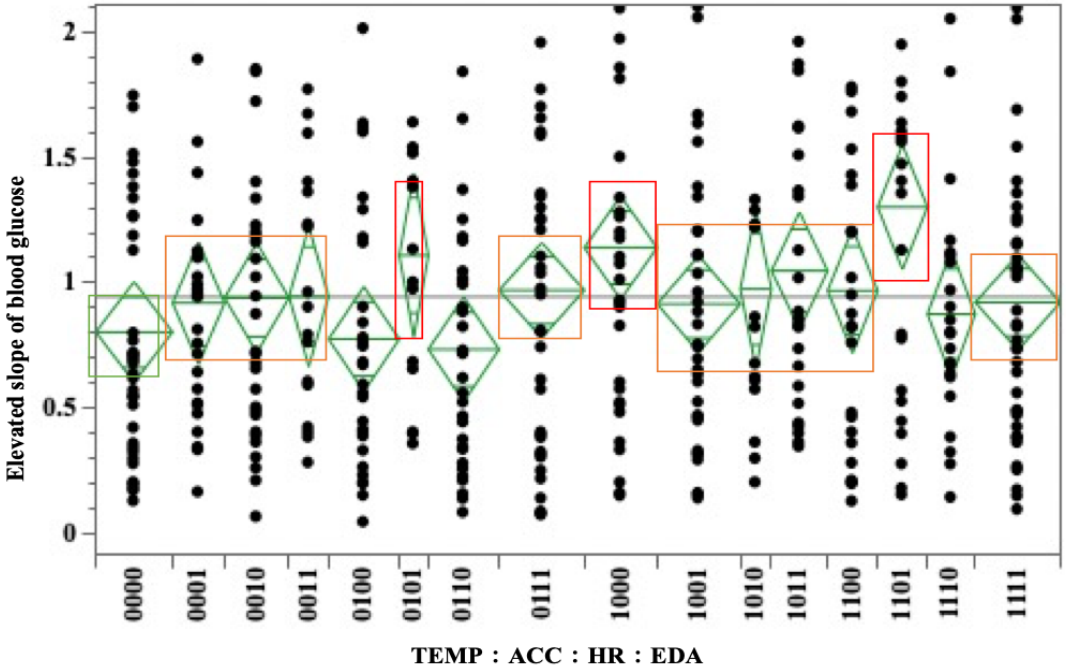
The results of the 1-way ANOVA of the slope of elevated blood glucose and the combined pattern for the mean values of physiological indicators (TEMP, ACC, HR, and EDA) are shown in Figure 4 and Tables S25 and S26 in Multimedia Appendix 1.

The combination patterns of the group with a greater upward slope of blood glucose than the group with TEMP, ACC, HR, and EDA values all below the median (TEMP:ACC:HR:EDA=0000; mean value of upward slope 0.803) were TEMP:ACC:HR:EDA=0101 (mean value of upward slope 1.110), 1000 (mean value of upward slope 1.140), 1011

(mean value of upward slope 1.048), and 1101 (mean value of upward slope 1.303), with a larger upward slope in the population with higher TEMP and EDA.

Combination patterns with slightly larger values were TEMP:ACC:HR:EDA=0001 (mean value of upward slope 0.920), 0010 (mean value of upward slope 0.940), 0011 (mean value of upward slope 0.946), 0111 (mean value of upward slope 0.970), 1001 (mean value of upward slope 0.916), 1010 (mean value of upward slope 0.975), 1100 (mean value of upward slope 0.969), and 1111 (mean value of upward slope 0.922), which were also similar to the larger combination pattern groups.

Figure 4. Relationship between the slope of blood glucose rise and the combination patterns (skin temperature [TEMP], triaxial accelerometer–derived acceleration [ACC], heart rate [HR], and electrodermal activity [EDA]).



Results of the 1-Way ANOVA of the Combined Pattern for Groups With the Downward Slope of Postprandial Blood Glucose and Higher and Lower Than Median Values of Each Physiological Index Mean

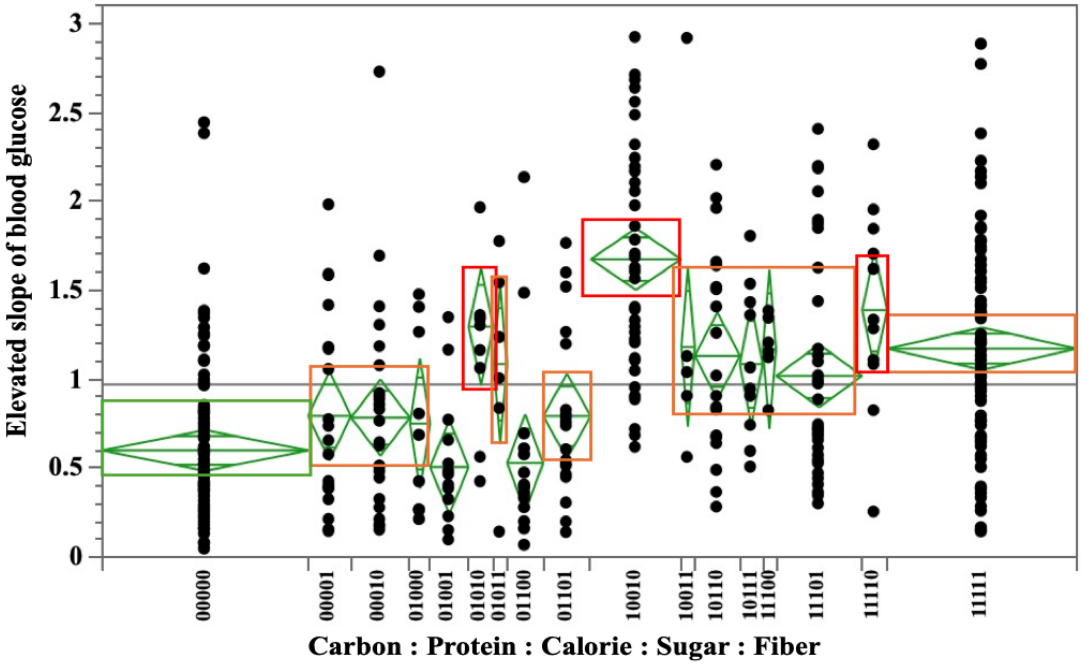
The results of the 1-way ANOVA of the combined pattern of the descending slope of blood glucose and mean physiological indices (TEMP, ACC, HR, and EDA) are shown in Figure S7 and Tables S27 and S28 in Multimedia Appendix 1.

The combination pattern with a greater downward slope of blood glucose than the group with TEMP, ACC, HR, and EDA values all below the median (TEMP:ACC:HR:EDA=0000, mean value of downward slope –0.663) was TEMP:ACC:HR:EDA=1011 (mean value of downward slope –1.045), with a greater downward slope in the population with higher TEMP, HR, and EDA. Combination patterns with slightly larger values were TEMP:ACC:HR:EDA=0111 (mean value of downward slope –0.751), 1000 (mean value of downward slope –0.752), 1010 (mean value of downward slope –0.785), 1100 (mean value of downward slope –0.787), and 1110 (mean value of downward slope –0.713), with the pattern combining HR and ACC with TEMP and EDA having a higher downward slope.

Results of the 1-Way ANOVA of the Slope of the Postprandial Rise in Blood Glucose and the Combined Pattern for Groups Above and Below the Median for Each Dietary Nutrient Value

The results of the 1-Way ANOVA of the combined pattern of the upward slope of blood glucose and dietary nutrient values (carbon, protein, calories, sugar, and fiber) are shown in Figure 5 and Tables S29 and S30 in Multimedia Appendix 1.

Figure 5. Relationship between the slope of the rise in blood glucose and dietary nutrient combination patterns (carbon, protein, calories, sugar, and fiber).



A slightly smaller upward slope of blood glucose was observed than the group where carbon, protein, calories, sugar, and fiber were all below the median (carbon:protein:calories:sugar:fiber=00000; the mean value of upward slope 0.599), for the combination pattern of carbon:protein:calorie:sugar:fiber=01001 (mean value of the upward slope 0.506), which was a combination of protein and fiber.

The larger combination patterns were carbon:protein:calorie:sugar:fiber=01010 (mean value of upward slope 1.296), 11110 (mean value of upward slope 1.389), and 10010 (mean value of upward slope 1.675), with high calories and sugar, and the upward slope of the low fiber group was large.

Slightly larger combination patterns were observed for carbon:protein:calories:sugar:fiber=00001 (mean value of upward slope 0.751), 00010 (mean value of upward slope 0.784), 01101 (mean value of upward slope 0.792), 00001 (mean value of upward slope 0.793), 11101 (mean value of upward slope 1.019), 10111 (mean value of upward slope 1.084), 01011 (mean value of upward slope 1.084), 10110 (mean value of upward slope 1.132), 11100 (mean value of upward slope 1.168), 11111 (mean value of upward slope 1.172), and 10011 (mean value of the upward slope 1.181). Compared with the combination of carbon and sugar above the median, the combination of carbon and sugar above the median and fiber above the median had a smaller upward slope (carbon:protein:calorie:sugar:fiber=01010 [mean value of upward slope 1.296] and 01011 [mean value of upward slope 1.084]), 11110 [mean value of upward slope; 1.389] and 11111 [mean value of upward slope 1.172], 10010 [mean value of upward slope 1.675] and 10011 [mean value of upward slope 1.181]).

Results of the 1-Way ANOVA of the Downward Slope of Postprandial Blood Glucose and the Combined Pattern for Groups Above and Below the Median for Each Dietary Nutrient Value

The results of the 1-way ANOVA of the combined pattern of the downward slope of blood glucose and dietary nutrient values (carbon, protein, calories, sugar, and fiber) are shown in Figure S8 and Tables S31 and S32 in Multimedia Appendix 1.

The combination pattern of carbon:protein:calories:sugar:fiber=01100 (mean value of the downward slope –0.408), which was a combination of protein and calories, showed a slightly smaller downward slope in blood glucose than the group where carbon, protein, calorie, sugar, and fiber were all below the median (carbon:protein:calories:sugar:fiber=00000; mean value of the downward slope –0.525).

The larger combination patterns were carbon:protein:calories:sugar:fiber=01010 (mean value of the downward slope –1.012), 10111 (mean value of the downward slope –0.978), and 10010 (mean value of the downward slope –1.028). The slightly larger combination patterns were carbon:protein:calories:sugar:fiber=01011 (mean value of downward slope –0.626), 11101 (mean value of downward slope –0.762), 11100 (mean value of downward slope –0.769) and 11110 (mean value of downward slope –0.783), 00010 (mean value of downward slope –0.793), 10110 (mean value of downward slope –0.826) and 10011 (mean value of downward slope –0.884), than those with carbon and sugar above the median. Compared with the combination of carbon and sugar higher than the median, the combination of carbon and sugar higher than the median and fiber or protein higher than the median had a smaller downward slope (carbon:protein:calorie:sugar:fiber=01010 [mean of downward slope –1.012] and 01011 [mean of upward slope –0.626], 10111 [mean of upward slope –0.978] and 11111 [mean of upward

slope –0.769], 10010 [mean value of upward slope –1.028] and 10011 [mean value of upward slope –0.884]).

Discussion

Correlation Analyses Between the Mean and SD of Glucose and the Mean of Each Physiological Index

We reviewed the evolution of the correlation coefficients, including the lag data for glucose, to determine whether the impact of each physiological indicator on glucose was influenced by physiological indicators before and after the time the glucose data were collected (Table 2).

The results showed that some indices such as ACC, TEMP, EDA, and IBI showed data correlations before and after the collection of blood glucose data. Activity, exercise, and stress are factors that influence blood glucose levels. Factors such as HR, body temperature, and autonomic nervous system function, including the sweating motor response, were associated with blood glucose variability [30]. The mean blood glucose and ACC SDs were negatively correlated; however, the uptake of blood glucose by mild to moderate physical activity is reported to cause decreased blood glucose levels and increased glucose production in the liver, leading to increased blood glucose [56]. This may be attributed to fluctuations in physical activity. The mean values of blood glucose and HR were negatively correlated; however, previous reports have indicated a negative relationship between blood glucose and HR variability, as sympathetic dominance increases with increasing blood glucose [57,58], which contradicts previous results. This could be attributed to, among others, increased in HR due to fasting-related hypoglycemia [58] and mild to moderate physical activity [56].

Regarding the correlation between mean blood glucose and mean TEMP, intravenous administration of blood glucose increased heat production by 20%, accompanied by an increase in TEMP after 55 minutes, which was presumed to be caused by this effect [59]. Regarding the correlation between blood glucose and EDA, EDA can increase during stress and is mediated by stress-induced activation of adrenergic hormones and cortisol. This increases blood glucose production and is thus positively related. Blood glucose levels increase in some individuals and decrease in others in response to stressful situations. Naturally occurring daily stressors may be associated with increased glycemic instability from hypoglycemia and decreased food intake, possibly due to these factors [60].

The mean blood glucose and SD of the physiological indices were negatively correlated.

This is because the mean and SD of physiological indicators were calculated from the mean and SD of the 3 points at individual 5-minute intervals, and the variation in physiological indicators was greater before and after the peak rise in glucose, whereas the variation in relevant physiological indicators was smaller at the peak of the rise in blood glucose. Meanwhile, the SD of blood glucose and physiological indicators were positively correlated, which was attributed to the increased variability in the SD of physiological indicators and blood glucose at times of blood glucose fluctuation (prepeak and peak transition).

Table 2. Summary of correlations between blood glucose and physiological indexes.

	r
Correlation coefficients between mean values of blood glucose and mean values of physiological indices	
Before blood glucose data collection	
HR[a]: negative correlation, peaking at –15 minutes	–0.147
TEMP[b]: positive correlation, peaking at 0 minutes	0.135
EDA[c]: negative correlation, peaking at 15 minutes	–0.164
After blood glucose data collection	
HR: negative correlation, peaking at 45 minutes	–0.147
TEMP: positive correlation, peaking at 60 minutes	0.161
EDA: negative correlation, peaking at 0 minutes	–0.161
IBI[d]: positive correlation, peaking at 120 minutes	0.120
Correlation coefficients between mean values of blood glucose and SDs of physiological indices	
Before blood glucose data collection	
ACC: negative correlation, peaking at 15 minutes	–0.190
HR: negative correlation, peaking at 15 minutes	–0.121
TEMP: negative correlation, peaking at 0 minutes	–0.121
EDA: negative correlation with EDA, peaking at 15 minutes	–0.237
After blood glucose data collection	
ACC: negative correlation, peaking at 0 minutes	–0.185
HR: negative correlation, peaking at 45 minutes	–0.127
TEMP: negative correlation, peaking at 0 minutes	–0.121
EDA: negative correlation, peaking at 0 minutes	–0.236
Correlation coefficients between SD of blood glucose and SD of physiological indices	
Before blood glucose data collection	
ACC: positive correlation, peaking at 0 minutes	0.157
HR: positive correlation, peaking at 0 minutes	0.142
TEMP: positive correlation, peak at 0 minutes	0.127
After blood glucose data collection	
ACC: positive correlation, peaking at 0 minutes	0.157
HR: positive correlation, peaking at 0 minutes	0.142
TEMP: positive correlation, peak at 0 minutes	0.127

[a]HR: heart rate.

[b]TEMP: skin temperature.

[c]EDA: electrodermal activity.

[d]IBI: interbeat interval.

Slopes of the Rise to the Peak and Fall After the Peak in Blood Glucose Over Time After a Meal and the Results of the Regression Analysis of the Mean and SD of Each Physiological Index and Nutrient Value

To investigate the relationship between the slopes of the blood glucose rise and fall peaks and the mean values of physiological indices and nutritional assessment indices, as well as the relationship between the slope of the blood glucose rise and fall peaks and the mean values of physiological indices, a multiple regression analysis was conducted. A summary of the results is shown in Table 3.

Table 3. Summary of the relationship between the slopes of the blood glucose rise and fall peaks and the mean values of physiological and nutritional assessment indices as well as the relationship between the slope of the blood glucose rise and fall peaks and the mean values of physiological indices.

	Slope of peak blood glucose increase		Slope of blood peak glucose decrease	
	t value	*P* value	*t* value	*P* value
Results of multiple regression analysis between the slope of the glucose peak and the mean values of physiological indices and nutritional assessment indices				
Physiological indices				
Temperature	2.52	.01	—[a]	—
ACC[b]	—	—	2.67	.008
HR_af[c]	—	—	3.86	<.001
HR_90[d]	—	—	2.27	.02
Nutritional assessment indices				
Calorie	3.98	<.001	—	—
Carbon	6.53	<.001	—	—
Dietary fiber	2.51	.01	—	—
Protein	3.82	<.001	—	—
Sugar	—	—	–3.72	<.001
Results of multiple regression analysis between the slope of the glucose peak and the SD of physiological indices				
Physiological indices				
ACC	2.06	.04	—	—
HR_30[e]	2.12	.03	—	—
EDA_90[f]	1.97	.049	—	—

[a]Not available.

[b]ACC: triaxial accelerometer-derived acceleration.

[c]HR_af: heart rate_af.

[d]HR_90: heart rate_90.

[e]HR_30 heart rate_30.

[f]EDA_90: electrodermal activity_90.

The physiological and nutritional assessment indices associated with the slope of the peak blood glucose increase were TEMP, calories, carbon, dietary fiber, protein, ACC, HR_30, and EDA_90. For TEMP, a positive association was observed; however, this was presumably due to the reported association between increased glucose and TEMP [59]. For carbon, a positive association was found, which was thought to be because carbohydrates contribute to the increase in blood glucose, although they are not absorbed as rapidly as glucose [61].

Although the upward slope of blood glucose and the calorie mean were negatively associated, the 1-way ANOVA revealed a positive association, as did carbon. Therefore, this result may be due to the multicollinearity effect of simultaneously introducing carbon and calories (r=0.78; P<.001), which are strongly correlated as explanatory variables.

Dietary fiber intake lowers postprandial and average daily blood glucose levels [62]. Protein intake does not increase plasma glucose levels but rather decreases them; thus, protein intake with glucose suppresses the postprandial increase in glucose [63], contrasts with the expected result. This was inferred to be due to increased carbohydrate intake since total carbon and protein intake were positively correlated (r=0.49; P<.001). A negative association was found for ACC and HR, which was presumed to be physical activity-related increased HR, accompanied by decreased blood glucose levels [56]. A positive relationship was found for EDA_90. EDA increases during stress and is mediated by stress-induced activation of adrenergic hormones and cortisol, which increases gluconeogenesis [60].

The physiological and nutritional assessment indices associated with the slope of the descending glucose peak were ACC, sugar, HR_af, and HR_90; positive associations were found between the downward slope of blood glucose and ACC and HR mean values. The decrease in blood glucose is potentially due to an increase from mild to moderate physical activity (HR also increased with physical activity), resulting in a smaller upward slope of blood glucose and therefore creating a smaller downward slope [56]. Although a negative relationship was observed between the downward slope of blood glucose and sugar, similar to carbohydrates, sugar intake has been reported to increase blood glucose [64], The upward slope of blood glucose is greater when carbohydrate intake is higher, and therefore the downward slope is also greater.

A 1-Way ANOVA for Groups With Higher and Lower Than Median Blood Glucose Rise and Fall Slopes and Mean Values of Each Physiological Indicator and Dietary Nutrient Value

As a supplementary analysis to the multiple regression analysis, a 1-way ANOVA was performed to compare the relationship between the upward and downward slopes of blood glucose and the groups above and below the median for each indicator, using variables created by patterned group combinations by physiological indicator mean and dietary nutrient value. In addition, below-median groups were used as comparison controls. A summary of the results is presented in Table S33.

The results of the multiple regression analysis showed that the physiological indicators associated with the slope of rising and falling blood glucose were TEMP, ACC, HR, and EDA, whereas the nutritional indicators were carbon, protein, calories, sugar, and dietary fiber; therefore, these indicators were of interest.

The combination pattern of physiological indicators TEMP:ACC:HR:EDA, which included TEMP and EDA, showed that the upward and downward slopes of blood glucose were greater in the group above than in the group below the median. The effect on the upward slope of blood glucose was particularly large, similar to the results of multiple regression analysis. The combination pattern TEMP:ACC:HR:EDA=1011, which had a large upward slope of blood glucose, was due to stress, with high EDA and HR. The combination patterns TEMP:ACC:HR:EDA=1101 and 1111 also reported high glucose levels during and after moderate-intensity exercise [65] and high EDA due to exercise-induced sweating [66]. TEMP and EDA are strongly associated with autonomic nervous system function, which, in turn, is sensitive to glucose fluctuations, especially hyperglycemia. Therefore, we inferred that a high association exists between these indicators and the increase and fall in blood glucose slopes [31].

Conversely, for ACC and HR, the upward and downward slopes of blood glucose were slightly smaller in the group above than in the group below the median, accompanied by decreased blood glucose levels due to mild to moderate increases in physical activity [56] and physical activity-related increased HR similar to the results of the multiple regression analysis.

In the combination pattern of the nutrient indices carbon:protein:calories:sugar:fiber, the combination pattern including carbon, calories, and sugar showed a greater upward and downward slope of blood glucose in the group above than in the group below the median.

Dietary fiber reduces postprandial and mean daily blood glucose levels [62]; however, a group pattern of combinations with a greater rise and fall slope in blood glucose levels exists, with fiber above the median. The rise and fall slopes were smaller than those for groups of combinations below the median, similar to the results of the multiple regression analysis.

Previous Analyses

Two previous studies have used the wearable database in this study, BIG IDEAs Lab Blood Glycemic Variability and Wearable Device Data [30,31]. These studies were conducted to establish a prediction model for blood glucose-related indicators using machine learning and used a random forest regression model as the method of analysis. This analysis can be difficult to interpret in a specific clinical context.

In contrast, this study used simple analysis methods, such as correlation and multiple regression analyses, to explore the relationship between blood glucose and each physiological and nutritional index in a real-world setting. Despite the difference in analysis methods, the results for glucose and related indicators of our study were consistent with those of previous studies, reinforcing the results of this study. In addition, compared with the random forest model, these simpler analyses revealed more details of the relationship between blood glucose and each physiological and nutritional index.

Other publicly available open datasets on diabetes are shown in Table S1 in Multimedia Appendix 1. In total, 4 studies were conducted using PhysioNet's D1NAMO Multimodal Dataset for Noninvasive Type 1 Diabetes Management Studies (2018) dataset. This dataset was collected to contribute to the development of data-centric algorithms and diabetes monitoring techniques by providing an openly available multimodal dataset. It was obtained from real patients in a nonclinical setting, containing electrocardiogram signals, respiratory signals, accelerometer output, blood glucose level information, and annotated food photographs [67]. Studies conducted with this dataset include the following: a study that used machine learning to predict blood glucose in patients with type 1 diabetes [20]; 1 study aimed at improving the accuracy of CGM systems [21]; an insulin absorption simulation study [22]; and a study for predicting diabetes [24], which is useful in several approaches.

This study has some limitations. First, as we used publicly available data, other data, such as detailed patient background data (height and weight) collected during a clinical study but not made publicly available, were not included in the analysis. Second, Empatica, a wearable device, continuously collects a vast amount of data on physiological indicators, whereas the Dexcom G6, which measures glucose, collects data at 5-minute intervals. For the analysis of the physiological indicators, data were extracted according to the glucose measurement interval, and data that were not extracted could not be considered. Third, as the data were from 16 participants, which is a small sample size, the calculation of correlation coefficients and multiple regression analysis were conducted; however, only exploratory studies were possible. Fourth, while data at the beginning of the meal were available for all cases, data at the end of the meal were available only for some cases. Therefore, in analyzing the relationship between the upward and downward slopes of postprandial glucose to the peak and the nutritional index of the meal, the nutritional index immediately before the peak was added together. Therefore, the effect of mealtime length may not have been considered.

Conclusions

Existing data from clinical studies on wearable-type devices (Dexcom 6 CGM and Empatica) from PhysioNet, a public open dataset, were used secondarily to examine the association of blood glucose with physiological and nutritional indices in 16 patients with borderline diabetes. The results showed that

physiological indices associated with blood glucose were physical activity, HR, TEMP, and EDA, a stress indicator. In addition, physiological indices that were associated with the slope of the peak of the rise and fall of blood glucose were TEMP, physical activity, HR, and EDA. Nutritional measures associated with the slope of the peak rise and fall of blood glucose were carbohydrates, dietary fiber, and sugars. For the 3 analyses, the physiological measures associated with blood glucose were similar and consistent with previous reports.

The wearable-type device dataset allowed for the examination of the relationship of blood glucose with physiological and nutritional indicators. Research using existing data is expected to increase as open datasets of wearable device data become more readily accessible through data sharing and as it becomes possible to perform statistical analysis from various angles using such data.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary tables and figures.
[DOCX File , 1007 KB - diabetes_v9i1e62831_app1.docx]

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Abbreviations

ACC: triaxial accelerometer-derived acceleration
BVP: blood volume pulse
CGM: continuous glucose monitor
DASH: dietary approaches to stop hypertension
EDA: electrodermal activity
HbA_{1c}: glycated hemoglobin
HR: heart rate
IBI: interbeat interval
TEMP: skin temperature

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Health and eHealth Literacy of Patients With Diabetes in Low-Income Countries: Perspective From Guinea and Burkina Faso

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Abstract

Background: Diabetes is a significant health concern in sub-Saharan Africa, emphasizing the importance of assessing the health literacy and eHealth skills of hospitalized patients with diabetes. This study evaluated the health literacy and eHealth literacy of patients with diabetes at Donka Hospital in Guinea and Sanou Sourou Hospital in Burkina Faso, providing insights for targeted interventions and mobile health (mHealth) solutions to improve self-management and treatment outcomes.

Objective: The aim of this study is to evaluate the levels of health literacy and eHealth literacy among patients at Sanou Sourou Hospital in Burkina Faso and Donka Hospital in Guinea.

Methods: The study included 45 participants from Donka Hospital and 47 from Sanou Sourou Hospital. Data collection took place in May 2022, focusing on variables such as gender, age, education, income, and technology access. Health literacy and eHealth literacy were measured using the Brief Health Literacy Screen (BHLS) and the eHealth Literacy Scale (eHEALS), respectively. Statistical analysis was performed using SPSS 28.

Results: The results indicated that 64% (64/99) of participants at Donka Hospital and 57% (57/99) at Sanou Sourou Hospital were female. The majority of participants (48/98, 49% in both hospitals) fell within the age range of 25-50 years. High rates of illiteracy were observed (62/100, 62% in Donka Hospital and 59/100, 59% in Sanou Sourou Hospital). Smartphone ownership was prevalent (62/99, 62% at Donka Hospital and 64/100, 64% at Sanou Sourou Hospital). Participants reported occasional use of technology for basic purposes and frequent internet usage for accessing health information. However, a significant proportion of participants demonstrated low health literacy (73/99, 73% at Donka Hospital; 79/101, 78% at Sanou Sourou Hospital) and inadequate eHealth literacy (57/100, 57% at Donka Hospital; 62/100, 62% at Sanou Sourou Hospital). Education was observed to positively correlate with health literacy, while age displayed a moderate negative correlation. Weak correlations were observed between gender, income, and health literacy, but these were not statistically significant. No significant correlation was found between the scores of the BHLS and the eHEALS in either hospital.

Conclusions: This study highlights the importance of targeted educational interventions and mHealth solutions aimed at enhancing health and eHealth literacy among hospitalized patients with diabetes. Addressing both health literacy and eHealth literacy is paramount for improving diabetes management and treatment outcomes in Guinea and Burkina Faso. Targeted interventions and mHealth solutions have the potential to empower patients, enabling their active involvement in health care decisions and ultimately improving overall health outcomes.

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KEYWORDS

health literacy; eHealth literacy; diabetic patients; Guinea; Burkina Faso; patients with diabetes; diabetes

Introduction

Global and Regional Burden of Diabetes

Diabetes remains a significant global health challenge. In 2021, there were 24 million people in Africa living with diabetes, a number projected to rise to 55 million by 2045 [1]. In Guinea, the prevalence of diabetes in adults was 1.7%, corresponding to 103,700 cases, while in Burkina Faso, the number of adult diabetes cases was 164,400, reflecting a similar prevalence rate [1,2]. Inadequate treatment frequently precipitates complications, including end-stage renal disease and blindness stemming from inadequate control of intermediate risk factors such as blood pressure and cholesterol levels [3,4]. The criticality of health literacy, defined as an individual's capacity to obtain, comprehend, and utilize health-related information to make informed decisions about their health, is palpable within the realm of diabetes management [5]. It correlates with deficits in diabetes knowledge and self-care, imposing a burden on health care providers [6-8]. Diabetes-related health literacy encompasses patients' ability to understand and effectively apply medical information—a crucial aspect given the complexity of diabetes care [4,9,10].

Mobile technology is becoming increasingly important in supporting health care, especially in sub-Saharan Africa, where it is widespread. In 2022, there were 489 million mobile subscribers in sub-Saharan Africa, with smartphones accounting for 51% of total connections [11]. Forecasts predict that the number of connections in the region will almost double by 2030, with 4G usage expected to reach 49% of total connections [11]. This significant mobile connectivity is evident in countries such as Burkina Faso, with a mobile phone ownership rate of 52.4% in 2019 [12], and Guinea, where the ownership rate reached 76.8% in 2018 [13]. However, mobile internet usage remains low, with only 25% of the population having access due to barriers such as affordability, low digital skills, and inadequate infrastructure [11].

Telemedicine platforms, including the integration of mobile serious health games, are enhancing patient engagement and education [14]. These platforms, which once primarily targeted rural access to health care [15], are now broadening their scope postpandemic to provide more comprehensive health care services. This broadened scope encompasses the delivery of sophisticated interventions, such as prognostic assessment for COVID-19 treatment. In Kenya, for example, an asynchronous provider-to-provider telemedicine model facilitated the delivery of essential health services during the second year of the pandemic [16]. In addition, Vingroup's DrAid software quickly identified abnormalities in chest X-rays to aid in COVID-19 prognosis [17].

The concept of eHealth literacy has garnered traction, underscoring the significance of patients' capacity to seek, comprehend, and assess online health information [18,19]. However, ensuring accessibility and user-friendliness remains challenging, particularly for patients with varying communication skills and digital literacy, particularly in low-resource settings [20-23]. With the continuous digitalization of health care, there is a mounting demand for accessible and intuitive health apps, particularly in the aftermath of the COVID-19 pandemic [24].

Although previous studies have investigated health literacy in Guinea [25] and Burkina Faso [26], to our knowledge, this is the first study to examine both health literacy and digital health literacy among hospitalized patients with diabetes in both countries.

Background on Health and eHealth Literacy

The concept of health literacy refers to an individual's capacity to access, comprehend, and apply basic health information for active engagement in health-related decision-making processes. It encompasses a diverse array of skills, including general literacy, numeracy, critical thinking, and information retrieval, all of which are essential for active participation in health care. Studies have shown that deficiencies in health literacy can adversely impact health metrics and outcomes [27]. With the health care system progressively embracing technology, the requisite skills for health literacy have similarly evolved.

Digital health literacy, an essential component of general health literacy, involves assessing health information obtained from electronic sources and applying this knowledge to tackle health-related problems. Although digital health literacy shares fundamental aspects with health literacy, it also includes additional skills such as computer literacy, technology literacy, media literacy for navigating search engines, and information literacy for evaluating various sources. Significant differences in digital health literacy and eHealth are particularly evident among demographic groups facing disadvantages in cardiovascular care [28]. Older individuals and those with chronic conditions tend to exhibit lower eHealth literacy [29]. Similarly, individuals with limited education levels are less likely to engage in common eHealth activities, such as monitoring diet and physical activity or communicating with health care providers online [30]. Previous research has shown that racial minorities, such as Black and Latino people, as well as older adults, are significantly less likely to use patient portals, even after accounting for education level [31]. These same demographic cohorts also often encounter challenges with health literacy [27]. Despite the surge in digital interaction within health care, these disparities persist.

In addition, individuals affected by social determinants of health have difficulty accessing eHealth services due to insufficient resources. Although certain groups utilize the internet and smartphones, others, especially older adults and individuals with low incomes, are less likely to possess these technological tools. In addition, understanding digital health content often requires a high level of general education beyond the recommended reading level for medical educational material [32,33]. Complex medical terminology, specialized jargon, dense formatting, and technical language pose significant barriers for people with limited health literacy [34]. Presenting health information in a digital format introduces additional challenges, such as website complexity, navigational difficulties, and the effort required to access web-based health services or apps [32,35]. A survey revealed that nearly half of the people who discontinued mobile health (mHealth) apps cited the tedious data entry or confusion in app usage [20]. Access to

health-related internet information, particularly for smartphone users, is critical, especially for underserved communities.

General Overview of Measurement Tools

With the advent of eHealth technologies, including telemedicine, health apps, and wearable devices, the health care landscape has undergone a substantial transformation. Most notably, these advancements have improved the accessibility of health-related information and facilitated health-related decision-making processes. However, concomitant with these advantages, challenges such as accessibility issues and disparities in technological access have emerged. Subsequently, a plethora of instruments have been devised to assess both health literacy and eHealth literacy, which are pivotal in comprehending individuals' abilities to effectively navigate and use health information. The Health Literacy Questionnaire by Osborne et al [36] comprehensively evaluates various aspects of health literacy, including the comprehension of health information, navigation of health systems, and social support. The Communicative and Critical Health Literacy Scale [37], introduced in 2013, also contributes to this assessment, as does the Brief Health Literacy Screen (BHLS), a concise clinical instrument [38]. Despite these advancements, research-based health literacy assessment instruments such as the Test of Functional Health Literacy in Adults [39] and the Rapid Estimate of Adult Literacy in Medicine [39] have limitations primarily associated with administration time and protocols [40]. In contrast, instruments such as the BHLS and the Newest Vital Sign offer a quicker, more straightforward assessment of health literacy.

Concurrently, numerous eHealth literacy assessment tools have been developed that focus on individuals' proficiencies in utilizing digital technologies for health-related purposes. These tools include the eHealth Literacy Scale (eHEALS) [41], developed by Norman and Skinner in 2006, which evaluates an individual's capacity to access and comprehend health information online. Subsequent instruments, such as the eHealth Literacy Scale [42], have expanded the assessment dimensions to include functional, interactive, and critical eHealth literacy. Furthermore, investigations have explored the interplay among health literacy, numeracy, computer literacy, and internet utilization, using a distinct instrument for each [36-38]. Multidimensional tools such as the eHealth Literacy Questionnaire [43] and initiatives such as the Optimising Health Literacy and Access (Ophelia) process [44] have further contributed to understanding and tackling eHealth literacy challenges.

The extensive utilization of instruments such as eHEALS across diverse studies emphasizes their versatility and reliability in assessing eHealth literacy across diverse populations and languages [45]. These diverse methodologies have enriched our understanding of eHealth literacy and facilitated progress in digital health research and practice.

The Case of Underserved Communities

Underserved communities in sub-Saharan Africa are confronted with significant health inequalities, characterized by prevalent diseases, limited access to health care, and resource scarcity [46]. The level of health literacy within sub-Saharan Africa remains a critical concern, emphasizing the need for accessible and reliable health information that supports informed decision-making at both the individual and community level. The Agency for Healthcare Quality and Research has addressed this issue in a report on health literacy [47], highlighting the objective measurement of health literacy and its impact on health in many developing countries. A cross-national study on health literacy in sub-Saharan Africa, conducted between 2006 and 2015, covered 14 countries, including Cameroon, the Democratic Republic of Congo, Ethiopia, Ghana, Guinea, Côte d'Ivoire, Lesotho, Rwanda, Niger, Namibia, Sierra Leone, Swaziland, Togo, and Zambia [48]. This study involved 224,751 individuals aged 15-49 years. The prevalence of health literacy was 35.77%, with notable differences between genders and educational levels. Health literacy scores varied significantly, ranging from 8.51% in Niger to 63.89% in Namibia, indicating considerable differences across countries. In addition, Nacanabo et al [26] used the Health Literacy Questionnaire to assess health literacy and its impact on health-related quality of life among patients with type 2 diabetes, suggesting that addressing different health literacy needs could mitigate inequalities and improve the quality of life for individuals with type 2 diabetes. Building upon these antecedent studies, our study aimed to assess the level of health literacy and eHealth literacy among patients with diabetes in hospitals situated in Burkina Faso and Guinea.

Methods

Justification of Sample Size and Power Analysis

The sample size was determined using OpenEpi 15 (version 3.01) [49], with a significance level of 95% and a power of 80%. Based on previous research [48], where an expected value of 40% was anticipated for both health literacy and digital health literacy, a risk-prevalence difference of 30% was considered, resulting in a minimum sample size of 88 participants. However, to ensure a better representative sample, 92 participants were ultimately included.

Settings and Study Participants

Data collection was conducted in May 2022 at Donka Hospital in Guinea and Sanou Sourou Hospital in Burkina Faso. Participants were selected based on eligibility criteria, including a diagnosis of diabetes, age over 18 years (or under 18 years with parental/guardian consent), and proficiency in local languages such as Dioula, Fula, or French.

Translation of Scales

We used the eHEALS, a widely used questionnaire, to evaluate participants' digital health literacy [50]. As shown in Table 1, the eHEALS was specifically designed to assess participants' perceived competencies and confidence in using eHealth information and digital health resources. It serves as a criterion for the suitability of an eHealth-based approach [41] and evaluates skills and knowledge in using eHealth information through 8 items rated on a 5-point Likert scale. These items evaluate the ability to locate, assess, and utilize health-related information from electronic resources, with scores ranging from 8 to 40. Previous studies have distinguished between low

eHealth literacy (eHEALS <26) and high eHealth literacy (eHEALS >26) [51].

Table . eHealth Literacy Scale items and Brief Health Literacy Screen tools.

Items and tools	
eHealth Literacy Scale	
Question 1	I know which health resources are available on the internet.
Question 2	I know where to find helpful health resources on the internet.
Question 3	I know how to find helpful health resources on the internet.
Question 4	I know how to use the internet to answer my health questions.
Question 5	I know how to use health information; I can use the health information I find on the internet to help me.
Question 6	I am good at assessing the health insurance companies I find on the internet.
Question 7	I can tell high-quality health resources from low-quality health resources on the internet.
Question 8	I feel confident using information from the internet to form an opinion about my health.
Brief Health Literacy Screen	
Question 1	How confident are you in filling in forms yourself? (1=Not at all confident; 2=Somewhat confident; 3=Little confident; 4=Confident; 5=Very confident)
Question 2	How often do you get someone to help you read health information? (1=Not at all; 2=Sometimes; 3=Occasionally; 4=Often; 5=Always)
Question 3	How often do you have problems getting information about your illnesses because of the difficulties you have in reading the health information? (1=Not at all; 2=Sometimes; 3=Occasionally; 4=Frequently; 5=Always)

To assess health literacy, we used the BHLS, a tool renowned for its efficacy in clinical practice and its utility in screening the health literacy of patients with diabetes in resource-limited settings [52,53]. This instrument, which is routinely used in acute care settings, comprises 3 questions on a 5-point Likert scale, aimed at assessing patients' ability to understand their health status, complete medical forms, and understand hospital materials [54-56]. The BHLS total score ranges from 3-15, with respondents categorized as having low health literacy (total score 3 - 9) or adequate health literacy (total score 10 - 15) [10,57,58].

As these questionnaires were not validated in the local languages, Dioula and Fula, we started with the translation. Inspired by a previous study by Tenibiaje [59] on the health literacy of ethnic groups in Nigerian prisons, where translation into local languages facilitated participation, we carefully translated the eHEALS and BHLS. This process involved an initial translation followed by a back-translation, which was overseen by an expert committee to ensure accuracy and reliability [60]. Two competent translators in Dioula, employed by the Ministry of Education in Burkina Faso, undertook the translation into Dioula and Fula. Discrepancies between the translations were resolved in a coordination meeting to obtain a standardized version of the questionnaire. The agreement between the translations was evaluated using Cohen κ statistics, resulting in a percentage agreement of 69.23%, which suggests good agreement [61]. Subsequent to the translation process, Cronbach α was computed to evaluate the reliability of the translated questionnaires. This statistical analysis is important for verifying that the items within each questionnaire consistently measure the same underlying construct across different language versions.

Ethical Considerations

This study was conducted following the principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of Souro Sanou University Hospital, Burkina Faso (approved January 28, 2022; number 2022/E 112), and from the Ethics Committee of the National Directorate of Epidemiology and Disease Control, Guinea (approved March 30, 2022; number 246/DNGLEM/MS/2022). Before participating in the study, every participant provided verbal informed consent, demonstrating their voluntary agreement to be involved in the research. Participants were provided with the equivalent of US $1 to cover the cost of a meal. Throughout the research process, strict measures were implemented to ensure the privacy and confidentiality of participant data, safeguarding their rights and well-being.

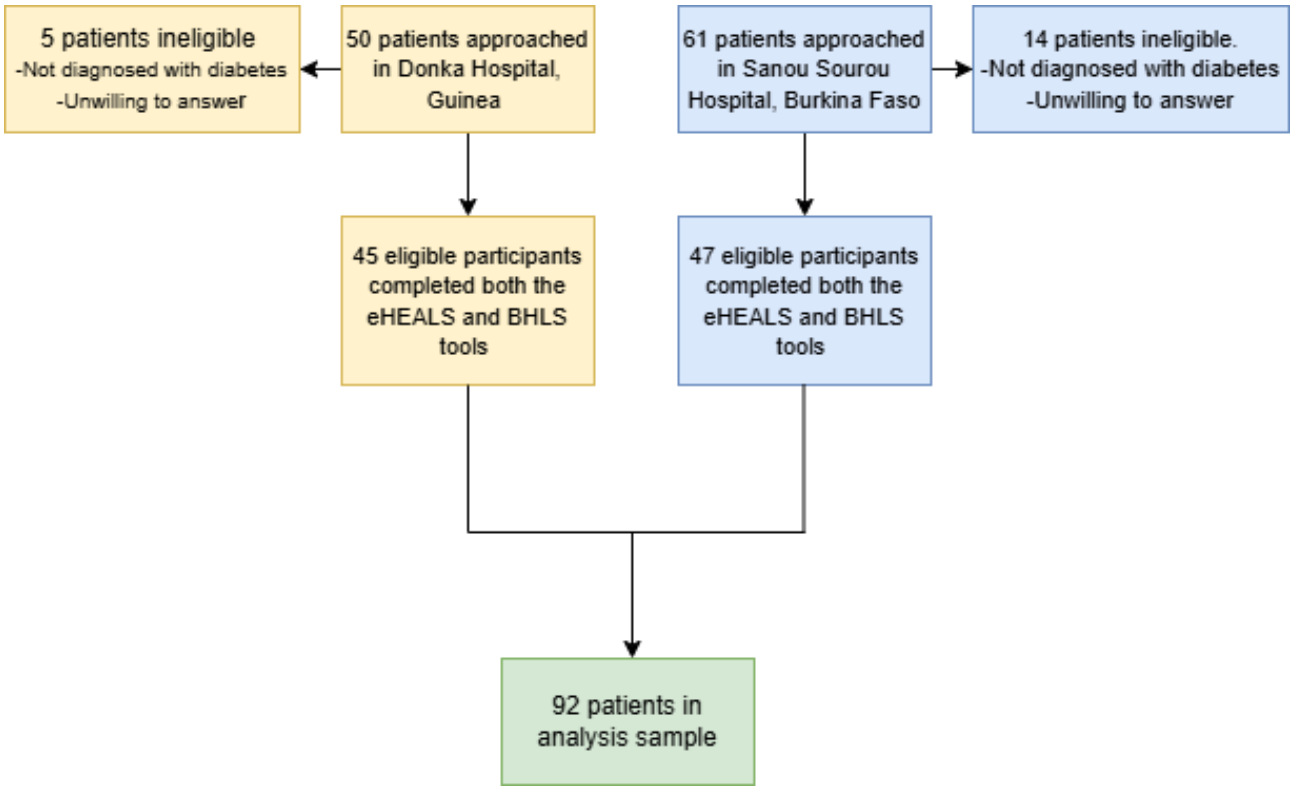
A verbal declaration of consent was obtained from all participants. For those under the age of 18 years, parental or guardian consent was also obtained, as required by ethical guidelines. Participants were assured of the confidentiality of their data, which was anonymized with unique identifiers to protect their privacy. To respect cultural norms and accommodate participants' limited literacy skills, verbal consent was preferred over written consent, consistent with the cultural preference for verbal agreements [62]. Throughout the study,

participants' identities were protected, and only identification numbers were used for data management.

Data Collection Procedure

As shown in Figure 1, data collection began with the identification of 92 potential participants at Donka Hospital in Guinea and Sanou Sourou Hospital in Burkina Faso in May 2022. After screening for eligibility based on age, confirmed diagnosis of diabetes, and language proficiency, verbal informed consent was obtained from each participant, emphasizing confidentiality and the right to withdraw. Trained research coordinators conducted structured face-to-face interviews in French. Four trilingual speakers, fluent in Dioula, Fula, and French, administered the translated questionnaires, including the eHEALS and the BHLS. Participants completed both scales during the interviews, guided by clear instructions to ensure the accuracy and honesty of their responses.

Figure 1. Flowchart of study. BHLS: Brief Health Literacy Screen; eHEALS: eHealth Literacy Scale.



Data Analysis

Data analyses were conducted using IBM SPSS Statistics (version 28; IBM Corp). Descriptive statistics were applied to demographic data, technology use variables, eHEALS scores, and BHLS scores. The internal consistency and reliability of the assessment tools were evaluated using Cronbach α. Multivariate analysis was utilized to explore potential associations between demographic characteristics, health literacy, and eHealth literacy, with statistical significance set at $P<.05$.

Results

Demographic Characteristics

Data analysis involved participants who consented to participate. Statistical analyses were conducted using SPSS 28. When comparing the 2 groups, Donka and Sanou Sourou, no statistically significant differences were observed (Table 2). Donka had a slightly higher proportion of women (64/99, 64%) compared to Sanou Sourou (57/99, 57%), although this disparity did not attain statistical significance ($P=.27$). Similarly, both groups demonstrated a comparable age distribution, predominantly falling between 25 and 50 years, with no discernible differences ($P=.67$). In terms of education level, both Donka (62/99, 62%) and Sanou Sourou (60/99, 60%) exhibited a similar proportion of individuals with no formal education or lacking primary school qualifications, with no significant difference observed between the groups ($P=.62$).There was no significant difference in income distribution (P=.71), with respondents earning less than 40,000 CFA francs (US $64), between 40,000–100,000 CFA francs (US $64–$160), or over 100,000 CFA francs (US $161) . Access to technology, as reflected by smartphone ownership, was comparable between Donka (62/99, 62%) and Sanou Sourou (64/99, 64%), with no statistically significant difference observed ($P=.72$). In addition, both groups reported similar patterns of technology use, with no significant difference in use observed ($P=.72$).

To summarize, the analysis shows that Donka and Sanou Sourou have comparable characteristics in terms of gender distribution, age distribution, education level, income distribution, access to technology, and technology use.

Table . Sample characteristics.

Characteristics and group		Donka Hospital Guinea (n=45), n (%)	Sanou Sourou Hospital Burkina Faso (n=47), n (%)	*t* test	*P* value
Gender				1.1116	.27
	Female	29 (64.4)	27 (57.4)		
	Male	16 (35.6)	20 (42.6)		
Age (years)				0.577	.67
	<18	2 (4.4)	1 (2.1)		
	18-24	3 (6.7)	2 (4.3)		
	25-49	22 (48.9)	23 (48.9)		
	≥50	18 (40)	21 (44.7)		
Education				–0.502	.62
	Uneducated	28 (62.2)	28 (59.6)		
	Primary school	17 (37.8)	19 (40.4)		
Income				0.374	.71
	<40,000 CFA (US $64)	23 (51.1)	27 (57.4)		
	Between 40,000 CFA and 100,000 CFA (US $64-$160)	11 (24.4)	13 (27.7)		
	>100,000 CFA (>US $161)	11 (24.4)	7 (14.9)		
Technology access				–0.372	.72
	Do not own a cellphone	7 (15.6)	6 (12.8)		
	Own cellphone	10 (22.2)	11 (23.4)		
	Own smartphone	28 (62.2)	30 (63.8)		
Technology use				0.368	.72
	Never internet use	16 (35.6)	19 (40.4)		
	Use sometimes for basic tasks (social media such as WhatsApp)	16 (35.6)	20 (42.6)		
	Internet use regularly for information (including health information)	13 (28.9)	8 (17)		

Internal Consistency and Reliability of Tools

Cronbach α was used to assess the internal consistency and reliability of the eHEALS and BHLS scales in both the Fula and Dioula populations. Normally, a Cronbach α value of .7 or higher is considered satisfactory, while a value exceeding .9 is considered excellent [63,64]. In this investigation, the Cronbach α values for both scales within both populations were determined as follows (Table 3). Specifically, the eHEALS had values of .98 each for both Fula and Dioula, while the BHLS had values of .919 for Fula and .977 for Dioula. These findings denote a notable level of internal consistency and reliability within the scales, indicating correlations between items within each scale and affirming their ability to measure the intended constructs in both populations.

Table . Cronbach α reliability.

Scales	Cronbach α values, Fula	Cronbach α values, Dioula
eHealth Literacy Scale	.982	.983
Brief Health Literacy Screen	.919	.977

Participants' Health Literacy and eHealth Literacy Assessment

At Donka, 73.3% (33/45) of respondents exhibited low health literacy, signifying a deficiency in comprehending and assimilating health information. Conversely, only 35.6% (16/45) demonstrated adequate health literacy, indicating that they are better able to understand and effectively apply health information. Similarly, at Sanou Sourou, 78.7% (37/47) of respondents showed low health literacy, while only 21.3% (10/47) showed adequate health literacy. These findings underscore substantial shortcomings in comprehending and assimilating health information across both hospitals, which emphasizes the necessity for targeted interventions and education. In addition, respondents in both hospitals showed low eHealth literacy, indicating limited mastery of the use of digital technologies for health-related purposes. At Donka, 57.8% (26/45) scored low in eHealth literacy, compared to 26.7% (12/45) who scored high. Similarly, at Sanou Sourou, 61.7% (29/47) had low eHealth literacy, compared to 42.6% (20/47) who had high eHealth literacy. These results emphasize the importance of improving digital health literacy alongside conventional health literacy to ensure the effective use of digital technologies for health purposes in both hospitals.

Correlations Between Health Literacy, eHealth Literacy, and Demographic Variables

The correlation coefficients presented in Table 4 illustrate the relationships between health literacy and various socioeconomic and demographic factors within the Sanou Sourou and Donka hospitals. In Sanou Sourou, the analysis showed a strong positive correlation between education and health literacy. This indicates that individuals with a higher level of education tend to exhibit higher health literacy scores. The correlation coefficient of 0.94 for education emphasizes the importance of this relationship, and the *P* value of <.001 confirms its validity. This result indicates that promoting education can positively influence health literacy. Of particular interest is the moderately negative correlation between age and health literacy in Sanou Sourou Hospital, with a correlation coefficient of −0.336, indicating that health literacy tends to decrease with age. The *P* value of .02 indicates statistical significance and emphasizes the importance of tailoring health communication strategies to the specific needs of older people.

Table . Correlation coefficients across health literacy and socioeconomic and demographic variables.

	Gender coefficient	*P* value	Age coefficient	*P* value	Income coefficient	*P* value	Education coefficient	*P* value
Brief Health Literacy Screen								
Health literacy mean score, Sanou Sourou Hospital (Burkina Faso)	0.094	.53	−0.336	.02	0.562	<.001	0.944	<.001
Health literacy mean score, Donka Hospital (Guinea)	0.067	.66	−0.286	.06	0.057	.005	0.924	<.001
eHealth Literacy Scale								
Health literacy mean score, Sanou Sourou Hospital (Burkina Faso)	−0.276	.06	−0.184	.22	0.407	.004	0.920	<.001
Health literacy mean score, Donka Hospital (Guinea)	−0.102	.50	−0.109	.48	0.417	.42	0.900	<.001

The correlations between gender, income, and health literacy in Sanou Sourou Hospital were weak and not statistically significant. The correlation coefficient for gender of 0.094 indicated a weak positive relationship, but the *P* value of .53 confirmed that this relationship was not statistically significant. Similar patterns were observed at Donka Hospital, where education emerged as the most influential factor positively associated with health literacy, with a correlation coefficient of 0.924 and a highly significant *P* value of <.001. Both hospitals also showed a moderately negative correlation between age and health literacy, although the *P* value for Donka was just above the significance threshold, indicating the need for further research to confirm this relationship.

As for gender and income, the correlations in Donka were weak and not statistically significant, with a coefficient of 0.067 and *P* value of .66. In summary, both Sanou Sourou and Donka

emphasized the crucial role of education in improving health literacy. A higher level of education had a strong correlation with better health literacy. Although age exhibited a negative correlation with health literacy, implying that younger people tend to possess higher health literacy, gender and income demonstrated no significant correlations with health literacy in either hospital.

Regarding the relationship between health literacy measured with the eHEALS and the demographic variables, the correlation coefficient between eHEALS and age in Sanou Sourou was −0.184, indicating a weak negative relationship. However, the *P* value of .22 indicates that age may not exert a significant influence on health literacy. In contrast, the correlation coefficient between eHEALS and income was 0.407, indicating a moderately positive relationship, with a significant *P* value of .004, meaning that higher income was associated with greater health literacy.

In Sanou Sourou, the correlation coefficient between eHEALS and education was 0.920, indicating a strong positive relationship, with a *P* value of <.001. The correlation coefficient between eHEALS and gender was −0.276, indicating a weak negative relationship, but the *P* value of .06 indicated that gender did not significantly influence health literacy.

Overall, in Sanou Sourou, education exhibited the strongest positive correlation with health literacy, followed by income, while age and gender exhibited no significant correlations. In Donka, none of the demographic variables analyzed demonstrate a significant correlation with health literacy as measured by the eHEALS, suggesting that age, income, education, and gender do not significantly influence the health literacy of the hospital's patients.

Relationship Between BHLS Scores and eHEALS Scores

The correlation between the results of BHLS and eHEALS was analyzed using the Pearson correlation. BHLS assesses traditional health literacy and focuses on understanding health conditions, filling out medical forms, and understanding hospital materials. The eHEALS, on the other hand, assesses skills in managing eHealth information and digital technologies. Participants completed both questionnaires and provided a score for each. It is possible for a participant to have low health literacy (as indicated by BHLS score) but high eHealth literacy (as indicated by eHEALS score). This discrepancy results from the different constructs each instrument measures. BHLS assesses traditional health literacy, while eHEALS assesses digital health literacy. Therefore, a participant may encounter difficulty with traditional health materials but demonstrate proficiency in utilizing digital health tools. This discrepancy emphasizes the necessity for a differentiated approach to literacy interventions in both traditional and digital health domains. The correlation analysis between the BHLS and eHEALS scores was conducted in the hospitals of Sanou Sourou and Donka. As shown in Figure 2, in Sanou Sourou, the correlation coefficient was −0.042, indicating a very weak negative relationship, with a nonsignificant *P* value of .78. In Donka Guinea, the correlation coefficient was −0.096, with a *P* value of .53, also without statistical significance (Figure 3).

These results indicate that there was no significant correlation between the BHLS and eHEALS scores at either site. This suggests that these measures of health literacy may capture different aspects and may not correlate consistently within these populations.

Figure 2. Scatter plot of correlation between eHEALS and BHLS scores at Sanou Sourou Hospital. BHLS: Brief Health Literacy Screen; eHEALS: eHealth Literacy Scale.

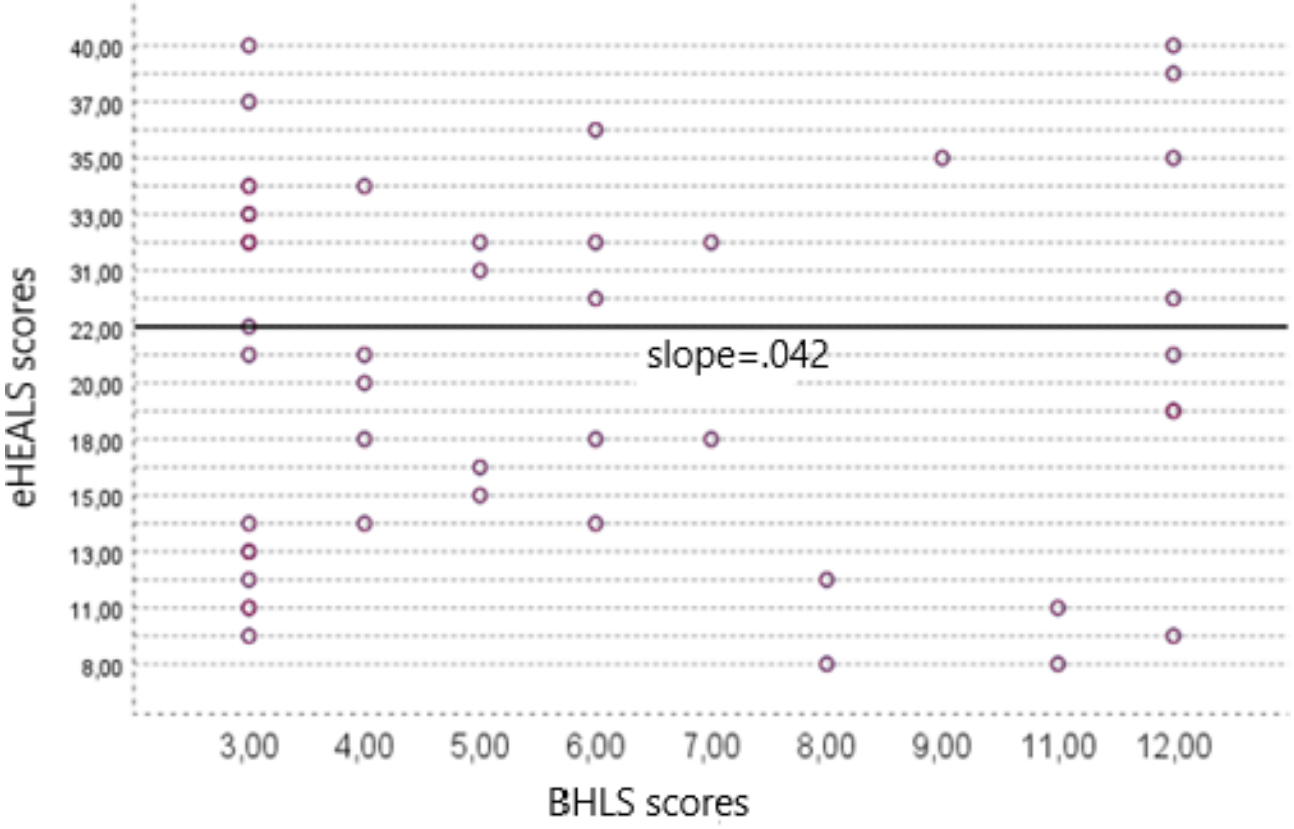
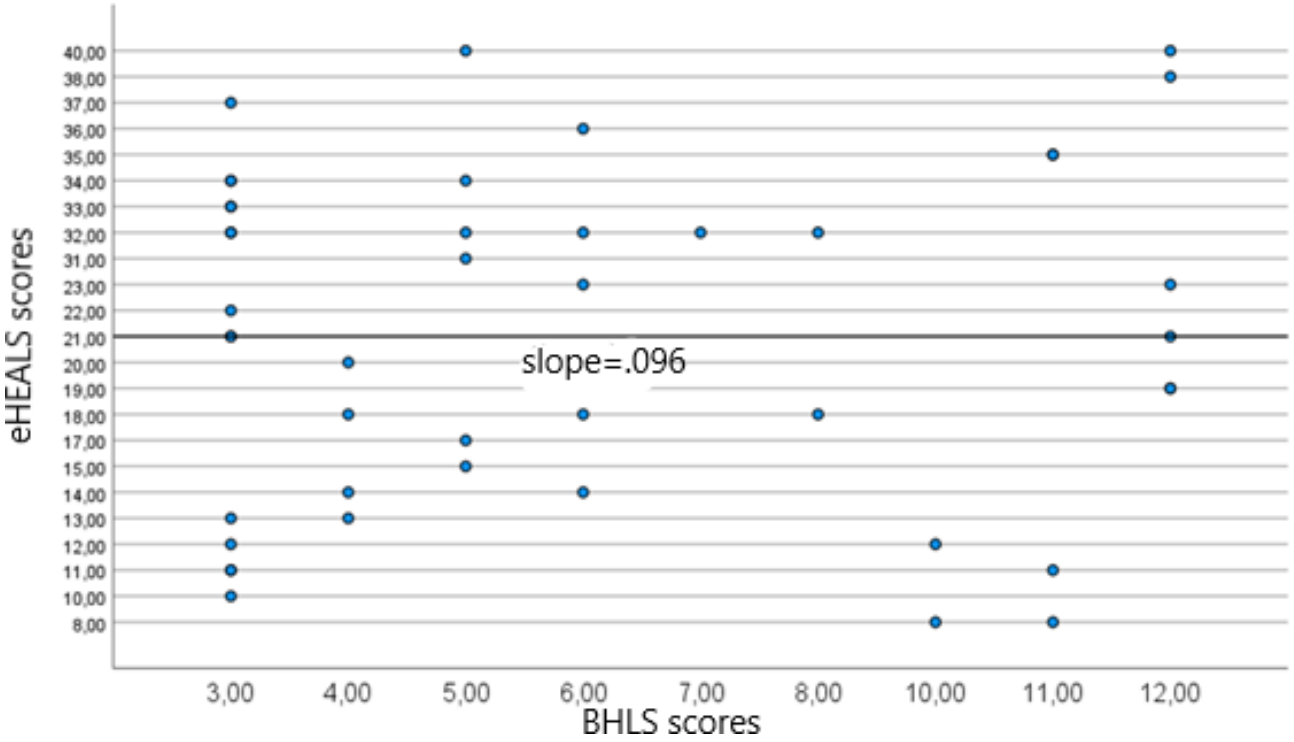


Figure 3. Scatter plot of correlation between eHEALS and BHLS scores at Donka Hospital. BHLS: Brief Health Literacy Screen; eHEALS: eHealth Literacy Scale.



Discussion

Principal Findings

This study analyses the health and eHealth literacy of patients with diabetes in Donka and Sanou Sourou hospitals. It highlights the critical issue of health literacy in underserved communities, specifically in Burkina Faso and Guinea [47]. The findings reveal significant deficits in patients' ability to comprehend and use health information, both in traditional and digital formats. Consistent with existing literature, lower educational attainment is associated with lower health literacy levels [65]. This study underscores the importance of educational interventions to enhance literacy in underserved populations. Age was also identified as a key factor, with younger individuals exhibiting higher health literacy [66]. This aligns with previous research showing an age-related decline in health literacy [67]. Tailoring health communication strategies to the needs of older adults can help mitigate this decline and promote better health outcomes.

In contrast to some previous findings [39,68], the study did not reveal significant correlations between gender, income, and health literacy levels. Although gender and income-related differences in health literacy are well-documented, the absence of significant correlations within this study population suggests the necessity for further investigation into the sociocultural factors that influence health literacy in these contexts. The low eHealth literacy observed among patients with diabetes in both hospitals emphasizes their limited competence in using digital technologies for health-related purposes [69]. This observation is consistent with previous research findings highlighting disparities in eHealth literacy, particularly among older people and those with lower levels of education [70]. Addressing these inequalities is crucial to ensuring equitable access to digital health resources and maximizing their benefits for health care delivery. The lack of a significant correlation between scores on the BHLS and eHEALS suggests that these measures may capture distinct facets of health literacy [71]. Although the BHLS focuses on traditional health literacy skills, such as understanding health information and completing medical forms, the eHEALS evaluates competencies in utilizing eHealth resources.

The discrepancy in the correlation between BHLS and eHEALS scores in Guinea and Burkina Faso may be attributed to health information–seeking behaviors influenced by cultural norms [72]. Although reliance on healers, elders, and oral communication for health advice is traditional in these regions [73], digital platforms play a more significant role elsewhere. Furthermore, with the advent of Web 2.0 technologies, renowned for interactivity and user-generated content, there is a revolution in global health information access. However, limited digital literacy and Web 2.0 access in countries such as Burkina Faso and Guinea may pose challenges to conventional health literacy assessments [74]. Therefore, incorporating Norman's perspective underscores the necessity to reassess eHealth literacy to accommodate these cultural nuances for effective interventions in diverse contexts [74].

Integrating both measures into the health literacy assessment can provide a more comprehensive understanding of individual skill levels and allow for customized interventions. This study underscores the importance of bridging health literacy and eHealth literacy gaps in underserved communities to improve health outcomes and promote equitable access to health resources [69]. Future research endeavors should examine the effectiveness of educational interventions and digital health literacy programs to improve educational attainment and empower patients to make informed decisions about their health.

Comparison With Prior Work

Compared to the studies conducted in Ethiopia (30.3%) [4] and Rwanda (14.3%) [75], more respondents at Donka Hospital had a high level of diabetes-related health literacy (35.6%). However, at Sanou Sourou Hospital in Burkina Faso, only 21.3% of the patients demonstrated adequate health literacy. Many participants obtained low health literacy scores, indicative of a deficiency in understanding and knowledge of health information. Health literacy scores exhibited an upward trend among individuals with higher levels of education. The correlation coefficient of 0.94 for education emphasizes the importance of this relationship, and the P value of <.001 supports its validity. Numerous studies have found significant correlations between health literacy and education; our results support this conclusion [76,77].

The positive correlation observed between education and health literacy suggests that endeavors aimed at enhancing education and literacy could have a significant impact on improving health literacy across both hospitals. Furthermore, the results from Sanou Sourou Hospital showed a moderately negative correlation between age and health literacy. The correlation coefficient of −0.336 indicates a propensity for health literacy to decrease with increasing age. This observation is consistent with the conclusions drawn in the study by Reisi et al [78], which reported a negative association between age and functional health literacy. The negative correlation between health literacy and age emphasizes the need for interventions tailored to the specific health literacy challenges of older populations.

Low levels of eHealth literacy were evident in both hospitals, indicating limited mastery of the use of digital technologies for health-related purposes. A study conducted by Shiferaw et al [79] in Ethiopia reported similarly low levels of internet use and eHealth literacy among patients with chronic illness in that setting. Consistent with findings regarding health literacy, education emerged as a significant predictor of eHealth literacy, with a higher level of education correlating with a higher level of eHealth literacy. This shows the importance of promoting digital health literacy through educational initiatives aimed at enhancing the utilization of digital technologies for health purposes. Notably, education exhibited the strongest positive correlation between health literacy and eHealth literacy in both hospitals. In Sanou Sourou Hospital, the correlation coefficient between eHEALS and education was 0.920, indicating a strong positive relationship between education and health literacy. This implies that individuals with higher levels of education exhibited correspondingly higher levels of health literacy. This result is

consistent with the findings of Shiferaw et al [79], who found a 3.48-fold higher likelihood of high eHealth literacy among patients with a diploma or higher education level compared to those with primary education or lower education level [79]. Such consistency underscores the significance of educational interventions targeted at enhancing the overall level of education.

Age correlated negatively with health literacy and only weakly with eHealth literacy, emphasizing the need for interventions tailored to older populations. Previous studies have likewise demonstrated a negative correlation between age and eHealth literacy [80,81]. Conversely, neither gender nor income correlated significantly with health literacy or eHealth literacy. In a study by Norman and Skinner [41], men displayed a higher baseline level of eHealth literacy. Studies conducted by Meppelink et al [82] and Neufingerl et al [83] revealed significant correlations between income, gender, and eHealth literacy. Nonetheless, in line with the findings of Xesfingi and Vozikis [84], this study did not uncover a strong correlation between gender and eHealth literacy.

The results of the correlation analysis between the BHLS and eHEALS scores in this study are consistent with those of Monkman et al [71], suggesting that these instruments may capture different aspects of health literacy and may not consistently correlate within these populations. Targeted interventions and educational programs are needed to improve health literacy and eHealth literacy in both hospitals. Education and literacy promotion initiatives can serve as pivotal avenues for bolstering health literacy. Individual interventions and educational programs need to be developed to address the specific health literacy challenges encountered by older populations. In addition, concerted efforts should be directed toward improving digital health literacy to facilitate the effective utilization of digital technologies for health-related purposes.

Implications for Practice and Research

This study emphasizes the urgent need to address the low level of health and eHealth literacy among the diabetic population in Burkina Faso and Guinea. Despite the widespread ownership of mobile phones, many people do not use internet services, which is a significant barrier to the effectiveness of eHealth solutions. To close this gap, it is essential to develop mHealth apps that also work offline and ensure access to health information regardless of the internet connection. In addition, the integration of voice interfaces into eHealth tools can improve usability for people with limited literacy skills, increasing participation and effectiveness. In addition to practical measures, policy measures to support the development and dissemination of these solutions are essential. Policymakers should allocate resources and create incentives to encourage the adoption of mHealth technologies tailored to the needs of underserved populations. In addition, partnerships between technology providers, health care organizations, and government agencies can facilitate the development and implementation of user-friendly eHealth solutions. By prioritizing eHealth literacy initiatives and integrating training into health care programs, stakeholders can empower people to use digital health resources effectively. Overall, these concerted efforts are critical to closing the health literacy gap and ensuring equitable access to digital health resources for all people, especially those in underserved communities.

Limitations

The study was constrained by several limitations. First, the small sample size, limited to 2 hospitals in Guinea and Burkina Faso, restricts the generalizability of findings to other regions in sub-Saharan Africa. Additionally, relying on self-reported health literacy and eHealth literacy introduces potential biases, with participants possibly overestimating their skills. The cross-sectional design offers only a snapshot of health literacy levels at a single point, lacking information on changes over time. Moreover, the study solely used the eHEALS and BHLS scales, potentially missing nuances in health literacy and eHealth literacy complexity.

Despite these constraints, the study offers valuable insights. It underscores the need for future research with larger sample sizes, broader geographic representation, comprehensive assessment tools, longitudinal designs, and attention to language barriers.

Conclusion

In analyzing data from Donka and Sanou Sourou hospitals, significant disparities in health and eHealth literacy were uncovered, underscoring the urgent need for targeted interventions. Education emerged as a key determinant of literacy levels, highlighting the importance of educational initiatives. Tailored interventions for older adult populations are imperative, given the negative correlation between age and health literacy. Although gender and income showed no significant correlation with literacy, the multifaceted nature of health literacy warrants comprehensive interventions. Prioritizing educational programs and digital literacy initiatives can empower individuals and foster better health outcomes in Burkina Faso and Guinea.

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Data Availability

The data and materials used in this study are available upon request. Researchers interested in accessing the data and materials can contact the corresponding author for further information and to discuss availability.

Authors' Contributions

IO and GD conceived the study. GD, BMJS, and RB validated the methodological approach and the research equations. All the authors analyzed the results. IO wrote the first draft of the manuscript. GD improved the manuscript in English. All authors participated in the final review, correction, and approval of the manuscript for submission.

Conflicts of Interest

None declared.

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Abbreviations

BHLS: Brief Health Literacy Screen
eHEALS: eHealth Literacy Scale
mHealth: mobile health
Ophelia: Optimising Health Literacy and Access

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Remote Foot Temperature Monitoring Among Veterans: Large Observational Study of Noncompliance and Its Correlates

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Abstract

Background: In-home remote foot temperature monitoring (RTM) holds promise as a method to reduce foot ulceration in high-risk patients with diabetes. Few studies have evaluated adherence to this method or evaluated the factors associated with noncompliance.

Objective: The aims of this study were to estimate noncompliance in patients who were enrolled in RTM nationwide across Department of Veterans Affairs (VA) and to evaluate characteristics associated with noncompliance.

Methods: We conducted an observational study including 1137 patients in the VA who were enrolled in RTM between January 2019 and June 2021, with follow-up through October 2021. Patient information was obtained from the VA's electronic health record and RTM use was obtained from the company. Noncompliance was defined as using the mat <2 days per week for ≥4 of the 12 months of follow-up. Using a multivariable model, we calculated odds ratios (ORs) and 95% CIs for associations between various factors and noncompliance and compared using Akaike information criterion statistics, a measure of model fit.

Results: The sample was predominantly male (n=1125, 98.94%) ; 21.1% (n=230) were Black and 75.7% (n=825) were White. Overall, 37.6% (428/1137) of patients were classified as noncompliant. In the multivariable model, an intermediate area deprivation index was statistically significantly and inversely associated with noncompliance (area deprivation index 50 - 74 vs 1 - 24; OR 0.56, 95% CI 0.35-0.89); factors significantly and positively associated with noncompliance included recent history of osteomyelitis (OR 1.44, 95% CI 1.06-1.97), Gagne comorbidity index score ≥4 (vs ≤0; OR 1.81, 95% CI 1.15-2.83), telehealth encounters (28+ vs <6; OR 1.70, 95% CI 1.02-2.84), hemoglobin A_{1c}≥10 (vs <5.7; OR 2.67, 95% CI 1.27-5.58), and current smoking (OR 2.06, 95% CI 1.32-3.20). Based on Akaike information criterion differences, the strongest factors associated with noncompliance were behavioral factors (poor glucose control [as measured by hemoglobin A_{1c}] and smoking), and to a lesser extent, factors such as a recent history of osteomyelitis and an elevated Gagne comorbidity index, indicating a high comorbidity burden.

Conclusions: To reduce the risk of ulcer recurrence and amputation, proactively providing additional support for self-monitoring to patients with characteristics identified in this study (poor glucose control, current smoking, high comorbidity burden) may be helpful. Furthermore, research is needed to better understand barriers to use, and whether the addition of design features, reminders, or incentives may reduce noncompliance and the risk of foot ulcers.

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KEYWORDS

diabetes; self-monitoring; ulceration; compliance; foot temperature monitoring; SmartMat; adherence; remote; monitoring; non-compliance; foot; ulcer; diabetic; veteran; observational; health record; EHR; noncompliance; electronic health record

Introduction

Diabetic foot ulcers are common, debilitating, and costly diabetes complications. Over 10 percent of US adults [1] and nearly a quarter of veterans enrolled in Veterans Health Administration (VHA) have diabetes [2]. In patients with diabetes, lifetime risk of ulceration is estimated to be 14% [3]. Ulcerations negatively impact mobility, mental health, and quality of life, and have high recurrence rates. Nearly two-thirds of patients have a recurrence within 5 years of ulcer healing [4]. Loss of pain sensitivity, foot deformity, and peripheral artery disease place individuals at high initial and subsequent risk of ulceration; these conditions do not resolve after healing.

Five systematic reviews and meta-analyses [5-9] have been conducted that each included the same 4 or 5 [10-14] randomized controlled trials of foot temperature monitoring. While there were slightly different analytic approaches in each meta-analysis, all estimated a substantially lower risk of ulceration in the groups assigned to monitor plantar foot temperatures compared to the usual care groups (meta-analysis odds ratios [ORs] or relative risks ranged from 0.37 [7] to 0.53 [8]). Based on this research, several clinical organizations have endorsed foot temperature monitoring [15-17], but it is rarely practiced because measuring temperatures on multiple parts of feet daily and then calculating differences between the feet is time consuming and burdensome. New technologies, including temperature sensing mats, have eliminated much of the burden, and made foot temperature monitoring easier [18,19].

In 2019, the VHA, the largest integrated health care system in the United States, began national implementation of remote foot temperature monitoring (RTM) using SmartMats. The VHA Innovation Ecosystem launched the Initiative to End Diabetic Limb Loss [20] in partnership with the VHA Podiatry Service, Office of Health Equity and Office of Connected Care to design new care models that incorporated emerging technologies such as the SmartMat in early detection of diabetic foot ulcers.

We are aware of a single study that published data on compliance with use of the SmartMat [21]. This study included 132 people with diabetes and a prior diabetic foot ulcer who were recruited from 7 outpatient sites in the United States. During 34 weeks of follow-up, patients used the device 5.0 days per week on average (SD not reported) and 86% of patients used the SmartMat ≥3 times per week [21]. Data on characteristics associated with use were not reported.

Understanding compliance outside of a study is valuable to assess the real-world potential for effectiveness. Additionally, identifying which patients might be less likely to comply with RTM recommendations could be helpful to identify barriers and determine which patients might benefit from additional support to improve compliance. Thus, the aims of this study were to estimate noncompliance in patients who were enrolled in RTM nationwide across VHA between 2019 and 2021 and to evaluate characteristics associated with noncompliance.

Methods

Study Data

Demographic, geographic, medical, and use data came from the corporate data warehouse (CDW). Race and ethnicity are determined based on self report. During this study's period, when a patient was enrolled in RTM, their Department of Veterans Affairs (VA) provider placed an order for the device through the Prosthetics Department. As the company making the devices only had 1 product, we were able to determine enrollment in RTM based on the Data Universal Numbering System number (DUN & Bradstreet). The company provided information on the average number of times per week that patients used the mat each calendar month from January 2019 until October 2021.

Study Population

We included individuals who were enrolled in RTM in VA between January 2019 and June 2021 (as identified in the CDW) and for whom we were also able to obtain SmartMat use data. Of those enrolled in January 2019 or later (n=1675), we were able to link 1641 individuals to other data in the CDW. We excluded 504 people with less than 12 months of follow-up, leaving 1137. Due to how the variables were constructed, individuals for whom we could not determine a home facility (n=123) were included in most analyses, but were missing for area deprivation index (ADI), VA district or region, and facility complexity.

RTM in VA

The device under investigation is a daily-use telemedicine foot temperature monitoring SmartMat made by Podimetrics. Patients with a high risk of ulceration (mainly due to a history of foot ulceration; lower limb, foot, or toe amputation; or Charcot foot) are eligible for RTM (Kyle Nordrum, DPT, personal communication). The device is ready to use without any configuration or set-up. A temperature scan takes 20 seconds, and the temperature data are transmitted to the cloud using an embedded cellular component. All scans are timestamped, allowing for objective measures of use. The software detects "hot spots," defined as asymmetries of ≥2.2˚C between the same region on the left and right foot or different regions on the same foot. Temperature asymmetries that persist for at least 2 days are predictive of ulceration [21]. When hot spots are detected, either clinical support staff from the company or the VA provider follows-up with the patient to evaluate risk factors and make recommendations about actions to take. Patients are also called if they fail to use the mat for several days in a row to assess reasons for nonuse and encourage re-engagement.

Definition of Noncompliance

While daily use is recommended, using the device at least 2 times per week is thought to be sufficient for the detection of hot spots (Jon Bloom, MD, personal communication). As we had a relatively long follow-up (12 mo), we defined noncompliance as using the mat less than 2 times per week for at least a quarter of the months under observation. Specifically, patients were considered noncompliant if they used the mat less than 2 days per week for 4 or more months out of 12.

Compliance Correlates or Predictors

We evaluated demographic, geographic, clinical, and facility factors, as well as health care use as potential correlates of nonadherence. Details about the data sources, definitions, and categories are included in Table 1.

Table . Data definitions, categories, and sources.

Domain, variable	Categories	Data sources, timing, and other details
Demographics		
Sex	Male or female	CDW[a]; assumed to be sex assigned at birth
Race	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White, or more than 1 race	CDW, based on self report
Hispanic or Latinx ethnicity	Yes or no	CDW, based on self report
Geographic access		CDW; drive distance and drive time used the most recent data (FY14-FY19[b])
Drive time to primary care	<30 minutes or ≥30 minutes	Estimated drive time between the coordinates of the primary care facility nearest to the veteran's home and the veteran's home address.
Drive time to specialty care	<60 minutes or ≥60 minutes	Estimated drive time (network distance) between the coordinates of the specialty care facility nearest to the veteran's home and the veteran's home address.
Rurality	Urban, rural, or highly rural	Determined using RUCA[c] codes, which are based on zip code approximations. RUCA codes of 10=highly rural; RUCA codes of 1 or 1.1=urban. All other codes were considered rural [22].
VA[d] districts	Continental, Midwest, North Atlantic, Pacific, and Southeast	
Area level factors		
Area Deprivation Index (ADI)	Quartiles—lower ADI[e] indicates *less* deprivation	The ADI is a measure of socioeconomic resources and well-being that includes factors for income, education, employment, and housing quality. The ADI has been adapted and validated to the Census Block Group [23] and allows for rankings of neighborhoods by socioeconomic disadvantage at the national level.
Clinical characteristics		CDW; ascertained in the 2 years prior to baseline
Other conditions: Chronic kidney disease or end stage renal disease, diabetes, and depression	Yes or no	At least 2 diagnosis codes or 1 procedure code.
Gagne comorbidity index	<0, 1 - 2, 3 - 4, >4	Measure of comorbidity burden. Higher scores indicate more comorbidities [24].
Body mass index	<18.5, 18.5 - 24.9, 25 - 29.9, 30 - 39.9, ≥40 kg/m^2	Weight and height measured closest to and prior to first scan.
Facility characteristics		CDW
Facility complexity	1a (most complex), 1b, 1c, 2, 3 (low complexity)	Determined based on a model that considers clinical programs and patient risk levels, as well as research and teaching. The model is reviewed and updated with current data every 3 years.
Use		CDW; ascertained in the 2 years prior to baseline
Inpatient stays	0, 1+	
Telehealth encounters	Quartiles	Determined by stop codes, and includes visits that were designated as telephone, video, "tele," or virtual

[a]CDW: corporate data warehouse.

[b]FY: fiscal year.

[c]RUCA: Rural Urban Commuting Area.

[d]VA: Department of Veterans Affairs.

[e]ADI: area deprivation index.

Statistical Analyses

We calculated the percentage of patients who were noncompliant, with 95% CIs. To evaluate associations between characteristics and noncompliance, we estimated OR and corresponding 95% CIs using a logistic regression model that included all covariates. The Akaike information criterion (AIC) was used to assess contributions of each covariate and groups of covariates to model fit along with a likelihood ratio test for a model that excluded the covariate or group of covariates [25]. AIC helps to quantify how well a model fits the data it was generated from relative to other models fit on the same data. AIC penalizes models that use more parameters to reduce the potential for overfitting. Lower AIC scores are considered evidence of better model fit.

Missing data were recovered using multiple imputation by chained equations using all covariates and the outcome and results displayed are from pooling the 20 imputed datasets [26-28]. Generalized variance inflation factors [29] for each of the covariates were calculated to assess correlation between covariates, and the impact it may have had on regression results. A variance inflation factor of 4 or more was used as evidence of substantial collinearity [30]; there was no evidence of substantial collinearity.

We conducted several sensitivity analyses. First, because there is no empirical basis for our definition of noncompliance [31], and some prior studies have used a higher cutoff, we conducted analyses using different cut points of minimum days per week on average (2 and 3) and months in the past 12 (11, 9, and 6) for defining noncompliance. Second, we graphically explored the association between hospitalization and separately, amputation, on SmartMat use by examining use in the 6 months prior to, and the 6 months after a hospitalization or amputation (separately). In these analyses, we categorized days per week into 4 categories: no use, <2 days per week, 2 to <5 days per week, and 5 - 7 days per week. We also graphed use over time in those with a hospitalization or amputation (separately) relative to those who had neither a hospitalization nor an amputation.

Ethical Considerations

This program evaluation qualified as a nonresearch quality improvement activity conducted under the authority of VHA operations. It complies with the VHA definition of “non-research operations activities” outlined in section 5a of the 2019 *VHA Program Guide 1200.21: VHA Operations Activities That May Constitute Research*, meeting both specified conditions: (1) the evaluation was designed and implemented for internal VHA purposes and (2) not designed to produce information to expand the knowledge base of a scientific discipline.

Results

The sample was predominantly male (n=1125, 98.94%); 21.1% (n=230) were Black and 75.7% (n=825) were White (Tables 2 and 3). Just over half (n=595, 53.8%) of the patients were married. Nearly half (n=525, 46.2%) of the patients were aged between 70 and 79 years and 96.9% (n=1102) had diabetes. In the 2 years prior to baseline, 82.0% (n=932) had a diabetic foot ulcer, 40.4% (n=459) had osteomyelitis, 41.6% (n=473) had chronic kidney disease or end stage renal disease, 30.7% (n=349) had depression, and 53.3% (n=606) were hospitalized. Over a third (n=409, 36.0%) had a Gagne comorbidity of 4 or greater and 59.8% (n=660) had a BMI>30 kg/m^2. About two-thirds of patients had poorly controlled diabetes based on a hemoglobin A_{1c} greater than or equal to 7.0, including 7% (n=80) with a hemoglobin A_{1c} greater than or equal to 10. Further, 31.2% (n=181) of patients were current smokers, though smoking status was missing for nearly half of the participants. Lastly, 74.9% (n=851) of the patients lived in urban areas and less than 20% (n=143, 12.6%) lived more than 30 minutes’ drive time from primary care or 60 minutes’ drive time from specialty care (n=182, 16%). Most of the patients came from the Midwest (n=361, 35.6%) or the Pacific region (n=335, 33.0%), while less than 5% (n=48) of the patients were from the Southeast. Multimedia Appendix 1 compares those included in analyses to those who were excluded because of insufficient follow-up. Briefly, the individuals with insufficient follow-up who were excluded from analyses had fewer ulcer risk factors, were predominantly from the Continental region, and were more likely to live in rural areas where they had longer drive times to primary and specialty care.

Table . Demographic, socioeconomic, and health characteristics of patients enrolled in remote foot temperature monitoring in the Department of Veterans Affairs between January 2019 and June 2021 (N=1137).[a,b,c,d]

Characteristic			Patients, n (%)
Demographic or socioeconomic			
	Sex		
		Female	12 (1)
		Male	1125 (98.9)
	Race		
		American Indian or Alaska Native	11 (1)
		Asian	1 (<1)
		Black	230 (21.1)
		More than one race	10 (1)
		Native Hawaiian or Other Pacific Islander	13 (1)
		White	825 (75.7)
	Ethnicity		
		Hispanic or Latino	77 (7)
		Not Hispanic or Latino	1038 (93.1)
	Marital status		
		Married	595 (53.8)
		Separated or divorced	317 (27.9)
		Single	136 (12.3)
		Widowed	58 (5)
	Area deprivation index (national rank)[e]		
		1 - 24	232 (22.9)
		25 - 49	281 (27.7)
		50 - 74	256 (25.2)
		75+	245 (24.2)
		Unknown	123 (10.8)
Health or comorbidities			
	Age (years)		
		<50	17 (2)
		50 - 59	123 (10.8)
		60 - 69	353 (31.0)
		70 - 79	525 (46.2)
		80+	119 (10.5)
	Diabetes		
		No	35 (3)
		Yes	1102 (96.9)
	Nonhealing ulcer		
		No	205 (18.0)
		Yes	932 (82.0)
	Osteomyelitis		
		No	678 (59.6)

Characteristic		Patients, n (%)
	Yes	459 (40.4)
Chronic kidney disease or end stage kidney disease		
	No	664 (58.4)
	Yes	473 (41.6)
Lower extremity amputation		
	Neither	664 (58.4)
	Partial foot	213 (18.7)
	Major lower limb	260 (22.9)
Gagne comorbidity index		
	≤0	319 (28.1)
	1 - 2	219 (19.3)
	3 - 4	190 (16.7)
	>4	409 (36.0)
Depression		
	No	788 (69.3)
	Yes	349 (30.7)
Body mass index (kg/m ^{2})		
	<18.5	2 (<1)
	18.5 - 24.9	136 (12.3)
	25 - 29.9	305 (27.7)
	30 - 39.9	547 (49.6)
	40+	113 (10.2)
Inpatient visits		
	0	531 (46.7)
	1+	606 (53.3)
Telehealth encounters		
	<6	141 (12.4)
	6 - 12	234 (20.6)
	13 - 27	361 (31.8)
	28+	401 (35.3)

[a]Noncompliance defined as mat use of <2 times per week for 4 or more of the 12 months of follow-up.

[b]Categories may not sum up to column total because of missing values.

[c]Percent calculated among those with nonmissing values.

[d]Unknown category presented if >5% of total sample.

[e]Lower area deprivation index indicates less deprivation.

Table . Behavioral, access to care, and practice patterns characteristics of patients enrolled in remote foot temperature monitoring in the Department of Veterans Affairs between January 2019 and June 2021 (N=1137).[a,b,c,d]

Characteristic			Patients, n (%)
Behavioral			
	Hemoglobin A $_{1c}$		
		<5.7	72 (6)
		5.7 - 6.9	298 (26.7)
		7 - 7.9	318 (28.4)
		8 - 9.9	315 (28.2)
		10+	80 (7)
		No diabetes	25 (2)
	Smoking status		
		Current smoker	181 (31.2)
		Former smoker	204 (35.1)
		Never smoker	196 (33.7)
		Unknown	556 (48.9)
	Substance use disorder		
		No	905 (79.6)
		Yes	232 (20.4)
Access to care			
	Rurality		
		Rural or highly rural	286 (25.2)
		Urban	851 (74.8)
	Drive time (primary care)		
		<30 min	991 (87.4)
		30+ min	143 (12.6)
	Drive time (specialty care)		
		<60 min	952 (84.0)
		60+ min	182 (16.0)
Practice patterns			
	Department of Veterans Affairs district or region		
		Continental	131 (12.9)
		Midwest	361 (35.6)
		North Atlantic	139 (13.7)
		Pacific	335 (33.0)
		Southeast	48 (5)
		Unknown	123 (10.8)
	Facility complexity		
		1a—high complexity	433 (42.7)
		1b—high complexity	315 (31.1)
		1c—high complexity	135 (13.3)
		2—medium complexity	71 (7)
		3—low complexity	60 (6)
		Unknown	123 (10.8)

[a]Noncompliance defined as mat use of <2 times per week for 4 or more of the 12 months of follow-up.

[b]Categories may not sum up to column total because of missing values.

[c]Percent calculated among those with nonmissing values.

[d]Unknown category presented if >5% of total sample.

Overall, 37.6% (428/1137) of patients were classified as noncompliant (Tables 4-6 and Figure 1). Mat use declined over time; by month 12, over 30% of patients never used the mat in the prior month. In descriptive analyses, the factors associated with higher noncompliance (5 percentage points or more above the mean) included race other than Black or White (43% noncompliance), Hispanic or Latino ethnicity (48%), widowed (47%), ADI <24 (47%), age <60 (47% for those aged <50 years and 44% for those aged 50 - 59 years), osteomyelitis (45%), major lower limb amputation (44%), Gagne comorbidity index >4 (48%), depression (44%), BMI <25 kg/m^2 (49%), inpatient visit in the 2 years before baseline (43%), more than 28 telehealth encounters (43%), hemoglobin A_{1c} ≥10 (60%), current smoking (54%), substance use disorder (53%), living in the Pacific region (44%), and receiving care at a high-complexity facility (44%). The factors associated with *lower* noncompliance (5 percentage points or more below the mean) included being a female (33% noncompliance) and living in an area with an ADI between 50 and 74 (31%); *not* having a recent history of ulceration (32%), osteomyelitis (33%), or hospitalization (31%); and having a lower comorbidity index score (≤0: 29% noncompliance; 1 - 2: 30% noncompliance); BMI ≥30 kg/m^2 (30 - 39.9 kg/m^2: 33% noncompliance; ≥40 kg/m^2: 30% noncompliance) fewer than 12 telehealth encounters (<6: 28% noncompliance, 6 - 12: 31% noncompliance); and hemoglobin A_{1c} between 7 and 7.9 (32% noncompliance). Lastly, noncompliance was lower among those from the Midwest (32%) and at low-complexity facilities (22%). In the multivariable model, compared to an ADI <25, intermediate ADI was inversely associated with noncompliance (ADI 50 - 74: OR 0.56, 95% CI 0.35-0.89); associations for the other categories were not statistically significantly different from the lowest ADI category. Recent history of osteomyelitis (OR 1.44, 95% CI 1.06 - 1.97), Gagne comorbidity index score ≥4 (vs ≤0: OR 1.81, 95% CI 1.15-2.83), telehealth encounters (13 - 27 vs <6: OR 1.65, 95% CI 1.01-2.70; 28+ vs <6: OR 1.70, 95% CI 1.02-2.84), hemoglobin A_{1c} ≥10 (vs <5.7: OR 2.67, 95% CI 1.27-5.58), and current smoking (vs never smoking: OR 2.06, 95% CI 1.32-3.20) were statistically significantly and positively associated with noncompliance. Using AIC to help inform the contribution of different variables to model fit, behavioral factors (hemoglobin A_{1c} and smoking), and to a lesser extent, health conditions or comorbidities (eg, osteomyelitis and Gagne comorbidity index) most contributed to model fit (Table 7). The results were not meaningfully different in the sensitivity analyses that used different cut points for minimum number of days per week and months in the past 12 to define noncompliance (data not presented).

Table . Estimated associations[a] of demographic or socioeconomic characteristics with remote foot temperature monitoring noncompliance[b] within conceptual groups using multiply imputed data (N=1137).

Demographic or socioeconomic characteristics		Noncompliant (%)	95% CI	Adjusted odds ratio	95% CI
Sex					
	Female	33	14 - 61	0.69	0.18 - 2.65
	Male	38	35 - 41	1.00	Reference
Race					
	Black	42	36 - 49	1.34	0.92 - 1.95
	Race other than Black or white	43	28 - 59	1.23	0.57 - 2.65
	White	36	33 - 39	1.00	Reference
Ethnicity					
	Hispanic or Latino	48	37 - 59	1.46	0.86 - 2.47
	Not Hispanic or Latino	37	34 - 40	1.00	Reference
Marital status					
	Married	35	32 - 39	1.00	Reference
	Separated or divorced	40	35 - 46	1.10	0.79 - 1.52
	Single	40	32 - 48	0.94	0.60 - 1.46
	Widowed	47	34 - 59	1.28	0.69 - 2.38
Area deprivation index national rank [c]					
	1 - 24	47	41 - 53	1.00	Reference
	25 - 49	41	35 - 46	0.77	0.51 - 1.16
	50 - 74	31	26 - 37	0.56	0.35 - 0.89
	75+	37	31 - 43	0.65	0.39 - 1.08

[a]A single multivariable model was used to estimate adjusted odds ratios; each factor was adjusted for all of the other factors in the model.

[b]Noncompliance defined by average weekly mat use of <2 days per week for at least 4 of the 12 months of follow-up.

[c]Lower area deprivation index indicates less deprivation.

Table . Estimated associations[a] of health characteristics with remote foot temperature monitoring noncompliance[b] within conceptual groups using multiply imputed data (N=1137).

Health or comorbidities characteristics		Noncompliant (%)	95% CI	Adjusted odds ratio	95% CI
Age (years)					
	<50	47	26 - 69	1.49	0.49 - 4.48
	50 - 59	44	35 - 53	1.19	0.75 - 1.89
	60 - 69	38	33 - 43	0.86	0.62 - 1.19
	70 - 79	35	31 - 39	1.00	Reference
	80+	40	32 - 49	1.48	0.92 - 2.38
Nonhealing ulcer					
	No	32	26 - 38	1.00	Reference
	Yes	39	36 - 42	1.02	0.68 - 1.52
Osteomyelitis					
	No	33	29 - 36	1.00	Reference
	Yes	45	40 - 49	1.44	1.06 - 1.97
Chronic kidney disease or end stage renal disease					
	No	35	34 - 42	1.00	Reference
	Yes	41	36 - 45	0.89	0.65 - 1.23
Lower extremity amputation					
	Neither	35	31 - 38	1.00	Reference
	Partial foot	38	32 - 45	1.01	0.70 - 1.46
	Major lower limb	44	38 - 50	1.11	0.77 - 1.60
Gagne index					
	≤0	29	24 - 34	1.00	Reference
	1 - 2	30	24 - 36	0.78	0.50 - 1.21
	3 - 4	40	33 - 47	1.37	0.86 - 2.18
	>4	48	43 - 53	1.81	1.15 - 2.83
Depression					
	No	35	32 - 38	1.00	Reference
	Yes	44	38 - 49	1.19	0.87 - 1.62
Body mass index (kg/m ^{2})					
	<25	49	41 - 58	1.00	Reference
	25 - 29.9	42	37 - 48	0.89	0.57 - 1.40
	30 - 39.9	33	29 - 37	0.70	0.45 - 1.08
	40+	30	22 - 39	0.73	0.40 - 1.33
Inpatient visits					
	0	31	27 - 35	1.00	Reference
	1+	43	40 - 47	0.89	0.62 - 1.28
Telehealth encounters					
	<6	28	21 - 36	1.00	Reference
	6 - 12	31	26 - 37	1.19	0.71 - 1.99
	13 - 27	40	35 - 45	1.65	1.01 - 2.70
	28+	43	38 - 48	1.70	1.02 - 2.84

[a]A single multivariable model was used to estimate adjusted odds ratios; each factor was adjusted for all of the other factors in the model.
[b]Noncompliance defined by average weekly mat use of <2 days per week for at least 4 of the 12 months of follow-up.

Table . Estimated associations[a] of behavioral, access to care, and practice pattern characteristics with remote foot temperature monitoring noncompliance[b] within conceptual groups using multiply imputed data (N=1137).

Characteristic		Noncompliant (%)	95% CI	Adjusted odds ratio	95% CI
Behavioral					
Hemoglobin A 1c					
	<5.7	42	31 - 53	1.00	Reference
	5.7 - 6.9	35	30 - 40	0.90	0.50 - 1.62
	7 - 7.9	32	27 - 38	0.89	0.49 - 1.61
	8 - 9.9	39	34 - 45	1.14	0.63 - 2.05
	10+	60	49 - 70	2.67	1.27 - 5.58
	No diabetes	34	21 - 51	0.96	0.37 - 2.44
Smoking status					
	Current smoker	54	47 - 61	2.06	1.32 - 3.20
	Former smoker	32	26 - 39	0.96	0.62 - 1.47
	Never smoker	35	29 - 42	1.00	Reference
Substance use disorder					
	No	34	31 - 37	1.00	Reference
	Yes	53	47-60	1.33	0.90 - 1.97
Access to care					
Rurality					
	Highly rural or rural	36	31 - 42	1.10	0.73 - 1.64
	Urban	38	35 - 41	1.00	Reference
Drive time primary care					
	<30 min	38	35 - 41	1.00	Reference
	30+ min	34	27 - 42	0.90	0.55 - 1.49
Drive time specialty care					
	<60 min	37	34 - 41	1.00	Reference
	60+ min	38	32 - 46	1.04	0.69 - 1.58
Practice patterns					
Department of Veterans Affairs district or region					
	Continental	38	30 - 47	1.00	Reference
	Midwest	32	27 - 37	0.90	0.54 - 1.49
	North Atlantic	42	35 - 51	1.46	0.82 - 2.58
	Pacific	44	39 - 50	1.22	0.71 - 2.10
	Southeast	40	27 - 54	1.94	0.84 - 4.49
Facility complexity					
	1a—high complexity	44	39 - 49	1.00	Reference
	1b—high complexity	37	32 - 43	0.89	0.56 - 1.40
	1c—high complexity	34	26 - 42	0.88	0.50 - 1.56
	2—medium complexity	34	24 - 45	0.80	0.41 - 1.55

Characteristic	Noncompliant (%)	95% CI	Adjusted odds ratio	95% CI
3—low complexity	22	13 - 34	0.50	0.23 - 1.06

[a]A single multivariable model was used to estimate adjusted odds ratios; each factor was adjusted for all of the other factors in the model.
[b]Noncompliance defined by average weekly mat use of <2 days per week for at least 4 of the 12 months of follow-up.

Figure 1. Average days per week remote temperature monitoring was used. Note that the group marked “0” is >0 but less than 1. Individuals who did not use the mat at all in the month are represented by the absence of any bars.

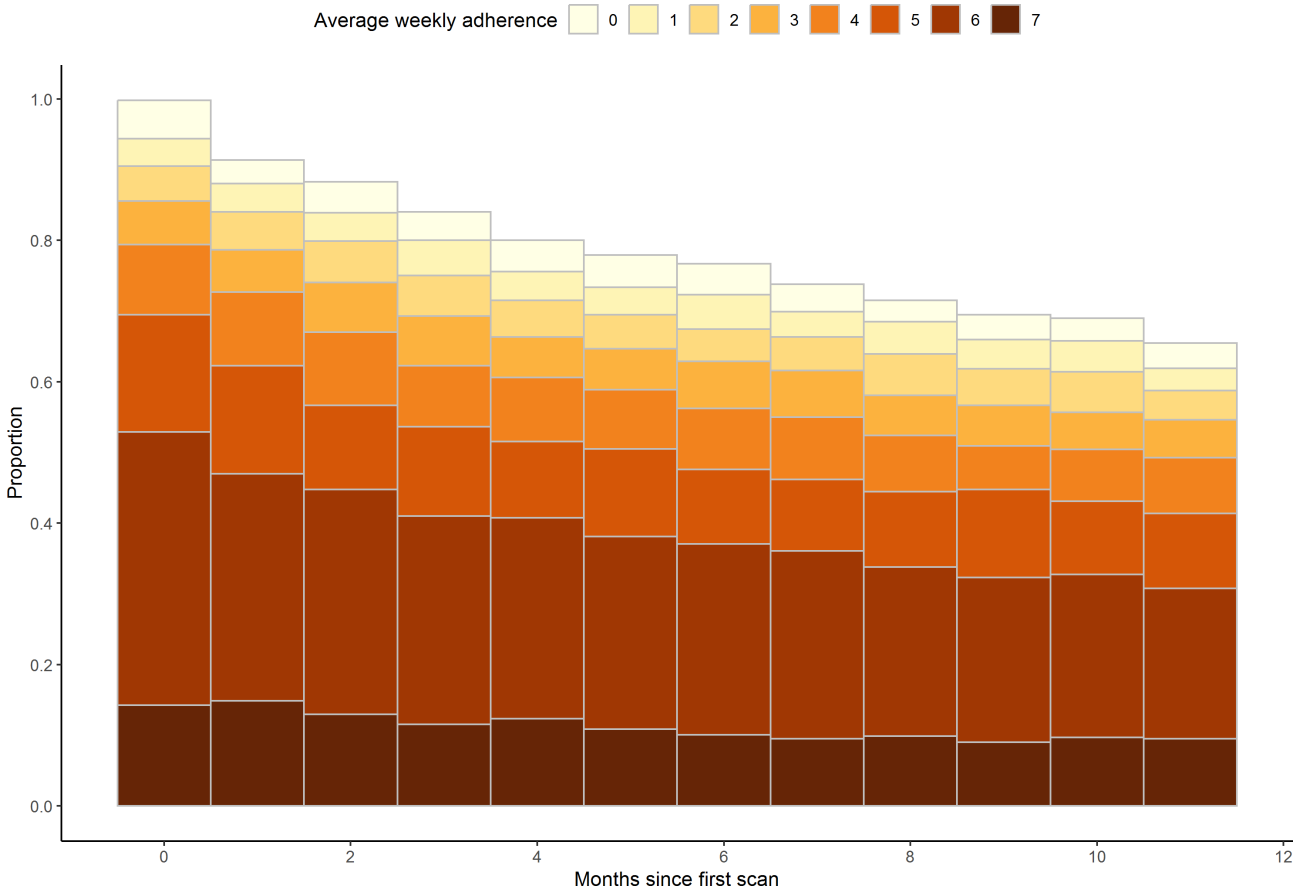

Table . Summary of AIC[a] for conceptual groups and variables for association with noncompliance[b].

Conceptual group	AIC	AIC difference versus saturated model	Likelihood ratio test *P* value[c]
Saturated model	1444	Reference	—[d]
Demographics	1437	−7	.30
Sex	1442	−2	.57
Race	1443	−1	.30
Hispanic or Latinx ethnicity	1444	0	.15
Marital status	1439	−5	.78
Area deprivation index	1445	+1	.11
Health conditions or comorbidities	1461	+17	<.001
Age	1442	−2	.23
Ulcer	1442	−2	.93
Osteomyelitis	1447	+3	.03
Chronic kidney disease or end stage renal Disease	1443	−1	.48
Lower extremity amputation	1440	−4	.84
Gagne comorbidity index	1454	+10	.002
Depression	1443	−1	.29
Body mass index	1442	−2	.28
Inpatient visits	1442	−2	.55
Telehealth encounters	1445	+1	.10
Behavioral	1473	+29	<.001
Hemoglobin A_{1c}	1452	+8	.005
Smoking	1460	+16	.007
Substance use disorder	1444	0	.11
Access to care	1438	−6	.95
Rurality	1442	−2	.65
30+ min to primary care	1442	−2	.67
60+ min to specialty care	1442	−2	.86
Practice patterns	1443	−1	.15
District	1445	+1	.15
Facility complexity	1441	−3	.46

[a]AIC: Akaike information criterion.

[b]Larger Akaike information criterion difference versus saturated model indicate more substantial contribution to the model fit.

[c]*P* values were calculated using a modification for multiply imputed data [25].

[d]Not applicable.

When considering changes in use around the time of a hospitalization or amputation, we found that the fraction of people with 5‐7 days per week of SmartMat use decreased, while the proportion of those with no SmartMat use increased in the month of the hospitalization or amputation (Multimedia Appendices 2 and 3). The proportion with *no* SmartMat use increased slightly in the 6 months after the hospitalization or amputation (Multimedia Appendices 4 and 5). Specifically, there was a larger increase in the proportion of patients with no use (and decrease in the proportion of patients with 5‐7 d of use) in the month concurrent with a hospitalization or amputation as well as in the 6 months after, compared to the reference group of patients with no hospitalization or amputation during follow-up.

Discussion

Principal Findings

Even though the requirements of monitoring are minimal (20 s per day to obtain a scan), nearly 4 in 10 patients did not use the SmartMat at least 2 days per week for at least 75% of the months under observation. Based on AIC differences, the strongest factors associated with noncompliance were behavioral factors (poor glucose control [as measured by hemoglobin A_{1c}] and smoking), and to a lesser extent, factors such as a recent history of osteomyelitis and an elevated Gagne comorbidity index, indicating a high comorbidity burden. Patients who are unable to manage their blood glucose levels or quit smoking, as well as those with osteomyelitis and numerous chronic comorbidities may also have challenges regularly using a home temperature monitoring device. Noncompliance was also higher among those who had a hospitalization or amputation. Although some results were different in descriptive analyses (eg, BMI and ADI) or statistically significant (eg, ADI) in our multivariable model, the absence of large AIC differences indicated that they did not contribute importantly to model fit and therefore may not be important factors for compliance. Additional research that replicates these findings and that can help us understand reasons for noncompliance in patients would be helpful to inform future interventions.

We are only aware of a single study [21] that evaluated compliance with a SmartMat for foot temperature monitoring, and that study found lower noncompliance using a more stringent definition. Unlike our study, the Frykberg et al [21] study excluded days during which a participant had a contraindication to using the mat (eg, for an open plantar wound) and considered those who did not use the mat for >28 consecutive days as lost to follow-up (18.6% of the sample) [21]. As our sensitivity analyses indicated a reduction in use following a hospitalization or amputation, differences in use between the prior study and ours may be partly because we did not exclude any days. In any case, noncompliance in this study is similar to prior studies of foot temperature monitoring involving handheld thermometers. For example, in a trial of 151 people randomized to daily foot temperature monitoring using a handheld thermometer, 62% of participants measured foot temperatures at least 70% of days (equivalent to 38% noncompliance) [14]. Likewise, a study of daily temperature monitoring in Peru observed 60% compliance when treating those who did not return logbooks as nonadherent (vs adherence of 87% when leaving them out of the analysis, equivalent to 40% and 13% noncompliance) [32]. Estimates for foot temperature monitoring are also similar to general adherence to a variety of self-management activities in people with diabetes observed in meta-analyses [33]. In summary, even though RTM is a relatively low burden intervention, noncompliance rates are strikingly similar despite different definitions of adherence and different activity or intervention burdens, suggesting that factors other than time burden likely impact compliance.

The Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) [34] is a helpful framework for understanding why individuals accept and use technology and may help to understand factors impacting compliance with RTM. UTAUT2 outlines how 7 constructs influence consumers' intention to use a technology: (1) performance expectancy (does it help?), which is analogous to relative advantage in the diffusion of innovation literature [35] and perceived usefulness in the technology acceptance model [36], (2) effort expectancy (how easy is it to use?), (3) facilitating conditions (are there resources available to support use?), (4) social influence (do those close to the individual support their use of the technology?), (5) hedonic motivation (is it fun?), (6) price value (is it worth it financially?), and (7) habit (does it become a habit?).

Because we lack data from patients' perspectives, it is unclear whether patients perceived a benefit, especially those who did not have any hot spots, or had many hot spots. Unlike a scale or a blood pressure monitoring device, which provides direct feedback with each use, and a sense of accomplishment for those who are losing weight or lowering their blood pressure, patients were not routinely provided direct feedback. They were called if they did not use the mat, or if temperature asymmetries were detected. If perceived benefit is low, use may decrease over time. Even though the apparent time burden is low, there may be steps (such as removing socks and shoes) that may be challenging and prevent people from using the mat more regularly. Given that an annual SmartMat subscription includes access to company personnel to answer questions, the third construct from the UTAUT2, facilitating conditions, may be high. As social influence is known to be important in diabetes management [37], social influence may be an important factor for this technology. Unfortunately, we had no direct measures of social influence, and marital status (a poor proxy) was not associated with compliance, which is understandable because marital status does not provide a direct measure of whether someone has a positive social influence. RTM is intended for disease management and was not designed to be fun, so hedonic motivation may be low. Gamification (eg, points and badges for streaks or other goals) could make it more fun and might improve compliance [38]. Price value is likely low since VA provides the SmartMat free of charge to patients. Future studies that collect self-report information from patients, including patient interviews, could help elucidate the extent to which factors in the model facilitate use.

Strengths and Limitations

A major strength of our study was its large size and ability to examine associations between various characteristics and SmartMat noncompliance. A potential limitation is that we did not have data on each day's use, but instead an average number of days per week per month of follow-up. Though less precise, this level of detail is informative to understand trends. Third, there are no standard definitions of adherence or noncompliance, and our definition was different from the 1 used in a prior study [21], though it was based on expert opinion. Fourth, we lacked information on factors not readily available in the medical record such as patient preferences, perceived benefits, beliefs, attitudes, social support, and environmental factors that may have impacted use of the mats. This information would be useful to collect in future studies. Finally, because our sample included VA patients, individuals were primarily older White males, so results may not generalize to more diverse samples. Future

research, particularly randomized trials testing different approaches to increase compliance (eg, gamification, incentives, patient and caregiver education, motivational interviewing, and reminders or alerts) in different patient populations, will be valuable to informing how to make technologies such as these more impactful.

Conclusion

Our study found that a large fraction of patients did not use the SmartMat as directed, and thus they would be unlikely to benefit from it. Testing approaches to proactively provide additional support for self-monitoring to patients with poor glucose control, current smoking, or high comorbidity burden (factors associated with high noncompliance) is an important area of future research. Future research should also seek to understand patients' perspectives on their experience with SmartMats and why they may have routinely used, rarely used, or stopped using the mat. Reducing the risk of ulcer recurrence and amputation could have enormous benefits for individual patients and lower health care costs. Thus, ensuring that patients effectively employ tools to reduce the risk of ulcer recurrence is paramount.

Acknowledgments

The views expressed in this paper are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient characteristics by study exclusion (N=1641).
[DOCX File, 24 KB - diabetes_v9i1e53083_app1.docx]

Multimedia Appendix 2
Average days per week remote temperature monitoring was used among patients with a hospitalization during follow-up (n=477). Note that month 0 represents the month of their hospitalization and negative numbers on the x axis are months prior to their hospitalization and positive numbers are months after.
[PNG File, 28 KB - diabetes_v9i1e53083_app2.png]

Multimedia Appendix 3
Average days per week remote temperature monitoring was used among patients with an amputation during follow-up (n=97). Note that month 0 represents the month of their amputation and negative numbers on the x axis are months prior to their amputation and positive numbers are months after.
[PNG File, 27 KB - diabetes_v9i1e53083_app3.png]

Multimedia Appendix 4
Average days per week remote temperature monitoring was used among patients with a hospitalization during follow-up (n=477) compared to a reference group includes those who did not have a hospitalization or amputation during follow-up.
[PNG File, 54 KB - diabetes_v9i1e53083_app4.png]

Multimedia Appendix 5
Average days per week remote temperature monitoring was used among patients with an amputation during follow-up (n=97) compared to a reference group that includes those who did not have a hospitalization or amputation during follow-up.
[PNG File, 43 KB - diabetes_v9i1e53083_app5.png]

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Abbreviations

ADI: area deprivation index
AIC: Akaike information criterion
CDW: corporate data warehouse
FY: fiscal year
OR: odds ratio
RTM: remote foot temperature monitoring
RUCA: Rural Urban Commuting Area
UTAUT2: Unified Theory of Acceptance and Use of Technology 2
VA: Department of Veterans Affairs
VHA: Veterans Health Administration

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Original Paper

Outcomes of an Asynchronous Care Model for Chronic Conditions in a Diverse Population: 12-Month Retrospective Chart Review Study

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Abstract

Background: Diabetes and hypertension are some of the most prevalent and costly chronic conditions in the United States. However, outcomes continue to lag behind targets, creating further risk of long-term complications, morbidity, and mortality for people living with these conditions. Furthermore, racial and ethnic disparities in glycemic and hypertension control persist. Flexible telehealth programs leveraging asynchronous care allow for increased provider access and more convenient follow-up, ultimately improving critical health outcomes across demographic groups.

Objective: We aim to evaluate the 12-month clinical outcomes of participants in the 9amHealth web-based clinic for diabetes and hypertension. We hypothesized that participation in the 9amHealth program would be associated with significant improvements in glycemic and blood pressure (BP) control across a diverse group of individuals.

Methods: We enrolled 95 patients in a completely web-based care clinic for diabetes and hypertension who received nutrition counseling, health coaching, and asynchronous physician consultations for medication prescribing. Patients received standard or cellular-connected glucose meters and BP cuffs in order to share data. Laboratory tests were completed either with at-home phlebotomy draws or a self-administered test kit. Patients' first and last hemoglobin A_{1c} (HbA_{1c}) and BP results over the 12-month period were compared, and analyses were repeated across race and ethnicity groups.

Results: Among all 95 patients, the average HbA_{1c} decreased by –1.0 (from 8.2% to 7.2%; P<.001) over 12 months of program participation. In those with a baseline HbA_{1c} >8%, the average HbA_{1c} decreased by –2.1 (from 10.2% to 8.1%; P<.001), and in those with a baseline HbA_{1c} >9%, the average HbA_{1c} decreased by –2.8 (from 11% to 8.2%; P<.001). Among participants who identified as a race or ethnicity other than White, the HbA_{1c} decreased by –1.2 (from 8.6% to 7.4%, P=.001). Further examination of subgroups confirmed HbA_{1c} lowering within each race or ethnicity group. In the overall population, the average systolic BP decreased by 17.7 mm Hg (P=.006) and the average diastolic BP decreased by 14.3 mm Hg (P=.002). Among participants self-identifying as a race or ethnicity other than White, the results similarly showed a decrease in BP (average reduction in systolic BP of 10 mm Hg and in diastolic BP of 9 mm Hg).

Conclusions: A fully web-based model leveraging all-asynchronous physician review and prescribing, combined with synchronous and asynchronous coaching and nutrition support, was associated with clinically meaningful improvement in HbA_{1c} and BP control over a 12-month period among a diverse group of individuals. Further studies should prospectively evaluate the effectiveness

of such models among larger populations, assess the longer-term sustainability of these outcomes, and explore financial models to make these types of programs broadly accessible.

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KEYWORDS

asynchronous; blood pressure; cardiology; chronic disease; cohort; diabetes mellitus therapy; diabetes; diabetics; eHealth; e-health; HbA1c; health disparities; heart; hemoglobin A1c; hypertension therapy; hypertension; hypertensive; remote care; retrospective; telehealth; telemedicine; virtual care

Introduction

Diabetes and hypertension collectively represent some of the most prevalent chronic conditions in the United States, affecting 11% and 45% of adults, respectively [1,2]. Despite the high prevalence of these conditions, improvements in care have lagged. For example, despite increased health care spending on people with diabetes and higher spending on diabetes medications [3], glycemic control has decreased over the past decade [4]. Similarly, rates of hypertension control have declined, with less than 50% of adults with hypertension meeting target blood pressure (BP) in 2020 [5].

When looking at outcomes across racial and ethnic groups, wider gaps in care are realized. The data show a higher incidence of diabetes-related complications in Black and Hispanic populations [6], in addition to racial disparities in glycemic control [7]. Hypertension, which disproportionately affects racial and ethnic minority individuals, is also less often controlled in Black American and Mexican American populations [8].

The causes of these suboptimal outcomes are multifactorial and include geographic and financial barriers to accessing care and broader systemic inequities. Transportation infrastructure and a limited number of providers pose challenges for patients living in rural areas [9]. Affordability is another significant barrier for patients. The data show an increase in national spending on diabetes medications over the past decade, with patients reporting cost-related underuse of critical diabetes medications [10].

Furthermore, over 40% of working-age adults are underinsured (uninsured, gaps in insurance, and inadequate coverage to ensure access to care) and potentially without access to consistent medical care for chronic conditions [11].

Telehealth has become an increasingly common method of care delivery that seeks to address many of these barriers [12-14]. However, the effectiveness of telehealth for chronic conditions remains unconfirmed, and the various telehealth solutions studied are heterogeneous, with some providing remote coaching only and others providing synchronous video visits with a prescribing provider [15-17]. Additional concerns over the effectiveness and value of telehealth include the potential widening of the digital divide and the worsening of health equity gaps [18,19].

This study evaluates the 12-month outcomes of a web-based clinic that is designed to overcome many of these barriers. The web-based clinic under study leverages an asynchronous physician consult model, where orders can be placed after chart and data review, plus relevant information provided by the patient. Asynchronous models reduce costs and increase efficiency and access due to the flexibility of prescriber availability. We hypothesized that participation in the 9amHealth web-based clinic, which combines telehealth coaching, remote monitoring, and asynchronous physician consultation for medication prescribing, would be associated with improvements in both glycemic and BP control over a 1-year period among a diverse group of individuals.

Methods

Ethical Considerations

All patients included in this cohort self-enrolled in the 9amHealth program, provided express consent to medical care by telemedicine, and agreed to our terms and conditions, which include authorization to conduct additional research using health care data obtained as part of the program. Ethics review board assessment was not sought as this study is a secondary analysis of previously collected deidentified data, considered secondary research for which consent is not required per federal regulation code 46.104 [20].

Study Design

This was a nonrandomized, retrospective observational cohort study evaluating the clinical outcomes among members with diabetes and hypertension who were enrolled in the 9amHealth web-based clinic program for 12 months. For inclusion in this analysis, we identified charts from members who enrolled in the 9amHealth program between 2020 and 2022, who remained with the program for at least 12 consecutive months, and who had at least 2 verified hemoglobin A_{1c} (HbA_{1c}) laboratory test results recorded.

Program Description

The 9amHealth program is a web-based clinic for people living with type 2 diabetes, prediabetes, hypertension, hyperlipidemia, and obesity. Participants learn about the program through web-based advertisements, social media groups, and community referrals. Individuals at risk for chronic conditions sign up for an initial screening, and those with new or existing diagnoses pay a monthly subscription fee to enroll in a chronic condition management program. The program's base fee (US $25 per month at the time of the study) includes unlimited synchronous and asynchronous care from registered dietitians and diabetes educators and unlimited asynchronous care from physicians. At-home laboratory test services and generic medications incur additional fees, with a fee range between US $25 and US $55

per month. Upon enrollment, members provide consent to be treated by telehealth. Members start the program with a web-based medical questionnaire that collects medical history; medications; allergies; and demographic information on insurance status, race, ethnicity, and gender identity. Diagnoses of type 2 diabetes are either self-reported by the patient and confirmed by HbA_{1c} laboratory test results ≥6.5% or determined based on HbA_{1c} laboratory test results ≥6.5% alone. Diagnoses of hypertension are self-reported by the patient or identified by screening BP readings done through the program.

BP cuffs (McKesson, Smart Meter) and glucose meters (Ascencia, Smart Meter) are provided to members based on their condition and the clinical need for monitoring, and continuous glucose monitors are ordered for individuals who meet their health plan's criteria for these devices. Members are also invited to share data through the program's app from their personal devices.

Laboratory Measures

Laboratory tests are ordered on a protocol-driven cadence specified by the 9amHealth clinical algorithm, which aligns with standards of care recommendations from the American Diabetes Association and includes HbA_{1c}, a comprehensive metabolic panel, a lipid panel, and a urine microalbumin to creatinine ratio test [21]. In brief, the protocol recommends an HbA_{1c} test every 3-6 months, depending on level of control and medication changes; a comprehensive metabolic panel and urine microalbumin to creatinine ratio tests are repeated annually; and lipid panels are repeated every 2 years unless abnormal results or medication changes necessitate interim testing.

Laboratory tests are collected by an at-home phlebotomy partner, and specimens are processed and analyzed at 1 of the 3 Clinical Laboratory Improvement Amendments of 1988 (CLIA)–certified, College of American Pathologists–accredited laboratories (Quest, Labcorp, or Bioreference). In regions where a phlebotomist cannot be deployed to the home, members are offered an at-home test kit (Molecular Testing Labs dried blood spot, Tasso device) that can measure creatinine, HbA_{1c}, and lipid panel, or they can travel to an in-person patient service center. Members can also share laboratory test results ordered by other providers directly into the 9amHealth patient management system.

BP Readings

BP readings are either self-reported by the member to the care team; through member upload to the app; or, in the case of cellular-connected BP cuffs, automatically uploaded through the device company's web-based portal.

Clinical Care

Diabetes education, coaching, and nutrition counseling are provided by Registered Dietitians and Certified Diabetes Care and Education Specialists through a combination of scheduled and unscheduled telephone visits, secure messaging, and SMS text messages. Topics are addressed according to the *Association of Diabetes Care and Education Specialists ADCES7 Self-Care Behavior Guidelines* [22]. No calorie restriction or specific macronutrient counting is required, and recommendations are customized to meet the preferences, lifestyle, and cultural requirements of the member.

After an asynchronous review of the web-based questionnaire; available glucose, BP, and weight data; and any additional clinical information gathered by the registered dieticians and coaches, medications are prescribed by physicians trained on the 9amHealth clinical algorithms. These algorithms are written by endocrinologists and primary care physicians and align with the American Diabetes Association's guidelines [23] and community standard practice. Algorithms include recommendations (within parameters) for medication management of hyperglycemia, hypertension, hyperlipidemia, and obesity and for addressing abnormal laboratory test results. Medication recommendations are tailored to the member based on other health conditions, side effect profiles, insurance coverage, and acceptability of copays and cost-shares. Within the diabetes algorithm, glucose patterns are identified, and dose escalation or de-escalation of medications or an additional medication is suggested. Similarly, within the hypertension algorithms, an average of 3 BP readings obtained on separate dates is evaluated, and antihypertensive doses are escalated, de-escalated, or an additional medication is suggested. All algorithm suggestions are reviewed by registered dietitians and diabetes educators with the patient and then reviewed asynchronously by the physician in the context of chart review and consultation, and prescription changes are submitted if deemed clinically appropriate. Medications prescribed include metformin, sodium-glucose transport protein 2 (SGLT2) inhibitors, glucagon-like peptide 1 (GLP1) receptor agonists, sulfonylureas, pioglitazone, and long-acting, intermediate-acting, and rapid-acting insulins for glucose control. Generic statins, ace inhibitors, angiotensin receptor blockers, amlodipine, and hydrochlorothiazide are prescribed for the management of hypertension and cardiovascular risk.

Statistical Methods

Demographic information is reported as the mean (SD) or n (%). The first and last available HbA_{1c} results were compared among all included members, as well as in the subgroups with a baseline HbA_{1c} >8% (poor control group) and a baseline HbA_{1c} >9% (uncontrolled hyperglycemia group) using paired 2-tailed *t* tests. The first and last available BP readings were compared among participants in the cohort with baseline BP ≥140/90 who had at least 2 BP readings, measured at least 1 month apart, and uploaded to the patient management system, which also used a paired 2-tailed *t* test.

Results

Participant Demographics

Table 1 describes the baseline and follow-up characteristics of the cohort, subgrouped by self-reported race or ethnicity. The average age of the overall population was 48 years, with 64% (61/95) of participants identifying as men and 34% (32/95) identifying as women. Nearly half of the population self-identified as a race or ethnicity other than White.

Table 1. Baseline and follow up characteristics of participants.

Characteristic	Overall population (N=95)	Self-identify as White (n=52)	Self-identify as race or ethnicity other than White (n=39)
Age (years), n (%)	48 (9)	49 (9)	46.5 (10)
Sex assigned at birth, n (%)			
Female	32 (34)	14 (27)	18 (46)
Male	61 (64)	37 (71)	21 (54)
Declined	2 (2)	1 (2)	0 (0)
Race or ethnicity, n (%)			
Asian	10 (11)	N/A[a]	N/A
American Indian or Alaska Native	1 (1)	N/A	N/A
Black or African American	13 (14)	N/A	N/A
Latinx	15 (16)	N/A	N/A
White	52 (55)	N/A	N/A
Other or unknown	4 (4)	N/A	N/A
Average number of days with the program, mean (SD)	488.5 (75.0)	N/A	N/A
Average baseline HbA_{1c}[b] (%), mean (SD)	8.2 (2.2)	7.8 (2.2)	8.6 (2.1)
Average last HbA_{1c} (%), mean (SD)	7.2 (1.9)	7.1 (2.0)	7.4 (1.9)
Average baseline BP[c] (mm Hg), mean (SD)			
Systolic	158.7 (16.9)	N/A	N/A
Diastolic	97.5 (4.5)	N/A	N/A
Average last BP (mm Hg), mean (SD)			
Systolic	141.0 (26.2)	N/A	N/A
Diastolic	83.3 (12.6)	N/A	N/A
Number of participants who were prescribed each medication by 9amHealth, n (%)			
Amlodipine	9 (10)	N/A	N/A
Atorvastatin	17 (18)	N/A	N/A
Glimepiride	4 (4)	N/A	N/A
Glipizide	8 (8)	N/A	N/A
Hydrochlorothiazide	7 (7)	N/A	N/A
Lisinopril	10 (11)	N/A	N/A
Losartan	9 (10)	N/A	N/A
Omega-3-acid ethyl esters	3 (3)	N/A	N/A
Metformin	32 (34)	N/A	N/A
Pioglitazone	19 (20)	N/A	N/A
Rosuvastatin	3 (3)	N/A	N/A
Simvastatin	1 (1)	N/A	N/A
Dulaglutide	1 (1)	N/A	N/A

[a]N/A: not applicable.

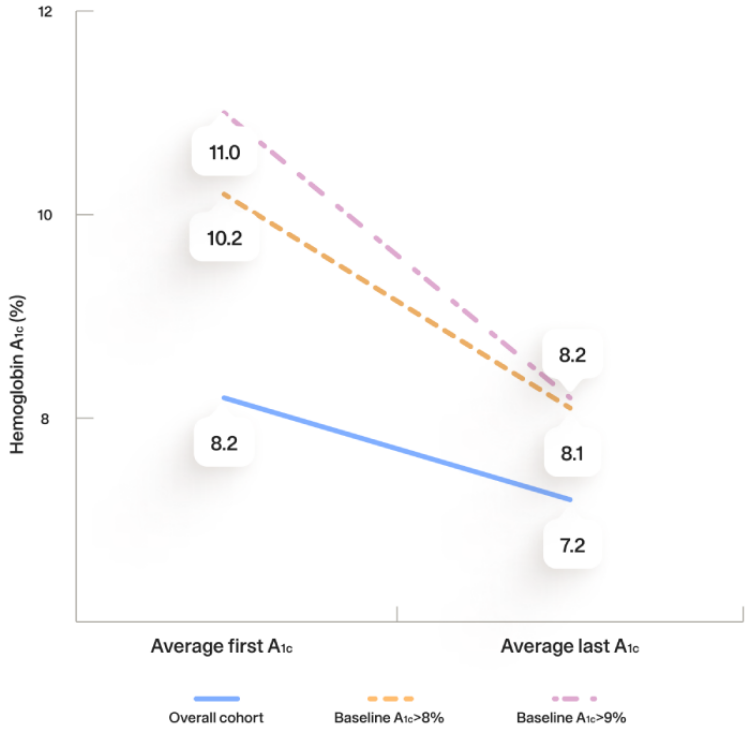
[b]HbA_{1c}: hemoglobin A_{1c}.

[c]BP: blood pressure.

HbA_{1c} Results

Figure 1 demonstrates the change in HbA_{1c} in all participants and in the baseline HbA_{1c} >8% and >9% cohorts. Among all 95 participants, the average HbA_{1c} decreased from 8.2% to 7.2% (–1.0; *P*<.001), with an average of 314 days between the first and last results. Among participants with a baseline HbA_{1c} >8%, the average HbA_{1c} decreased from 10.2% to 8.1% (n=46; –2.1; *P*<.001). Among those with a baseline HbA_{1c} >9%, the average HbA_{1c} decreased from 11% to 8.2% (n=32; –2.8; *P*<.001).

Figure 1. Change in hemoglobin A1c (HbA_{1c}) over the study period.

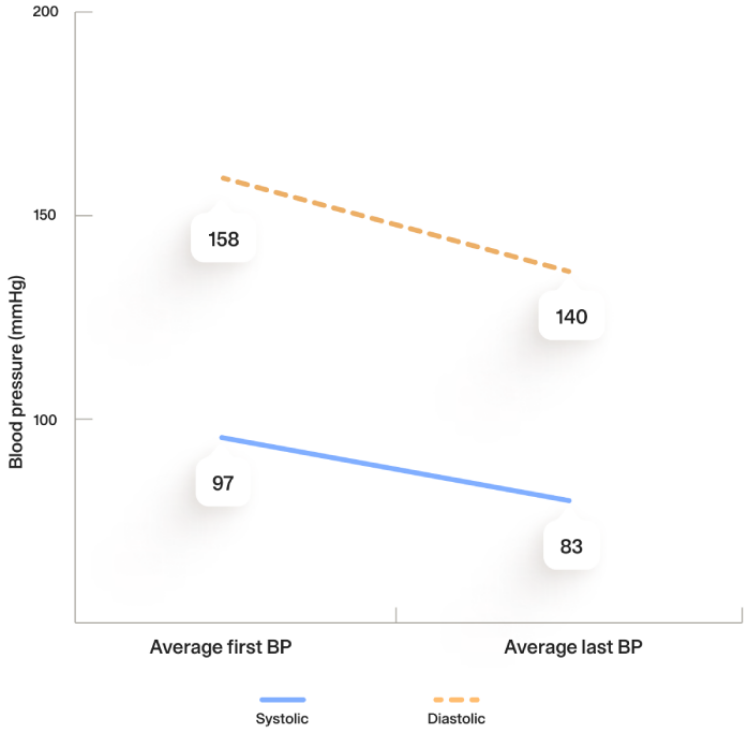


The results were consistent among members identifying as a race or ethnicity other than White. The average HbA_{1c} among participants who identified as a race or ethnicity other than White decreased from 8.6% to 7.4% (n=39; –1.2; *P*=.001). Further examination of subgroups confirms HbA_{1c} lowering within each race or ethnicity group, however, in small numbers. Among Asian participants, the average HbA_{1c} decreased from 8.8% to 6.9% (n=10; –1.9; *P*=.004); among Black or African American participants, the average HbA_{1c} decreased from 7.5% to 7.1% (n=13; –0.3; *P*=.46); and among Hispanic or Latinx participants, it decreased from 8.9% to 7.9% (n=15; –1.1; *P*=.07). Of note, the baseline HbA_{1c} in Black participants was the lowest of any group, close to target upon starting the program at 7.5%.

BP Results

Figure 2 shows the change in BP among all participants in the program for at least 12 months with baseline BP ≥140/90 and available first and last BP readings. The average systolic BP decreased by 17.7 mm Hg (n=12; *P*=.006) and the average diastolic BP decreased by 14.3 mm Hg (n=12; *P*=.002). Among participants self-identifying as a race or ethnicity other than White, the results similarly showed a decrease in BP (average reduction in systolic BP of 10 mm Hg and in diastolic BP of 9 mm Hg), but with a very small number of individuals meeting the criteria for analysis (n=5). Results for BP were not further parsed by race or ethnicity due to the small sample size.

Figure 2. Change in blood pressure (BP) over the study period.



Clinical Interventions

Participants were prescribed an average of 2.2 active medications for diagnoses of diabetes, hypertension, and hyperlipidemia. Of these, an average of 1.4 medications were new and added through asynchronous 9amHealth physician consultations.

Discussion

Principal Findings

Members participating in a fully web-based model leveraging all-asynchronous physician review and prescribing, combined with synchronous and asynchronous coaching and nutrition support, experienced significant and clinically important improvements in HbA_{1c} and BP control over a 12-month period.

Comparison With Previous Work

It has long been established that intensive glucose control in type 2 diabetes ($HbA_{1c} \leq 7\%$) decreases the risk of microvascular complications, including kidney and eye disease and neuropathy, and these benefits are durable over time [24,25]. Hypertension management has also been shown to reduce adverse cardiovascular outcomes, and meta-analysis data from over 400,000 participants demonstrate that a reduction of systolic BP by 10 mm Hg or a reduction of diastolic BP of 5 mm Hg predicts a 25% reduction in coronary heart disease events and a 36% reduction in strokes [26]. Racial and ethnic minority individuals experience a higher burden of chronic condition complications [6], so it is imperative that a web-based program aimed at lowering HbA_{1c} and BP does so effectively for all racial and ethnic groups. Our results support a positive impact on glycemic control and BP across all race and ethnic groups participating in the program.

Strengths and Limitations

While many digital programs offer web-based or live coaching and nutrition, and select companies provide medication management along with live telehealth encounters, the 9amHealth program is unique in several ways. In addition to the core elements of coaching, diabetes education, and nutrition, it also integrates key components of medical care—laboratory draws and physician consultations—into one digital experience. The program is also unique in its use of asynchronous physician consultation and prescribing. The asynchronous model drives efficiency and scalability and removes barriers that may exist for certain populations when required to participate in synchronous or scheduled visits. It also reduces the impact of the digital divide since SMS text messages and messaging-based asynchronous clinical communications can occur on a mobile phone without the need for high-speed internet, which may not be available for some underresourced and rural populations.

This analysis has several strengths. First, the population studied was diverse, including a greater percentage of racial and ethnic minority individuals (Table 1) than the average US population [27] and most study populations of digital health solutions [16,28,29]. Second, the glycemic outcomes analyzed in this study are defined by laboratory-measured HbA_{1c} and not extrapolated from self-monitored blood glucose readings, as has been done in previous studies [28]. Third, our analysis included participants regardless of baseline HbA_{1c} or BP. Therefore, we can demonstrate a positive association across a population with varying levels of glycemic and hypertension control at the time of their enrollment, rather than just among individuals starting the program with highly uncontrolled conditions. Finally, participants were included only if they remained in the program for 12 months, demonstrating that

initial glucose or BP lowering in the early, high-engagement weeks was sustained throughout the year.

Several limitations must be considered. First, program participants became aware of the program predominantly through advertisements and self-referral. Therefore, the study cohort may represent a motivated population that is more likely to improve health measures such as HbA_{1c} and BP and to engage successfully in digital health solutions. This may have positively impacted the outcomes, suggesting greater HbA_{1c} and BP reductions. Second, nearly half of our participants lack insurance coverage or were enrolled in a high-deductible health plan and, therefore, could not otherwise easily access or afford traditional care. Thus, our results may not generalize to a broader population of predominantly insured individuals. Third, while the population included in this analysis is more diverse than previous studies of digital health solutions, the sample size for racial and ethnic minority individuals was small. Fourth, the financial burden of a monthly subscription fee, although relatively low-cost, may not be sustainable for many individuals in the long term. Therefore, associated reductions in HbA_{1c} and BP may not be sustainable or may only be sustainable for individuals with financial means to remain with the program. Finally, our analysis does not include a comparison to "usual care" or a control group, so the impact of the intervention in isolation cannot be fully separated from other confounding factors. However, existing data suggests that usual care results in a smaller decrease in HbA_{1c} (from –0.5 to –0.9) [16,30,31] than seen with our intervention, which supports the improvement of outcomes seen with the 9amHealth program beyond that of usual care.

Future Directions

The 1-year outcomes of this web-based clinic demonstrate that participation in a flexible digital health program leveraging asynchronous care is associated with improved chronic condition outcomes beyond just initial engagement in a diverse group of individuals. Future prospective studies, including a comparison control arm, should examine the effectiveness and longer-term sustainability of glucose and BP lowering through this model and evaluate which elements of care are most strongly associated with improved outcomes. Coverage through existing health plans, employer-sponsored programs, and public health benefits should be explored to ensure long-term, affordable access to these types of programs. Finally, studies of larger populations to allow for appropriate power to determine if outcomes are consistent across race or ethnicity groups and broader age groups will allow for further generalizability of these findings.

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Data Availability

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

ACW and MH undertook the study's conception and design. ACW, MH, and PH are responsible for the data curation and formal analysis. ACW, DD, and SP wrote the original draft of this study. All authors reviewed the results, participated in writing, review, and editing, and approved the final version of the manuscript.

Conflicts of Interest

MH, DD, and ACW are employees of 9amHealth, Inc and receive salary and stock options. PH is a part-time contracted employee of 9amHealth, Inc.

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Abbreviations

BP: blood pressure
CLIA: Clinical Laboratory Improvement Amendments of 1988
GLP1: glucagon-like peptide 1
HbA_{1c}: hemoglobin A1c
SGLT2: sodium-glucose transport protein 2

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Original Paper

Impact of Telemedicine Versus In-Person Pediatric Outpatient Type 1 Diabetes Visits on Immediate Glycemic Control: Retrospective Chart Review

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Abstract

Background: Children and adolescents with type 1 diabetes require frequent outpatient evaluation to assess glucose trends, modify insulin doses, and screen for comorbidities. Continuous glucose monitoring (CGM) provides a detailed glycemic control assessment. Telemedicine has been increasingly used since the COVID-19 pandemic.

Objective: To investigate CGM profile parameter improvement immediately following pediatric outpatient diabetes visits and determine if visit modality impacted these metrics, completion of screening laboratory tests, or diabetic emergency occurrence.

Methods: A dual-center retrospective review of medical records assessed the CGM metrics time in range and glucose management indicator for pediatric outpatient diabetes visits during 2021. Baseline values were compared with those at 2 and 4 weeks post visit. Rates of completion of screening laboratory tests and diabetic emergencies following visits were determined.

Results: A total of 269 outpatient visits (41.2% telemedicine) were included. Mean time in range increased by 1.63% and 1.35% at 2 and 4 weeks post visit (*P*=.003 and .01, respectively). Mean glucose management indicator decreased by 0.07% and 0.06% at 2 and 4 weeks post visit (*P*=.003 and .02, respectively). These improvements in time in range and glucose management indicator were seen across both telemedicine visits and in-person visits without a significant difference. However, patients seen in person were 2.69 times more likely to complete screening laboratory tests (*P*=.03). Diabetic emergencies occurred too infrequently to analyze.

Conclusions: Our findings demonstrate an immediate improvement in CGM metrics following outpatient visits, regardless of modality. While statistically significant, the magnitude of these changes was small; hence, multiple visits over time would be required to achieve clinically relevant improvement. However, completion of screening laboratory tests was found to be more likely after visits occurring in person. Therefore, we suggest a hybrid approach that allows patient convenience with telemedicine but also incorporates periodic in-person assessment.

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KEYWORDS

diabetes; type 1 diabetes; pediatrics; continuous glucose monitoring; time in range; glucose management indicator; telemedicine; screening labs

Introduction

Type 1 diabetes affects millions worldwide with up to 75% of cases diagnosed during childhood [1]. Pediatric type 1 diabetes care necessitates frequent outpatient visits to assess glycemic trends and adjust insulin doses, stay up to date with routine screening [2,3], provide reinforcement of diabetes education such as management of hypoglycemia, hyperglycemia, and illnesses, and prevent potentially life-threatening diabetic emergencies including level 3 hypoglycemia or diabetic ketoacidosis. In the past decade, continuous glucose monitors (CGMs) have become increasingly prevalent in place of traditional finger sticks [4]. By providing more frequent real-time blood glucose data with trends and safety alerts for glycemic excursions, CGM use has positive effects on clinical diabetes outcomes including less frequent episodes of hypoglycemia and lower hemoglobin A_{1c} (HbA_{1c}) values [5,6]. Time in range (TIR) and glucose management indicator (GMI) are 2 key measures of glucose control generated from CGM data. TIR is the percentage of the time during a CGM window for which the blood sugar falls within a preset target range (typically 70-180 mg/dL). GMI is a surrogate measure for HbA_{1c} calculated from all the available blood sugar data used to quantify overall glycemic control. GMI has the advantage of being applicable to custom time periods as opposed to the fixed red blood cell lifespan of 90-120 days, which HbA_{1c} reflects. Frequent monitoring of HbA_{1c} remains the gold standard of assessing diabetes management with tighter glycemic control being associated with less frequent complications of diabetes over time, even in youth [7-9]. But with CGM use rising, many have advocated for using these CGM based metrics to assess overall diabetes control in addition to, or even in lieu of, HbA_{1c} [10,11]. In addition to glycemic control monitoring, outpatient type 1 diabetes visits also serve the purpose of making sure patients are up to date with routine screening. The American Diabetes Association recommends periodic laboratory assessment to screen for comorbidities of type 1 diabetes, as well as associated autoimmune diseases [2,3,12,13]. Finally, these visits reiterate diabetes education to patients and families which can help prevent complications of the disease including severe hypoglycemia, or the life-threatening diabetic ketoacidosis that can result from untreated hyperglycemia.

The use of telemedicine for outpatient medical visits has skyrocketed in recent years as a response to the COVID-19 pandemic [14]. Outpatient type 1 diabetes care was no exception, with some centers citing as much as 99% of their visits being converted to telemedicine within the first year of the pandemic [15]. However, even before the pandemic, telemedicine had been studied as a possible modality for type 1 diabetes health care delivery given the ability to evaluate objective data from glucose and CGM logs to guide management decisions. Telemedicine visits have been shown to improve diabetes clinical outcomes [16], while potentially removing key barriers, such as geographic distance, for patients and families. Even after widespread vaccination strategies allowed the safe return of in-person visits, it has been reported that many patients and families continue to express a preference for telemedicine [17].

Because clinic visits generally entail adjusting insulin doses, promoting adherence, and reinforcing education about insulin administration and carbohydrate counting, it is reasonable to expect that CGM profile parameters should improve immediately after an outpatient encounter. Previous studies have confirmed that increased outpatient type 1 diabetes visits lead to improved clinical outcomes [18,19]. To our knowledge, our study is the first to evaluate emerging CGM profile parameters in pediatric patients in the periods directly before and after outpatient follow-up visits, and concurrently examine whether telemedicine versus in-person visits have differential effects on glycemic control, completion of screening laboratory tests, or frequency of diabetic emergencies.

Methods

Overview

Our study was conducted across 2 diverse pediatric endocrinology sites in Southern California, University of California Los Angeles Mattel Children's Hospital (UCLA) in Westwood and Memorial Care Miller Children's and Women's Hospital (MCH) in Long Beach. Electronic health record (EHR) data were retrospectively collected for pediatric patients with type 1 diabetes (based on the *ICD-10* [*International Statistical Classification of Diseases, Tenth Revision*] codes at visits) using Dexcom CGM who presented for at least 1 outpatient follow-up appointment during the study window of calendar year 2021. We included visits with patients who were aged 5-21 years old with disease duration at least 1-year, last HbA_{1c} <10%, a minimum of 70% CGM use, and no serious and possibly confounding medical conditions. We excluded patients that were documented to have type 2 diabetes or indeterminate type.

Baseline demographic information collected from the EHR included patient age, sex, race, ethnicity, duration of disease, insurance type, and insulin pump use. For each visit, CGM TIR and GMI were collected from the Dexcom Clarity app at 4 different time points, that is, 4 weeks and 2 weeks before each visit and then 2 weeks and 4 weeks afterward. Notably, the parameters for each 4-week period were inclusive of the corresponding 2-week period. Changes from baseline analyses were examined comparing TIR and GMI values from 4 weeks before the visit with the values obtained at 2 and 4 weeks post visit. Because of this design, analyses were performed at the visit level to look for changes in these parameters to account for patients presenting for multiple visits during the study window. Completion of screening laboratory tests completion was defined as a binary outcome and considered "complete" if all recommended laboratory tests were up to date by the next outpatient visit. EHR data were also collected on all diabetic emergencies following each visit during the study window,

defined as a binary yes/no for the occurrence of glucagon use or a diabetes-related emergency department visits or hospitalization occurring before the next outpatient visit.

Ethical Considerations

Institutional review board approval was obtained at both UCLA (IRB#21-002033) and MCH (IRB #278-22). Patient consent was waived given retrospective chart review study design.

Statistical Methods

Patient characteristics were summarized overall and by site using means, SDs, medians, and IQRs for continuous variables, and frequencies and percentages for categorical variables. The number of visits per patient were also summarized overall and by visit type (in-person vs telemedicine). Random effects models were used for all statistical analyses since multiple visits could be potentially included for each patient. First, to examine differences in TIR and GMI over time, we conducted a linear mixed effects model using data from both sites with fixed effects for time (2 weeks and 4 weeks) and the baseline value (4 weeks before the visit). We then compared changes in TIR and GMI from baseline (4 weeks before the visit) with 2 and 4 weeks post visit by visit modality using a linear mixed effects model with fixed effects for visit type (ie, telemedicine vs in-person visit) and the baseline measurement. A second model added an interaction term between time and visit type to determine if any changes by visit type differed by time point. Multivariate models were also constructed to assess the effect of potential confounding variables collected such as age, sex, site, duration of disease, race, ethnicity, insurance type, and pump use that could affect measured outcomes. A mixed effects logistic regression model was used to determine if there was an association between visit type and the odds of completing screening laboratory tests. All analyses were conducted in SAS (version 9.4; SAS Institute). *P* values of <.05 were considered statistically significant.

Results

A total of 535 visits across 278 patients at both sites were considered, of which 269 outpatient visits met inclusion criteria among 135 unique patients. Of these, 81 visits among 39 patients took place at UCLA and the remaining 188 visits among 96 patients were at MCH. Of all included visits, 111 were performed by telemedicine (41.2%, Figure 1).

A total of 73 patients within the study were male (n=73, 54.1%), mean age was 13.3 years old, and mean duration of type 1 diabetes was 5 years. There were no significant differences in these metrics between sites. However, insurance type, race, and ethnicity varied significantly between UCLA and MCH. Of the patients seen at UCLA (36/39, 92.3%) had private insurance compared with only (43/96, 44.8%) of patients seen at MCH. A majority of patients seen at UCLA were White (29/39, 74.4%), followed by Asian (2/39, 5.1%) with (7/39, 17.9%) documented as “Other” or “Unknown” and (1/39, 2.6%) with Hispanic or Latino ethnicity. Conversely, Hispanic or Latino ethnicity comprised (57/96, 59.4%) of patients seen at MCH, followed by White at (25/96, 26%), Black at (7/96, 7.3%), and (10/96, 10.4%) documented as “Other” or “Unknown.” Finally, most patients across both sites used an insulin pump, encompassing (23/39, 59%) of UCLA patients and (52/96, 54.2%) of MCH patients (Table 1).

Across all visits, mean TIR increased by 1.63% and 1.35% during the 2-week and 4-week period after each visit, respectively (*P*=.003 and *P*=.01, respectively; Figure 2). Mean GMI decreased by 0.07% and 0.06% during the 2-week and 4-week period after each visit, respectively (*P*=.003 and *P*=.02, respectively; Figure 3). TIR and GMI at 2 and 4 weeks post visit were not statistically different from each other (*P*=.61 and *P*=.51, respectively). Following telemedicine visits, TIR increased from baseline by 1.9% at 2 weeks and 1.7% at 4 weeks, while those seen in-person had TIR improvement from baseline of 1.4% at 2 weeks and 1.1% at 4 weeks. This change in TIR between visit modality was not significant at either time point (*P*=.54 and *P*=.48, respectively; Figure 2). GMI following telemedicine visits decreased from baseline by 0.1% at 2 weeks and 0.08% at 4 weeks, while those seen in-person had GMI decrease from baseline by 0.06% at 2 weeks and 0.05% at 4 weeks. This change in GMI between visit modality was also not significant at either time point (*P*=.39 and *P*=.44, respectively; Figure 3). After adjusting for site, age, sex, race, ethnicity, insurance type, and duration of disease, baseline values of TIR and GMI that were farther from goal were associated with a greater improvement (*P*=.02 and *P*<.001, respectively). In addition, pump use was found to be associated with improvement in TIR, but not GMI (*P*=.045 and *P*=.36, respectively). Site, age, sex, race, ethnicity, insurance type, and duration of disease were not statistically associated with CGM metrics.

Screening laboratory tests were completed following 81/111 telemedicine visits (73%) compared with 138/157 visits in-person (87.9%) with 1 patient seen in-person lost to follow-up. This difference was statistically significant with patients seen in-person being 2.69 times more likely to have up-to-date screening laboratory tests by the next visit compared with those seen by telemedicine (*P*=.03). Diabetic emergencies could not be assessed following 9 visits where patients were lost to follow-up at the time of the data collection. However, there were only 2 instances (0.8%) of documented interim diabetic emergencies, and so were deemed too infrequent to meaningfully analyze.

Figure 1. Visit breakdown.

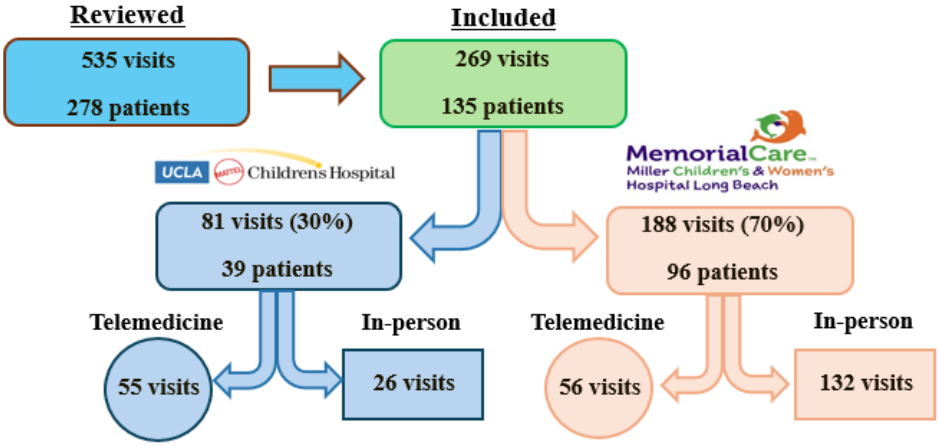


Table 1. Patient demographics.

Characteristics	UCLA[a] (n=39)	MCH[b] (n=96)	Overall (n=135)
Sex, male, n (%)	19 (48.7)	54 (56.3)	73 (54.1)
Age (years), mean	13.5	13.2	13.3
Duration (years), mean	5.1	5.0	5.0
Private insurance, n (%)	36 (92.3)	43 (44.8)	79 (58.5)
Pump use, n (%)	23 (59)	52 (54.2)	75 (55.6)
Race or ethnicity, n (%)			
White	29 (74.4)	25 (26.0)	54 (40.0)
Hispanic or Latino[c]	1 (2.6)	57 (59.4)	58 (43.0)
Black	0 (0)	7 (7.3)	7 (5.2)
Asian	2 (5.1)	3 (3.1)	5 (3.7)
Native Hawaiian	0 (0)	1 (1.0)	1 (0.7)
American Indian	1 (2.6)	0 (0)	1 (0.7)
Other	2 (5.1)	7 (7.3)	9 (6.7)
Unknown	5 (12.8)	3 (3.1)	8 (5.9)

[a]UCLA: University of California, Los Angeles.

[b]MCH: Miller Children's and Women's Hospital.

[c]In the EHR, Hispanic or Latino ethnicity is coded separately and lists race as "other."

Figure 2. Time in range.

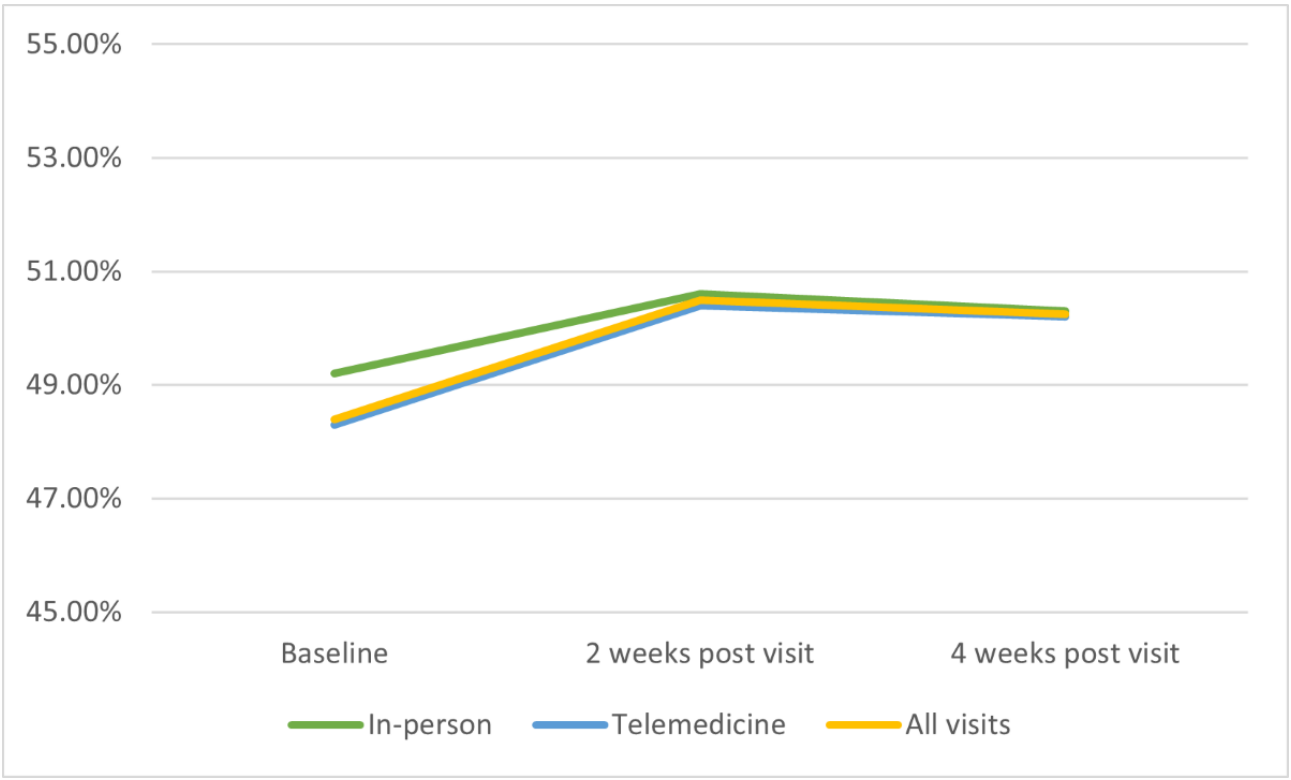
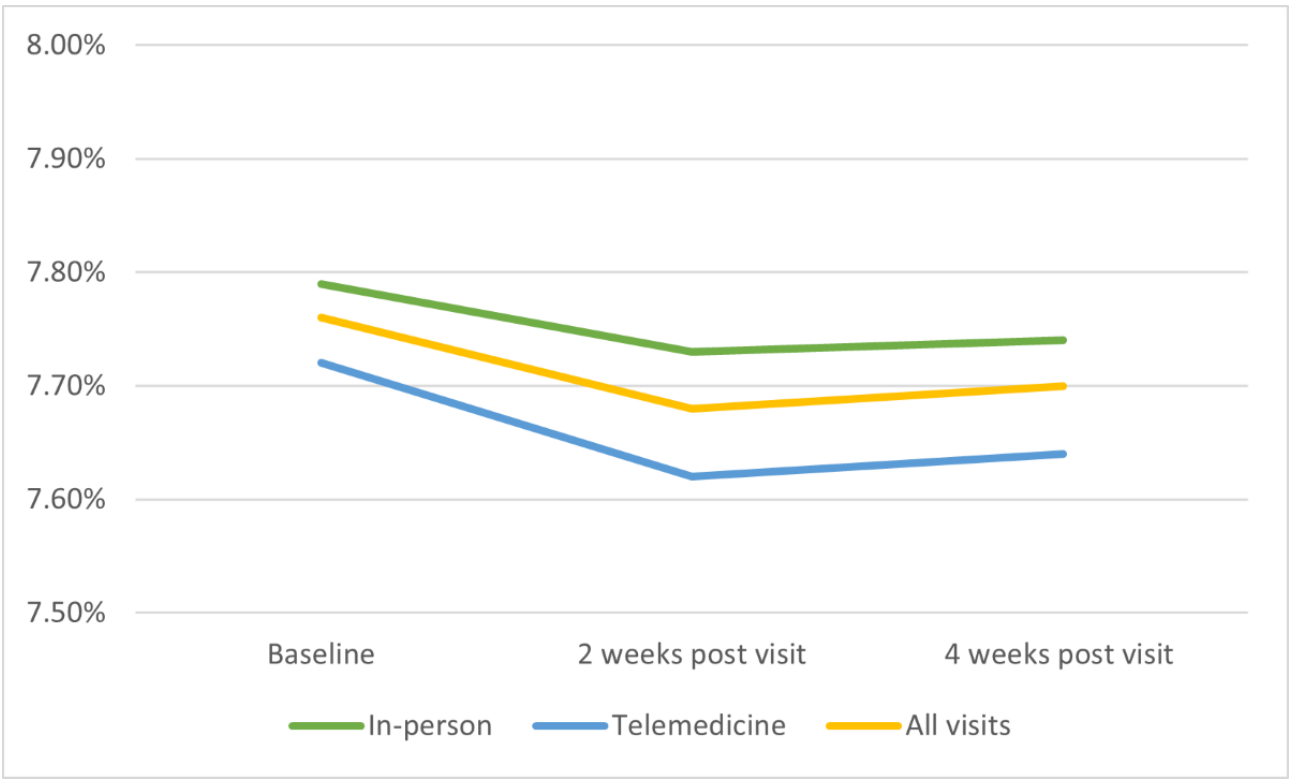


Figure 3. Glucose management indicator.



Discussion

Principal Findings

Our study demonstrated a statistically significant improvement in both TIR and GMI at 2 and 4 weeks after outpatient type 1 diabetes visits compared with baseline values during 4 weeks before. This improvement was observed even after adjusting for patient demographics and study site and was similar by visit modality, indicating that clinically stable pediatric patients using CGM from diverse backgrounds can have immediate improvement in glycemic control following both telemedicine and in-person visits. While not statistically significant, there were greater improvements in TIR and GMI in the immediate

2-week postvisit period, with a slight reversal toward baseline at the 4-week period. Possible explanations include recency of reviewed diabetes education at the outpatient visit (ie, decreased retention of information over time), or potential decrease in motivation to follow recommendations as more time elapsed following a clinical encounter. This would be expected to be more prominent for patients on multiple daily injections since with insulin pump therapy, settings are programmed directly into the pump which alleviates some patient burden for remembering and incorporating dose adjustments. This may result in a greater likelihood for the patients on pumps to be compliant with current insulin regimen recommendations. Regardless, an overall improvement in both TIR and GMI was maintained at 4-weeks post visit, though the magnitude of these changes was small. Goal TIR is typically at least 70% and extrapolating GMI to HbA_{1c} targets suggest an ideal value of <7% (53 mmol/mol) for most pediatric patients [2,11]. This reinforces a need for multiple outpatient visits or insulin regimen adjustments over time to attain a clinically relevant, maintained change in TIR or GMI.

We found no significant difference in improvements in our CGM parameters of interest between patients seen in-person versus by telemedicine. Previous studies have shown that telemedicine is not inferior to in-person visits in terms of key diabetes clinical outcomes among patients on CGM [16]. A likely reason is that data provided by CGM can be easily generated and transmitted remotely, and thus, easily incorporated into a telemedicine type 1 diabetes outpatient visit. Therefore, when CGM data are available, the option for telemedicine encounters in patients who are clinically stable can be a viable alternative to traditional in-person assessment.

Completion of screening laboratory tests was significantly higher among patients seen in-person compared with those seen through telemedicine. This may be explained by the accessibility of on-site laboratory tests available to patients seen in-person (ie, blood samples in the laboratory can be conveniently collected after the visit). Patients seen in-person at UCLA always had access to an on-site laboratory, while only patients with public insurance seen at MCH could have blood drawn in the laboratory on site due to insurance contracts. Because not all pediatric endocrinology practices have access to an on-site laboratory, our findings may not be wholly generalizable. Two recent articles identified a similar pattern in adults, both reporting that patients had statistically higher completion of recommended laboratory tests if seen in-person versus by telemedicine [20,21]. These findings suggest that some degree of in-person visits remain beneficial to facilitate the completion of screening laboratory tests, and so perhaps a hybrid approach of using both telemedicine and periodic in-person evaluations would be appropriate.

Diabetic emergencies occurred too infrequently to meaningfully analyze in our data set (episodes occurred following 0.8% of visits). Certainly, this is influenced by the inclusion criteria of last HbA_{1c} <10% as poorly controlled patients are at much higher risk for hyperglycemia-related emergency department visits and hospitalizations. Another possible explanation could be the previously reported protective nature of CGM use. This was reiterated by a recent publication from the type 1 diabetes exchange data showing that CGM users were about one third as likely to endure a diabetic ketoacidosis event compared with nonusers [22].

Baseline TIR and GMI values farther from goal were associated with greater magnitude of change. This is not surprising as these patients inherently have more room for improvement. Also, while maximizing TIR is an appropriate goal in all patients, minimizing GMI in those with near optimal control can come at the cost of more frequent hypoglycemic episodes. However, we cannot exclude that a regression to the mean may also contribute to the bigger improvement in those with worse baselines. Pump use was also associated with greater improvement in TIR from baseline, although not in GMI. This implies that patients using insulin pumps had more blood sugars centered within the target range, while not necessarily affecting average blood sugar. This decreased variability has been historically reported in patients on insulin pumps, and intuitively makes sense if using a hybrid-closed loop algorithm that acts to mitigate both hypo- and hyperglycemia [23].

Our study design had several key strengths including a diverse patient population across both centers representing a spectrum of pediatric ages, durations of disease, and insurance types. Furthermore, within the study period many patients were seen by both telemedicine and in-person visits which mitigated potential patient demographic differences when comparing visit modality. However, there are several notable limitations of this study. This was a retrospective analysis of EHR data so our findings are subject to confounding factors that may have contributed to the patient or health care team decisions on whether to perform an in-person or telehealth visit. In addition, our results are limited to patients who met inclusion criteria of using Dexcom CGM with most recent HbA_{1c} <10%, and therefore may not be generalizable to children and adolescents using other CGM devices or traditional finger sticks for glucose monitoring, with lower CGM adherence rates, or with higher HbA_{1c} levels. Furthermore, there is potential for sampling bias since patients already using CGM to manage diabetes may have increased motivation or investment in their care to follow recommendations from outpatient encounters which could manifest as improved clinical outcomes. In addition, since rates of completion of screening laboratory tests were measured by being up to date by the following visit, it includes visits in which patients were not due for any screening laboratory tests and so it is possible that our 2 cohorts already had a baseline difference in the necessity for screening laboratory testing. Finally, our data are limited to 269 total patient encounters and therefore, larger scale and prospective trials are needed to verify our findings as well as to adequately analyze the risks of low frequency events such as diabetes emergencies.

Conclusion

Our study found small but statistically significant improvements in TIR and GMI within 2-4 weeks following outpatient pediatric type 1 diabetes visits, which was not statistically different whether conducted in-person or through telemedicine. Because of the small magnitude of these changes, subsequent visits and CGM reviews remain important to achieve clinically relevant

improvements over time. However, our study found that completion of screening laboratory tests occurred more often following in-person visits which highlights the importance of alternating between periodic telemedicine and in-person visits at a frequency according to individual patient care needs. Since multiple outpatient visits are necessary for a clinically meaningful and maintained impact on glycemic control, hybrid approaches using both telemedicine and in-person visits for type 1 diabetes care in pediatric patients to improve access to care and visit efficiency is an area in need of further study.

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Authors' Contributions

CF contributed to conceptualization, methodology, investigation, data curation, writing-original draft preparation, visualization, and project administration. SDM contributed to conceptualization, methodology, writing-review and editing, visualization, and supervision. TM contributed to conceptualization, methodology, writing–review and editing, visualization, and supervision. HW conducted formal analysis, resources, data curation, and writing–review and editing. RH contributed to conceptualization, methodology, writing–review and editing, visualization, and supervision.

Conflicts of Interest

None declared.

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Abbreviations

CGM: continuous glucose monitor
EHR: electronic health record
GMI: glucose management indicator
HbA1c: hemoglobin A1c
ICD-10: International Statistical Classification of Diseases, Tenth Revision
MCH: Miller Children's and Women's Hospital
TIR: time in range
UCLA: University of California, Los Angeles

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Original Paper

A Self-Guided Web-Based App (MyDiaMate) for Enhancing Mental Health in Adults With Type 1 Diabetes: Insights From a Real-World Study in the Netherlands

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Abstract

Background: MyDiaMate is a web-based intervention specifically designed for adults with type 1 diabetes (T1D) that aims to help them improve and maintain their mental health. Prior pilot-testing of MyDiaMate verified its acceptability, feasibility, and usability.

Objective: This study aimed to investigate the real-world uptake and usage of MyDiaMate in the Netherlands.

Methods: Between March 2021 and December 2022, MyDiaMate was made freely available to Dutch adults with T1D. Usage (participation and completion rates of the modules) was tracked using log data. Users could volunteer to participate in the user profile study, which required filling out a set of baseline questionnaires. The usage of study participants was examined separately for participants scoring above and below the cutoffs of the "Problem Areas in Diabetes" (PAID-11) questionnaire (diabetes distress), the "World Health Organization Well-being Index" (WHO-5) questionnaire (emotional well-being), and the fatigue severity subscale of the "Checklist Individual Strength" (CIS) questionnaire (fatigue). Two months after creating an account, study participants received an evaluation questionnaire to provide us with feedback.

Results: In total, 1008 adults created a MyDiaMate account, of whom 343 (34%) participated in the user profile study. The mean age was 43 (SD 14.9; 18-76) years. Most participants were female (n=217, 63.3%) and higher educated (n=198, 57.6%). The majority had been living with T1D for over 5 years (n=241, 73.5%). Of the study participants, 59.1% (n=199) of them reported low emotional well-being (WHO-5 score≤50), 70.9% (n=239) of them reported elevated diabetes distress (PAID-11 score≥18), and 52.4% (n=178) of them reported severe fatigue (CIS score≥35). Participation rates varied between 9.5% (n=19) for social environment to 100% (n=726) for diabetes in balance, which opened by default. Completion rates ranged from 4.3% (n=1) for energy, an extensive cognitive behavioral therapy module, to 68.6% (n=24) for the shorter module on hypos. There were no differences in terms of participation and completion rates of the modules between study participants with a more severe profile, that is, lower emotional well-being, greater diabetes distress, or more fatigue symptoms, and those with a less severe profile. Further, no technical problems were reported, and various suggestions were made by study participants to improve the application, suggesting a need for more personalization.

Conclusions: Data from this naturalistic study demonstrated the potential of MyDiaMate as a self-help tool for adults with T1D, supplementary to ongoing diabetes care, to improve healthy coping with diabetes and mental health. Future research is needed to explore engagement strategies and test the efficacy of MyDiaMate in a randomized controlled trial.

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KEYWORDS

type 1 diabetes; e-mental health; web based; self-help; real world; naturalistic; uptake; adoption; usage; mental health; distress; emotional well-being; cognitive behavioral therapy; internet-based cognitive behavioral therapy; Europe; Netherlands; Dutch

Introduction

Living with and self-managing type 1 diabetes (T1D) can be psychologically burdensome. Indeed, diabetes-related distress (diabetes distress) [1-3], depression [4], fatigue [5], and disordered eating [6] are frequently experienced by people with T1D. Emotional distress is associated with reduced quality of life and can negatively affect diabetes self-care and subsequent glycemic outcomes [7].

The significance of addressing mental health issues in diabetes care has gained increasing recognition over the years. Accordingly, psychological interventions specifically tailored to reduce psychological distress related to diabetes have been developed and shown to be effective [8,9]. These interventions may be more widely available when provided digitally, especially in settings where there is limited access to professional psychological support [10]. Self-guided digital interventions, that is, without any professional involvement, may help to expand reach at relatively low costs. Such digital self-help programs would be particularly suited for people with mild to moderate symptoms of distress, and with the advantage of providing flexibility and anonymity which could attract users who are normally unable or unwilling to seek help [11-14]. However, uptake and engagement with self-guided applications for mental health may be challenging [15].

Over the past years, numerous digital interventions for people with diabetes have been developed focusing on lifestyle changes and blood glucose control, that do not address coping with the psychological burden of T1D [16]. To fill this gap, we worked with end users and professionals to develop MyDiaMate, a fully self-guided web-based intervention specifically designed for adults with diabetes that aims to help them maintain and improve their mental health. MyDiaMate was pilot-tested, confirming its acceptability, feasibility, and usability [17].

Before evaluating the efficacy of MyDiaMate and subsequently embedding MyDiaMate into routine diabetes care, it can be useful to examine its performance in a naturalistic setting. This can improve our understanding of the potential uptake, user profiles, and user behaviors that can give directions to the further development of effective strategies for engagement and dissemination [12,18]. The main purpose of this study, therefore, was to investigate the uptake and usage of MyDiaMate in the Netherlands for the duration of 21 months. To gain more insight into the characteristics and experiences of the users, we offered the option to participate in a user profile study. This would allow us to explore the associations between user characteristics and user behaviors.

Methods

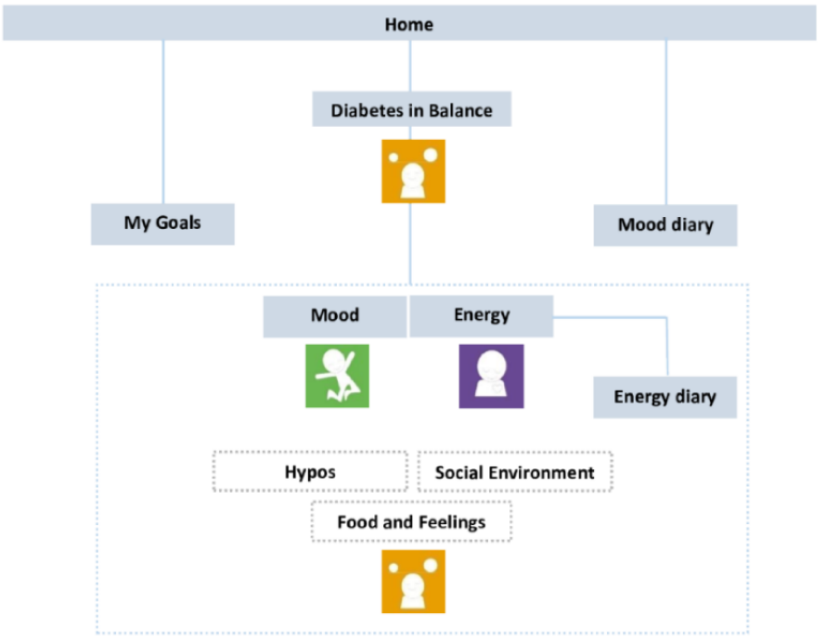
MyDiaMate

MyDiaMate is a web-based, multimodular self-help application, designed to assist adults with diabetes in preserving and improving their mental health. The development process of the app and content has previously been described in detail [17]. MyDiaMate is largely psychoeducational in nature and covers a range of topics known to be sources of diabetes distress—coping with the daily demands of self-managing diabetes; fear of hypo's and worries about complications; problems around social interactions and communication with others, including medical professionals; and 2 more in-depth modules tapping into "Mood" and "Energy," both of which are based on guided internet-based (cognitive behavioral therapy) interventions for people with diabetes, depression, and fatigue, respectively [5,19]. "Diabetes in Balance" is presented as the starting module and finishes with the recommendation to proceed with any of the following modules in any preferred order.

Originally intended for individuals with type 1 or type 2 diabetes, MyDiaMate's content was modified to specifically target T1D, based on user feedback in the pilot study. In December 2021, we launched a second version of the app based on user feedback, where we reduced the density of content in the diabetes in balance module by separating out the sections on "Social Environment" and "Hypos," and added a "Food and Feelings" module addressing problematic eating in relation to diabetes, and included 9 patient testimonial videos to enhance user engagement across different modules. Figure 1 visually demonstrates the app's 2 versions.

MyDiaMate is offered on an eHealth platform, using the Minddistrict Content Management System [20]. It can be used on a laptop, tablet, or a mobile phone (iOS and Android) as preferred. The program offers different features known to promote active use, such as goal setting, exercises, tips, quotes, milestones, a mood diary, and an energy diary including notifications, and links to resources. "My Goals" is a tool that can be used parallel to the other modules, to help formulate a personal goal for the duration of the program. At the end of the different modules, users are offered self-reflection questions, that prompt an answer to help the user decide what next step to take—to continue working in a specific module, to promote further progress, or engage in other modules to assist them in resolving specific problems. For example, the mood or energy modules are suggested when experiencing low mood or persistent symptoms of fatigue. The 6 modules of MyDiaMate differ in terms of richness of content and reading time, and thus the participants' effort required to complete. The estimated reading time for the modules varies between 5 minutes for hypos and 34 minutes for energy. The latter was developed to be followed over several weeks and to be stopped depending on progress in reducing symptoms of fatigue.

Figure 1. Content and structure of release 1 and release 2 of MyDiaMate. In release 2, the modules hypos and social environment were separated from the diabetes in balance module, and the food and feelings module was added.



Study Procedure

Between March 2021 and December 2022, MyDiaMate was offered freely to adults with T1D in the Netherlands via the Minddistrict platform. The launch of the app was announced via different diabetes organizations in the Netherlands on their websites and social media platforms. Health care professionals within our network were informed about the possibility of joining the study. We developed a website with information on MyDiaMate for potential users, health care professionals, and the general public. It was used as a hub to link to the Minddistrict platform, where an individual account could be created. Certified health care professionals could request access via email to a separate platform to get acquainted with MyDiaMate outside the study. Information on the duration of the MyDiaMate project, ending in December 2022, was mentioned on the website.

Ethical Considerations

After signing informed consent, at the start of MyDiaMate, users could volunteer to participate in the user profile study. Participation required filling out a set of questionnaires at the start and filling out an evaluation questionnaire 2 months after creating a MyDiaMate account. The questionnaires were sent out via the secured survey platform Castor Electronic Data Capture (EDC). For technical issues, participants could email the research coordinator (JE). The study protocol was approved by the Medical Ethics Committee of VU University Medical Center (2021.0007).

Outcome Measures

Uptake

Uptake of MyDiaMate was registered by observing the number of monthly created MyDiaMate accounts.

Usage

The usage of MyDiaMate was studied based on user log data. A user of MyDiaMate was defined as having an account and having at least opened the starting module diabetes in balance. The participation rate was determined by assessing the number of users who opened the first page of each module, based on the total number of app users for each release. The completion rate was determined by evaluating the number of users who opened the final page of each module, based on the number of users who opened each module.

User Profile

For those who consented to take part in the user profile study, we collected sociodemographic data (age, sex, education, and living status), history or current psychological symptoms, and current psychological treatment at baseline. Furthermore, we measured emotional well-being with the 5-item “World Health Organization Well-being Index” (WHO-5) [21]. Diabetes distress was measured with the 11-item “Problem Areas in Diabetes” questionnaire (PAID-11) [22]. Fatigue was measured with the 8-item fatigue severity subscale of the “Checklist Individual Strength” (CIS) questionnaire [23]. A WHO-5 score of less than 50 (range 0-100), indicates poor emotional well-being [21], a PAID-11 score of score of 18 or higher (range 0-44) suggests elevated diabetes distress [22] and a CIS subscale score of 35 or higher (range 8-56) indicates severe fatigue [5].

Usage by Profile

Participation and completion rates of diabetes in balance, mood, and energy were determined for all study participants (scoring above and below the cutoffs: PAID-11 score≥18 [diabetes distress], WHO-5 score≤50 [emotional well-being], and CIS score≥35 [fatigue]).

User Experiences

To assess experience and satisfaction with MyDiaMate, we measured user expectations at the start and user-friendliness, satisfaction with the number of notifications linked to the mood and energy diary, and clarity of instructions at follow-up. Likert scales ranging from 1 “completely disagree” to 5 “completely agree” were used, with higher scores indicating higher satisfaction. Participants were asked to grade MyDiaMate on a scale from 1 to 10, with higher scores representing higher appreciation. We used an open-ended question to ask for any remarks or recommendations for further improvement.

Statistical Analysis

The usage of MyDiaMate was summarized using descriptive statistics. Baseline measures of the user profiles were summarized using mean and SD or frequencies and percentages in the case of categorical data. The answers to the open-ended question regarding the user experience were thematically grouped. The chi-square tests were used to look at differences between study participants scoring above and below the PAID-11, WHO-5, and CIS cutoff points in terms of how many of them opened the first and final page of each module. SPSS (version 28.0; IBM Corp) was used to conduct the analyses.

Results

Uptake

In total, 1008 people created a MyDiaMate account. Among them, 798 accounts were created during the first release of MyDiaMate, with 497 accounts initiated within the first month. The second release saw 210 new accounts, of which 41 accounts were created in the first month following the release. There was a steady increase of new MyDiaMate accounts each month.

Usage

Out of the 1008 persons that created an account, 926 actually opened the first module and were classified as users. Their usage data are displayed in Table 1. A total of 726 accounts opened the default module diabetes in balance during the first release and 200 opened diabetes in balance during the second release of MyDiaMate.

Table 1. Usage data (participation rate and completion rate; n=926).

Module	Values (number of pages/estimated reading time in minutes)	Opened (participation), n (%)	Closed (completion)[a], n (%)
First release (n=726)			
Diabetes in balance	37/31	726 (100.0)	207 (28.5)
Mood	38/24	124 (17.1)	30 (24.2)
Energy	55/34	142 (19.6)	9 (6.3)
Second release (n=200)			
Diabetes in balance	26/24	200 (100.0)	62 (31.0)
Social environment	9/6	19 (9.5)	12 (63.2)
Hypos	10/5	35 (17.5)	24 (68.6)
Mood	38/24	23 (11.5)	6 (26.0)
Energy	55/34	23 (11.5)	1 (4.3)
Food and Feelings	14/11	46 (23.0)	23 (50.0)
My Goals	1/0.5	167 (18.0)	N/A[b]
Mood diary	1/0.5	133 (14.4)	N/A
Energy diary	1/0.5	5 (0.5)	N/A

[a]Based on the number of users who opened the associated module, the completion rate estimates the percentage of users who completed the module.

[b]N/A: not applicable.

User Profile

Table 2 provides the demographic and diabetes-related characteristics of the participants in the user profile study. Most participants were female (n=217, 63.3%) and higher educated (n=198, 57.6%). The mean age was 43 (SD 14.9; 18-76) years. The majority had been living with T1D for over 5 years (n=241, 73.5%). Of the study participants, 59.1% (n=199) reported low emotional well-being (WHO-5 score≤50), 70.9% (n=239) reported elevated diabetes distress (PAID-11 score≥18), and 52.4% (n=178) reported severe fatigue (CIS score≥35); 21.9% (n=75) reported to currently receiving psychological treatment. Of those participants who reported currently not receiving psychological treatment (78.1%, n=267), 171 (50.7%) participants reported elevated diabetes distress, 141 (41.8%) participants reported low emotional well-being, and 127 (37.4%) participants reported severe fatigue. Over 60% (n=208) stated that the diabetes care team pays enough attention to their feelings with regard to diabetes. As to the expectations regarding MyDiaMate, all precoded responses were endorsed, with the highest for “gaining new insights” and “helping me cope better with diabetes.”

Table 2. Demographic and diabetes-related characteristics of participants of the user profile study.

Characteristics	Participants
Age (n=342; years)	
Mean (SD)	43 (14.9)
Range	18-76
Sex (n=343), n (%)	
Female	217 (63.3)
Different	1 (0.3)
Educational level (n=343), n (%)	
Lower secondary education	3 (0.9)
Higher secondary education	129 (37.5)
Secondary vocational education	13 (3.8)
Tertiary education (bachelor, master, or equivalent)	198 (57.6)
Living status (n=343), n (%)	
Alone	57 (16.6)
With 1 or more persons	286 (83.1)
Time of diagnosis of type 1 diabetes[a] (n=328), n (%)	
Less than 12 months ago	24 (7.3)
1 to 3 years ago	37 (11.3)
3 to 5 years ago	26(7.9)
Longer than 5 years ago	241 (73.5)
How did you hear about MyDiaMate? (Multiple answers possible), n	
Health professional	38
Social media	162
MyDiaMate website	118
Friend, family, or acquaintance	32
I am worried about my diabetes regulation (n=342), n (%)	
I strongly agree	72 (20.9)
I agree	173 (50.3)
I disagree	83 (24.1)
I strongly disagree	14 (4.1)
I expect MyDiaMate to...(multiple answers possible), n	
To help me relax	127
To help me regain energy	137
To improve my mood	122
To help me better cope with diabetes	166
To gain new insights	170
I am currently undergoing treatment for psychological complaints (n=342), n (%)	
Yes	75 (21.9)
No	267 (78.1)
My diabetes care team pays enough attention to my feelings with regard to diabetes (n=342), n (%)	
Yes	208 (60.8)
No	134 (39.2)
Elevated scores of baseline questionnaires, n (%)	

Characteristics	Participants
WHO-5[b] (≤50; n=337)	199 (59.1)
PAID-11[c] (≥18; n=337)	239 (70.9)
CIS[d] (≥35; n=340)	178 (52.4)

[a]14 participants reported having a different type of diabetes.

[b]WHO-5: World Health Organization Well-being Index.

[c]PAID-11: Problem Areas in Diabetes.

[d]CIS: Checklist Individual Strength.

Usage by User Profile

Due to the small sample size, data from the second release was excluded from the analyses concerning the link between user profiles and usage data. See Multimedia Appendix 1 for the user profile of study participants from the first release and the second release. Tables 3-5 show data from usage of diabetes in balance, mood, and energy, during the first release, differentiating between participants scoring above and below the cutoffs of PAID-11 (diabetes distress), WHO-5 (emotional well-being), and CIS (fatigue). The chi-square tests showed no significant differences for the usage of study participants scoring above and below the cutoffs, in terms of participation and completion rates.

Table 3. Usage data (participation rate and completion rate) of participants stratified by diabetes distress (PAID-11[a] cutoff score ≥18[b]; n=289).

Modules	First page opened (participation), PAID-11 score				Final page opened (completion), PAID-11 score			
	≥18 (n=203), n (%)	<18 (n=86), n (%)	Chi-square (*df*)	*P* value	≥18 (n=203), n (%)	<18 (n=86), n (%)	Chi-square (*df*)	*P* value
Diabetes in balance	203 (100)	86 (100)	N/A[c]	N/A	79 (38.9)	37 (43)	0.4 (1)	.52
Mood	44 (21.7)	15 (17.4)	0.7 (1)	.41	12 (5.9)	5 (5.8)	0.7 (1)	.20
Energy	51 (25.1)	14 (16.3)	2.7 (1)	.10	18 (8.9)	4 (10.8)	0.2 (1)	.64

[a]PAID-11: Problem Areas in Diabetes.

[b]PAID-11 ≥18 indicates elevated diabetes distress.

[c]N/A: not applicable.

Table 4. Usage data (participation rate and completion rate) of participants stratified by emotional well-being (WHO-5[a] cutoff score ≤50[b]; n=289).

Modules	First page opened (participation), WHO-5 score				Final page opened (completion), WHO-5 score			
	≤50 (n=170), n (%)	>50 (n=119), n (%)	Chi-square (*df*)	*P* value	≤50 (n=170), n (%)	>50 (n=119), n (%)	Chi-square (*df*)	*P* value
Diabetes in balance	170 (100)	119 (100)	N/A[c]	N/A	61 (35.8)	55 (46.6)	3.1 (1)	.08
Mood	37 (21.8)	22 (18.6)	0.5 (1)	.50	10 (5.9)	7 (5.9)	0.2 (1)	.69
Energy	26 (15.3)	39 (33.1)	0.0 (1)	.83	15 (8.8)	7 (5.9)	0.9 (1)	.34

[a]WHO-5: World Health Organization Well-being Index.

[b]WHO ≤50 indicates poor emotional well-being.

[c]N/A: not applicable.

Table 5. Usage data (participation rate and completion rate) of participants stratified by fatigue (CIS[a] cutoff score ≥35[b]; n=291).

Modules	First page opened (participation), CIS score				Final page opened (completion), CIS score			
	≥35 (n=147), n (%)	<35 (n=144), n (%)	Chi-square (*df*)	*P* value	≥35 (n=147), n (%)	<35 (n=144), n (%)	Chi-square (*df*)	*P* value
Diabetes in balance	147 (100)	144 (100)	N/A[c]	N/A	55 (37.4)	61 (42.4)	0.7 (1)	.39
Mood	30 (20.4)	29 (20.1)	0.1 (1)	.82	8 (5.4)	9 (6.3)	0.0 (1)	.84
Energy	31 (21.1)	33 (22.9)	0.1 (1)	.71	13 (8.8)	9 (6.3)	1.5 (1)	.22

[a]CIS: Checklist Individual Strength.

[b]CIS ≥35 indicates severe fatigue.

[c]N/A: not applicable.

User Experiences

Not a single technical problem was reported. A total of 53 study participants made use of the option to provide us with their feedback. MyDiaMate was rated with a median of 6.5 (IQR 6-8; range 3-9) on a 1-10 scale. Suggestions for further development of the app included shortening the amount of text, simplifying the text, and including more clarifying examples and video materials, along with the suggestions to offer reminders within modules and to further explore options for personalization within MyDiaMate.

Discussion

Principal Findings

Here we presented the results of a real-world study on the uptake and use of MyDiaMate, which was offered freely to adults with T1D in the Netherlands for a period of 21 months. We collected data on user profiles and user experiences of a self-selected group of participants. Over nearly 2 years, a total of 1008 unique accounts were created, accounting for roughly 1% of the total population of adults with T1D in the Netherlands [24]. But it should be noted that approximately a third of adults with T1D experience elevated diabetes distress and may benefit from some sort of psychosocial support [1-3]. The number of unique MyDiaMate accounts created each month demonstrates that despite only 2 short promotional campaigns that mostly took place via (social) media channels, we were able to reach a sizable audience. These findings suggest good potential for reaching the population of adults with T1D and coping difficulties. Of note in this context is the fact that MyDiaMate was not in any way integrated into the health care system and indeed only a few users reported having heard about MyDiaMate from their health care provider. We can expect a larger reach of MyDiaMate were it to be embedded in routine diabetes care and actively promoted by clinicians.

Usage data, including participation and completion rates of the modules, showed large variations. Participation rates ranged from 9.5% (n=19) for social environment to 100% (n=726) for diabetes in balance. The latter was accessible from the home page, and opened by default. The other modules may have been opened less frequently for a variety of reasons including low perceived need, and the extra effort required to open the modules, as users have to navigate to the catalog and open the module on a different page. Completion rates ranged from 4.3% (n=1) for energy, which is an extensive cognitive behavioral therapy module, to 68.6% (n=24) for the shorter module on hypos. This suggests a higher risk of attrition for longer and more intensive modules, at least without offering reminders or guidance. It is well-known that self-guided e–mental health programs run a higher risk of attrition compared to guided intervention, particularly those requiring more effort, that is, motivation from the user side [25]. Of course, we should acknowledge that not completing a module can be a rational choice of the user, in case sufficient progress has been made and, therefore, low perceived need to continue using the module. Since we did not survey our users on this topic, we cannot be certain as to the causes of incompletion. To further our understanding, qualitative interviews with end users should prove helpful. Here it would also be interesting to gain more insight into how and at what time of the day the app is used, and explore the potential of ecological momentary assessment [26].

The engagement (as observed by participation and completion rates) in this study was lower compared to what was found in the feasibility study of MyDiaMate. This difference could be explained by the fact that this study was set out to be naturalistic, fully relying on self-referral, and without a clear presence of the academic institution conducting the study, or a study coordinator. In traditional research settings (such as in the feasibility study) there is a higher chance of recruiting people who already are more likely to adhere to e–mental health interventions, than people in the general population who install and try available interventions “in the wild” [12,27]. Therefore, we cannot rule out the possibility that a proportion of the accounts created were from people who were just curious to see the application, rather than having a real need and the intention to actually invest in working through the various modules. This may have inflated our results.

Indeed, we also found higher mean completion rates of modules in individuals who volunteered to participate in the profile study (those who partly agreed to participate in traditional research), compared to the total user group. Whereas self-selection is intrinsic to a fully self-guided app, the experienced lack of human contact may at least partly be resolved by adding a conversational user interface, that is, a chatbot. While not preferred by all, and issues around psychological distance and trust exist, studies on chatbots in digital mental health applications show promising results [28-30]. Also, adding

optional online peer support groups may be helpful in this respect, and deserves to be further explored.

User profile data collected at baseline showed that the majority of the participants expressed concerns about their diabetes regulation, and reported low emotional well-being and high diabetes distress and fatigue, while the vast majority (78.1%) reported they were not receiving psychological treatment at the time. This indicates an unmet need for psychological support. It is not part of this study but it would be interesting to see whether MyDiaMate impacts self-awareness and stimulates participants to seek professional psychological help when needed [31].

Interestingly, in this study, we did not find evidence to suggest that study participants with a more severe profile, that is, lower emotional well-being, greater diabetes distress, or more fatigue symptoms had lower participation or completion rates of the modules than those with a less severe profile. The level of severity has previously been shown not to moderate the efficacy of (guided) online depression treatment in diabetes and apparently is not critical for developing engagement-enhancing strategies, provided the user is sufficiently motivated [32-34].

Finally, we observed a large variety in user experiences and feedback, ranging from tips on how to shorten the amount of text, to adding more text examples and videos. Additionally, we noted that users' expectations for MyDiaMate varied, which might explain the variance in the satisfaction ratings of the app. Accommodating individuals' wishes and needs speaks to the relevance of personalization which is a challenge with a fully self-guided application such as MyDiaMate. Clearly, tailoring content and reminders to users' individual preferences is key and deserves further research [35]. To this purpose, a baseline assessment of problem areas and preferences could help to offer personalized advice on which modules of MyDiaMate might be most relevant and customized reminders.

Strengths and Limitations

We succeeded in conducting a real-world study to demonstrate the potential uptake and usage of the intervention in the target population. This is a strength, given that many internet or mobile-based interventions developed for people with chronic medical conditions strand at the pilot-testing phase [36]. Our study has some limitations that are worth mentioning.

First, for pragmatic reasons, we decided to release a second version of MyDiaMate to improve our users' experience during this naturalistic study. Although in line with the principles of iterative development of digital health applications [37], this did complicate data analysis of the total usage and led us to limit part of the analyses to the first version.

Second, although we provided health care professionals with the opportunity to test MyDiaMate on a separate platform (and 69 professionals made use of this), we cannot rule out the possibility that more health care professionals and others without T1D created a MyDiaMate account and that, therefore, their usage data are included in the analyses.

Third, we only collected data on user profiles of roughly a third of the total group of MyDiaMate users. We should, therefore, be cautious in generalizing our findings to the larger audience, although user behaviors (based on log data) did not appear to be different from the total group. Also, for self-guided interventions, dissemination through web-based marketing appears to be considerably more efficient and cost-effective than dissemination through clinics or pharmacies [38]. MyDiaMate was, therefore, mostly advertised through social media, attracting predominantly those individuals who engage active on such platforms. This was further supported by the survey, indicating that the majority of users were informed about the app through social media, while only a small group learned about it from their health providers. Furthermore, as in many internet-based intervention programs, higher educated people and women were overrepresented in the user-profile study, limiting external validity [38].

To expand and broaden future dissemination, efforts should be made to reach a more diverse user group, taking eHealth literacy, socioeconomic status, and ethnicity into consideration. Health care providers can play a significant role in promoting the use of MyDiaMate supplementing routine diabetes care. For the maintainability of the app, reimbursement should be in place, preferably as an integral part of diabetes care. Alternatively, the app could be made accessible to consumers at a low price to cover maintenance costs and updates. Clearly, demonstrating cost-effectiveness should help to convince health authorities to financially compensate use of the application. eHealth literacy is an important factor to take into consideration when aiming to maximize the reach of a self-guided web-based intervention such as MyDiaMate. This would call for targeted promotional activities to increase the uptake and involvement of a diverse user group in further improving the cultural validity of the intervention [39].

Finally, the study did not set out to evaluate the intervention's efficacy, which is now the next step, also looking into potential moderators and mediators of effectiveness. Evidence of efficacy will be important to help gain reimbursement and foster the dissemination of MyDiaMate on a larger scale. Here we need to recognize that given the level of distress of the target population, small effects are to be expected, that however, are likely to have clinical relevance from a public mental health perspective [40].

Conclusions

The findings of this naturalistic study demonstrate the potential of MyDiaMate as a self-help tool for adults with T1D supplementary to ongoing diabetes care, to improve healthy coping with diabetes and mental health. Future research is warranted to explore effective strategies to enhance engagement with the app and test the efficacy of MyDiaMate in a randomized controlled trial.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic and diabetes-related characteristics of participants of the user profile study, releases 1 and 2.
[DOCX File , 16 KB - diabetes_v9i1e52923_app1.docx]

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Abbreviations

CIS: Checklist Individual Strength
EDC: Electronic Data Capture
PAID-11: Problem Areas in Diabetes
T1D: type 1 diabetes
WHO-5: World Health Organization Well-being Index

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Original Paper

Service Users' Experiences of a Nationwide Digital Type 2 Diabetes Self-Management Intervention (Healthy Living): Qualitative Interview Study

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Abstract

Background: Diabetes Self-Management Education and Support programs for people living with type 2 diabetes mellitus (T2DM) can increase glycemic control and reduce the risk of developing T2DM-related complications. However, the recorded uptake of these programs is low. Digital self-management interventions have the potential to overcome barriers associated with attendance at face-to-face sessions. *Healthy Living* is an evidence-based digital self-management intervention for people living with T2DM, based on the Healthy Living for People with Type 2 Diabetes (*HeLP-Diabetes*) intervention, which demonstrated effectiveness in a randomized controlled trial. NHS England has commissioned Healthy Living for national rollout into routine care. Healthy Living consists of web-based structured education and *Tools* components to help service users self-manage their condition, including setting goals. However, key changes were implemented during the national rollout that contrasted with the trial, including a lack of facilitated access from a health care professional and the omission of a moderated online support forum.

Objective: This qualitative study aims to explore service users' experiences of using Healthy Living early in the national rollout.

Methods: A total of 19 participants were interviewed via telephone or a videoconferencing platform. Topics included users' experiences and views of website components, their understanding of the intervention content, and the overall acceptability of Healthy Living. Transcripts were analyzed thematically using a framework approach.

Results: Participants valued having trustworthy information that was easily accessible. The emotional management content resonated with the participants, prompting some to book an appointment with their general practitioners to discuss low mood. After completing the structured education, participants might have been encouraged to continue using the website if there was more interactivity (1) between the website and other resources and devices they were using for self-management, (2) with health professionals and services, and (3) with other people living with T2DM. There was consensus that the website was particularly useful for people who had been newly diagnosed with T2DM.

Conclusions: Digital Diabetes Self-Management Education and Support programs offering emotional aspects of self-management are addressing an unmet need. Primary care practices could consider offering Healthy Living to people as soon as they are diagnosed with T2DM. Participants suggested ways in which Healthy Living could increase interaction with the website to promote continued long-term use.

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KEYWORDS

type 2 diabetes; digital interventions; behavior change; self-management; implementation; qualitative methods

Introduction

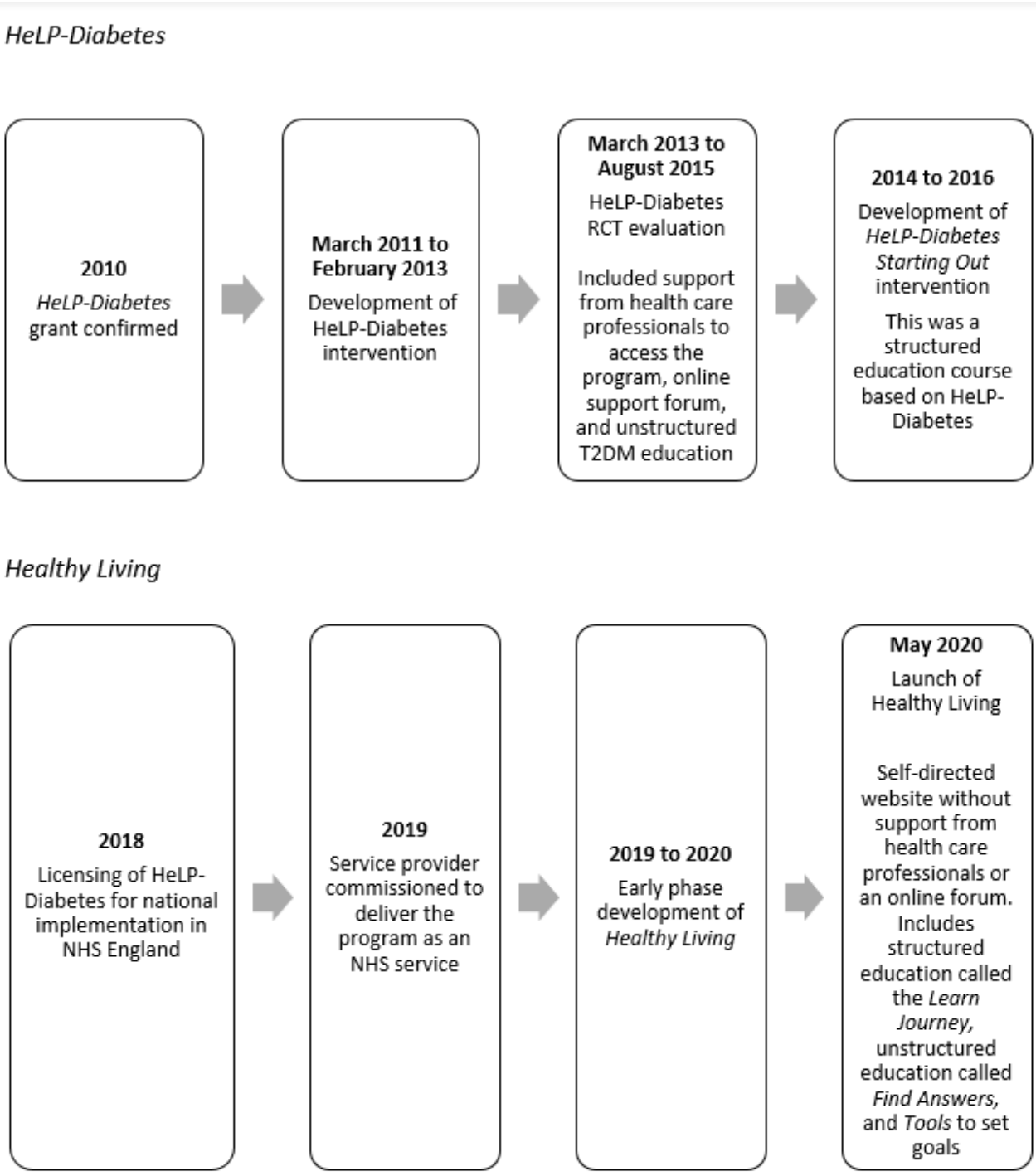
Background

People living with type 2 diabetes mellitus (T2DM) are at risk of developing a range of health complications, including loss of vision, nerve pain, limb amputation, and cardiovascular problems [1]. However, many of these complications can be prevented when individuals self-manage their condition effectively. Diabetes Self-Management Education and Support (DSMES) programs can provide information to guide behavior changes such as improving diet and increasing physical activity to support blood glucose control and learning to cope with negative emotions [2,3]. Systematic reviews have shown that DSMES programs improve service users' clinical and psychosocial outcomes (eg, improved glycemic management and improved diabetes knowledge) and reduce health care costs [3,4]. Therefore, DSMES programs are now recommended by the National Institute of Health and Care Excellence for all people diagnosed with T2DM [1].

DSMES programs are typically delivered via face-to-face group sessions (eg, Diabetes Education and Self-Management for Ongoing and Newly Diagnosed [5] and X-PERT Health [6] in the United Kingdom). However, recorded attendance at these face-to-face programs remains low globally [2]. For example, in the United States, only 6.8% of the people who were newly diagnosed with T2DM and held private health insurance attended a DSMES session within the first 12 months of diagnosis [7]. Figures are comparable in the United Kingdom, with only 7% of newly diagnosed patients with T2DM recorded as attending a session within their first year of diagnosis [8]. Further research in the United Kingdom has shown that younger people were less likely to attend a 9-month face-to-face behavior change program targeting the prevention of T2DM [9,10]. Digital interventions have the potential to address logistical challenges that attending face-to-face sessions might pose (eg, scheduling, travel, work, and childcare) [11], providing an alternative for those who do not want to attend group sessions [12], and thus may meet the needs of younger people. Therefore, NHS England has recently committed to expanding T2DM support through digital technologies and self-management programs [13].

A digital intervention designed to provide ongoing self-management support for people living with T2DM was Healthy Living for People with Type 2 Diabetes (*HeLP-Diabetes*). A randomized controlled trial (RCT) of HeLP-Diabetes found that the digital program was feasible to deliver, was acceptable to service users, reduced blood glucose, and was cost-effective for the National Health Service (NHS) [14]. HeLP-Diabetes was an unstructured program, which provided access to educational content without following a linear pathway [15]. Following this RCT, the researchers developed an additional structured educational component called *Help-Diabetes: Starting Out*, based on the content in the original HeLP-Diabetes website [16]. This additional development was due to changes in NHS policy in 2013, which stipulated that self-management programs were only eligible for accreditation if they followed a structured pathway with a clear curriculum (Figure 1).

Figure 1. Timeline of intervention development since 2010. HeLP-Diabetes: Healthy Living for People with type 2 diabetes; NHS: National Health Service; RCT: randomized controlled trial; T2DM: type 2 diabetes mellitus.



In 2019, NHS England commissioned a national rollout of a version of HeLP-Diabetes into routine health care [17] (Figure 1 [18]). The program is called *Healthy Living*, which has been developed and delivered by an external digital service provider as an NHS service [19] and includes the structured education component developed after the RCT. Access to Healthy Living is currently by self-referral and general practitioner (GP) referral, and it is a self-contained, self-directed service. Healthy Living is a web-based program that includes a structured education pathway (*Learn journey*) and a *Tools* section where service users can set goals; self-monitor their health (eg, diet, steps, weight, and blood glucose levels); and find answers to specific questions. The program includes behavior change techniques (the "active ingredients" of interventions to produce behavior change) [20] and self-management content based on those that were originally included in the HeLP-Diabetes intervention. The self-management content was guided by the Corbin and Strauss [21] model, which includes 3 types of tasks: medical management (eg, adopting healthy behaviors and taking medicines); emotional management (eg, managing emotions including anger, guilt, shame, and despair); and role management (eg, managing changes in relationships, work patterns, and day-to-day activities). Multimedia Appendix 1 [14,16,18,22-36] provides further information on the

development and content of Healthy Living, including screenshots of website content. A detailed description of the behavior change content in Healthy Living is described elsewhere [18].

Previous research from this program of work has assessed the extent to which the content of Healthy Living retained fidelity to the intervention content of the original HeLP-Diabetes RCT and identified reasons for changes implemented in the national rollout of Healthy Living [18]. This assessment found that Healthy Living had good fidelity to the behavior change techniques and self-management content of the HeLP-Diabetes RCT. However, there were key changes implemented during the national rollout that contrasted with the RCT, comprising (1) the inclusion of a structured web-based learning curriculum due to changes in the NHS policy, (2) a lack of facilitated access to the program from a health care professional due to fewer resources in general practice, and (3) the omission of a moderated online support forum due to low uptake in the HeLP-Diabetes RCT [14].

Given that Healthy Living has been rolled out nationally across England, it is important to understand how Healthy Living is experienced by service users and the extent to which the program is acceptable for people using the service. Previous qualitative research has investigated participant experiences of using the original HeLP-Diabetes intervention in the RCT. For example, participants who used HeLP-Diabetes reported feeling better informed and more aware of their T2DM self-management, and they valued the support they received from the program, including having access to health care professionals [37]. Further qualitative research on the structured education component, *HeLP-Diabetes: Starting Out*, suggested that the course was acceptable to service users, although completion rates were low, some of whom attributed this to competing priorities such as work and family responsibilities [16]. However, research is yet to obtain the views from service users who have not taken part in a trial, and we are yet to understand whether any of the changes in the current nationally implemented version of HeLP-Diabetes (eg, reduced interaction with health care professionals and other patients living with T2DM) have implications for service user experience. Furthermore, it is important to assess how the intervention content is understood, as this will impact program engagement and outcomes.

Objectives

This study aimed to explore service users' experiences of using Healthy Living. Specific objectives were to (1) understand the extent to which the different components of Healthy Living were acceptable to service users; (2) understand the contents of Healthy Living that the service users engaged with; (3) understand any barriers to engagement with, and use of, Healthy Living; and (4) investigate how the Healthy Living intervention material is understood ("intervention receipt") and how this impacts the use of intervention materials ("intervention enactment") [38].

Methods

Methods are reported in accordance with the Standards for Reporting Qualitative Research [39] (Multimedia Appendix 2).

Design

This study used a cross-sectional design, where semistructured qualitative interviews asked service users for their views about using Healthy Living.

Participants

Participants were people living with T2DM who had actively engaged with Healthy Living within the last 12 months (completed at least 30% of the structured education or set a goal using the Tools) to assess how the program was experienced by users and to ensure participants were able to answer the interview questions with sufficient detail.

Sampling and Procedures

The service provider delivering the intervention sent emails to cohorts of service users inviting them to complete a web-based screening survey (via REDCap [Research Electronic Data Capture]; Vanderbilt University) [40], which asked service users to fill out a demographic questionnaire and register their interest in taking part in an interview (Multimedia Appendix 3). Of those service users who registered their interest, a member of the research team (JSB) purposively sampled a selection of service users (aiming to achieve demographic diversity in age, gender, ethnicity, socioeconomic status, and time since T2DM diagnosis) to invite them to take part in an interview, before requesting the service provider to send the next batch of recruitment emails. This enabled us to review the demographic groups of users who had already been recruited and revise the email strategy accordingly (Multimedia Appendix 4). The selected service users were emailed an invitation to take part in an interview along with an information sheet. The recruitment strategy (eg, the wording of the recruitment email from the service provider and contents of the REDCap questionnaire) was discussed and refined with members of a Patient and Public Involvement and Engagement (PPIE) group before commencing recruitment. Of the 29 participants who were contacted to take part, 8 (28%) refused to participate (no response after contact: 3/8, 38%; participants felt they were unsuitable candidates for the interview: 3/8, 38%; participants did not remember signing up via the REDCap survey: 1/8, 12%; participants wanted a face-to-face interview: 1/8, 12%). A further 2 (7%) of the 29 participants took part in an interview, but it was apparent that they had taken part in a different program, so they were excluded from the final analysis.

One-to-one semistructured interviews were conducted by a male researcher (JSB; research associate) who had a PhD and training in qualitative methods. JSB described the aim of the study to participants as wanting to understand their experiences of using Healthy Living. Participants were interviewed via either telephone or a videoconferencing platform (Zoom; Zoom Video Communications, Inc), and complete informed consent was audio recorded before the interview. There were no individuals present during the interviews other than the researcher (in a private office) and the participant. Each interview was recorded

using an encrypted audio recorder, transcribed verbatim, and pseudonymized for analysis. Interviews lasted between 30 and 60 minutes. Recruitment was stopped when it appeared to the researchers (JSB and DPF) that no new content was being discussed in the final 2 interviews.

Materials

A topic guide was used to organize the semistructured interviews, with open-ended questions and additional probes (Multimedia Appendix 5). Questions were asked in line with the objectives, including service users' experiences of using Healthy Living and its components. Field notes were made following each interview.

Researcher Positioning

The researcher who conducted the interviews (JSB) had a background in health psychology and thus had a strong understanding of the type of behavior change support delivered to people living with long-term health conditions. This may have influenced some of the questions asked in the interviews (eg, with more focus on the individuals rather than wider socioeconomic status constraints). The lead author who analyzed the data (REH) also had a background in health psychology, with >5 years of experience working in diabetes prevention and self-management research.

The wider team (SC, CS, and DPF) has extensive experience conducting independent evaluations of large-scale behavior change programs, including T2DM projects. No members of the research team are currently living with T2DM. We worked closely with a PPIE group (n=8; female: n=5, 62%; male: n=3, 38%; all who were at risk of or living with T2DM). The PPIE group advised the research team on all patient-facing materials, including the wording of the interview schedule, and they advised on the recruitment strategy before data collection. They also provided feedback and interpretations of the findings during the analysis stages, including a discussion on the importance of interactive digital technology and the emotional management aspects of living with T2DM, which was incorporated into the final analysis.

Analysis

As we wanted to understand participants' views and experiences of specific features of the intervention that had been adapted for the national program implementation, we analyzed the data thematically and organized them using a framework approach [41]; this involved the development of a framework matrix that allowed for the comparison of findings across participants on key issues where relevant. Data were analyzed from a realist perspective, which assumes that the language used directly reflects participants' perception of their reality.

A coding framework was developed based on what had changed from the original HeLP-Diabetes RCT [18] and the National Institutes of Health Behavior Change Consortium framework to assess intervention receipt [38]. This informed the development of a priori thematic codes (eg, "understanding of self-management content," "enactment of educational content," and "online forum"). Additional codes were also developed inductively during data analysis to capture nuances in the data (eg, "support sought as a result of the program"). This approach allowed us to answer the specific research questions while allowing important insights to be produced inductively. Transcripts were coded to items in the coding framework (Multimedia Appendix 6) and then charted into a framework matrix by 1 researcher (REH), where a succinct description of what was coded for each item of the framework was summarized for each participant. This allowed for the comparison of findings across participant cases. Data were discussed among the authors to identify themes relevant to the research questions, with illustrative extracts and interpretive themes refined through discussion at regular analysis meetings. NVivo software (version 12; Lumivero) was used to facilitate the coding and analysis of the data.

Ethical Considerations

This study was reviewed and approved by the Yorkshire and the Humber–Leeds West NHS Research Ethics Committee (20/YH/0250). Interview data were deidentified during transcription. All participants provided complete informed consent before the interview. As a "thank you" for taking part in this research, participants could opt to receive £50 (US $65) compensation (either via a voucher or bank transfer).

Results

Overview

The 19 interviewees comprised almost even numbers of male (n=10, 53%) and female (n=9, 47%) participants and had a median age of 61 (IQR 53-73, range 43-81) years. The sample had little ethnic diversity but a good spread in terms of deprivation (Table 1). A total of 12 (63%) interviews took place via telephone and 7 (37%) took place via Zoom between October and December 2021.

Table 1. Participant characteristics (N=19).

Characteristic	Values
Age (y), median (IQR)	61 (53-73)
Sex, n (%)	
Female	9 (47)
Male	10 (53)
Ethnicity, n (%)	
Black British	1 (5)
White British	18 (95)
IMD[a] score, n (%)	
1 (least deprived)	2 (10.5)
2	6 (32)
3	5 (26)
4	4 (21)
5 (most deprived)	2 (10.5)
Time since diagnosis (y)	
Values, median (range)	5 (11 months-29 years)
Values, n (%)	
0-1	3 (16)
1-2	4 (21)
2-5	3 (16)
5-10	3 (16)
>10	6 (32)

[a]IMD: Index of Multiple Deprivation scores associated with the lower super output area derived from venue postcodes, ranging from the most deprived areas in England to the least deprived areas in England [42].

A total of 4 themes were generated from the analysis: information is there at the touch of a button; improved emotional management; experiences of structured education; and the importance of technological, professional, and social interactivity (Multimedia Appendix 7).

Theme 1: Information Is There at the Touch of a Button

Healthy Living was valued by participants, as it provided them with a trusted source of information that was "there at the touch of a button" (P6). The NHS branding of the website was perceived as crucial (P6, P10, P13, P16, and P17), especially by participants who had received conflicting information from other sources in the past (P13). Participants contrasted this to websites such as Facebook, which was described as a less-trusted source of information (P10 and P16). A participant stated as follows:

> *I'm not interested in treating myself as a Guinea pig, I want something which is the proper facts. And because this says NHS, I believe they're going to be proper facts.* [P13, male participant aged 65 years]

Most participants (15/19, 79%) reported learning something new from the educational content of Healthy Living, including clarifying things regarding their medical management that were previously misunderstood (P14) and increasing the awareness of how to self-manage their condition (P1 and P19):

> *Well I think it's helped me realise that there is hope obviously outside of just avoiding sugar, on the diabetes front. There are lots of other aspects to healthy living that need to be maintained and used.* [P1, male participant aged 74 years]

Even participants who had been diagnosed with T2DM for a long time reported to have learned something new from reading the educational content (P1, P4, P10, P13, and P14):

> *It would be the learning goals definitely, because there was stuff, even though I am ten plus years diagnosed there was still bits I didn't know. And obviously there's scope there to put new research in, so it's got a really good potential place ahead.* [P10, female participant aged 43 years]

Participants placed value on continually learning and updating their knowledge on how to manage their T2DM. Some participants (8/19, 42%) expressed a desire to know more about the dietary aspects of their self-management, including what foods they should and should not be eating (P5), recipes (P3, P7, P8, P9, and P16), substitutes for sugary food (P5 and P16), the amount of sugar (P12) and carbohydrates (P7) in different foods, and how specific foods impacted on blood glucose levels

(P3 and P18). Others wanted information on actions to take if blood sugar levels became too high (P10) and the methods to bring blood sugar levels under control (P13). However, some participants (4/19, 21%) reported already knowing most of the information presented in the educational content and consequently felt they had not learned anything new from engaging with the website (P4, P12, and P18). This caused some to disengage (P4 and P5). A participant stated as follows:

> *I think if you don't know anything it's probably useful but I already...I've had numerous health problems so I have reasonable knowledge of useful information and some information about diabetes along with that. It was probably a bit condescending if you already know all of this stuff but good if you don't know anything.* [P12, female participant aged 57 years]

Therefore, while most participants found some information on Healthy Living useful, some participants (2/19, 11%) who had been diagnosed with T2DM for a long time felt that this program was particularly suited to those who were newly diagnosed (P4 and P18), with newly diagnosed participants reporting that Healthy Living would have been more beneficial if it was offered straight away after their diagnosis (P2 and P12).

Theme 2: Improved Emotional Management

Participants had expected Healthy Living to include information on ways to manage their diet and medications, but many had not expected to see information on emotional management. This was a welcome addition to the website for most participants, as they had not been told about the emotional impact of T2DM previously and had not encountered it on other self-management programs they had attended (P4, P10, P16, and P19):

> *I thought it was interesting that it wasn't just about what the causes are and how you should control your sugars, but things like emotional impact, just general well-being impact.* [P14, male participant aged 69 years]

> *...[E]veryone has told me what diabetes was going to do me physically but no one had said anything about mentally. So, that's the site that I learnt more about it, no one had mentioned that at a doctor's appointment, no one had mentioned it at the nurse's appointments, it was the first place it had even been mentioned to me and all of a sudden, I thought I've got that problem and now I know, is this the reason why I'm feeling like that. It hadn't been mentioned anywhere else, I hadn't learned about it from a book or anywhere else and I remember reading it and deciding that from being not happy in life a little bit, thinking, well this must be what the problem is, thinking hilariously I felt a little bit better, thinking this might be what the problem is and then I spoke to my nurse in the doctor's surgery.* [P16, male participant aged 45 years]

Many participants (12/19, 63%) reported to find the emotional management content useful (P2, P4, P6, P8, P9, P10, P11, P13, P14, P16, and P17), increasing their understanding of the link between low moods and T2DM (P6). Even those who had not experienced low mood appreciated receiving informational support about this aspect of their self-management (P11, P14, and P15). Reading the emotional management content prompted some participants to book an appointment with their GP or nurse to discuss their low moods (P4, P6, and P16), thus suggesting that participants felt comfortable to subsequently discuss aspects of emotional management with health care professionals. This emotional management content seemed to be legitimizing the experiences of participants and reassured them that their experiences of low mood could be explained, despite the self-led nature of the program with no interaction from others:

> *Yeah, yes, it was, it was, it was kind of reassuring you that it wasn't just something that you were going through, it was linked with your diabetes, and it's very common as well and I think that was reassuring, to learn that it wasn't just me, that it was fairly common for sufferers of diabetes to experience like depression and low mood. And it was also reassuring to know that the experts who'd written the website or designed it or helped design it were aware of that as well, and you then think, well, I'm sure my doctor will, when I go and approach him about it that he'll know too that it's not just because of some random thing happening in my life that's caused me to feel a little bit down or depressed, low mood, it's also because I'm diabetic.* [P6, female participant aged 46 years]

However, some participants (2/19, 11%) reported having encountered very little of the emotional self-management content or did not recall this content at all (P5 and P7), primarily because they had stopped engaging with the structured education content early on during the program (P5).

Theme 3: Experiences of Using Structured Education

Many participants (10/19, 53%) enjoyed working through a structured learning pathway and the ordering of the content in a logical progression (P1, P3, P7, P9, P10, P11, P13, P15, P16, and P17), which prevented them from becoming "sidetracked" (P17). Participants liked that information was presented to them in modules, so they could take in as much information as they needed at any one time (P2, P10, P14, and P15). This was particularly valued by participants who were newly diagnosed and acknowledged that it can feel like "information overload" (P9) at the start of their diagnosis and thus appreciated having sections of the website that they could work through systematically:

> *Well it was just it was in bite size chunks so I could pick a topic and finish it within ten or 15 minutes. I have lousy concentration, so it was good to be able to stop and not think, I'm going to lose my place now.* [P10, female participant aged 43 years]

> *It was never one huge meal to swallow, it was snacks. And you could have as many of those as you wanted at a time.* [P14, male participant aged 69 years]

However, the structured education did not suit everyone; some wanted the option to select topics of their choice (P5 and P18),

and another participant disengaged once he encountered a section that was not applicable to him (P13):

> *But working through it, it started off getting started, what to know about diabetes, well, I've covered this, I want to be over there and I'm stuck here, and I think that may have been something that put me off going in further because it was like I haven't got time for this, I need to know this. I need to click on subjects and then find what I want to know and listen to that rather than go from start to finish, because it got a bit boring, it did, and I think that's why I stopped, because it got...it was too slow for me.* [P5, female participant aged 56 years]

After completing the structured education, most participants described wanting to use the website as an information tool as and when it was required, for example, to skim the contents to refresh memory on particular topics. However, others described feeling that after reading all the content on the website, it was no longer relevant (P11), or Healthy Living had been forgotten about over time (P5). Some participants (3/19, 16%) reported completing the structured education but not using it afterward (P11, P15, and P18) as follows:

> *In the longer term, the rest of this year where I've been bringing my weight down, the website didn't seem to have any relevance. It sort of disappeared. When I couldn't record stuff on it and I'd done all the training, it sort of...the relationship came to an end.* [P11, male participant aged 75 years]

Theme 4: Importance of Technological, Professional, and Social Interactivity

Overview

In order to maximize the acceptability and continued engagement with Healthy Living in the longer term, participants suggested the need for more interactivity. This included increased technological interactivity between Healthy Living and other devices that they were already accessing (eg, wearable technology), interactivity from the website itself (eg, notifications), and interpersonal interactions both formally with health care professionals and informally with other people living with T2DM.

Subtheme 4.1: Interaction With Other Apps and Devices

Although Healthy Living included *Tools* for users to set goals and self-monitor their steps, weight, and hemoglobin A_{1c} level, participants reported that they did not use these Tools regularly. Instead, participants were already accustomed to using existing methods of self-monitoring via other apps and devices, which were not contingent with the Healthy Living website:

> *I did have a look at them [Tools]. And I think again for somebody who doesn't have the access to other tools that I have, ideal. Absolutely ideal. But the Fitbit gives you the goals to set and it also wants your weight and your height and targets and everything.* [P7, female participant aged 79 years]

Therefore, participants already had a good understanding of techniques such as self-monitoring. They reported understanding the link between their behaviors (eg, diet and physical activity) and outcomes (eg, weight and blood glucose levels), helping them adequately self-regulate their health behaviors as part of their T2DM medical self-management (P3, P14, and P16).

These digital tools that the participants were already using outside of Healthy Living logged their behaviors automatically and provided feedback, which was a valuable part of their self-management (P1, P4, P5, P6, P12, and P17). Consequently, some participants (3/19, 16%) wanted Healthy Living to provide more personalized feedback, similar to what their existing tools and resources were already offering (P1 and P11) but with more tailored recommendations in relation to their T2DM self-management (P1 and P5) to encourage more interactivity with the website:

> *...[I]f there was some sort of feedback perhaps from the Healthy Living site that just says, well [Name], we've not progressed very well, there are these 12 different things that you might want to try and improve on. But there isn't that sort of feedback at the moment which I think would be helpful, I really do.* [P1, male participant aged 74 years]

Therefore, it was suggested that Healthy Living could be more useful as an app (P5, P10, P12, and P17) to enable better integration of the education provided by Healthy Living with the existing apps that participants were already using on their phones. Participants felt that complementarity with other technologies could prevent users from forgetting about the website over time:

> *So again it needs to be connected to something that's in my face, that works like that...as I say I use Samsung Health, I do my exercise with it. When I walk I switch it on then I know that does me good but then if that would automatically log with that I wouldn't have to go in, oh, well, I've walked this much today. Because you forget, you've walked, you don't think I'll get home and I'm going to go and log that, but because the app does it automatically, just say walking it follows me and it does it, and that's what it needs to do. It would be perfect if it did that.* [P5, female participant aged 56 years]

It was also suggested that more interactivity from the Healthy Living website itself would help improve the experience and continued use. For example, some participants suggested email nudges (P7 and P11) and notifications (P13) from Healthy Living to keep people engaged with the program over time.

Subtheme 4.2: Interaction With Health Care Professionals

It was noted that the lack of health care professional support from Healthy Living meant that nobody was monitoring the website to review service users' progress with the program:

> *And I have a problem sometimes getting self-motivated...And that's what I'm conscious of, in terms of the website...There's actually no one there that I've got to see every week to review what I've*

> *done. I've got to do it myself.* [P19, male participant aged 70 years]

While some participants (6/19, 32%) used Healthy Living to support conversations with their health care professionals outside of the program (P1, P4, P6, P13, P14, and P16), including discussions around their emotional self-management, it was also acknowledged that other people living with T2DM may not receive the same level of support from their local health service and thus may rely more on the support from Healthy Living:

> *So yeah, maybe...I've got a particularly good diabetic nurse...But yeah, I count myself lucky in that sense. And so maybe some of the things that other people might need from a programme like this, I'm already getting elsewhere.* [P14, male participant aged 69 years]

Participants provided suggestions on how to improve the interactivity with health care professionals via the Healthy Living website. These included live webinars (P5), a question and answers section (P6), and a Healthy Living email address to submit questions to health care professionals (P13). Other participants suggested the functionality to link Healthy Living to their GP practice systems to enable GP practices to access the data inputted into Healthy Living and to guide conversations with health care professionals at upcoming appointments (P5, P10, and P16). Most participants (14/19, 74%) did not feel that they needed any form of facilitated access from a health care professional when first signing up to Healthy Living, as they felt the website was easy to understand without this additional support.

Subtheme 4.3: Interaction With Other People Living With T2DM

In response to a question about whether there was a need for an online support forum in Healthy Living, some participants (4/19, 21%) said they would have liked the opportunity to interact with other people living with T2DM (P7, P8, P9, and P12):

> *You know, like, if you're on Diabetes UK you've got forums and things and there isn't...that would be a useful addition I think to this, would be to have some, kind of, forum where people can network a little bit.* [P9, female participant aged 54 years]

However, there was a concern that a forum might spread misinformation, and participants compared this to websites such as Facebook, and to avoid this, it would have to be moderated by health care professionals (P5, P10, P11, P13, P16, P17, and P18):

> *I suppose that [group forum] would be good but again it's got to be managed to make sure it's reliable information. My go to website is, if I don't find what I want on the NHS website is Diabetes UK. I don't go to Facebook pages anymore I learnt that lesson years ago because you just get chatter and you get, don't do that, I do this and ends up with arguments and false information or drug names getting confused and misspelt. So there's definitely a need for more reliable information for patients, especially as the web grows and more and more people are using smartphones.* [P10, female participant aged 43 years]

> *I probably wouldn't bother [with an online forum] because I find places like Facebook and Twitter, people, a large group of people say things that are actually wrong.* [P18, male participant aged 65 years]

The videos embedded into the structured education content about other people's stories living with T2DM offered an opportunity for peer support for some participants (P2, P3, P4, P6, P11, P15, and P17). This gave them the opportunity to "listen to other people's experiences" (P11) and "sympathize" with others on the "same journey" as them (P3), which in turn validated their own experiences of living with T2DM. Some newly diagnosed participants reported these videos to be especially useful (P2, P3, and P17). Therefore, although not a live interaction with others, the videos provided a form of support that some participants benefited from:

> *...[I]t's almost like having your chat group, but with people with videos, because I actually learn well via videos as opposed to reading, and I just thought people have got similar problems, and they're all talking about it and how they cured it and their problems. I just found that was really very good empathy for me.* [P17, female participant aged 61 years]

Discussion

Principal Findings

Service users valued Healthy Living, as it provided them with a reliable source of information, which they could access when they needed to as part of their T2DM self-management. The emotional self-management content particularly resonated with some participants, prompting them to book an appointment with their GP or nurse to discuss their low mood. Participants suggested that they might have been encouraged to use the website in the longer term if there was more interactivity with the website. These aspects of interactivity included (1) interaction with the existing technologies and the website itself, (2) formal interaction with health care professionals and services for T2DM self-management, and (3) informal interactivity with other people for social support. Although most participants reported finding some information on Healthy Living useful, there was consensus that the website was particularly suitable for those newly diagnosed with T2DM.

Strengths and Limitations

This study presented a unique opportunity to assess service user experiences of a digital DSMES program that has demonstrated effectiveness in a trial and is being rolled out nationally across England. Efforts were made to secure a broad representation of participants across age, sex, ethnic groups, and length of diagnosis, although the sample had little ethnic diversity, which was reflective of the sample of people using Healthy Living at the time of the interviews. The median age of participants in this study was 61 (IQR 53-73, range 43-81) years; however, younger participants may have had different perceptions of the program. Given that the recruitment for this study took place

during the COVID-19–related restrictions and that the participants who had used the program would have used it during the pandemic, these may have impacted people's engagement with the program and subsequent recruitment to the study.

We deliberately spoke with the most engaged users, with the intention of interviewing those who had used a sufficient amount of the website content to allow an in-depth understanding of how people were using the digital program. The current sample of participants was useful for the purpose of this study; however, other samples of service users (eg, those who are less engaged or who did not take up the program) would have different views on some aspects of the intervention. Therefore, the current results are more applicable to people who are more engaged with (1) their own T2DM self-management and (2) using digital interventions. However, in cases where this sample of engaged participants reported not using components of Healthy Living, it provides a strong argument for where improvements could be made to the program to increase engagement.

Comparison With Prior Work

There were 3 key changes in the implementation of Healthy Living into routine care since the HeLP-Diabetes RCT [18]. First, due to changes in the NHS policy, Healthy Living included a structured education component that service users had to work through in a linear fashion. Prior research found that users with long-term health conditions preferred to have control over what topics they accessed for information at any one time, and those who were already knowledgeable about their condition preferred to be provided with in-depth information [43]. Improvements have since been made to Healthy Living so that it is clearer for service users that they can either complete the structured element or choose their own topics via the unstructured education element of the program. Second, Healthy Living did not incorporate facilitated access into the program (ie, where a health care professional helps users to sign up and access the program) due to (1) challenges in scaling up the HeLP-Diabetes RCT into routine practice and (2) updated access to Healthy Living since the RCT, which had improved usability for low digital literacy. Therefore, the program is entirely self-led [18]. Previous qualitative research has reported that participants were strongly in favor of health care professionals providing support for how to use the website in the HeLP-Diabetes RCT [44], although participants in this study felt the website was self-explanatory and easy to use.

Third, Healthy Living did not include an online peer-support forum due to the low uptake of this feature in the original RCT, so there was insufficient evidence that justified the cost of delivering it at scale [18]. Previous qualitative work exploring service users' experiences of using the HeLP-Diabetes RCT reported that some felt "part of a community" with the inclusion of an online forum and valued the opportunity to interact with others on the website [37]. Participants in this study felt that an online forum would only be a useful addition to the website if it was moderated by health care professionals to prevent the spread of misinformation. Despite this perspective, there is much evidence in the literature highlighting the importance of online forums for people with T2DM; for example, service users have reported drawing on shared experiences from others, which empowered them to engage with health care services [45]. Given the underpinning evidence, intervention developers of digital DSMES programs could consider signposting service users to other group forums (eg, Diabetes UK) if they lack the resource to run their own moderated peer-support forum.

Participants in this study found the emotional management content valuable. It is particularly noteworthy that some participants who were already engaged with their T2DM self-management were still unaware of the link between their T2DM and low mood, and this prompted them to book an appointment to discuss with a health care professional, which was an intended purpose of the website [18]. In this context, participants were not receiving emotional support via interaction but valued the informational support that they received about the emotional impact of illness and how to manage it. Previous qualitative research found that emotional support was valued for T2DM self-management [16] and self-management training for other chronic illnesses [46]. Research has also highlighted that people living with T2DM find it difficult to manage their emotions and adapt to changes in their lifestyle after receiving their diagnosis [47]. Given the calls to prioritize the psychological well-being of people living with T2DM [48], there is the argument to include emotional management content earlier on in the T2DM self-management program curricula to reduce the risk of users missing this important content if they disengage from the structured education. Since this study was conducted, NHS England has made improvements to signposting to emotional well-being content in the nonstructured part of the program to allow service users to access some content without needing to work through the structured education element of Healthy Living.

Participants suggested that Healthy Living would be more useful as an app that is immediately accessible on their phones to increase the ease of access and enable interaction with other technologies that they were regularly using as part of their self-management; similar findings have been reported previously [16]. Thus, interaction with the existing technologies seems important in order for an informational website to complement what people are already doing to self-manage their T2DM. Further interactivity from the website itself, including more tailored feedback on a person's T2DM self-management, could also promote continued engagement. User engagement research has found that sending a push notification containing a tailored health SMS text message was associated with greater engagement in a mobile health app [49], and apps that were tailored to users' preferences and contained personalized feedback resulted in continued engagement [50,51]. Thus, to sustain engagement with digital DSMES programs in the longer term, intervention developers could consider ways to increase the interconnectivity both within the interventions (eg, via notifications and prompts) and with existing technologies. NHS England has since implemented notifications on the Healthy Living website following this interview study.

Implications

There was consensus across participants that they would recommend Healthy Living to those who are newly diagnosed,

and many felt that the website was especially useful for this group of people. Interviewees newly diagnosed with T2DM also expressed that they would have liked access to this website as soon as they were informed about their diagnosis. Furthermore, participants reported to learn something new from the website, even if they had used face-to-face services in the past. Thus, there is a need for a clear pathway in primary care to establish where Healthy Living fits with the other DSMES programs. For example, general practices could be encouraged to inform people about Healthy Living as soon as they receive their T2DM diagnosis, which could work in conjunction with the face-to-face DSMES programs on offer. The face-to-face sessions could offer the opportunity for (1) formal interaction with other professionals and services for managing T2DM and (2) social and informal support from peers, while the website could allow service users to obtain informational support and work through the educational content at their own pace. Further research could also explore which content is most useful for those who have been living with T2DM for a longer period of time to promote self-management maintenance.

This study explicitly aimed to obtain the views of service users who had sufficient engagement with Healthy Living. Thus, future research may need to use other sampling processes to assess how the intervention could be modified to limit digital exclusion, avoid exacerbating health inequalities, and assess whether Healthy Living meets the needs of people from different ethnic groups. Another fruitful avenue for further research would be to interview service users who either chose not to take up the Healthy Living program or stopped using the program early on. Future research could also speak to people at the point of referral in primary care about their experiences of being referred to a program like Healthy Living, exploring reasons why people may choose to take up a self-management program and what support is required at referral [52]. Such research could also help to understand any potential inequalities with access to digital interventions, such as Healthy Living, and whether inequalities might be increased.

The participants in this study were more engaged in the use of Healthy Living, so they may also be more likely to have engaged with other tools and technologies outside of the program. For users who do not have access to other tracking tools, Healthy Living may be more useful. It would therefore be informative to interview people who do not otherwise have access to external tracking tools and devices, to establish whether the self-regulatory Tools on Healthy Living are providing value for this group of people. The assessment of usage data would provide an understanding of the use of these tools for all users enrolled in Healthy Living and shed light on the extent to which the users are engaging with the structured education content and where a drop-off in engagement might occur.

Conclusions

This study offers valuable insights into service users' experiences of a nationally implemented digital DSMES program. Digital DSMES programs offering emotional aspects of self-management are addressing an unmet need. Healthy Living was of most value as a trusted source of information, in particular, to those who were newly diagnosed with T2DM. Primary care could usefully offer digital DSMES programs to people as soon as they are diagnosed.

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Data Availability

Some data sets are available from the corresponding author on reasonable request, although authors will require the explicit permission of the relevant external organizations.

Authors' Contributions

SC, DPF, and CS secured funding for the Healthy Living Diabetes-Long-term Independent National Evaluation project. DPF designed the research study and supervised the research conduct. JSB developed the interview schedule, was in contact with the service provider to facilitate study recruitment, and conducted the interviews. REH analyzed the interview data and prepared the manuscript. All authors contributed substantively to the interpretation of the data, helped to prepare the manuscript, and read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Healthy Living website content.
[DOCX File , 455 KB - diabetes_v9i1e56276_app1.docx]

Multimedia Appendix 2
Standards for Reporting Qualitative Research.
[DOC File , 67 KB - diabetes_v9i1e56276_app2.doc]

Multimedia Appendix 3
REDCap (Research Electronic Data Capture) questionnaire.
[PDF File (Adobe PDF File), 36 KB - diabetes_v9i1e56276_app3.pdf]

Multimedia Appendix 4
Criteria for participant recruitment.
[DOCX File , 45 KB - diabetes_v9i1e56276_app4.docx]

Multimedia Appendix 5
Interview topic guide.
[DOCX File , 48 KB - diabetes_v9i1e56276_app5.docx]

Multimedia Appendix 6
Coding framework.
[DOCX File , 30 KB - diabetes_v9i1e56276_app6.docx]

Multimedia Appendix 7
Thematic structure.
[DOCX File , 77 KB - diabetes_v9i1e56276_app7.docx]

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Abbreviations

DSMES: Diabetes Self-Management Education and Support
GP: general practitioner
HeLP-Diabetes: Healthy Living for People with Type 2 Diabetes
NHS: National Health Service
PPIE: Patient and Public Involvement and Engagement
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
T2DM: type 2 diabetes mellitus

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Original Paper

Implementation of a Technology-Enabled Diabetes Self-Management Peer Coaching Intervention for Patients With Poorly Controlled Diabetes: Quasi-Experimental Case Study

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Abstract

Background: Patients with diabetes experience worse health outcomes and greater health care expenditure. Improving diabetes outcomes requires involved self-management. Peer coaching programs can help patients engage in self-management while addressing individual and structural barriers. These peer coaching programs can be scaled with digital platforms to efficiently connect patients with peer supporters who can help with diabetes self-management.

Objective: This study aimed to evaluate the implementation of a technology-enabled peer coaching intervention to support diabetes self-management among patients with uncontrolled diabetes.

Methods: MetroPlusHealth, a predominant Medicaid health maintenance organization based in New York City, partnered with Pyx Health to enroll 300 Medicaid patients with uncontrolled diabetes into its 6-month peer coaching intervention. Pyx Health peer coaches conduct at least 2 evidence-based and goal-oriented coaching sessions per month with their assigned patients. These sessions are focused on addressing both behavioral and social determinants of health (SDoH) with the goal of helping patients increase their diabetes self-management literacy, implement self-management behaviors, and reduce barriers to ongoing self-care. Data analyzed in this study included patient demographic data, clinical data (patient's hemoglobin A_{1c} [HbA_{1c}]), and program implementation data including types of behavioral determinants of health and SDoH reported by patients and types of interventions used by peer coaches.

Results: A total of 330 patients enrolled in the peer mentoring program and 2118 patients were considered to be on a waitlist group and used as a comparator. Patients who enrolled in the peer coaching program were older; more likely to be English speakers, female, and African American; and less likely to be White or Asian American or Pacific Islander than those in the waitlist condition, and had similar HbA_{1c} laboratory results at baseline (intervention group 10.59 vs waitlist condition 10.62)

Patients in the enrolled group had on average a –1.37 point reduction in the HbA_{1c} score (n=70; pre: 10.99, post 9.62; *P*<.001), whereas patients in the waitlist group had a –0.16 reduction in the HbA_{1c} score (n=207; pre 9.75, post 9.49; *P*<.001). Among a subsample of participants enrolled in the program with at least 2 HbA_{1c} scores, we found that endorsement of emotional health issues (β=1.344; *P*=.04) and medication issues (β=1.36; *P*=.04) were significantly related to increases in HbA_{1c}.

Conclusions: This analysis of a technology-enabled 1-on-1 peer coaching program showed improved HbA_{1c} levels for program participants relative to nonprogram participants. Results suggested participants with emotional stressors and medication management issues had worse outcomes and many preferred to connect through phone calls versus an app. These findings support the effectiveness of digital programs with multimodal approaches that include human support for improving diabetes self-management in a typically marginalized population with significant SDoH barriers.

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KEYWORDS

type 2 diabetes; type 1 diabetes; diabetes experiences; eHealth; mHealth; peer coaching; peer coach; peer support; self-management; social determinants of health; behavioral determinants of health

Introduction

Diabetes is a significant public health problem that contributes to worsening overall health. Diabetes rates are highest among marginalized (low-income racial and ethnic minority) patients and contribute to high rates of disability and health care costs. Patients with diabetes experience more than double the direct health care expenditures [1], greater comorbidities and disabilities, including depression [2], obesity [3], and increased mortality [4] compared with those without diabetes. Improving diabetes outcomes requires self-management that includes medication management, a healthy diet, and physical activity. Peer support programs can be effective at providing targeted support and increasing motivation to engage in self-management while addressing barriers related to the social determinants of health (SDoH), such as food insecurity and transportation. These programs can be scaled through digital platforms to organize and connect patients with supporters.

Peer coaching interventions can facilitate diabetes self-management and behavior change by addressing both individual and broader SDoH factors that are barriers to self-management. The combination of peer coaching and digital diabetes self-management interventions has the potential to improve health outcomes for patients from marginalized backgrounds. For example, both peer coaching and digitally enabled interventions focused on diabetes self-management are associated with positive behavior change and health outcomes, including reductions in hemoglobin A_{1c} (HbA_{1c}) [5-8]. Yet, additional research is needed to elucidate what factors are most salient for patients and how implementation of remote peer coaching diabetes self-management interventions for diverse populations works in real-world settings [9].

Adults who struggle with diabetes may face a variety of challenges with SDoH, such as food insecurity and housing instability [10]. Peer coaches are well-equipped to assist with SDoH barriers related to diabetes self-management as they are often individuals with lived experience representing similar identities as those whom they support. In addition to providing information and skill-building around diabetes self-care strategies (eg, medication adherence, diet, and exercise) [11], they can also provide empathy, concrete strategies, and navigation support for addressing SDoH barriers to diabetes management through referrals and support to cope with or overcome barriers.

Given the existing shortage of licensed health care professionals in chronic and primary care, capacity-building programs focused on peer coaching may help health care providers reach a wider range of their patient population while promoting more individualized and personalized support to these patients [12]. Further, peer coaches may be integrated into health care through task shifting or task sharing, resulting in cost reductions for the system while improving health care delivery and outcomes [6]. Finally, digital health platforms can help scale peer coaching programs more efficiently than in-person programs by reducing geographic and transportation limitations. Private companies developing these platforms may be well-equipped to serve as partners of health care providers and have already been hired to implement digital diabetes interventions, including peer coaching interventions for patients with diabetes.

The purpose of this study is to evaluate the implementation of a technology-enabled peer coaching intervention to support diabetes self-management among patients with uncontrolled diabetes, which was conducted in partnership between a Medicaid health plan and a digital health company. We examine the impact of the program on changes in HbA_{1c}, factors associated with changes in HbA_{1c}, and implementation outcomes such as program use rates (eg, user engagement measures) in order to develop a comprehensive understanding of program outcomes on patients and health care systems.

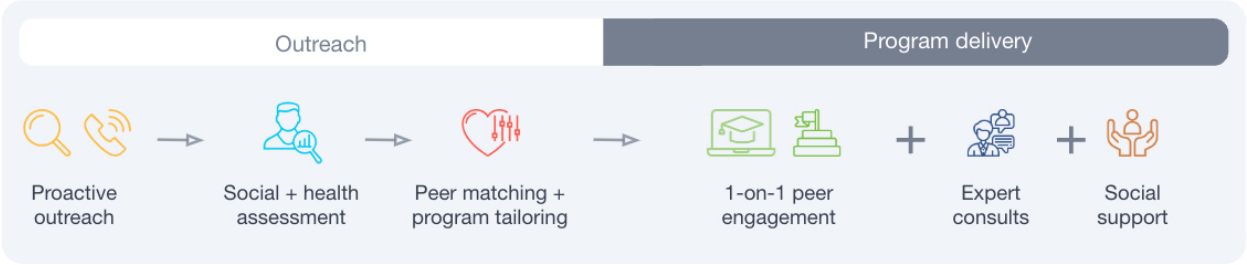
Methods

Intervention

Pyx Health (previously known as InquisitHealth, during the time of the intervention) is a digital health company providing remote peer mentoring services to help patients manage chronic diseases such as diabetes. Pyx Health has developed a services framework characterized by recruiting and training patients who are successful at managing their own health to serve as peer mentors who provide evidence-based and up-to-date educational interventions to patients through telephone or smartphones in both English and Spanish. By partnering with existing health

plans and health systems, Pyx Health receives information about patients with uncontrolled diabetes and conducts outreach and enrollment of patients into its programs, matches patients and peer mentors based on shared characteristics (eg, race and language), and conducts a thorough health needs assessment that is used to guide the tailored-content interventions for the patient. Pyx Health also conducts interventions addressing behavioral determinants of health (BDoH) and SDoH that directly impact diabetes self-management. Over the course of 6 months, Pyx Health peer mentors conduct at least 2 evidence-based and goal-oriented coaching sessions per month with their assigned patients. These sessions are focused on addressing both BDoH and SDoH with the goal of helping patients increase their diabetes self-management literacy, implement self-management behaviors, and reduce barriers to ongoing self-care. All peer coaches are trained to follow HIPAA (Health Insurance Portability and Accountability Act)–compliant procedures and use HIPAA-compliant communication methods. A description of Pyx Health workflow and services is presented in Figure 1. Throughout the course of the program, peer mentors are trained to deploy and keep a record of intervention "Tracks" (ie, coach, consult, refer, and share) deployed to best address the needs of their patients.

Figure 1. InquisitHealth workflow diagram.



Implementation at MetroPlusHealth

MetroPlusHealth, a predominant Medicaid HMO based in New York City, partnered with Pyx Health to enroll 300 Medicaid patients with uncontrolled diabetes into its peer mentoring intervention. A joint approach between these 2 partners took place in 2019 to reach the targeted patient population. MetroPlusHealth case management and quality team members were onboarded to Pyx Health's Care Coordination platform to receive individual patient escalations. Biweekly meetings between stakeholders were established to oversee the implementation of the Pyx Health program. After the implementation of the program, Pyx Health partnered with the University of California, San Francisco S.O.L.V.E. Health Tech to conduct the evaluation of this program.

Participants and Recruitment

First, in June 2019 MetroPlusHealth mailed letters and sent an SMS text message to eligible patients (eg, uncontrolled diabetes, HbA_{1c}>9%) notifying them about the Pyx Health program. Next, Pyx Health's outreach team called individual members, and for those reached, eligibility was confirmed (ie, uncontrolled diabetes, English or Spanish speaker, MetroPlusHealth member, and able to participate at least through a landline phone), and if interested, they were enrolled into the program. Pyx Health paused outreach by late August 2019 after enrolling 304 patients into the program. At this time, several patients were already in the recruitment process (eg, scheduled calls), and by early September, 330 patients had enrolled in the peer mentoring program. As the targeted enrollment was met, patients who did not receive an outreach call were part of the "waitlist" group.

On the enrollment call, Pyx Health performed a needs assessment with each patient, which included (1) asking about their behavioral determinants and SDoH that posed barriers to diabetes self-management and ongoing care; (2) matching patients with a peer mentor based on shared lived experience with diabetes, language, race and ethnicity, availability, age, gender, as well as factors like the peer's capacity, and expertise; (3) scheduling the first call between the patient and their matched peer mentor; and (4) creating a custom program for the patient based on the specific needs, barriers, and challenges identified through the initial assessment using Pyx Health's platform (which enables both digital and phone engagement).

Data Sources and Analysis

MetroPlusHealth provided patient demographic data, care use, and clinical data to Pyx Health for the purpose of patient recruitment and data analysis. This included study outcomes data, specifically the patient's HbA_{1c}. Pyx Health collected program implementation data including types of BDoH and SDoH reported by patients. BDoH included personal barriers related to appointments, disease knowledge, disease self-management, emotional health, glucose monitoring, physical activity, healthy eating, medication adherence, co-occurring health conditions, and alcohol use. SDoH included structural barriers to accessing appointments, health literacy, food insecurity, housing instability, glucose monitor, glucose test strips access, medication cost, insurance coverage, and alcohol abuse. We also calculated what types of intervention tracks were used (ie, coach, consult, refer, and share) by peer coaches, as well as user-engagement metrics (ie, phone calls, phone minutes, check-ins, messages exchanged, mailings, and app use frequency).

Pyx Health conducted data analysis while consulting with the University of California, San Francisco S.O.L.V.E. Tech.

We began by conducting *t* test analyses comparing the demographics and HbA_{1c} data between patients enrolled in the program versus those in the waitlist group (ie, not yet contacted for recruitment). The data and outcomes from the patients in

the waitlist group serve as a basis of comparison in this study to contextualize the results of the Pyx Health peer mentoring program implementation; however, they do not represent a random control condition.

To analyze changes in HbA_{1c} scores between the waitlist and enrolled groups, individuals needed to have at least 2 HbA_{1c} readings during the study. For the enrolled group, at least 1 HbA_{1c} needed to be 90 days before the specific individual's program start date. For the waitlist group, since no individual start date was available, at least 1 HbA_{1c} needed to be 90 days before the overall program start date. For both groups, we defined preintervention as 90 days before the program start date, June 19, 2019, and postintervention as 90 days after the program start date through March 30, 2020, when in-person labs were no longer happening consistently due to the COVID-19 pandemic. Finally, we report descriptive statistics for the program implementation data and report results of an exploratory analysis examining factors (eg, demographics, BDoH, and SDoH) associated with changes in HbA_{1c} among the participants in the peer mentoring program.

Ethical Considerations

This work was approved by the University of California San Francisco institutional review board (#19-28839) as exempt research.

Results

Primary Analysis

Pyx Health received a total of 3127 patient records from its MetroPlusHealth partners. A total of 391 patients were successfully contacted during the phone-based outreach process to meet the enrollment target. At that point, 84.4% (330/391) enrolled in the peer mentoring program, 11.5% (45/391) were not eligible for enrollment, and 4.1% (16/391) were not interested in participating. Of the initial registry list, a total of 618 patients were unreachable and excluded from subsequent analysis. The remaining 67.7% (2118/3127) of patients were considered to be on the waitlist group and used as a comparator. Figure 2 shows a CONSORT (Consolidated Standards for Reporting Trials) diagram with the participant breakdown. For subsequent analysis and when possible, we compared differences between the enrolled and waitlist groups.

First, we examined demographic variables baseline differences across these 2 groups (Table 1), and the results indicated patients who enrolled in the peer mentoring program were older; more likely to be English speakers, female, and African American; and less likely to be White or Asian American or Pacific Islander than those in the waitlist condition. There were no statistically significant differences between the enrolled patients' HbA_{1c} (mean 10.59, SD 1.79) and those in the waitlist condition (mean 10.62, SD 1.75) at baseline.

Patients enrolled in the peer mentoring program endorsed a variety of behavioral and SDoH challenges to diabetes self-management with the top 3 issues being navigating medical appointments, knowledge about diabetes and disease self-management, and concerns with emotional health (Table 2).

To address these concerns, peer mentors primarily used the intervention tracks of coaching and sharing of resources (Table 3), which accounted for 536 (31.2%) and 889(51.8%), respectively, of all 1717 interventions used.

Finally, patient engagement metrics indicate that on average patients participated in an average of 16.4 calls and 146.3 minutes of intervention by peer coaches during their program participation (Table 4).

Figure 2. Consort diagram.

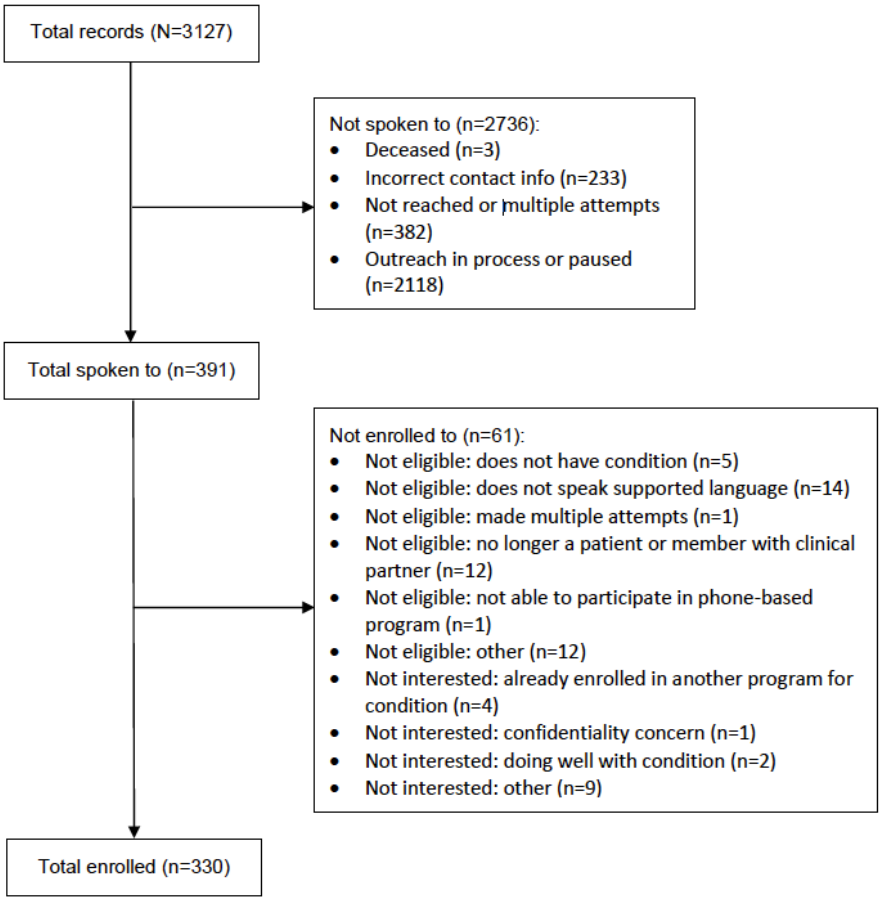


Table 1. Baseline participant demographics and clinical data.

Participant characteristics	Enrolled (n=330)	Waitlist (n=2118)	*P* value
Age (years), average (SD)	53.35 (9.47)	51.84 (10.95)	.009
Gender (male), n (%)	149 (45.15)	1090 (51.46)	.04
Race or ethnicity, n (%)			
White	10 (3.03)	114 (5.38)	.09
Black or African American	151 (45.76)	717 (33.85)	<.001
Asian, Native Hawaiian, or other Pacific Islander	49 (14.85)	422 (19.92)	.04
Other	64 (19.39)	474 (22.38)	.25
Hispanic or Latino	27 (8.18)	151 (7.51)	.75
Unknown	28 (8.48)	207 (9.77)	.52
Language, n (%)			
English	302 (91.52)	1847 (87.2)	.03
Spanish	25 (7.58)	194 (9.16)	.40
Lives in a disadvantaged zip code, n (%)	82/328 (25)[a]	452/2115 (21.37)[b]	.16
Hemoglobin A_{1c} data			
Baseline hemoglobin A_{1c}, average (SD)	10.59 (1.79)[c]	10.62 (1.75)[d]	.81
Has follow-up hemoglobin A_{1c}, n (%)	70 (21.21)	207 (9.77)	<.001

[a]Includes 328 participants.
[b]Includes 2115 participants.
[c]Includes 329 participants.
[d]Includes 1867 participants.

Table 2. Patients endorsing behavioral and social determinants of health issues (n=330).

Issue category	Behavioral determinant of health patient (n=330), n (%)	Social determinant of health patient (n=330), n (%)
Appointments	252 (76.4)	240 (72.7)
Knowledge	169 (51.2)	56 (17.0)
Emotional health	174 (52.7)	N/A[a]
Food insecurity	N/A	162 (49.1)
Housing	N/A	149 (45.2)
Glucose monitoring	63 (19.1)	81 (24.6)
Physical activity	144 (43.6)	N/A
Healthy eating	143 (43.3)	N/A
Medication	52 (15.8)	50 (15.2)
Insurance	N/A	68 (20.6)
Alcohol	10 (3.9)	5 (1.5)

[a]N/A: not applicable.

Table 3. Intervention tracks used by peer mentors and frequency of use.

Category	Definition	Total (n=1717), n (%)
Coach	Provide evidence-based strategies for addressing the presenting concern through empathy, understanding, and goal-setting	536 (31.2)
Consult	Escalate the issue to the Pyx Health team to triage and escalate concerns to health plan resources (member services, case management, etc) or community-based partners who will proactively engage with the patient for targeted SDoH[a] concerns	111 (6.5)
Refer	Provide resources, including contact details (website, phone number, addresses, etc), to help patients proactively reach out and engage	181 (19.5)
Share	Provide printed educational materials (mailed to participant), digital content (shared through SMS or smartphone app), and guidance for peer mentor to discuss real-time while on the phone with the participant	889 (51.8)

[a]SDoH: social determinants of health.

Table 4. Pyx Health patient engagement metrics (n=330).

Engagement variables	Values, mean (SD)	Range
Phone calls (n)	16.4 (9.4)	2-64
Phone (min)	146.3 (137)	8-826
Check-ins and goals (n)	63.4 (35.4)	5-291
Messages exchanged (n)	12.6 (18.5)	0-127
Mailings (n)	0.2 (0.4)	0-1
App use (0 or 1)	0.2 (0.4)	0-1

Post Hoc Exploratory Analysis and Results

To compare changes in HbA_{1c} between enrolled participants and the waitlist comparison group, we conducted a post hoc analysis and examined differences between the baseline and postintervention HbA_{1c} by group for patients with at least 2 HbA_{1c} laboratory results (n=277). Patients in the enrolled group had on average a –1.37 reduction in the HbA_{1c} score (n=70; pre 10.99, post 9.62; P<.001), whereas patients in the waitlist group had a –0.16 reduction in the HbA1c score (n=207; pre 9.75, post 9.49; P<.001).

Finally, to understand factors related to improvement in HbA_{1c} levels, we examined the relationship between demographic variables and endorsement of social and BDoH issues and changes in HbA_{1c} among patients in the enrolled group who had at least 2 HbA_{1c} laboratory results (n=70; Table 5).

We conducted a linear regression analysis with age, gender, and dichotomous (0=no and 1=yes) variables indicating endorsement of the particular issue as predictors of change in HbA_{1c} (Change = post-HbA_{1c} – pre-HbA_{1c}). The results of the regression indicate the predictors accounted for 26.5% of the variance in HbA_{1c} changes with the endorsement of emotional health issues (β=1.344; P=.04) and medication issues (β=1.36; P=.04) as significantly related to increases in HbA_{1c} (Table 6).

Table 5. Demographic variables and endorsement of issues by a subsample of patients with at least 2 hemoglobin A_{1c} (HbA_{1c}) scores (n=70).

Variable	Patients with at least 2 HbA_{1c} scores
Age (years), mean (SD)	53.81 (8.65)
Gender (male), n (%)	29 (41.4)
SDoH[a] (yes), n (%)	59 (84.3)
Appointments BDoH[b], n (%)	57 (81.4)
Knowledge BDoH, n (%)	43 (61.4)
Emotional health BDoH, n (%)	41 (58.6)
Healthy eating BDoH, n (%)	38 (54.3)
Physical activity BDoH, n (%)	30 (42.9)
Medication BDoH, n (%)	15 (21.4)
Glucose monitoring BDoH, n (%)	14 (20.0)
Alcohol BDoH, n (%)	4 (5.7)

[a]SDoH: social determinant of health.

[b]BDoH: behavioral determinant of health.

Table 6. Regression of demographics, endorsed issues, and changes in hemoglobin A_{1c} (HbA_{1c}) among patients with at least 2 HbA_{1c} scores (n=70).

Variable	β	SE	*t* test (2-tailed), (*df*)	*P* value
(Intercept)	0.102	1.777	0.058 (58)	.95
Age	–0.035	0.032	–1.095 (58)	.28
Gender (1=male, 0=female)	–0.159	0.541	–0.295 (58)	.77
SDoH[a]	1.432	1.691	0.847 (58)	.40
Alcohol BDoH[b]	1.59	1.072	1.483 (58)	.14
Appointments BDoH	–2.20	1.528	–1.44 (58)	.16
Emotional health BDoH	1.344	0.625	2.151 (58)	.04
Glucose monitoring BDoH	0.648	0.667	0.971 (58)	.33
Healthy eating BDoH	0.052	0.593	0.088 (58)	.93
Knowledge BDoH	–0.381	0.626	–0.609 (58)	.54
Medication BDoH	1.36	0.636	2.139 (58)	.04
Physical activity BDoH	–0.103	0.571	–0.181 (58)	.86

[a]SDoH: social determinant of health.

[b]BDoH: behavioral determinant of health.

Discussion

This study assessing the implementation of a technology-enabled peer coaching program for patients with uncontrolled diabetes enrolled in a New York City-based managed care plan found that the majority of these patients were from historically marginalized populations (eg, low-income and racial or ethnic minorities) and experiencing high disease burden as measured by average HbA_{1c} >9%. This high level of participation from marginalized and underserved populations is rare in private digital health interventions [13]. Participants in the peer coaching program were more likely to conduct follow-up HbA_{1c} testing compared with their waitlist counterparts (70/330, 21.21% vs 207/2118, 9.77%), which may be attributed to engagement with the peer coaching program and is associated with improvements in glycemic control [14]. In terms of glycemic control, participants had a greater and more significant reduction in HbA_{1c} compared with a waitlist comparison group (n=70; pre 10.99, post 9.62, 12.5% reduction vs n=207; pre 9.75, post 9.49, 1.6% reduction), suggesting the effectiveness of the intervention. In addition, significant predictors of higher HbA_{1c} levels included endorsement of emotional health concerns and medication management issues indicating these issues as prime targets for diabetes self-management interventions. The results of this study add to the literature on the effectiveness of peer coaching [11] and technology-enabled interventions [15] for diabetes self-management among underserved and historically marginalized patients with uncontrolled diabetes.

Historically marginalized populations impacted by diabetes are at increased risk for poor health outcomes [16]; yet digital and technology-enabled interventions for diabetes self-management may help address the unique challenges faced by these communities and promote health equity. Three aspects of Pyx Health's intervention may help explain its positive results, that is the process of matching patients to peer coaches with lived experience with uncontrolled diabetes [12], the focus on addressing SDoH that exacerbates diabetes poor health outcomes [17], and strong collaboration with a health plan. Specifically, telephone-based peer coaching has been shown to be effective at improving medication adherence among Black adults living in rural communities [18]. Thus, the matching process may have helped patients feel more comfortable endorsing a mix of behavioral and SDoH issues impacting their diabetes care including issues with appointments, disease self-management knowledge, and emotional health. Finally, MetroPlusHealth's support, infrastructure, and endorsement helped engender trust in the peer program, which helped with member recruitment, ongoing engagement, and the overall positive impact of the program.

Evidence suggests that some low-income and minoritized patients do not feel comfortable enrolling and using digital diabetes self-management tools possibly due to low digital and tech literacy, which would impact their ability to download a mobile app, navigate a website, and create an account [19]. Further, these patients experience significant disparities in accessing digital health information [20], leading to potential distrust of digital-only solutions. Thus, establishing a telephone-based relationship with the peer coach may be preferable for Black and Latinx patients. In turn, developing trust with the peer coach can result in greater endorsement of SDoH concerns that would otherwise go unaddressed. This study provides evidence that digital health and peer-based programs for underserved populations can be successful when they account for digital literacy challenges and provide trusted support.

The value of addressing SDoH in health interventions cannot be overstated. There is a strong relationship between housing and food insecurity on worsening diabetes self-management and diabetes-related outcomes [10]; unfortunately, few digital health solutions adequately address SDoH despite the call to address social justice concerns [21]. The potential negative impact of not addressing SDoH is the perpetuation of health inequities and not realizing the full potential of digital tools. In this study, in addition to addressing knowledge of diabetes care and emotional health management, the most common issue addressed was managing medical appointments (including addressing barriers such as transportation, accessibility, and cost related to maintaining appointments). Further, nearly 50% (143/330) of patients endorsed housing and food insecurity as directly impacting their diabetes self-care. The results also suggest that endorsement of emotional health and medication adherence issues were related to a lack of improvement in HbA_{1c} relative to when these issues were not present in the patients' lives. It is possible that comprehensive programs that address these SDoH barriers can result in health improvements.

This study provides important information regarding the role of technology-enabled peer coaching and addressing SDoH for patients with uncontrolled diabetes. Yet, the findings are not without limitations. First, the study does not include a randomly assigned control condition and thus causality could not be established. Future studies should consider a randomized controlled trial design in order to minimize the potential effect of confounding variables. Second, the COVID-19 pandemic impacted the process of program implementation and data collection, for example, patients were not able to continue routine HbA_{1c} testing due to social distancing mandates that may confound the outcomes of the program. This limitation also resulted in a smaller subsample of participants who had at least 2 HbA_{1c} laboratory test scores; thus, the analysis of factors attributed to changes in HbA_{1c} was exploratory and should be interpreted with caution. Nonetheless, it appears that patients who participated in the peer coaching program experienced greater reductions in HbA_{1c} and completed more HbA_{1c} monitoring than those not participating in the program. Further, digital coaching interventions for patients with type 2 diabetes have been found to be effective at improving health outcomes (eg, HbA_{1c}, weight loss, fasting blood glucose, and BMI) ranging from 3 months up to 24 months; suggesting digital coaching programs have the potential to be effective and sustainable beyond 6 months [22]. In the long run, a reduction in clinical symptoms and improved disease monitoring may result in overall health improvements and a reduction of health care use costs. Finally, the sample demographics may not be generalizable to all settings, but we consider the overrepresentation of traditionally understudied groups as a strength, as well.

In conclusion, this analysis of a digital, remotely delivered 1-on-1 peer coaching program shows promise in improving diabetes self-management in a typically marginalized population with significant SDoH barriers. Program participants showed improved HbA_{1c} levels, and the analyses found that people with emotional stressors and medication management issues had worse outcomes and that many preferred to connect through phone calls versus an app. Altogether, these findings support the effectiveness of digital programs with multimodal approaches that include human support, showing success when they engage with empathy and address real-world issues including digital literacy and both BDoH and SDoH.

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Conflicts of Interest

AP is an employee and equity holder at InquisitHealth/Pyx Health. HD was a consultant at InquisitHealth/Pyx Health. US holds current research funding from the National Cancer Institute of the National Institutes of Health, California Healthcare Foundation, the Patient-Centered Outcomes Research Institute, and the Agency for Healthcare Research and Quality, as well as contract funding from RecoverX. MR, ES, and SS are employees of MetroPlusHealth. US also serves as a scientific/expert advisor for nonprofit organizations HealthTech 4 Medicaid (volunteer), member of the American Medical Association's Equity and Innovation Advisory Group (honoraria), board member of the Collaborative for Accountability and Improvement (volunteer), and an advisor for Waymark (shares) and for Ceteri Capital I GP, LLC (shares). All other authors declare no competing interests.

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Abbreviations

BDoH: behavioral determinants of health
CONSORT: Consolidated Standards of Reporting Trials
HbA1c: hemoglobin A1c
HIPAA: Health Insurance Portability and Accountability Act
SDoH: social determinants of health

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Beyond Hemoglobin A1c—Outcomes That Matter to Individuals With Type 1 Diabetes in Adopting Digital Health Interventions for Self-Management Support: Qualitative Study

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Abstract

Background: Type 1 diabetes is a demanding chronic condition that requires diligent blood glucose monitoring and timely insulin administration by patients who must integrate self-management into their daily lives.

Objective: This study aimed to better understand what outcome measures are important to individuals living with type 1 diabetes (T1D) in Ontario, Canada, to help inform the development of type 1 diabetes virtual self-management Education and support (T1ME) trial.

Methods: A qualitative approach was used, in which we conducted 6 focus groups with a total of 24 adult participants living with T1D (from age 18 to >65 years) in Ontario. Each focus group was semistructured in nature; participants were encouraged to talk openly about their experiences with T1D self-management and provide their perspectives on more focused topics such as technology and relationships with health care providers.

Results: An interpretive analysis helped us devise a framework for our results that centered around 6 main discussion themes: (1) adapting self-management to meet evolving needs, (2) looking "beyond A1c" toward more personalized indicators of glycemic management, (3) the benefits and challenges of adopting new T1D technology, (4) establishing trusting relationships with diabetes care providers, (5) perceived benefits of peer support, and (6) pre– and post–COVID-19 perspectives on virtual care.

Conclusions: Our goal is for these findings to help facilitate the development of patient-oriented outcome measures that are in line with the unique needs and preferences of T1D patients in this new, more virtual landscape of clinical care, education, and self-management support.

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KEYWORDS

T1D self-management; patient reported outcomes; patient reported outcome measures; virtual care; mobile phone; type 1 diabetes

Introduction

Type 1 diabetes (T1D) is one of the most complex chronic conditions to manage on a daily basis, requiring constant vigilance through self-monitoring of glucose levels and moment-to-moment decision-making regarding insulin dosing. To monitor an individual's glycemic control and risk for long-term complications, hemoglobin A_{1c} (HbA_{1c}) is the gold standard biometric used in diabetes practice [1-3]. Given the demanding nature of self-management, receiving a poor HbA_{1c} result can be discouraging for those living with T1D [4,5], which can lead to feelings of guilt [6], burnout, loss of motivation, and diabetes distress [7,8]. In addition to HbA_{1c}, there has been a greater shift toward using time in range in diabetes care [9], which represents the percentage of one's time spent with normal or near-normal glucose levels as encapsulated by data from continuous glucose monitoring (CGM) [10]. This continuous metric of glycemic control is helpful for providers to facilitate meaningful dialogue with individuals living with T1D and helps clarify what may be affecting their glycemic management outside of the clinic [11].

The work associated with T1D self-management has been compared with a 7-day-a-week, 24-hour-a-day job that involves diligent blood glucose monitoring and frequent decision-making to match insulin administration with dietary intake [12,13]. In addition, individuals living with T1D have to consider the impact that other aspects of daily life have on their glycemic management, including work schedules, exercise regimens, sleep, and stress [14]. Due to the "24/7" nature of self-managing T1D, there is immense potential for improvements in glycemic management associated with digital health interventions that promote frequent communication and facilitate peer mentorship and support (eg, text messaging, emails, and videoconferencing) [15-18]. Indeed, online care has become more commonplace in T1D care and is routinely available to patients in Canada [19], but we are still learning how to deliver virtual care in a way that best meets patients' unique needs.

In our qualitative study, we set out to address the research question, that is, what outcomes matter to patients with T1D and what would make them want to adopt new virtual care technology? To address this question, we facilitated open-ended dialogue with participants in the context of both in-person and virtual focus groups. These focus group discussions were moderated using a focus group guide (Multimedia Appendix 1) that helped participants converse openly about their lived experiences of T1D self-management, as well as their unique education and support needs, including their perspectives on using virtual care. Our aim is that our findings and analysis can help inform the design of patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) [20] in the Type 1 diabetes virtual self-Management Education and support Trial (T1ME) trial in Ontario [21], and more broadly, help diabetes care providers better individualize their self-management support.

Methods

Context of the TIME Study

This qualitative study was undertaken to inform a randomized controlled trial, the T1ME Trial [21]. The T1ME Trial aims to test a high-frequency, low-touch (virtual) model of care for persons with T1D. Patient partnership is a core feature of the T1ME Trial, and the Patient Advisory Committee (PAC) has been contributing to its design and implementation. Early on, the PAC members commented that the planned primary outcome for the trial (HbA_{1c}), struck them as problematic, given that many people living with T1D dislike being "defined" by their HbA_{1c} and HbA_{1c} cannot capture other, more relevant aspects of life with T1D. They asked us to explore what other outcomes might be relevant to people living with T1D, and how these inform their daily self-management practices, which was the impetus for this qualitative investigation. The goal of the study was to understand the types of outcomes that were perceived as meaningful by a diverse sample of adults living with T1D in Ontario, in the context of their usual care and self-management experiences. In order for the study to inform the trial's design, we also needed to understand their education and support needs. In addition, we aimed to identify the aspects of a digital health care intervention that were important to individuals living with T1D.

Qualitative Study Design

We sought to understand participants' lived experiences managing T1D along with their perspectives on self-management support, education, and outcomes, with an emphasis on virtual care. To do this, we used an interpretive, qualitative methodology, which was exploratory in nature [22,23], and patient-centered in its design [24]. A thematic approach to qualitative analysis was adopted to generate themes based on focus group discussions [25]. Each focus group was semistructured in nature, in which a focus group guide contained open-ended and probing questions to help facilitate dialogue amongst participants. In this dialogical approach [26], we used our guiding questions to help frame discussions but we encouraged participants to convey their distinct lived experiences [26,27]. We intend for quotes to help define our themes in the analysis [25] and we also provide interpretations around similarities and diverging viewpoints conveyed through

discussions amongst participants, such as *"information overload"* presented later on.

Ethical Considerations

The study was reviewed and approved by the St. Michael's Hospital, Unity Health Toronto Research Ethics Board (#19-201). All participants gave written informed consent.

Sampling and Recruitment

Through a convenience sampling approach, we were able to include participants living with T1D from diverse sociodemographic positions, with a range of perspectives [28,29]. Eligible participants included Ontario residents 18 years of age or over living with T1D. Participants were recruited by BM from multiple sources, including a diabetes clinic in Toronto, internet-based study advertisements posted by a national diabetes organization (Diabetes Canada), and snowball sampling [29]. With the onset of the COVID-19 pandemic, participant recruitment became increasingly difficult; while we stopped at 6 focus groups, we feel that conceptual saturation was achieved, in that no further themes were being identified [28].

Data Collection

We conducted focus groups with participants [30] either in-person (at St. Michael's Hospital, Unity Health Toronto) or virtually using videoconferencing technology (Zoom Video Communications) between January 2020 and July 2020. The shift to virtual groups was necessitated by the onset of the COVID-19 pandemic, all focus groups conducted after March 1, 2020, were conducted virtually due to COVID-19 pandemic containment measures. Focus groups lasted from 60 to 120 minutes, were audio recorded and transcribed, and field notes were recorded. Participants also completed a demographic questionnaire.

We created a semistructured focus group guide without predetermined hypotheses, rather we wanted to ground our analysis in the discussions with participants [31] and identify patient-oriented outcomes that would reflect their unique perspectives and experiences [32]. The focus group guide was developed by an endocrinologist (GLB), researchers with previous experience in T1D (BM, JAP, and CP), and individuals with lived experience of T1D (ie, input from the Patient Advisory Committee; Multimedia Appendix 1). The focus group guide included open-ended questions regarding participants' self-management experiences, along with questions regarding their use of various technologies, and any experiences with virtual care or incorporating technologies into their self-management. We also included a hypothetical scenario regarding a digital health (smartphone application) intervention. The objective of each focus group discussion was to encourage participants to describe their own experiences with self-management and elicit their perspectives on self-management education and support, delivered either virtually or in person. The moderators of the focus groups (BM and JAP) are individuals with expertise in qualitative research methodology, and who had previously conducted research on the topic of T1D.

Data Analysis

Focus group transcripts were analyzed using an inductive, interpretivist approach [31], in which we developed a thematic framework that encapsulated our interpretations of the dataset [25]. We defined themes [31], looking for patterns within and across focus group transcripts [32,33]. Building themes from the perspective of participants [24,31], allowed us to devise a conceptual framework that portrays what life with T1D is like for them, along with commonalities and differences in their first-hand accounts.

During the course of analysis, we met periodically to discuss the evolving conceptual framework and link our findings to relevant literature [34]. These analytical meetings involved input from the whole analytical team (SD, BM, GLB, and JAP). In particular, we benefited from the guidance of our senior authors, which provided us with clinical insight from a practicing endocrinologist and health services researcher (GLB), along with methodological expertise in qualitative social science (JAP). We sought clarification of participants' responses during the focus groups (question-answer technique) [35], in addition, we participated in discussions with our project's patient partners, and we refined our interpretation of the results and our conceptual framework based on this feedback.

While our approach to qualitative analysis was inductive, interpretivist, and stayed close to participants' accounts [22], our analysis was also informed by theory [26,27,36]. We drew on theory as we were analyzing the first-hand participant accounts to help make sense of the evolving qualitative dataset [36]. From this approach, we used theory for interpretive purposes to help build our thematic framework during analysis [22]. Our interpretations were rooted strongly in the notions of the "work" of chronic illness self-management [37], including the work entailed in managing T1D [13,14], and how technology might play a role in mitigating this work [38].

Given our practical focus on moving beyond HbA_{1c} toward (patient-centered) outcome measures that matter to people with T1D [7,9], social theory helped us think about how a multitude of biopsychosocial factors interplay in complex narratives about life with T1D, including how factors such as "A1c," time in range, the T1D community and social relationships (eg, with family, friends, and health care providers) can influence one's perspective on self-management. In particular, narrative theory [26,27] played a prominent role throughout the analysis, as we thought about how individual participant stories about the T1D experience, along with focus group dialogue, came together to illustrate broader themes related to the social context of living with T1D in Ontario. From this narrative stance [26,27], theory helped us think about what life with diabetes was like from the perspectives of participants and to better understand what challenges or aids their self-management outside of the clinic.

Results

Overview

From January to July 2020, we conducted 6 focus groups (5 virtual and 1 in-person) with a total of 24 participants (an average of 4 participants in each focus group). Table 1 outlines

the demographic and clinical characteristics of participants. In terms of age, participants ranged from emerging and young adults (aged 18-30 years) to older adults (aged 65 years and older). Time living with T1D ranged from 1 to 56 years.

Our analysis identified 6 main themes from participant discussions around self-management, including (1) adapting self-management to meet evolving needs, (2) looking "beyond A1c" toward more personalized indicators of glycemic management, (3) the benefits and challenges of adopting new T1D technology, (4) establishing trusting relationships with diabetes care providers through holistic care, (5) perceived benefits of peer support, and (6) pre– and post–COVID-19 perspectives on virtual care. Each theme is discussed in detail below.

Table 1. Demographic and clinical characteristics of the participants.

Characteristic (N=24)	Values, n (%)
Gender	
Men	9 (38)
Women	15 (62.5)
Age ranges [a] of participants (years)	
18 to 24; emerging adults	2 (8)
25 to 44; young adults	12 (50)
45 to 64; middle-aged adults	7 (29)
≥65; older adults	3 (13)
Duration of diabetes at focus group	
1 to 10 years	6 (25)
11 to 20 years	4 (17)
21 to 30 years	3 (12)
31 to 40 years	4 (17)
≥ 41 years	7 (29)
Insulin administration	
Continuous subcutaneous insulin infusion	17 (71)
Open artificial pancreas system (Closed Loop)	1 (4)
Multiple daily injections	7 (29)
Continuous glucose monitoring technology	21 (88)
Occupation	
Full-time student	2 (8)
Full-time work	14 (58)
Part-time work	2 (8)
Unemployed	2 (8)
Retired	3 (13)
Place of residence in Ontario	
Urban	23 (96)
Rural	1 (4)

[a]Age ranges were classified based on literature looking at type 1 diabetes throughout distinct periods of adulthood [39].

Adapting Self-Management Strategies to Meet Evolving Needs

This theme relates to the learning process, in which participants described an ongoing need to adapt diabetes self-management to their evolving needs. Participants described the complex and unrelenting work of self-management. Many participants faced ongoing struggles and challenges trying to keep their blood sugar levels within a target range,

> *I find it a bit of a struggle every day, to be honest… I do have low blood sugars in the early mornings, before I even wake up, pretty often.* [P11]

However, as people live longer with T1D, self-management began to feel more like a "habitual" or "natural" part of everyday life. Participants explained that they achieved a sense of confidence and "control" through an active learning process guided by regular support from their health care team:

> *I feel so much more in control of what I can control, in the last six months than let's say, the first six months, cause it was [a] big, big change, at my age [mid-forties at diagnosis]… at first, I used to see the nurse and the doctor…every month …I was just learning… reading, trying to understand this new disease and how to control it. So now, I feel, I don't need them as often.* [P12]

Soon after diagnosis, participants reported that they developed confidence for managing diabetes on their own, as they acquired lived experience. For example, one participant characterized people with T1D as "*ambitious people*" (P13) who have to acquire their own set of skills and expertise for self-management, a skill set they described as being unique from the diabetes education they received from health care providers.

Adaptation was a key part of this skill set, as participants constantly had to adjust to new challenges associated with changing life circumstances, such as adapting to parenthood, a new job, or beginning post-secondary school in a new city:

> *One of the challenges that I'm finding is that as we age, and go through different stages of life, we have to find ways to adapt to whatever's changing. So, for instance… getting married, having children… not being able to focus solely on yourself, because you're concerned about other people now… So it's more about adapting to life as it changes.* [P14]

Participants portrayed living with T1D as a dynamic experience that occurs within a psychosocial context that fluctuates across the life course.

Looking Beyond HbA_{1c} Toward Personally Meaningful Indicators of Glycemic Management

Looking beyond "A1c," participants spoke about the benefits of using more nuanced outcomes, such as time-in-range, to assess their glycemic management. For example, participants discussed a desire to shift the conversation with providers away from $HbA_{1c,}$ and recognized its many limitations,

> *A1c, it's an average and it's an average that doesn't necessarily tell the truth. You could be consistently at seven or you can go … up and down like a yo-yo and then, it'll still average it out to seven. It can still look like 'Oh, you're doing perfectly well.' whereas you're doing anything but well. So you can't really count on the A1c alone.* [P17]

Some participants explained that they valued measures that were more relevant to their lived experience over more quantitative indicators such as HbA_{1c} or time-in-range. A key example related to the physical symptoms associated with high or low blood glucose levels (essentially how physically comfortable they felt throughout the course of a day). As one participant recounted,

> *I think a lot of it is just, I don't want to be in discomfort. When I'm high, I'm uncomfortable; when I'm low, I'm uncomfortable.* [P18]

Participants also commented on how these symptoms interrupted aspects of their life such as job performance or being able to participate in hobbies.

The Benefits and Challenges of Adopting New Type 1 Diabetes Virtual Self-Management Education and Support Technology

Participants reported using a range of technologies to manage their T1D, and to experience life without feeling as though diabetes was dominating their attention. One participant described how "looping" technology saved them from having to make a "hundred thousand decisions" each day [P7]. "Looping" refers to either commercial or open-source, community-developed closed-loop systems that use CGM readings and algorithms to automatically adjust insulin delivery from a pump [38]. Aside from looping, participants spoke about how they used different insulin pumps, glucose monitors, and smartphone apps. Many of the participants recounted the time when they switched from insulin injections to an insulin pump as a particularly memorable moment, one that made self-management feel easier, and gave them more freedom.

> *I've only been on the pump for about five years. And I'm thirty years into this, and I'm kicking myself, literally. I should have been on it ten years ago. Because the impact on my hemoglobin A1c and so forth… but more, it is more convenient … and it is just a real game changer, switching over to that pump.* [P10]

Participants also offered their perspectives on what outcomes they would like to see if or when adopting a (new) digital health intervention. In particular, they spoke about how willing they would be to take on a new self-management support and education application. A participant characterized it this way.

> *If I were about to take on another intervention and you're calling it an app, I'd want to make sure that it's integrated into everyday life, and not become another task. So, I'm not adding on to the maintenance, I'm either increasing the efficiency of the maintenance or replacing some of those tasks.* [P10]

This notion of easing the burden of decision-making was important to participants and would factor into their willingness to adopt a new smartphone application, for example. Indeed, when talking about their "ideal diabetes app," many participants explained that they would love to use an application that adapted to their behavioral habits and lifestyle,

> *If I could have anything, in…an app or…in a dream world… it would be something …that would go "You usually go to the gym at six pm on Tuesday. It's three pm on Tuesday. Do you want to lower your basal?" Or … "You're often low during the night at three am, after you go to the gym… you know, stuff like that…to try and help me predict and be that little … angel on my shoulder."* [P18]

In addition to describing what an "ideal" app would look like, participants reported on their experiences using a range of apps and technology, as well as accessing online information from

a variety of different sources (social media and patient organizations). Although most participants described access to technology and rapid access to information as being very beneficial, some said they could feel overwhelmed at times, because of "information overload" associated with technologies. From this perspective, a participant felt that trying to be overly precise could result in a sense of guilt or failure with glycemic management.

> *I think knowing your exact blood sugar can play little games with your head, I guess. You know? "Oh crap, it's not six point seven exactly."* [P1]

Participants shared their views on using a trusted information portal or digital library that could help them find useful online resources, personalized to their individual needs. A conversation among participants within focus group 2 highlights views on the potential benefits of an information portal or technology to build community.

> *I kind of love the idea of even like, I'm using this term really loosely, but like, an online library that has all of these resources that either our team has or other people have brought to them. … 'cause you can Google stuff, but it's nice to feel like you're getting something from a source that's a little more legitimate.* [P7]

> *The staff and the nurses at the hospital, they seemed to have a lot of knowledge,…they are suggesting events, and readings and … articles, …that could benefit from being shared on such a portal.* [P6]

Throughout this discussion, responses were uniformly favorable toward the possibility of having an internet-based portal to find trusted information, with resources that were vetted by health care professionals and T1D peers going through similar challenges. Furthermore, the potential of using an app to build community posits benefits for participants in this discussion group, as it can act as an outlet to share first-hand T1D information and connect people with T1D within their local community.

Establishing Trusting Relationships With Diabetes Care Providers Through Holistic Care

As participants gained experience and confidence with self-management, they said they relied less on their health care teams. However, most participants reported that they needed to check in periodically with their health care teams to keep them on track and help navigate new challenges. For instance, a participant compared their regular diabetes care visits to a "vaccine; [P17]" something they felt could prevent them from experiencing long-term complications. Another participant characterized their regular follow-up visits as a "wake-up call" [P19], which could keep them from becoming too complacent.

Participants also described the importance of building trusting relationships with their health care teams. As one participant described, their relationship with their nurses became like a "*borderline friendship* (P5)." Another participant highlighted the importance of psychosocial support given how self-management is "*entwined (P7)*" with everything else in their life,

> *The nature of being diabetic, it just gets wrapped up in everything in your life. So, I often think… my nurses … have to kind of be a therapist as well. (laugh) Because, when I go in and I say, like, you know, this week, or, 'These months have been bad, because… I lost my job.' or whatever the reasoning is. Like, it always ends up being about everything else that's going on in your life, because diabetes is so entwined in everything you do. And they are so supportive about that. And they just listen (laugh) and they let you… get your emotions out if you need to. And I find that incredibly helpful.* [P7]

Although participants emphasized that frequent interactions with providers helped them stay on course with their self-care, they also noted that these interactions represented only a fraction of the time they spent self-managing and navigating through the complex social contexts of everyday life. As one participant commented,

> *When I see my endocrinologist, it's very quick…I see her for ten minutes.* [P24]

Perceived Benefits of Peer Support

Beyond the assistance offered by clinicians, participants spoke about the benefits of being involved with the T1D community and engaging with peer support. For instance, one participant explained that using social media allowed them to connect with other people living with T1D facing similar challenges:

> *And it's just more… quick, to get responses from social media, as opposed to getting appointments with specialists … Like, all these small issues that we deal with every day, not in textbooks that they [health care professionals] can't necessarily relate to. So it's good… to get different perspectives, from different people.* [P8]

Connecting with others living with T1D can be helpful for patients. Indeed, participants stated that they enjoyed participating in the focus groups and talking to others about their self-management experiences as it gave them an opportunity to share views and compare knowledge:

> *This is the first time I've been invited to something like this. So thank you, … But you know, it's a pleasant surprise that there's, obviously, other [people] who are dealing with the same potential struggles. And you know… I don't know very many diabetics, so it's nice to know that there are other [people], of similar age brackets, out there, that you know, are dealing with the same things that we're dealing with.* [P4]

Unlike a typical Facebook group, participants noted that our focus groups provided an opportunity for participants to interact (either virtually or in person) and learn from one another. This positive feedback regarding the focus groups reflects the potential benefits of incorporating more peer support programs into T1D care.

Pre– and Post–COVID-19 Perspectives on Virtual Care

A central focus of discussions was on participant perspectives and experiences related to virtual care (ie, clinical care provided

through phone or videoconference). Notably, the first 4 focus groups occurred before the onset of the COVID-19 pandemic and the enforcement of physical distancing measures in Canada (March 2020), which reflects a different context compared with the 2 later groups, when there was a far greater uptake of virtual visits for diabetes patients across Ontario. Throughout this section, we will consider virtual care across participant discussions, highlighting what may have changed due to COVID-19 or stayed the same.

Participants explained that the pandemic marked a time in which virtual visits became the new "normal," mandated by public health measures. During the prepandemic focus groups, participants generally agreed that a shift toward more virtual visits made sense for diabetes care, and it was already "*going this way in the future* (P24)"

> *I did just have, actually, a virtual appointment. It was done over the phone…and it was perfect. It saved me a very long commute. (laugh) And, we accomplished all the same things, so it was pretty great.* [P5]

Aside from physical examinations, many participants said that most diabetes care could be done virtually, and they highlighted specific advantages of virtual care, such as saving travel time and reduced time off work. However, participants questioned what might be "lost" in virtual encounters:

> *What about the human interchange factor? We're not robots…There's always something lost in translation… I'm not sure what would be lost yet … so it's good to have the option of both [virtual and in-person visits.* [P17]

Participants valued having in-person touch points with providers; physically being in the clinic made some participants feel as though they were more engaged with their care:

> *I find that when I go, I'm a hundred percent there, in mind and spirit. And you know, I feel a little bit more engaged.* [P4]

However, participants noted that having trusting relationships with healthcare providers that they have already met face-to-face in the clinic enhanced their engagement and satisfaction during virtual appointments:

> *I wouldn't mind the virtual appointments at all. Because I know my team. I've met them face to face…But, if I didn't know those people as well as I do right now, I would not be as happy doing it in a virtual environment.* [P20]

Overall, participants appeared to value the ability to contact providers when urgent issues arose between clinic visits. They clarified that they did not need providers to be at their "*beck and call*" (*P4*). Rather, it was important to know that they could get a timely response from a trusted health care provider when more unanticipated situations occurred related to their self-management.

Discussion

Principal Findings

We conducted focus groups with adults living with T1D in Ontario, Canada, to better understand their self-management experiences and how they viewed virtual care (comparing perspectives both before and after the pandemic). Participants represented a diverse group of adults with T1D from various life stages, occupations, and duration of diabetes. Our findings illuminate some common concerns, experiences, and needs of adults living with T1D at various life stages. These are important to consider, in this increasingly virtual era of diabetes care.

Looking beyond HbA_{1c} toward more nuanced indicators of glycemic management, participants noted that using "time in range" to identify glycemic patterns and focusing on physical symptoms associated with high or low blood glucose levels might be more valuable and practical for informing their self-management. Moreover, participants spoke about the critical role of incorporating technology within their lives to ease the burden of daily decision-making. Although participants generally spoke positively about advances in diabetes technologies (including insulin pumps, artificial pancreas, and looping systems [38]), some also expressed concern regarding information overload from the abundance of CGM data. Previous research suggests that information overload can decrease maintained use of CGM devices [10]. More research needs to be done to highlight ways in which diabetes technology can decrease the workload associated with T1D self-management rather than add to it.

Furthermore, participants spoke about the benefits of peer support, and leveraging the knowledge and skills of the T1D community, to learn how to adapt self-management education to evolving needs. This finding was similar to other studies in the T1D literature related to peer support; for instance, Elnaggar et al [18] found that the sharing of T1D experiences and first-hand knowledge through social media can serve as a catalyst for motivation and self-efficacy. Similarly, in our focus groups, there was also a general consensus that leveraging the support of the diabetes community (either online or in-person) was beneficial to participants by allowing them to connect with other people living with T1D who were going through similar life circumstances. Therefore, diabetes care teams may benefit patients by trying to find innovative ways to facilitate community-building amongst patients within their clinic.

In addition to engagement with peer support, mobile self-management interventions for people with T1D, have the potential to improve glycemic control when paired with input from clinicians (eg, through SMS text messaging or other communication modalities that promote frequent patient-provider interactions) [15-17]. Participants recounted that in order to establish trusting relationships with health care teams, diabetes care providers must try to individualize self-management education and to do this, mobile and online care may be the tool providers need to better connect with people with T1D and learn what their needs are outside of the clinic [15].

Participants in our study spoke at length about trying to find ways to adapt their diabetes self-management practices to their evolving lifestyle changes, which they described as an ongoing learning process. In doing so, they often used the language of "control". Specifically, participants spoke about how the notion of trying to be "in control" of their blood sugars can feel burdensome, especially during challenging life periods. Given that the term "glycemic *control*" is widely used in the diabetes literature and in clinical practice, we have reflected on the use of this terminology throughout our qualitative analysis and in the writing of this manuscript after hearing from our patient partners. Using words such as "control" can leave individuals with feelings of guilt and being a "bad" patient when they are not reaching their target ranges or personal diabetes goals [5-8]. Moreover, the word "control" can invoke ideas of power struggles; for example, between parents and emerging adults [13], or people living with diabetes and their health professionals [14]. Our discussions with our patient partners about the language used in diabetes care and education reflect a greater movement in the literature toward being sensitive to issues of judgment (or even stigma) in patient encounters [5].

One of the key strengths of this project was using a patient engagement approach in all aspects of the study [24]. The conception, planning, design, analysis, and drafting of the manuscript were guided by people with lived experience of T1D. Collaboration with people with lived experience can improve the quality and relevance of research by focusing on the priorities set by patients [24]. Furthermore, the present qualitative study is informing the design of the broader T1ME trial [21] with the intent that engaging patients in the study design and selection of outcomes can lead to increased recruitment and retention in the trial, because study measures will be more meaningful and applicable to the lived experience of the target population [20].

Finally, there are some important limitations in our study that we would like to address. In terms of recruitment, we had to cease data collection after the sixth focus group as we were unable to continue recruiting participants in person at diabetes clinics due to the onset of the COVID-19 pandemic and local social distancing policies enacted in Ontario. Although some studies have shown that virtual recruitment may have benefits for qualitative research, such as the inclusion of a more diverse population [40], we found that it was much more difficult to recruit participants through advertisements and flyers compared with approaching them in person at clinics. We also acknowledge that there may have been an accessibility barrier for some individuals with T1D in Ontario (who may have trouble accessing technology) and these individuals may have different views compared with the perspectives shared within this study. Another limitation was that all but one of our participants lived in urban settings. Thus, our results may not fully reflect the experiences of those living in rural areas. Furthermore, the issue of "dominant voices" taking over a focus group discussion can be a concern for the interpretability of qualitative findings [41]. Finally, we appreciate diabetes care providers may have different views on the implementation of virtual care programs compared with patient participants. For instance, virtual care has been reported to increase the workload for nurse educators in some telehealth programs [42]. Therefore, it is important to consider what additional support may needed for health care providers while implementing virtual health care interventions.

Conclusion

Type 1 diabetes care has shifted toward a more virtual model of care that is in line with the unique needs and preferences of a diverse patient population with T1D who require personalized education and timely support to help manage a relentless and complex chronic condition. In our study, we have highlighted the perspectives of people with T1D in Ontario who are trying to adapt to this more virtual landscape of diabetes care in Canada. Our findings help explore the ways in which people with T1D want technology to meet them "where they are at" in their unique T1D journey and provide an opportunity to think about more patient-centric outcome measures that go beyond HbA_{1c}, such as symptom control (alleviating fluctuations in highs or lows) and the patient perceived benefits associated with time-in-range. Although participants generally spoke positively about technological advancements in CGM and insulin delivery systems (CSII), there were contrasting perspectives related to the issue of information overload, which sheds light on the need for additional support to navigate the increasingly data-driven nature of T1D self-management. Our findings indicate that finding ways to use technology to leverage the provision of personalized support of peers, as well as providers, can help build a sense of community, and bridge the gap between the clinical care needs of individuals with T1D and the complex social context that surrounds their daily glycemic management.

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Authors' Contributions

BM, AN, CP, DG, MG, CMC, GL, GLB, JAP, and the T1ME PAC were integral in planning the study. BM, CP, CMC, GL, GLB, and JAP created the interview guide. BM and JAP conducted the focus groups. GM, RS, HOW, CHY, and GLB provided guidance throughout the data collection process. SD and JAP conducted an initial qualitative analysis. BM, SD, AN, DG, MG,

SJ, GLB, and JAP conducted secondary qualitative analysis. BM, SD, and AN drafted the manuscript. BM, SD, AN, CP, DG, MG, CMC, GL, SJ, GM, RS, HOW, CHY, GLB, and JAP edited and approved the final version of the manuscript. GM, RS, HOW, CHY, GLB, and JAP obtained funding for this study.

Conflicts of Interest

RS has received speaking and advisory board fees from Dexcom Canada.

Multimedia Appendix 1
Focus Group Guide.
[DOCX File , 19 KB - diabetes_v9i1e60190_app1.docx]

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Abbreviations

CGM: continuous glucose monitoring
HbA_{1c}: hemoglobin A_{1c}
PAC: Patient Advisory Committee
PREM: patient-reported experience measure
PROM: patient-reported outcome measure
T1D: type 1 diabetes
T1ME: Type 1 diabetes virtual self-Management Education and support

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Original Paper

Four New Patient-Reported Outcome Measures Examining Health-Seeking Behavior in Persons With Type 2 Diabetes Mellitus (REDD-CAT): Instrument Development Study

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Abstract

Background: The management of type 2 diabetes mellitus (T2DM) includes mastery of complex care activities, self-management skills, and routine health care encounters to optimize glucose control and achieve good health. Given the lifelong course of T2DM, patients are faced with navigating complex medical and disease-specific information. This health-seeking behavior is a driver of health disparities and is associated with hospitalization and readmission. Given that health-seeking behavior is a potentially intervenable social determinant of health, a better understanding of how people navigate these complex systems is warranted.

Objective: To address this need, we aimed to develop new patient-reported outcome (PRO) measures that evaluate health-seeking behavior in persons with T2DM. These new PROs were designed to be included in the Re-Engineered Discharge for Diabetes-Computer Adaptive Test (REDD-CAT) measurement system, which includes several other PROs that capture the importance of social determinants of health.

Methods: Overall, 225 participants with T2DM completed 56 self-report items that examined health-seeking behaviors. Classical Test Theory and Item Response Theory were used for measurement development. Exploratory factor analysis (EFA; criterion ratio of eigenvalue 1 to eigenvalue 2 being >4; variance for eigenvalue 1 ≥40%) and confirmatory factor analysis (CFA; criterion 1-factor CFA loading <.50; 1-factor CFA residual correlation >.20; comparative fit index ≥0.90; Tucker-Lewis index ≥0.90; root mean square error of approximation <0.15) were used to determine unidimensional sets of items. Items with sparse responses, low-adjusted total score correlations, nonmonotonicity, low factor loading, and high residual correlations of high error modification indices were candidates for exclusion. A constrained graded response model was used to examine item misfit, and differential item functioning was examined to identify item bias. Cronbach α was used to examine internal consistency reliability for the new PROs (criterion ≥0.70), and floor and ceiling effects were examined (criterion ≤20%).

Results: Four unidimensional sets of items were supported by EFA (all EFA eigenvalue ratios >4; variance for eigenvalue 1=41.4%-67.3%) and CFA (fit statistics all exceeded criterion values). This included (1) “Health-Seeking Behavior: PCP-Specific” (6 items); (2) “Health-Seeking Behavior: General Beliefs” (13 items); (3) “Health-Seeking Behavior: Family or Friends-Specific” (5 items); and (4) “Health-Seeking Behavior: Internet-Specific” (4 items). All items were devoid of differential item functioning

for age, sex, education, or socioeconomic status factors. “Health-Seeking Behavior: General Beliefs” was developed to include both a computer adaptive test and a 6-item short form version; all other PROs were developed as static short forms. The psychometric reliability of these new PROs was supported; internal consistency ranged from acceptable to excellent (Cronbach α=.78-.91), and measures were free of significant floor or ceiling effects (floor effects range: 0%-8.9%; ceiling effects range: 0%-8.4%).

Conclusions: The new REDD-CAT Health-Seeking Behavior PROs provide reliable assessments of health-seeking behaviors among those with T2DM.

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KEYWORDS

diabetes mellitus; social determinants of health; patient-reported outcome measures; outcomes assessment; health care; patient reported; health-seeking behavior; type 2 diabetes; hospitalization; diabetes computer adaptive test; primary care; socioeconomic; assessments

Introduction

Over 37 million Americans live with diagnosed diabetes, accounting for 7.8 million hospitalizations and over US $327 billion in annual health care costs [1]. The lifelong course of type 2 diabetes mellitus (T2DM) demands mastery of complex care activities, self-management skills, and routine health care encounters to optimize glucose control and achieve good health. Through evidence-based diabetes self-management education programs, patients gain the essential knowledge, skills, and support to practice diabetes self-care and navigate the health care system as informed and engaged participants in their care [2]. Simultaneously, increased access to online resources and shifts toward shared decision-making models in medicine have promoted a culture where patients can more readily seek and acquire health services, information, and knowledge for themselves [3,4].

Health seeking is broadly characterized as “any activity undertaken by individuals who have a health problem or to be ill for the purpose of finding an appropriate remedy” [5]. Health-seeking behaviors are further contextualized by culture, language, and socioeconomic factors, all of which underscore individual decision-making and behavior change processes in response to illness [5,6]. Comprised of both information-gathering and use of services, health-seeking behaviors have been studied in the context of coping among patients with cancer and other serious illnesses [7], and to a lesser extent, as a marker of patient activation [8,9]. A systematic review of literature on health-seeking behavior concluded that routine assessments of patients’ health-seeking behaviors and attitudes are warranted as a marker of patient activation and healthy coping with illness [4]. The credibility of patients’ information sources and their intent to act on such information should also be considered in the context of their social environment [4,6].

Researchers have identified individual sociodemographic differences in health-seeking behaviors, with higher levels of health literacy and younger age linked to active health-seeking among White adults [7,9,10]. These empiric findings implicate health-seeking behavior as a possible driver of health disparities for those living with diabetes and a possible marker forecasting poor coping with illness situations leading to increased risk for hospitalization and readmission. By nature of their lifelong disease, patients with T2DM rely on disparate sources for medical and disease-specific information, ranging from interpersonal connections, such as friends and family, to health care professionals, as well as more ubiquitous sources, including the internet, television, and social media [11]. In doing so, patients seek to weave a web of information that is relevant and personalized to their needs and experiences, thus influencing their immediate or delayed interactions with health systems [8]. However, few studies on health service attainment and seeking behavior have focused specifically on diabetes care.

The role and patterns of health-seeking behavior as a potentially intervenable social determinant of health remain underexplored in research and medical literature. Understanding the circumstances and patient- and system-level factors that drive such behaviors have clinical implications, both positive (eg, adherence) and negative (eg, nonadherence) [4,6]. In the context of diabetes, health-seeking behavior is a component of diabetes self-management skills. The degree to which an individual masters disease self-management strongly influences the likelihood of serious complications, hospitalizations, and premature death, and reflects the individual level of coping with this serious chronic disease.[2] Thus, there is a valid need to better understand the factors that influence health-seeking behavior and its role as a social determinant of health.

The purpose of these analyses was to develop new patient-reported outcomes (PROs) according to established measurement development standards [12] that assess health-seeking behavior in persons with T2DM. These new measures of health-seeking behavior will be included in part of a larger, more comprehensive measurement system designed to capture important social determinants of health that are related to readmission risk in people with T2D. This measurement system, the Re-Engineered Discharge for Diabetes-Computer Adaptive Test (REDD-CAT), includes PROs that capture personal (health literacy, mood, pain management, stigma, illness burdensomeness, caregiver needs, substance abuse, finances, food, and transportation), social (social support, isolation, and provider connection), and community factors (health care access, medication access, health care environment, and housing security). Publications highlighting the development and validation work supporting the other measures in the system are reported elsewhere [13-21].

Methods

Study Participants

We screened a total of 614 potentially eligible participants; of these, 292 were eligible and 225 were enrolled. The participants were enrolled from August 16, 2019, through March 5, 2020. Data for these analyses were collected as a part of a broader study designed to develop multiple PROs that capture important social determinants of health and behavior; data supporting this development work are reported elsewhere (ie, housing security [13], illness burden [14], medication adherence [15], and health care access [16]). Inclusion criteria for this study were broad and there were no specific exclusion criteria. To qualify, individuals had to have a diagnosis of T2DM, be at least 18 years of age, be fluent in English, and be able to provide informed consent. The participants completed surveys independently if they were able to correctly pronounce the first 10 words on the Wide Range Achievement Test Fourth Edition (WRAT4) reading subtest [22], and those with 1 or more errors were assisted with survey completion by a study coordinator. Potential participants were identified and recruited at Boston Medical Center (BMC), a safety-net health care system, through their clinical data warehouse (primary recruitment source), internal census reports from electronic health records (tertiary recruitment source), or local lists of individuals that had previously participated in research at BMC and had given permission to be contacted for future studies in T2DM (secondary recruitment source).

Measures of Health-Seeking Behavior

The new health-seeking behavior PROs were developed using both qualitative and quantitative methodologies. The initial pool of items included content that examined the actions and inactions of persons with T2DM who perceive themselves as needing medical care. Briefly, this item pool was refined using feedback from patients with T2DM and professionals (in both T2DM and measurement development); items were written and revised using the Lexile framework to ensure they were no higher than a fifth-grade reading level, and a translatability review was completed to ensure that future measure translation into other languages would be possible. In this study, we tested the finalized item pool in a sample of individuals with T2DM. As a result, 4 new PROs were developed (the development process is detailed below). All of the PROs generate scores that are on a T-score metric (mean 50, SD 10); higher scores indicate more health-seeking behavior. FireStar Version 1.3.2 (SW Choi) [23] was used to generate computer adaptive test (CAT) scores when appropriate. Preliminary reliability and validity data are reported for all PRO CAT, short form (SF), and full measure scores.

Data Collection

REDCap (Research Electronic Data Capture; Vanderbilt University), a HIPAA (Health Insurance Portability and Accountability Act)–compliant online data capture system, was used to collect survey response data. The WRAT4 reading subtest [22] was used to assess reading level. In all, 34.5% (212/614) of participants passed the WRAT4 and were able to complete study assessments independently; those with 1 or more errors on the first 10 words (13/614, 2.1%) completed the assessments with the assistance of a study coordinator. Data were collected in accordance with local institutional review boards (IRBs), and the participants were required to provide informed consent before study participation.

Ethical Considerations

Approval was obtained from the ethics committee of BMC, which served as the single IRB of record for this study (H-38545). The University of Michigan IRBMED ceded to the BMC/BUMC IRB (HUM00165735). The procedures used in this study adhere to the tenets of the Declaration of Helsinki. We followed the activities described in the Agency for Healthcare Research and Quality Informed Consent and Authorization Toolkit for Minimal Risk Research. This toolkit was developed to facilitate the process of obtaining informed consent and HIPAA authorization from potential research participants. Specifically, for those patients who met all criteria for participation, the consent process included a discussion of (1) the purpose of the study; (2) IRB safeguards; (3) informed consent; (4) permission for phone contacts; (5) permission for medical record review; and (6) the use of their health information. A waiver of documentation of informed consent was approved for this study, as the research presented no more than minimal risk of harm to participants. To protect privacy, the information obtained from the participants was the minimum necessary to conduct the study. All study documents were identified with a unique study ID to protect confidentiality. The study ID was linked to a master-code list, which contained all direct identifiers and was stored on a password-protected, encrypted computer on the BMC secure network with access limited to BMC study staff. Consent forms were stored separately in a locked file cabinet. The private health information (PHI) collected from the clinical data warehouse was also password protected and stored on an encrypted and HIPAA-compliant BMC-issued computer. Only the minimally necessary PHI was gathered, and all PHI shared with the University of Michigan was transmitted through the secure BMC server on the HIPAA-compliant Box, Inc. platform in accordance with their data-sharing agreement. Finally, the participants received a total of US $75 compensation for their participation.

Sample Size Requirements

There is evidence to indicate that a constrained graded response model (GRM) model is appropriate for sample sizes that are smaller than 500 [24]. Recommendations indicate that stable parameter estimates can be achieved with this model, given a minimum size of 200 [24,25]. These recommendations also support iterative Wald 2-based differential item functioning (DIF) testing when there is a minimum sample size of ~100 participants per each investigated population subgroup [26].

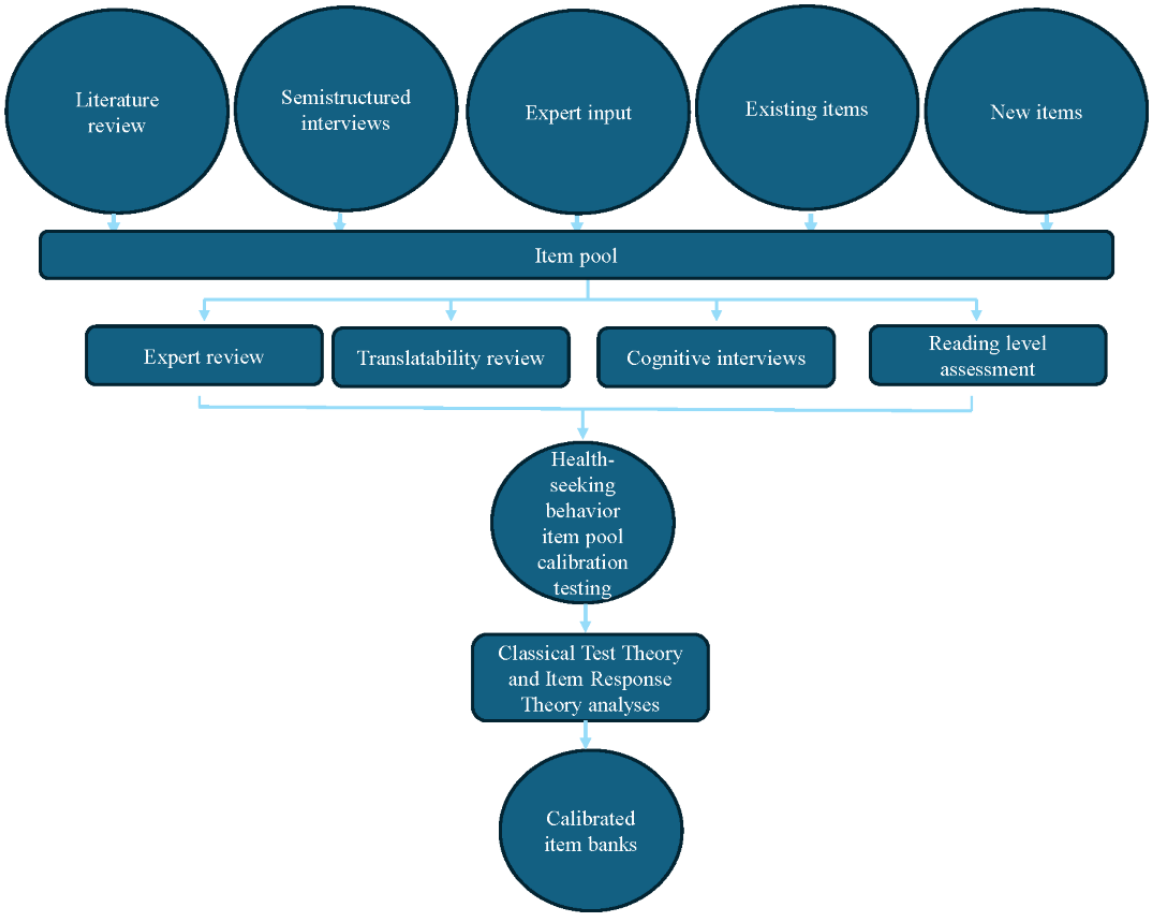
Statistical Analyses

Item Bank Development

Following established measurement development standards [12], Classical Test Theory and Item Response Theory (IRT)–based analyses were used to inform the development of these new PROs (Figure 1). The initial item pool development is described elsewhere [27,28]. Specifically, general medical

patients (n=37), caregivers (n=2), and care providers (n=9) completed semistructured interviews to identify concepts related to readmission risk. The item development process was iterative and included input from providers with expertise in T2DM and PRO measurement development; cognitive interviews with individuals with T2DM; reading level assessment (to ensure items were at fifth-grade reading level or below); and translatability review (ie, to facilitate future Spanish-language translation).

Figure 1. Process for new patient-reported outcome measurements development.



After the item pools were developed and administered to the 225 (36.6%) out of 614 participants, exploratory factor analysis (EFA; principal-axis factoring with a geomin [oblique] rotation) and confirmatory factor analysis (CFA; items were considered as categorical, interitem polychoric correlations were obtained and analyzed, a weighted least squares mean and variance adjusted estimator was used, and a pairwise-inclusion strategy was used for forming polychoric correlation matrices, which allowed for the incorporation of study participants with missing response data) were used to identify unidimensional sets of items (using Mplus version 7.4; LK Muthén and BO Muthén [29]) [30-32]. Essential unidimensionality would be supported by EFA if (1) the ratio of eigenvalue 1 to eigenvalue 2 is ≥4 and (2) ≥40% of item response variance is accounted for by eigenvalue 1. Items with (1) n<5 responses in any response category, (2) low item-adjusted total score correlations (ie, <0.40), or (3) nonmonotonicity (according to Testgraf Software; J Ramsay) [33] were candidates for exclusion. Essential unidimensionality would be supported by CFA: (1) comparative fit index ≥0.90, (2) Tucker-Lewis index ≥0.90, and (3) root mean square error of approximation (RMSEA) <0.15 [34-37]. Items with low factor loadings (lx <0.50), high residual correlations (>0.20), or high correlated error modification indices (≥100) were candidates for CFA-based exclusion [30-32].

Next, a constrained GRM [38], that is, a common-slope GRM, was estimated and used to obtain item parameters and identify item misfit (ie, S-X2 divided by *df* effect size >3 using IRTPRO) [39,40]. We also examined items for DIF: (1) candidates for exclusion exhibited statistically significant (P<.01) item parameter differences and (2) >2% of DIF-corrected versus uncorrected score differences were more than the uncorrected score SE (analyses were conducted in IRTPRO version 3.1.2 [L Cai, D Thissen, and SHC du Toit] [31] using iterative Wald-2 testing [41,42]). DIF was examined for four factors: (1) age (<60 vs ≥60 years), (2) sex (male vs female), (3) education (≤high school vs >high school), and (4) socioeconomic status ("have enough income to pay rent or mortgage" and "can afford to pay bills on time," both categorized as never, rarely, sometimes, usually, and always). After the GRM and DIF analyses were completed and item parameters estimated, CFA was again used to confirm unidimensionality (according to the criteria presented above). As previously noted, the GRM

analyses produced calibrated item parameters, that is, the slope and threshold estimates characteristic of an IRT-developed item bank. This item parameter information was also used to program CAT administration for measures or banks that included more than 10 items. CAT scores were simulated using FireStar software [23]; they were then used for analyses that examined preliminary reliability and validity. To begin, CAT item responses were simulated from a sample of 2000 cases drawn from a clinical population (ie, having a mean 50, SD 10 score in the direction of worse health status; ie, T-scores >60 for negatively worded concepts or T-scores <40 for positively worded concepts) so as to obtain a rigorous CAT performance assessment based on patients in a clinical context. CAT administration parameters (eg, number of items to administer and targeted score reliability level) were optimized to balance response burden and score precision. For calibrated measures or item banks that included greater than 6 items, 6-item SFs were created by balancing clinician input on item content with psychometric considerations, which included score-level reliability.

Preliminary Descriptive Data for the New PROs

PRO scores were normally distributed and supported the use of parametric data analyses. With regard to reliability, we estimated Cronbach α internal consistency for full-length measures and SFs (a priori criterion: α≥.70) [43]. The a priori criterion for acceptable floor and ceiling effects was ≤20% [44,45].

Results

Study Participants

A total of 225 participants with T2DM were included in this sample. Table 1 lists the sample descriptive data.

Table 1. Descriptive data for the study participants (N=225).

Variables	Values
Age (years), mean (SD)	57.7 (11)
Sex, n (%)	
Female	118 (52)
Male	107 (48)
Ethnicity, n (%)	
Not Hispanic or Latino	187 (83)
Hispanic or Latino	38 (17)
Race, n (%)	
White	40 (18)
Black or African American	169 (75)
Other	16 (7)
Education, n (%)	
Less than high school	42 (19)
High school graduate or equivalent	73 (32)
Some college, no degree	49 (22)
Associate or vocational degree	29 (13)
4-Year college degree	19 (8)
Master's degree or above	13 (5)
Marital status, n (%)	
Single	123 (55)
Married or cohabitating	34 (15)
Separated or divorced	48 (21)
Widowed	19 (8)
Missing	1 (<1)
Insurance Coverage, n (%)	
Medicare or Medicaid	178 (79)
Commercial	40 (18)
Other	7 (3)
Charlson Comorbidity Index	4.4 (2.73)
At the end of the month..., n (%)	
I do not have enough money to make ends meet	139 (62)
I have enough money to make ends meet	66 (29)
I have money left over	20 (9)
Do you usually ask someone to help you read materials you receive from the hospital doctor? n (%)	
Yes	54 (24)
No	169 (75)
Missing	2 (1)
HbA_{1c}[a](%), mean (SD)	8.1 (2.2)

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

Item Bank Development

The initial item pool contained 56 items. Table 2 includes the results of the EFA supporting a 4-factor model. The first factor included 6 items that generally represented contacting a primary care physician (PCP) for specific symptoms; the second factor included 13 items about general beliefs concerning health care and when it is appropriate or advisable to seek help from a PCP; the third factor included 5 items that generally represented contacting a friend or family member for health advice; and the fourth factor included 4 items that generally represented using the internet for researching and obtaining health advice. Table S1 in Multimedia Appendix 1 provides a summary of the iterative process that was used to identify these 4 different unidimensional item sets. A constrained (common slope) GRM did not identify any items with significant misfits in these 4-item sets. In addition, there were no items identified across item sets with impactful DIF. The final CFA (Table 3) supported the unidimensionality of these 4 separate PROs.

The 4 new PROs included (1) Health-Seeking Behavior: PCP-Specific; (2) Health-Seeking Behavior: General Beliefs; (3) Health-Seeking Behavior: Family or Friends-specific; and (4) Health-Seeking Behavior: Internet-Specific. Item information is highlighted in Figure 2 for each of these PROs. A total of 3 of the 4 newly developed PROs are calibrated measures (Table 4), while Health-Seeking Behavior: General Beliefs is an item bank, which can be administered as a CAT or a 6-item SF (the items selected for inclusion in the Health-Seeking Behavior: General Beliefs SF are italicized in Table 4). With a minimum number of items as 4, a maximum number of items as 12, and a targeted score-level reliability of 0.85, the CAT tended to administer the minimum number of items from –3.5 SD units to –1.0 SD units. Conversely, the CAT administered the maximum number of items at ≥+1.2 SD units. Figure 3 illustrates the minimum and maximum number of items administered by the Health-Seeking Behavior: General Beliefs CAT. Tables S2-S5 in Multimedia Appendix 1 can be used to convert SF raw summed scores to T-scores, with their associated SEs.

Table 2. Exploratory factor analysis results for REDD-CATa Health-Seeking Behavior items. Italicized values indicate primary factor loadings.

REDD-CAT Health-Seeking Behavior item	Factor 1: PCP[b] for health advice	Factor 2: General belief about when to seek out health advice	Factor 3: Family or friends for health advice	Factor 4: Internet for health advice
When I experience minor symptoms, I go to my PCP[c]	*0.613*	–0.049	0.004	0.004
When I experience serious symptoms, I contact my PCP[c]	*0.572*	0.164	0.011	–0.033
When I have questions about my medication(s), I ask my PCP[c]	*0.429*	0.416	0.023	–0.054
When I have health questions, I immediately call my doctor [c]	*0.774*	–0.005	0.034	-0.143
When I call my PCP, I have specific questions[c]	*0.710*	0.102	–0.012	0.022
When I experience worrisome symptoms, I go to my PCP[c]	*0.589*	0.158	–0.050	0.126
If I have minor symptoms for more than a week I call my PCP[d]	0.379	*0.398*	0.034	–0.061
I feel confident asking questions about my health[d]	–0.144	*0.762*	–0.104	0.013
I trust the information I receive from my PCP about my health[d]	0.036	*0.753*	–0.027	–0.011
I call my PCP for advice about my health[d]	0.228	*0.677*	–0.026	–0.019
I set up an appointment with my PCP when I have questions about my health[d]	0.295	*0.571*	–0.071	0.075
My health is a top priority[d]	–0.012	*0.806*	0.020	–0.114
I make sure to ask my PCP questions when I don't understand something[d]	–0.021	*0.885*	–0.031	–0.022
I reach out to my PCP when I have questions about my health[d]	0.215	*0.758*	0.051	0.006
I like staying informed about my health[d]	–0.084	*0.863*	–0.027	0.166
I seek the advice of my doctor to inform me about my health[d]	0.094	*0.859*	0.055	–0.045
I seek out ways to better my health[d]	0.002	*0.744*	0.054	0.104
I have someone to contact when I have questions about my health[d]	0.082	*0.531*	0.187	–0.056
I am confident about my abilities to answer questions about my health[d]	0.067	*0.671*	0.002	0.149
When I experience serious symptoms, I ask a friend or family member for advice[c]	–0.011	–0.008	*0.706*	0.000
When I have questions about my health, I ask my friends or family members to explain things[c]	–0.018	0.000	*0.836*	0.024
When I have questions about my medication(s), I ask friends or family members for assistance[c]	0.052	–0.006	*0.790*	0.084
When I experience worrisome symptoms, I ask my friends and family for advice[c]	0.041	–0.113	*0.849*	0.215
I reach out to friends and family members when I have questions about my health[d]	–0.173	0.130	*0.830*	–0.070
When I experience serious symptoms, I use the internet to find information[c]	–0.012	–0.038	0.049	*0.899*

REDD-CAT Health-Seeking Behavior item	Factor 1: PCP[b] for health advice	Factor 2: General belief about when to seek out health advice	Factor 3: Family or friends for health advice	Factor 4: Internet for health advice
When I experience minor symptoms, I use the internet to find information[c]	0.157	–0.127	–0.018	*0.933*
When I have questions about my health, I use the internet to find information[c]	–0.062	0.090	0.001	*0.958*
When I have questions about my medication(s), I use the internet for help[c]	–0.042	0.070	0.208	*0.767*

[a]REDD-CAT: Re-Engineered Discharge for Diabetes-Computer Adaptive Test.

[b]PCP: primary care physician.

[c]The response set for these items was never, rarely, sometimes, usually, and always.

[d]The response set for these items was strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree.

Table 3. Final overall model fit and reliability characteristics for the Re-Engineered Discharge for Diabetes-Computer Adaptive Test (REDD-CAT) Health-Seeking Behavior measures.

Health-Seeking Behavior measure	Items, n	CFI[a] (criterion ≥.90)	TLI[b] (criterion ≥.90	CFA[c]-based RMSEA[d] (criterion <.15)	SRMR[e] (criterion <.08)	α reliability (criterion ≥.80)	IRT[f]-based RMSEA (criterion <.15)	Response pattern or person-centered reliability (criterion ≥.80)
PCP[g]-Specific	6	.994	.990	.048	.036	.780	.07	.80
General Beliefs	13	.962	.955	.099	.059	.908	.05	.90
Family or Friends-specific	5	.997	.995	.061	.027	.865	.06	.86
Internet-Specific	4	.998	.995	.120	.017	.908	.12	.78

[a]CFI: comparative fit index.

[b]TLI: Tucker-Lewis Index.

[c]CFA: confirmatory factor analysis.

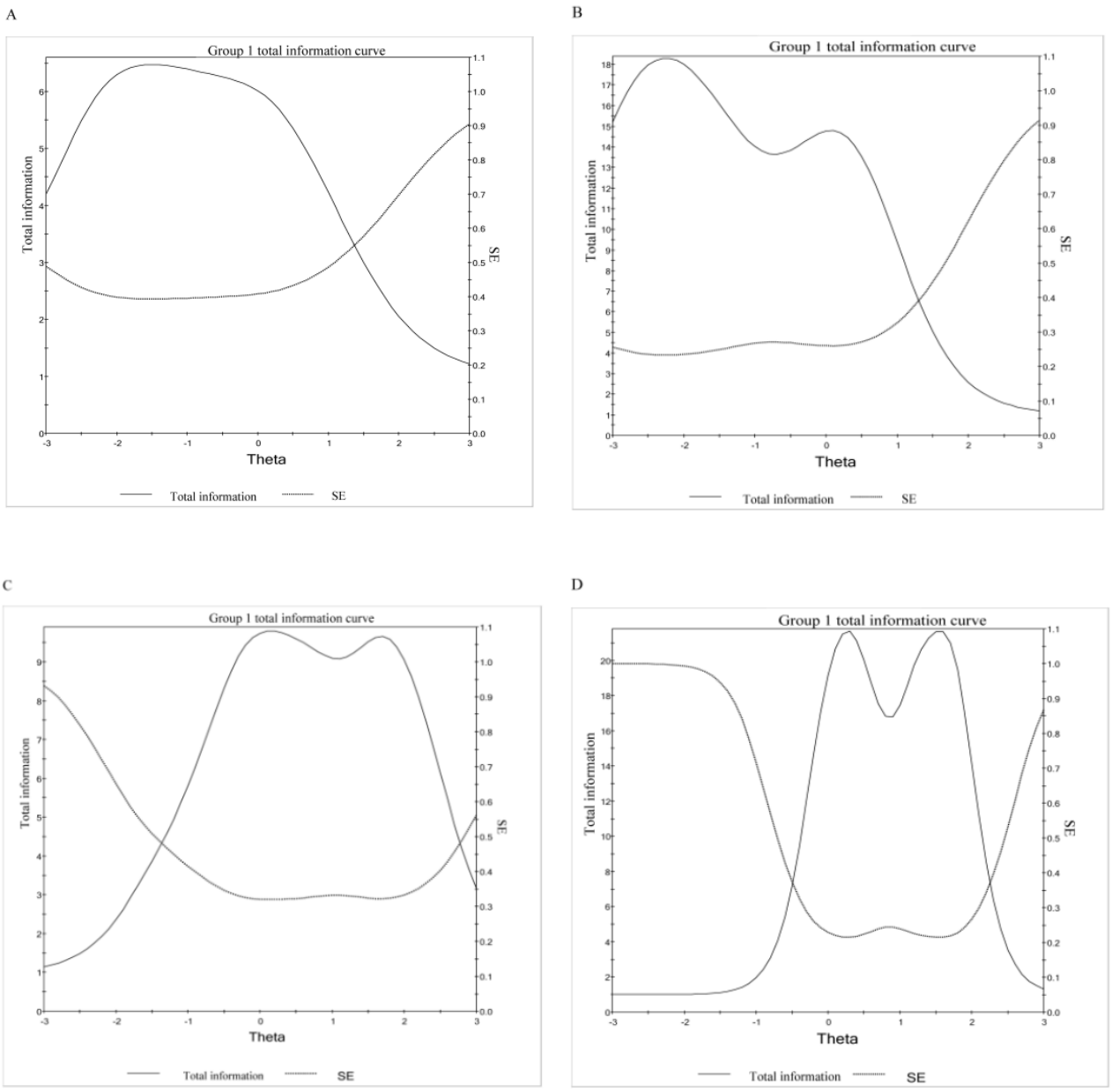
[d]RMSEA: root mean square error of approximation.

[e]SRMR: standardized root mean residual.

[f]IRT: Item Response Theory.

[g]PCP: primary care physician.

Figure 2. Health-seeking behavior measure test information plots: (A) Health-Seeking Behavior: PCP-Specific; (B) Health-Seeking Behavior: General Beliefs; (C) Health-Seeking Behavior: Family or Friends-Specific; and (D) Health-Seeking Behavior: Internet-Specific.



In general, if the total information per score level is ≥3.3 and the resultant SE is ≤0.55, this will provide an acceptable score-level reliability of ≥0.70. These figures show acceptable total information and SE: (1) Health-Seeking Behavior: PCP-Specific theta scores between approximately –3.0 and 1.3 (T-scores between approximately 20 and 63); (2) Health-Seeking Behavior: General Beliefs theta scores between approximately –3.0 and 1.8 (T-scores between approximately 20 and 68); (3) Health-Seeking Behavior: Family or Friends-Specific theta scores between approximately –1.6 and 2.9 (T-scores between approximately 34 and 79); and (4) Health-Seeking Behavior: Internet-Specific theta scores between approximately –0.7 and 2.5 (T-scores between approximately 43 and 75).

Figure 3 shows the number of CAT items used for different score levels in SD units: from approximately –3.5 SD units to –1.0 SD units, the CAT tended to use the minimum of 4 items from the item bank; at approximately ≥+1.2 SD units, the maximum of 12 items from the item bank were used by the CAT.

Table 4. Item parameters for the Re-Engineered Discharge for Diabetes-Computer Adaptive Test (REDD-CAT) Health-Seeking Behavior: General Beliefs item bank. Items in italics were selected for the Health-Seeking Behavior 6-item Short Form.

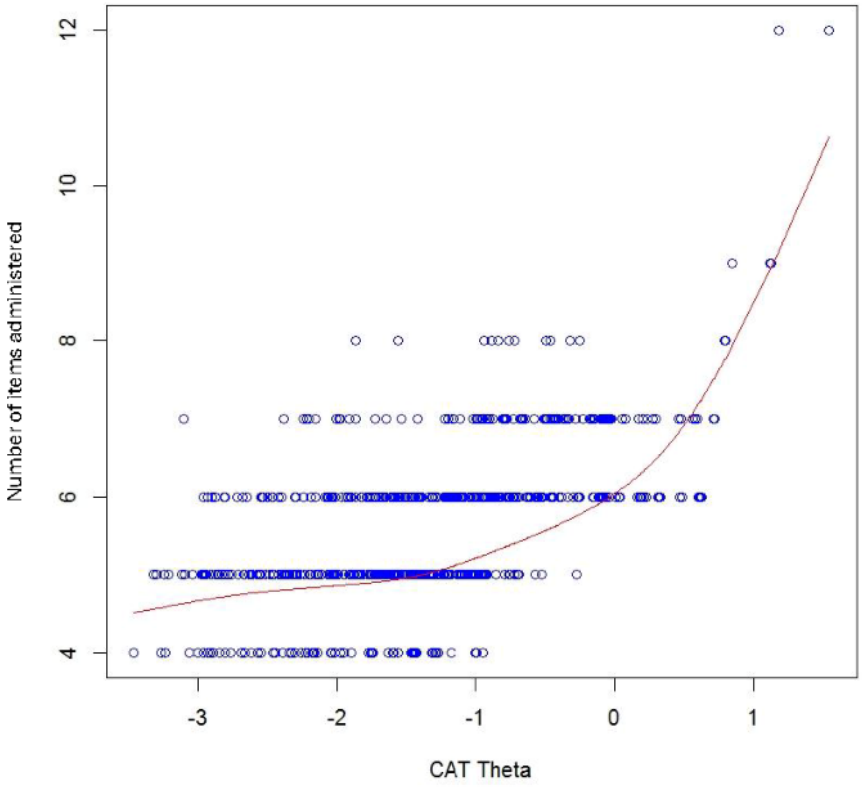
Item	Slope[a]	Threshold 1[b]	Threshold 2[b]	Threshold 3[b]	Threshold 4
If I have minor symptoms for more than a week, I call my PCP[c]	2.16	–2.13	–1.47	–1.08	0.68
I feel confident asking questions about my health	2.16	–2.42	–2.32	–1.76	–0.18
I trust the information I receive from my PCP about my health	2.16	–3.01	–2.78	–1.85	–0.10
I call my PCP for advice about my health	2.16	–2.63	–1.67	–1.20	0.58
I set up an appointment with my PCP when I have questions about my health	2.16	–2.45	–1.54	–1.06	0.59
My health is a top priority	2.16	–3.35	–2.99	–2.58	–0.53
I make sure to ask my PCP questions when I don't understand something	2.16	–3.10	–2.66	–2.37	–0.17
I reach out to my PCP when I have questions about my health	2.16	–3.04	–2.16	–1.83	0.28
I like staying informed about my health	2.16	–3.33	–2.75	–2.24	–0.10
I seek the advice of my doctor to inform me about my health	2.16	–3.02	–1.97	0.15	—
I seek out ways to better my health	2.16	–2.89	–2.26	–1.58	0.33
I have someone to contact when I have questions about my health	2.16	–2.15	–1.40	–0.99	0.80
I am confident about my abilities to answer questions about my health	2.16	–2.58	–1.96	–1.63	0.39

[a]Slopes are the discrimination parameters [which are held constant in a constrained (common slope) graded response model].

[b]Thresholds are the location (or difficulty parameters); they indicate the locations on the measurement continuum where an item can provide its most precise measurement. Thus, items with lower-value thresholds measure most precisely at those lower score values; such an item can therefore be thought of as an "easier" item. Items with higher threshold values measure most precisely at those higher score values; such an item can therefore be thought of as a "harder" item. All items use the following Likert response set: 1=strongly disagree, 2=disagree, 3=neither agree nor disagree, 4=agree, and 5=strongly agree.

[c]PCP: primary care physician.

Figure 3. Health-Seeking Behavior: General Beliefs—number of CAT items by CAT theta. CAT: computer adaptive test.



Preliminary Descriptive Data for the New PROs

Internal consistency reliability ranged from acceptable (≥0.70 for Health-Seeking Behavior: PCP-Specific and Health-Seeking Behavior: General Beliefs-SF) to good (≥0.80 for Health-Seeking Behavior: Family or Friends-Specific) to excellent (≥0.90 for Health-Seeking Behavior: General Beliefs-Full Bank, Health-Seeking Behavior: General Beliefs-CAT, and Health-Seeking Behavior: Internet-Specific). There were no significant floor or ceiling effects (Table 5).

Table 5. Descriptive data for the different Re-Engineered Discharge for Diabetes-Computer Adaptive Test (REDD-CAT) Health-Seeking Behavior patient-reported outcomes.

Health-Seeking Behavior	Patients, n	Internal consistency reliability	Score, mean (SD)	% at floor	% at ceiling
General Beliefs–CAT[a]	225	0.91	50 (9.1)	0	0
General Beliefs–SF[b]	225	0.78	49.9 (8.4)	0.4	7.6
General Beliefs Full Bank	225	0.91	50.1 (9.4)	0	0
PCP[c]-Specific Full Bank	225	0.78	50 (8.9)	0.4	8.4
Family or Friends-Specific Full Bank	225	0.87	50 (9.3)	8.9	0
Internet-Specific Full Bank	225	0.91	50 (9.1)	5.3	0

[a]CAT: Computer Adaptive Test.

[b]SF: Short Form.

[c]PCP: primary care physician.

Discussion

Principal Findings

The purpose of this study was to develop new PROs that capture patterns of health-seeking behaviors in persons with T2DM. Health-seeking behaviors may influence diabetes-related self-management decisions among patients that may lead to acute complications, poor health outcomes, and unplanned hospitalizations. As such, health-seeking behaviors should be explored as a potential social determinant of health and risk factor for hospital readmission.

Our findings support the development of four new measures banks: (1) Health-Seeking Behavior: PCP-Specific (6 items); (2) Health-Seeking Behavior: General Beliefs (13 items); (3) Health-Seeking Behavior: Family or Friends-Specific (5 items); and (4) Health-Seeking Behavior: Internet-Specific (4 items). These measures were developed for inclusion in the REDD-CAT measurement system, designed to assess important social determinants of behavior that are related to readmission risk in persons with T2DM. The REDD-CAT includes the first CATs developed specifically for use in T2DM; this includes the REDD-CAT Health-Seeking Behavior: General Beliefs-CAT. This CAT performs well, that is, 4-9 items administered, with reliability ≥0.85, for individuals with General Beliefs T-scores from 15 to 61. CATs administer more items to individuals with "extreme scores" (ie, scores at one or both ends of a measure's scoring continuum; for General Beliefs, that would be T-scores ≥62). Thus, persons with T2DM having General Beliefs T-scores ≥62 would consistently need to take the maximum 12 items administered by a CAT (assuming its maximum number of items=12) in order to terminate the CAT scoring session. However, little to no gain in score precision would be achieved for those persons by the administration of additional items beyond 9 (ie, items 10-12). We therefore recommend setting the CAT "maximum items to administer" criterion to 9 items to ensure an adequate balance between precision and test burden when using this measure in populations where individuals report unusually high health-seeking behavior.

The new REDD-CAT Health-Seeking Behavior PROs were developed according to established methodology [12]; these new measures are homogenous (ie, they are composed of unidimensional item sets); have acceptable excellent psychometric reliability; and do not include items with a bias for age, sex, education, or socioeconomic status. All measures are scored on a T-score metric (mean 50, SD 10), with scores ≥60 indicating high health-seeking behavior (ie, ≥1 SD above average health-seeking behavior for persons with T2DM) and scores ≤40 indicating low health-seeking behavior (ie, ≥1 SD below average health-seeking behavior for persons with T2DM). For these new measures, more health-seeking behavior reflects "appropriate" behavior (ie, seeking out information when one is experiencing significant symptoms), whereas low health-seeking behavior indicates that the individual is not seeking out treatment, even though treatment might be warranted.

Limitations

This study has several limitations. First, the CAT data represented were based on simulations and, therefore, need to be replicated in a sample that is tested using the actual CAT engine. In addition, generalizability may be limited given that the sample only included patients from a safety-net health system. Future work in other T2DM samples is needed to fully understand both the utility and specific relationship to readmission risk, as well as the strengths and weaknesses of these measures, including their overall validity, responsivity, and sensitivity.

Conclusions

These new Health-Seeking Behavior PRO measures provide exciting tools for assessing self-reported health-seeking behavior

in persons with T2DM. Furthermore, the relationship of these new measures, in conjunction with the rest of the REDD-CAT measurement system—which includes several measures of other important social determinants of health and behavior, including new measures of Housing Security [13], Illness Burden [14], Medication Adherence [15], Health Care Access [16], as well as measures from the HEAL (Healing Encounters and Attitudes List) measurement system [17], Neuro-QoL (Quality of Life in Neurological Disorders) [18,19], and PROMIS (Patient-Reported Outcomes Measurements Information System) [20,21])—provides a complementary arsenal of tools that can aid in identifying individuals with unmet social needs and those who are at increased risk for hospital readmission. Together, these new measures and the larger REDD-CAT system are designed to provide researchers and clinicians with a comprehensive toolkit to assess important social determinants of health and behavior related to readmission risk in patients with T2DM.

In sum, the REDD-CAT Health-Seeking Behavior measures provide a brief, reliable, and valid assessment of patients' health-seeking behaviors and represent a marker for healthy coping amid the demands of diabetes care. This new measure can be used to aid in hospital discharge planning as a screening tool to identify those individuals with T2DM who are experiencing difficulties with the demands of diabetes management and require tailored education and support before leaving the hospital setting. In addition, although this measure was developed specifically for use in persons with T2DM, it may also have clinical use in other medical populations.

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Authors' Contributions

NEC was a principal investigator and contributed to data coordination and site analysis; design analysis, initial draft of introduction, methods, results, and discussion; and incorporation of revisions. MAK contributed as a study coinvestigator and statistician, assisted with analysis design, was a primary statistician for the measurement development portions of manuscript (eg, factor analyses and Item Response Theory analyses), and drafted statistical analysis section and a template for the results section. JPT contributed as a statistician and data analyst, was a primary statistician for descriptive and reliability analyses, assisted with writing methods and results sections, and provided review and feedback on manuscript drafts. JAM was the study data manager, conducted critical review of the methods and results, and provided review and feedback on manuscript drafts. AB contributed as the study research coordinator and was responsible for data collection, and review and feedback on manuscript drafts (critical review of the methods). JMH was the study grants manager and project coordinator, provided review and feedback on manuscript drafts, and assisted with study regulatory documents. BDLC was the project manager and handled review and feedback on manuscript drafts and assisted with synthesis of revisions. IM was the study research coordinator and was responsible for data collection, and review and feedback on manuscript drafts (critical review of the methods). BWJ was the principal investigator of the Patient Readmission Evaluation Tool study and was responsible for review and feedback on manuscript drafts (critical review of the summary of the qualitative work that informed this study). SM was the principal investigator and contributed to site data collection, study design, critical review of the introduction and discussion, and review and feedback on manuscript drafts.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Unidimensional modeling and analyses, and conversion tables.
[DOCX File , 25 KB - diabetes_v9i1e63434_app1.docx]

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Abbreviations

BMC: Boston Medical Center
CAT: computer adaptive test
CFA: confirmatory factor analysis
DIF: differential item functioning
EFA: exploratory factor analysis
GRM: graded response model
HEAL: Healing Encounters and Attitudes List
HIPAA: Health Insurance Portability and Accountability Act
IRB: institutional review board
IRT: Item Response Theory
Neuro-QoL: Quality of Life in Neurological Disorders
PCP: primary care physician
PRO: patient-reported outcome
PROMIS: Patient-Reported Outcomes Measurements Information System
REDCap: Research Electronic Data Capture
REDD-CAT: Re-Engineered Discharge for Diabetes-Computer Adaptive Test
RMSEA: root mean square error of approximation
SF: short forms
T2DM: type 2 diabetes mellitus
WRAT4: Wide Range Achievement Test Fourth Edition

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Original Paper

Exploring Opportunities and Challenges for the Spread, Scale-Up, and Sustainability of mHealth Apps for Self-Management of Patients With Type 2 Diabetes Mellitus in the Netherlands: Citizen Science Approach

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Abstract

Background: Technologies evolve at a breakneck pace, and the success of mobile health (mHealth) for people with type 2 diabetes mellitus (T2DM) depends on whether health care professionals, care management, government regulators, and consumers will adopt the technology as a viable solution to enhance patient self-management.

Objective: In this study, we explored the challenges of the implementation of mHealth apps in care for patients with T2DM and determined to what extent these challenges complicate the dissemination, limit scale-up, and influence the sustainability of technological interventions for patients with T2DM.

Methods: The nonadoption, abandonment, and challenges to scale-up, spread, and sustainability (NASSS) framework served as the basis for our study. The 7 domains of the NASSS framework were explored with a citizen science approach using questionnaires, semistructured in-depth interviews, and focus groups together with patients with T2DM, care professionals, technology developers, policy officers, and a patient organization.

Results: Regarding the domain "condition," being aware of their condition and changing lifestyle were crucial for patients with T2DM to get to grips with their life. The rapid development of health apps for T2DM was highlighted in the domain "technology." Users should be aware of these apps and know how to use them. The domain "value proposition" included the patient perspective and elaborated on personal values, as well as care professionals who focus on personalized care and pressure on health care. Regarding the "adopters," it is crucial to know who needs to use and introduce the apps. Responsibility, a shared vision, and resistance among care professionals were mentioned as important determinants for "organization." Finally, the domain "wider system" showed the importance of involving multiple institutes, care guidelines, and reimbursements.

Conclusions: This study investigated the implementation of mHealth apps in an early stage of the implementation process. Key stakeholders were involved, who attributed to the possibilities and limitations of the implementation. It is crucial to have a clear

vision from an organizational perspective and specific prerequisites for implementation strategies at micro, meso, and macro levels. Essential strategies at the national level include guidelines for regulations, privacy, and security; the integration of mHealth into T2DM care guidelines; and sufficient reimbursement by health insurers.

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KEYWORDS

mHealth; type 2 diabetes mellitus; implementation; self-management; health care system; citizen science; mobile health; mobile app; digital health; digital technology; digital intervention; smartphone; diabetes; DM; type 2 diabetes; type 1 diabetes

Introduction

Health technologies evolve at a breakneck pace. The future success of mobile health (mHealth) for patients with type 2 diabetes mellitus (T2DM) depends on whether health care professionals, care management, government regulators, and patients will adopt the technology to enhance patient self-management [1]. During past years, a large number of mHealth apps for T2DM have been developed and evaluated, for example, to improve self-management, provide lifestyle coaching, or provide continuous glucose monitoring. These apps can have a positive impact on patients with T2DM, that is, improving hemoglobin A_{1c} levels, medication adherence, and facilitating self-management [2,3]. Although there is a wide array of evidence-based mHealth apps for patients with T2DM available, apps often stand alone and are not integrated into care pathways. Care professionals mainly experience time and work pressure–related barriers, but their familiarity with apps is low as well [2]. Hence, the development of strategies to support the incorporation of mHealth apps in care practices is needed. These strategies can include the integration of advice on the use of apps in existing care pathways to improve knowledge regarding self-management of diabetes for the patients and assist professionals to provide personalized care. In Norway, mobile apps are recommended within diabetes guidelines to track physical activity in combination with blood glucose monitoring [4]. In the United States, guidelines take a stance toward preventing the development of T2DM with the use of mHealth [5]. However, the guidelines of the European Association for the Study of Diabetes do not recommend the use of technology [6].

In previous research, we applied so-called citizen science research methods to explore the acceptability, experiences, and acceptance of the use of mHealth by patients with T2DM [7]. Most patients with T2DM were positive about the use and potential added value of mHealth apps [7]. However, both patients and professionals experienced difficulties in incorporating the collected personal data into care pathways and consultations [8,9]. Also, in other studies, it was found that mHealth was not structurally implemented as integral part of care pathways [10]. There is a need to learn more about approaches that can promote the integration of mHealth in the care of patients with T2DM among a variety of health care stakeholders, including care professionals, technology developers, policy officers, and patient organization.

In this study, we aimed to explore the challenges of the implementation of mHealth apps in care pathways for patients with T2DM and determine to what extent these challenges complicate the dissemination, limit scale-up, and influence sustainability of technological interventions for T2DM. The nonadoption, abandonment, and challenges to scale-up, spread, and sustainability (NASSS) framework served as the basis for this study [11]. This framework is useful to incorporate the perspectives of different stakeholders in different research and development stages of technological innovations in health and social care [11]. The framework consists of seven domains: (1) condition, (2) technology, (3) value proposition, (4) adopters, (5) organization, (6) wider system, and (7) embedding and adaptation over time. The different domains were used to provide insight into the challenges that stakeholders experience when using and implementing technology.

Methods

Design and Setting

This research is based on data from previous research [7-9,12] and newly obtained data. Although all data were used to take perspectives of different stakeholders into consideration and analyze all the domains of the NASSS framework, not all datasets contributed equally to each domain. In our study design, we followed the NASSS toolkit of Greenhalgh et al [13]. They described which stakeholders seemed the best fit to complete each domain. In this toolkit, the stakeholders that should be part of each domain: (1) domain 1 should include the clinicians, social workers, or researchers; (2) domain 2 should include the technology developers; (3) domain 3 should include the technology developers and business lead for the organization; (4) domain 4 should include stakeholders on behalf of everyone who might use the technology; (5) domain 5 should be discussed by people who know the organization and the challenges it faces, for example, board member, human resources lead, and staff representative; (6) domain 6 should include a "horizon-scanner" who looks beyond the organization; and (7) domain 7 should pull together the bottom row of each of the previous domains. All data collection steps and thereby all stakeholders contributed to each domain. However, some datasets acquired from specific stakeholders contributed more to a certain domain and less to the other domains.

We were able to use the previously acquired data mostly to discuss the first, second, third, and fourth domains. However, the data can as well partly contribute to the analysis of the other domains. The previous data collection included questionnaires among patients with T2DM on their desired involvement in citizen science research [12], questionnaires with follow-up interviews considering the use of technology by patients with T2DM [8], and interviews and follow-up focus groups with patients and lifestyle coaches about their expectations and

experiences before and after testing mHealth apps for patients with T2DM [7]. We obtained new data to mainly discuss the third, fourth, fifth, sixth, and seventh domains of the NASSS framework, but the new data also added relevant information to the first and second domains. The cross-pollination of previous and newly collected data led to the incorporation of perspectives of different stakeholders in each of the domains. To obtain new data, we applied a qualitative research design with a citizen science approach [14] to explore the subjective expectations, perceptions, and experiences of different stakeholders involved in the care of patients with T2DM in the Netherlands.

This study was part of TOPFIT Citizenlab, a 3-year research and innovation program in the Netherlands. Here, citizens, care professionals, and companies joined forces with researchers to develop and implement technology for health and well-being. The stakeholders involved were not only respondents of the research but became coresearchers who had an active role in the design, data collection, or analysis process.

Recruitment

To involve different stakeholders in this study, we used a variety of recruitment strategies. First, the 4 involved development companies in our previous study [8] were asked to continue collaboration. Second, flyers and announcements on social and regional media were used to recruit health care professionals. Third, purposive sampling was used to include a specific group of stakeholders. We reached out to project managers, insurance companies, policy officers of care organizations, the Dutch Diabetes Association, and different regional care organizations. Knowledge on mHealth was not required. All interested in participation received an information letter about the project and an informed consent form. Informed consent was obtained before the data collection. All stakeholders who had the intention to work together with the researchers, as coresearchers, were included in this citizen science project.

Coresearchers

Table 1 shows the different data sources (column 1), which include previously acquired data and new data, with number (column 2) and function of all involved stakeholders (column 3). As coresearchers, they were involved in different phases of research design, execution, and evaluation.

Table 1. All data sources, number and function of coresearchers, and coresearcher IDs corresponding with results.

Data source	Coresearchers, n	Function of coresearchers	Coresearcher ID
Questionnaires on desired involvement in citizen science research (previous [12])	160	Patients with T2DM[a]	—[b]
Questionnaires on knowledge and use of technology for diabetes (previous [8,9])	103	Patients with T2DM	—
Follow-up interviews on knowledge and use of technology for diabetes (previous [8,9])	16	Patients with T2DM (10 users and 6 nonusers of technology)	Patient 1-16
Interviews on expectations before using a technology for diabetes (previous [7,9])	27	Patients with T2DM (n=25) and lifestyle coaches (n=2)	Patient 17-43
Follow-up focus groups on experiences after using a technology for diabetes (previous [7,9])	25	Patients with T2DM	Patient 17-44
Recurring cocreation sessions (previous [9])	4-6	Patients with T2DM	Patient 45-50
Interviews with development companies on technology for diabetes (new)	6	Developers of 4 companies	Developer 1-6
Focus group with healthcare professionals on digital care for diabetes (new)	8	Health care professionals	Professional 1-8
Interviews with specific stakeholders on implementation of digital care for diabetes (new)	10	Employees of the Dutch Diabetes Association (n=2), health care professionals (n=3), management or overarching function (n=4), and involved in development of care guidelines (n=1)	Professional 9-18

[a]T2DM: type 2 diabetes mellitus.

[b]Not applicable.

Previous Data Collection

The dataset of this study consists of earlier collected data and newly obtained data (Table 1). In previous research, we have performed questionnaires about patients' preferences regarding their involvement in citizen science research [12]. Data were collected from 160 patients with T2DM. Second, questionnaires were collected from 103 patients with T2DM to investigate their knowledge on and use of technologies for diabetes [8,9]. Third, as a follow-up study to these questionnaires, semistructured in-depth interviews were conducted on the knowledge and use of technologies for diabetes [8,9]. These interviews were conducted over the internet with 16 patients with T2DM, 10 of whom were users of technology for diabetes and 6 of whom

were nonusers of technology for diabetes. Fourth, 25 patients with T2DM were invited to test an mHealth for T2DM, and 2 lifestyle coaches were involved to assist some of the patients with the process [7,9]. In this study, we collaborated with 4 companies (ie, Clear.bio, mySugr, MiGuide, and Selfcare) with whom we organized a webinar to inform the patients about the mHealth apps and gave the patients the ability to choose their preferred technology. Before the testing phase started, we conducted semistructured interviews with the patients and lifestyle coaches about their expectations regarding the technology. Fifth, after the testing phase we organized focus groups in collaboration with the patients [7,9]. These focus groups aimed to discuss their experiences with and after using the technology. Finally, we organized a series of cocreation sessions to understand the desired direction of research on technologies for patients with T2DM, according to the patients themselves [9]. A group of 6 patients was formed and 4-6 of them were present at each session. At the end, the group made an agenda for follow-up research directions and wrote a letter of recommendation to the Dutch government.

Data Collection of New Data

Interviews With Developers

Data were collected between October and November 2021. Semistructured in-depth interviews were conducted with 4 companies (ie, Clear.bio, mySugr, MiGuide, and Selfcare). A total of 6 developers of technology for diabetes who were employed at the 4 development companies and 1 lifestyle coach became our coresearchers. The interviews were conducted over the internet and lasted between 60 and 105 minutes. During each of the interviews, 2 researchers were present—1 had a leading role, and the other researcher took notes, and audio recordings were made. The interviews focused on the experiences of the companies in developing digital technologies specifically for patients with T2DM and an outlook toward future developments or apps within their technology. Furthermore, we discussed findings including experiences regarding the use of mHealth among patients with T2DM [7,8] and how the companies can use these findings.

Focus Group With Health Care Professionals

Data were collected in June 2022. In addition, 1 focus group was organized in which 8 health care professionals participated. All professionals were involved in care of patients with T2DM, both in general practice and hospital settings. The group of professionals consisted of 3 general nurse practitioners, 4 diabetes nurses, and 1 lifestyle coach. The focus group lasted for 120 minutes. Furthermore, 5 researchers were present of whom 1 took extensive notes, and an audio-recording was made. In total, 3 statements, developed in cooperation with patient coresearchers, were discussed, that are (1) the use of digital technology in care adds value to the treatment of patients with T2DM, (2) I should use more digital technologies in the treatment of patients with T2DM, and (3) I have a crucial role in the implementation of digital technologies as part of the treatment of patients with T2DM. A discussion on these statements was followed by a discussion on the needs for education and training.

In-Depth Interviews With Stakeholders in Health Care

Data were collected between October and November 2022. A total of 10 semistructured in-depth interviews were conducted with different stakeholders related to the care system or the care of patients with T2DM. These stakeholders included 2 employees of the Dutch Diabetes Association, 3 health care professionals, 4 professionals with a management or overarching function, and 1 stakeholder involved in the development of general practice guidelines. All interviews were conducted over the internet with 1 or 2 researchers present and lasted for 30-60 minutes. Notes were taken during the interviews and audio recordings were made. The interview guide was based on the NASSS framework [11,13], which meant that all 7 domains were included in the data collection. The interviews with health care professionals focused more on value proposition and adopters before getting into depth to the other domains, and the interviews with the stakeholders with management or overarching functions focused on the organization and wider system. All interviews ended with the domain embedding and adaptation over time.

Data Analysis

All data, meaning the previously and newly obtained data, were combined and analyzed. Descriptive statistics were applied to the quantitative data [8,12] to analyze willingness to participate in research, preferences about methods of participation, motivation and competencies to participate, the actual use of apps, performance expectancy, effort expectancy, social influences, and facilitating conditions. Regarding the qualitative data, all audio recordings were transcribed verbatim and combined with extensive observation notes. A deductive data analysis was applied based on the domains of the NASSS framework [11]. The transcripts and observation notes were read, and codes were assigned to fitting passages. After discussion with the entire research team, 1 researcher coded the data. The findings were discussed with the research team during biweekly analysis meetings. Software package NVivo 11 (Lumivero) was used to analyze the qualitative data. Data saturation was achieved when no new themes emerged.

Trustworthiness

We used several procedures to obtain credibility and transferability [14]. Questionnaires, interviews, and focus groups were conducted to increase the credibility by method triangulation. Investigator triangulation was reached since 6 researchers were involved in the study design, data collection, and analysis of all datasets. Furthermore, this team consisted of researchers from different research institutes, and in several research phases, patients with T2DM collaborated as coresearchers. Peer debriefing took place at weekly meetings with the research team, where both scientific and organizational aspects were discussed. Summaries with findings of different research phases were shared with the coresearchers as part of the member check, and preliminary findings were shared and discussed during a workshop at a care festival in the Twente region. A thick description was developed for transferability to a different context.

Ethical Considerations

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

Results

Overview

The results are categorized according to the 7 domains of the NASSS framework [11]. We aimed to explore perspectives and challenges on the implementation of mHealth in T2DM care pathways. The findings include quotes from the involved patients, health care professionals, and other stakeholders involved in health care. An overview of the main findings is presented in Table 2.

Table 2. The main findings for each of the 7 domains of the NASSS[a] framework [11].

NASSS framework	Main themes	Findings by the coresearchers
Condition	• Lifestyle • Self-management • Listen to your body • Learning	• You have to change your lifestyle after the diagnosis T2DM[b]. • Changing your lifestyle is a learning process. • Listening to your body is crucial.
Technology	• Usefulness • Multiplicity of apps • Connecting • Information provision • Usability • Availability	• Technology could assist in changing your lifestyle. • There is rapid development of new apps. • It is challenging to combine and connect different apps. • Information on usefulness of the technology is necessary. • Unclear for whom the technology is available and what it costs.

Value proposition	• For patients with T2DM:
	  • Insight
	  • Alarms
	  • Self-management
	  • Value
	• For care professionals:
	  • Explainability
	  • Personalized care
	  • Insight
	  • Pressure on care system
		• For patients with T2DM:
		  • To know what happens to your body.
		  • Receiving continuous signals through an app.
		  • Increased self-management and self-reliance.
		  • Personal values are most important.
		• For care professionals:
		  • Provide specific explanation for an individual patient.
		  • Obtain more information about the individual course of the disease.
		  • Lower pressure on health care.

Adopters	• Multiplicity of apps • Learning • Responsibility	• More clarity is needed about the most suitable apps. • Training for care professionals. • Unclear who will introduce the technology in practice.
Organization	• Shared vision • Comparison with current • Work pressure • Responsibility • Resistance	• An overview of who is responsible for what is needed. • Create a shared vision and pathway for digital health care together. • Digital care must be as good as or better than current care. • Workload is already high in many organizations. • Dealing with resistance among care professionals is difficult.
Wider system	• Benefits • Multiplicity of organizations • Reimbursement • Care guidelines • Stigma	• Multiple institutes are involved in decision-making regarding health care innovations. • Long-term health benefits and costs are important. • T2DM has to deal with its stigma. • Lack of reimbursement is a crucial topic. • The Dutch care guidelines are leading in care practices.
Embedding and adaptation over time	• Normal future • Personalized care • Pressure on care system • Gradual implementation	• Telemonitoring and digital health will be normal in the future. • Digital care will reduce pressure on the healthcare system. • Care pathways will be personalized per individual.

[a]NASSS: nonadoption, abandonment, and challenges to scale-up, spread, and sustainability.

[b]T2DM: type 2 diabetes mellitus.

Condition

T2DM is one of the most common and complex chronic conditions in the Netherlands, with an enormous impact on quality of life and health care costs. It is expected that the number of people with T2DM will only increase further in the coming years due to an aging population and an unhealthy lifestyle. Patients with T2DM shared that they had to change their lifestyle.

> *In the beginning it was very hard to get used to the fact that I have diabetes. I was not allowed to live my life anymore. For now, it is just part of my life.* [Patient 13]

A healthy lifestyle plays a fundamental role in the prevention and treatment of chronic diseases such as T2DM. It has a positive effect on glucose regulation, use of less or even no medication, and can lead to significant improvements in risk factors for complications such as cardiovascular disease.

> *Something changed when my doctor told me that I might need insulin. The possibility to live with less medication became a driving force to start changing my lifestyle.* [Patient 6]

However, adapting their lifestyle and coping with T2DM is a learning process in which patients must learn to understand and listen to their body.

> *Listening to my body helps in coping with the diabetes.* [Patient 1]

When someone is capable of understanding the development of complications, such as dangerously low blood glucose levels, they can possibly prevent it. Various lifestyle factors such as nutrition, physical activity, sleep, and stress play an important role in the lifestyle management of patients with T2DM.

Technology

Technology has the potential to support patients with T2DM in providing better insight into their health, greater awareness of their symptoms, insight into the effect of various lifestyle factors on their condition, and the capacity to manage their own health. Among all available apps, our patient coresearchers claim that apps including tailored education, personal data analysis, personalized feedback, and the option to communicate with a care professional are most effective. The care professionals worried about the compatibility of apps with sensors, personal devices, and electronic patient records. To avoid information differences, it is necessary that information is available to patients and professionals in order to properly use the technology and understand what it is for. Another issue regarding technology was costs and thereby low inclusiveness of technology.

> *Innovations and apps like that are only for the happy few, that's what it comes down to.* [Patient 46]

In addition, possible differences between younger and older patients are mentioned.

> *The younger people, yes, they have already grown up with that, they are so mature with the mobile. For them it will be easier, yes.* [Professional 3]

Although this is an opinion most have, it is not always the case that older patients cannot use it.

> *It is very special to see which people can and cannot join and that is sometimes surprising, very often surprising that someone 90 plus and then use it without any problems.* [Professional 4]

Value Proposition

Based on the interviews and focus groups, we identified different kinds of values and asked 4 patient coresearchers whether they recognize these values and how they can be prioritized. Table 3 shows these values and how they were prioritized.

Table 3. Six values, prioritized and discussed by coresearchers.

Priority	Value	Example
1	Personal value	Happiness, convenience, and health
2	Value for health care system	Better health care and cooperation
3	Moral value	Justice, fairness, freedom, privacy, and autonomy
4	Technical value	Better technology, usability, and integration
5	Business value	Efficiency and effectiveness
6	Commercial value	Money, revenue, profit, and savings

This distinction helped to have a more nuanced discussion on the values of technology from the perspective of patient coresearchers. One of the coresearchers claimed the following:

> *…personal values should come first and business values should come last.* [Patient 45]

In addition, all reached the general consensus that personal values must come first and money-oriented values last. An important remark with the latter is that everything should be paid for and therefore money-related value cannot be ignored.

While discussing how personal values can go together with the interests of, for example, health care insurance companies, a coresearcher said the following:

> *we should come closer together and find a way in the middle.* [Patient 50]

Professionals thought it was valuable that patients know what happens to their bodies during the day. Information through the app could provide a type of coaching for patients and continuous monitoring of changes in their health. In addition, mHealth apps

can increase self-management and self-reliance; however, this requires a certain level of intrinsic motivation of patients.

> *I think that the sense of independence and self-reliance and the responsibility for how they manage the disease, that puts much more on the patient. This could also ensure an equal relationship with the healthcare provider, because they have insight and can form an opinion about it.* [Professional 4]

According to professionals, technology provides more specific information about what diabetes does to the body of an individual patient thereby preventing the progression of the disease. In addition, professionals stated that apps can lower the pressure on health care and save time. Although these aspects remain a point of discussion and a question mark, health gains are underlined by everyone. As 1 lifestyle coach argued:

> *…by using this type of technology, you can prevent a progressive course of the disease, or go into remission and use less medication during treatment. This can ultimately lead to a reduction of the pressure on the healthcare system.* [Professional 11]

Adopters

In our previous research, we explored the adoption of mHealth apps among patients with T2DM. The main reason to use apps was the possibility to manage diabetes and gain insight in your personal health. However, using apps and keeping track of the personal data was time- and energy-consuming, and professionals were often not supportive or actively encouraging the use of apps [7-9,12]. Our new data provided similar findings, because there were still few professionals that used apps in their practice. To improve this, more information is needed about which apps are most suitable or user-friendly. More and more care practices provide patients the opportunity to view their files digitally and share personal health data with the care professional.

> *As a healthcare professional, it is very nice to see that people get to work with the information on our platform. It's just not fun, and that has of course happened for years, when we told the same story three times a year and then that doesn't help.* [Professional 7]

To use technology together with patients, training seems necessary for the health care professionals.

A point of discussion is who will explain the options and information about available apps to the patients. The health care professionals with whom they have already built a relationship of trust seem the best option. Furthermore, a solution is using apps in a collaborative way. It will have to become something of the patients and health care professionals together, especially at the start.

> *One-on-one attention must continue alongside the app. Especially in the beginning, later the app can take over.* [Professional 3]

When the professional can view the patient's data and thus provide targeted advice, it is more likely something will be done with this advice compared with advice without the information provided by the app. One professional experienced that her patient followed advice she had given multiple times, but the advice was not followed by the patient before, but this time she provided feedback based on her personal data. The use of patient data in providing personalized feedback is experienced as pleasant and fun by professionals. Furthermore, it is more difficult for the patient to give desirable answers to questions, because the professional can actually check.

> *After all these years, they know what I want to hear. So, they also show desirable behaviour during consultation hours.* [Professional 2]

Organization

For the organization of digital care for diabetes, it is necessary that there is a basic list with information about available and reliable apps. In addition, the path for digital health care needs to be designed together, involving patients, care professionals, and care organizations. This pathway should be integrated into the current care practices for diabetes according to a coresearcher from a regional care organization.

> *I think you need to have some kind of care pathway in which it is normal to use an app. The management should really stand for that, fed by their healthcare professionals to make agreements.* [Professional 14]

It certainly seems possible, but it is necessary to take small steps to achieve these pathways. Also, the care provided with apps must be as good as or better than current care, otherwise no transition will be made within organizations.

> *If you want to replace face-to-face with digital care, it must have at least the same quality and yield the same effects, otherwise you will not take that step. From that point of view, we think it's possible, that is already positive.* [Professional 12]

However, current health care challenges, such as staff shortages, could enhance the transition because less staffing is required, and apps could assist with easier and faster access to care.

Some organizations do not offer digital care, and professionals only respond to it if the patient asks about apps. Not all organizations are willing to invest extra time to innovate. This is mainly due to high workload and underlines the importance of insight into the added value of innovations. We had regular conversations about resistance among health care professionals, mainly because they have to adapt their way of working.

> *But the resistance at an individual level, that staff should do something different from what they are used to, is enormous. If they do not participate, then the patients will not participate at all.* [Professional 16]

To improve the implementation of technology in diabetes care, there must be a clear vision and strategy within organizations.

> *A very clear vision should provide direction. And as far as I'm concerned, the step we need to take is to make concrete choices.* [Professional 14]

When this is in place, most health care professionals go along with it and determine the care pathway and the information they provide to patients.

Wider System

When reflecting on society, T2DM has to deal with stigma. As our coresearchers mentioned, they often hear that T2DM is their "own fault," whereas many external factors play a role. The entire society will have to be organized differently, such as products in supermarkets. Connected to this issue of stigma, financial reimbursements remain an issue and a difficult point on all fronts. The Dutch Government or national organizations must define the ambitions, which care organizations and practices can work on. Also, regulations are needed to properly manage aspects related to privacy and data.

> *If medical technology takes such a huge flight, regulations must be introduced, even though there is also a kind of medical professional secrecy, it is of course extremely lucrative if you can sell all this health data.* [Developer 2]

Collaboration between patients, hospitals, and other care practices is necessary to understand all needs. Furthermore, involved managers have to steer or control the processes in all instances. Besides control by management, physicians and nurses must become leaders within their organizations.

Care practices need to take their own decisions regarding the use of apps and which apps since there is no intention to develop Dutch care guidelines on apps.

> *We will never include something about specific apps in the care guidelines. In a manner of speaking, we will not include what can be effective or helpful, because we want to act independently and will therefore never provide a list of apps.* [Professional 18]

Currently, patients already use a variety of apps that are unknown by the care professionals. Not only professionals but also a patient's social network can help in gaining knowledge about apps and also in using the apps. It is now assumed that this is only necessary for older patients; the younger patients will know and can do everything themselves.

> *If you think about the older patient, then knowing about apps can really be something for the social networks or the informal caregiver who sees what it's all about or where they can support.* [Professional 10]

Embedding and Adaptation Over Time

When considering the implementation over time and changes to health care settings, all health care professionals agree that where it is still an exception now, telemonitoring or digital care will be standard care in the future.

> *I expect many more people to use the online applications, many more patients, I believe. And I hope the healthcare providers too.* [Professional 1]

Digital care might even reduce the pressure on the health care system, and it might lower the costs of diabetes care. It is becoming easier and better to offer personalized care to patients, developed within a generic care path for digital care. Another way of consulting will be determined and implemented which is largely hybrid care and, in addition, consultations more on request than periodic check-ups.

> *If a trend goes in the wrong direction, you can signal it earlier, but also when things are going well, there is no need to contact the healthcare provider. When interaction is needed, that it becomes accessible, so that you can send an app and that you do not have to visit the doctor or the hospital to get advice.* [Professional 7]

Some of the professionals think that these changes in digital care and monitoring for diabetes will become the end point in diabetes treatment.

> *Especially when it comes to regulating glucose levels. I think app use will really be a revolution in the treatment of diabetes, once it's through and on the market and reimbursed, 30 years from now you're going to see people with barely any complications from diabetes. I really think this is going to be a final destination for healing.* [Professional 14]

Discussion

Principal Findings

This study aimed to explore perspectives and challenges on the implementation of mHealth in T2DM care pathways. The domain condition showed that being aware of their condition and changing lifestyle were crucial for patients with T2DM to get to grips with their life. Regarding the domain technology, there is a rapid development of mHealth apps, and users should know and understand how to use them to achieve assistance in lifestyle. The domain value proposition was divided in patients with T2DM who elaborate on personal values and care professionals who elaborate on personalized care and lower pressure on health care. For the domain adopters, it is crucial to know who needs to use and introduce the apps in practice. On the organization domain, responsibility, a shared vision within organizations, and resistance among health care professionals were mentioned as important. The domain wider system showed the importance of involvement of multiple institutes and reimbursements. However, digital and personal care will become the normal future when regarding the domain on embedding and adaptation over time.

Although care professionals of this study argue that it will become care as usual in the future, at the moment, they are not taken action to start the transition toward including apps in care pathways. The different stakeholders know about (some) technological possibilities but seem to procrastinate implementation in their care pathways. There are some early adopters, such as Santeon [15]. Santeon is the Dutch hospital group in which 7 top clinical hospitals collaborate openly with the aim of improving medical care through continuous innovation. In 2022, Santeon initiated the "Zorg bij Jou" (Care with you) program, which aims ultimately to nationally implement uniform hybrid care pathways with digital services,

such as telemonitoring and internet-based consultations. These services are centrally coordinated from a medical service center. Another goal is to implement this program for more than 30 (chronic) health conditions within 5 years to lower health care consumption and costs against the same or higher quality of care, and to facilitate more integrated and tailored care. In this way, a national open platform is being built with 24×7 services, where other health care services can also make use of, making it scalable to other types of health care and social services as well. These kinds of early adopters aim to get more health care professionals to join and implement hybrid care. Some coresearchers argued that they want to incorporate the technology as part of care, if it was tested by several others, for example, general practitioners. Our coresearchers claimed that a group of committed innovators, including patients, care professionals, and management stakeholders, seems needed to reach a specified ambition and prove the effectiveness of apps. However, among current care professionals, it seems hard to find this small group of innovators. Furthermore, the involved professionals point to a lack of an overarching vision by organizations. This vision could also assist in lowering the fragmented implementation approach in care practices. Often the organizations take a top-down approach and only involve care professionals and patients in a later stage [16,17]. With our citizen science approach, we show the desire from all different stakeholders to be involved in the development of a strategy toward the best implementation of apps in the care pathways.

The health care guidelines shape care pathways on the basis of evidence-based medicine. Evidence-based medicine remains needed to provide care for which a professional could take responsibility [18]. However, current ideas about personalized medicine slightly takes the focus off evidence-based medicine [19] and give professionals the opportunity to share responsibility with their patients. A professional often decides whether a technology is suitable for the patient or not. However, there is gradual change from paternalistic to shared decision-making [20,21]. In shared decision-making there is a need for the professional to actively assist the patients in preference elicitation and align these with the patients' unique situation and preferences for care [12]. Introducing and discussing a technology could not only become part of shared decision-making but also share responsibility.

The determinants acquired from our study can form a base toward strategies. To improve the uptake of mHealth by all different stakeholders, strategies that complement each other seem necessary. First, there is a need for commitment of organizations to use the knowledge and experience of patients and health care professionals with regard to the available range and proven effective apps. Second, there is a need for commitment of patients with T2DM to use apps, and of health care professionals to adapt their work process where technology is proven as a self-evident solution direction. Third, the implementation and adaptation of care and work practices needs to be gradual with assistance from management or more overarching organizations with a clear ambition for future care provision. And fourth, a learning network, in which the added value and effectiveness of technology are regularly examined together, could be created taking the user and their context into account.

Strengths and Limitations

To get a more extensive understanding of different perspectives, we used a citizen science approach with a multiplicity of stakeholders. Collaboration during this study offered added value, because coresearchers have firsthand experiences with the disease, the use of apps, care practices, care professionals, and health insurance. The insight of coresearchers enriched our understanding and led to a wider perspective. Involving coresearchers can be seen as a moral obligation for researchers but has several benefits. Being a coresearcher can have direct mental and physical health benefits since it actively involves people with their own health, brings purpose, a social network, and possibly even acceptance of their condition. It thereby has several benefits for the research itself. Coresearchers often have better access to other citizens and know important issues from experience and therefore enhance the relevance of the research. Furthermore, the coresearchers can guide the researchers toward the most relevant directs of current and future research by sharing their experiences. Using the NASSS framework strengthens both the researchers and coresearchers to dive into not only the value for the patients, but also their vision toward societal embedding.

As Schoville and Titler [22] argue, most models on adoption focus on the end user of the technology and implementation models mainly consider the necessary changes and methods of interventions. We applied the NASSS framework because it offers a complete approach to study the multiplicity of health care stakeholders and the variety of perspectives on the implementation of mHealth. Although most of the involved coresearchers are already interested in T2DM innovation, the involvement of this multiplicity of stakeholders is a main strength of this research. The different domains of the NASSS framework complement each other, and in each of the domains a different multiplicity of stakeholders could be incorporated. The NASSS framework is a combination of different implementation models that complemented each other into this framework consisting of 7 overarching domains. In comparison to other implementation models, the NASSS framework focuses more specifically on the current state and the future, besides the actual implementation process. The generic implementation framework (GIF) seems to have most resemblance with the NASSS framework [23]. Both are designed to take a variety of perspectives into account when designing an implementation effort. Differences between these frameworks are the additional focus on future embedding in the NASSS framework, and where the concepts within the GIF are seen as a memory aid to develop an implementation protocol, NASSS provides hands-on guidelines for the usage of each domain. As part of the NASSS framework, we discussed the embedding and adaptation over time. This domain was most difficult for the stakeholders to elaborate on. Possibly research methods that enhance creativity and reflecting on the future, could add another layer to the findings.

Recommendations

According to our coresearchers, it is necessary to start forming an overarching vision on a regional level. A start with regional initiatives to incorporate technology in care pathways has been made during this study, which will continue. Many regional organizations already cooperate and know each other. However, on this level, it is also needed to have a similar view toward the future and needs for innovation and implementation. If there is no mutual vision on the regional level, it seems hard to continue toward national or international levels. Collaboration of researchers with all the different stakeholders on a regional level could improve the cooperation and vision within a region and afterward, translate the regional findings toward national or international levels, or perform research on a larger scale. Furthermore, regarding the practical use of the findings, our research could enhance awareness of technologies suitable for patients with T2DM, which could become part of care pathways. Based on barriers and drivers of the use and implementation of these technologies, organizations can reflect and define a strategy suitable for their organization. Also, the findings can make organizations and management aware of mHealth readiness, with a reflection on necessary changes before use and implementation are possible in view of the involved stakeholders and care process.

With regard to organizing the cocreation sessions, it was paramount to invest in close contact with coresearchers and to maintain this contact. According to the coresearchers it was best to have short meetings at short intervals. In our experience, it was relatively easy to find older male coresearchers since this group is highly motivated through their negative experiences with health care professionals and interest in technology. This group of retired men also has relatively much spare time to invest. In order to have a more heterogeneous group of coresearchers, consisting of younger people, more time needs to be spent on recruitment before starting the group. Once a group is established it can be hard for new coresearchers to become part of the group and feel safe to share personal ideas and experiences.

Most research in which the NASSS framework was applied [24,25], considered the implementation of 1 specific technology or app. This is similar for other implementation frameworks, such as the GIF, which as well focus on implementation processes of 1 specific technology [23]. Our study used the NASSS framework to gain insight in the implementation of digitalized care with a variety of apps, which is probably more difficult by applying other frameworks of implementation due to the focus on a technology and less on the context. Although the focus on 1 specific technology might provide in-depth information about the implementation of this technology, the focus on a spectrum of similar technologies with comparable aims is valuable as well. In addition to specific insight in the technology, the focus on similar technologies provides a wider understanding of the organizational structures and the system in which it might be implemented. The guidelines of the NASSS framework, and specifically the toolkit with specific questions as part of each domain [13], were useful in practice to create meaningful conversations with all stakeholders and understand the wider context. In a context in which there is a variety of similar technologies, such as T2DM, we would recommend broadening the focus when applying the NASSS framework.

Conclusion

This study emphasized the added value to discuss the implementation of mHealth apps with different stakeholders. They attributed to the possibilities and limitations of the implementation of apps in diabetes care pathways. A clear vision for an organizational perspective and specific prerequisites for implementation is crucial to developing responsible implementation strategies at micro and meso levels. At the national level, guidelines for regulations, privacy, and security are essential, as well as the integration of mHealth into T2DM care guidelines and sufficient reimbursement by health insurers. The context has to change to ensure that mHealth becomes accessible to all patients with T2DM, regardless of personal financial capabilities or the severity of the disease, and to shift the focus toward T2DM prevention using apps as support.

The following were this study's contributions to literature:

1. Building on literature on patients and health care professionals, this study provides a complete overview of opportunities and challenges expressed by multiple stakeholders in care of T2DM.
2. Previous studies applied the NASSS framework to investigate a specific digital health app. This study shows that the NASSS framework could also provide insight into the implementation of digitalized care with a variety of apps.
3. The use of citizen science methods in this study follows and contributes empirical examples to the existing literature on citizen science.

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Data Availability

All relevant data are in the manuscript and its supporting information files. The dataset that supports the findings and conclusion of this study is available from the corresponding author on reasonable request. The data are not publicly available due to privacy and/or ethical restrictions.

Authors' Contributions

All authors contributed to the design and preparation of the study. CMvL, MB, ES, and TJJO conducted the research. CMvL, MB, and TJJO read and compared findings. Peer debriefing took place at biweekly meetings with the project team (CMvL, MB, ES, TJJO, and REMB). All authors (CMvL, MB, ES, TJJO, REMB, AAJK, and MEMdO) contributed to writing the manuscript and have approved the latest version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

GIF: generic implementation framework
mHealth: mobile health
NASSS: nonadoption, abandonment, and challenges to scale-up, spread, and sustainability
T2DM: type 2 diabetes mellitus

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Original Paper

Recommendations to Address Barriers to Patient Portal Use Among Persons With Diabetes Seeking Care at Community Health Centers: Interview Study With Patients and Health Care Providers

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Abstract

Background: Community health centers (CHCs) are safety-net health care facilities in the United States that provide care for a substantial number of low-income, non-English speaking adults with type 2 diabetes (T2D). Whereas patient portals have been shown to be associated with significant improvements in diabetes self-management and outcomes, they remain underused in CHCs. In addition, little is known about the specific barriers to and facilitators of patient portal use in CHCs and strategies to address the barriers.

Objective: The objectives of this qualitative study were to explore the barriers to and facilitators of the use of patient portals for managing diabetes in 2 CHCs from the perspective of adults with T2D and clinicians (community health workers, nurses, nurse practitioners, and physicians) and to make recommendations on strategies to enhance use.

Methods: A qualitative description design was used. A total of 21 participants (n=13, 62% clinicians and n=8, 38% adults with T2D) were purposively and conveniently selected from 2 CHCs. Adults with T2D were included if they were an established patient of one of the partner CHCs, aged ≥18 years, diagnosed with T2D ≥6 months, and able to read English or Spanish. Clinicians at our partner CHCs who provided care or services for adults with T2D were eligible for this study. Semistructured interviews were conducted in either Spanish or English based on participant preference. Interviews were audio-recorded and transcribed. Spanish interviews were translated into English by a bilingual research assistant. Data were collected between October 5, 2022, and March 16, 2023. Data were analyzed using a rapid content analysis method. Standards of rigor were implemented.

Results: Themes generated from interviews included perceived usefulness and challenges of the patient portal, strategies to improve patient portal use, and challenges in diabetes self-management. Participants were enthusiastic about the potential of the portal to improve access to health information and patient-clinician communication. However, challenges of health and technology literacy, maintaining engagement, and clinician burden were identified. Standardized implementation strategies were recommended to raise awareness of patient portal benefits, provide simplified training and technology support, change clinic workflow to triage messages, customize portal notification messages, minimize clinician burden, and enhance the ease with which blood glucose data can be uploaded into the portal.

Conclusions: Adults with T2D and clinicians at CHCs continue to report pervasive challenges to patient portal use in CHCs. Providing training and technical support on patient portal use for patients with low health literacy at CHCs is a critical next step.

Implementing standardized patient portal strategies to address the unique needs of patients receiving care at CHCs also has the potential to improve health equity and health outcomes associated with patient portal use.

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KEYWORDS

community health centers; patient portal; type 2 diabetes; self-management; qualitative study; mobile phone

Introduction

Background

Diabetes remains a significant public health concern in the United States, currently affecting 14.7% of the adult population [1]. The prevalence of diabetes is disproportionately higher among racial and ethnic minority individuals and those with lower socioeconomic status. Diabetes is the 8th leading cause of death in the United States and costs the nation >US $410 billion in both direct and indirect costs [1]. The disease can lead to microvascular and macrovascular complications that may increase the risk of morbidity and mortality as well as reduce the quality of life of persons living with the disease [2]. The American Diabetes Association recommends that persons with diabetes be supported to engage in self-management behaviors, including healthy eating, taking medication, glucose self-monitoring, healthy coping, and physical activity. These behaviors have been shown to improve glycemic control, psychosocial outcomes, and delaying or preventing complications [3].

Patient portals are increasingly recognized as important tools to support diabetes self-management [4]. Patient portals are digital platforms that allow patients to access their electronic health records (EHRs) to view their health information and securely communicate with their health care team. Patient portals vary, but common features allow patients to request appointments, view laboratory findings, request medication refills, view medication lists, and exchange nonurgent messages with clinicians [5].

Patient portal use is associated with significant improvements in diabetes self-management behaviors and outcomes. Studies have shown that users of patient portals, compared to nonusers, are more likely to meet glycemic targets and have better lipid profiles [6-8]. In a retrospective cohort study among 95,043 persons with diabetes, individuals who used the patient portal every month of the year had 0.41% lower hemoglobin A_{1c}, 6.25 mg/dL lower low-density lipoprotein, and 1.01 mmHg lower systolic blood pressure compared with those who used the patient portal for only 1 month in a year [8]. Previous qualitative studies show that patient portals provide patients with easy access to timely information [5,9-11], foster family involvement in diabetes care [12], improve the quality of patient-clinician communication [13-15], and help to facilitate lifestyle changes [10,16]. For instance, in 1 study, persons with diabetes reported that the ability to access their laboratory results and notes from previous visits enabled them to track changes in their overall health, and thus, empowered them to take charge of their disease management [17].

Despite the known benefits of patient portals, disparities exist in their access and use. Patient portal use is significantly lower among Black individuals, Hispanic individuals, and Asian individuals living with diabetes compared to their White counterparts [18-22]. In a cross-sectional study of >38,000 persons living with diabetes, individuals with low income and those living in rural areas were less likely to use patient portals [23]. Low literacy and low educational attainment have been linked to a lower likelihood of adopting patient portals among persons with diabetes [19,24]. There is evidence of low patient portal use among patients with Spanish as their preferred language. In a retrospective study, Spanish speakers in safety-net clinics were less likely to receive a patient portal access code, activate an account, and use the patient portal more than once in 2 years compared to English speakers [25]. This disparity is likely at least partly attributable to the limited number of bilingual (English and Spanish) patient portals in the United States which means that individuals with limited English proficiency are practically excluded [12,26]. Despite their advantages, patient portals remain underused in the populations that need them most.

Several studies have examined the barriers to and facilitators of patient portal use among persons living with diabetes [5,10,13,16,27]. Barriers include poor internet connection [10], limited computer knowledge [5,10,27], being unaware of patient portal features [13,16], privacy concerns [10,27], and not feeling the need to use the patient portal when health outcomes are perceived as stable [10]. In other studies, participants report that the need to maintain face-to-face interaction with their clinicians discourages the adoption of patient portals [27]. Persons with diabetes are more likely to use the patient portal if they are dissatisfied with the diabetes-related information they receive from their clinician, thus, resorting to the patient portal as an additional source of information [11]. Patient portal use also increases when caregivers or family members are involved in helping patients with the portal and detailed instructions on use are provided to patients and their families [12,27].

Whereas perspectives from some patient populations have been studied, there is limited qualitative evidence from low-income and non-English speaking individuals with diabetes in the United States. Non-English speakers and low-income individuals have limited access to diabetes self-management support due to language barriers and are at a higher risk of diabetes complications. In addition, fewer studies incorporate the views of clinicians to obtain a complete picture of the challenges of patient portal use and recommendations to address them. In the United States, community health centers (CHCs), formerly called federally qualified health centers [28], provide care for a substantial number of low-income and non-English speaking

individuals. CHCs are safety-net health care centers that offer outpatient services at a lower cost to more than 30 million individuals in the United States. The aims of CHCs are to provide high quality, comprehensive primary care to medically underserved populations, regardless of insurance status or ability to pay for care. Most CHC patients (90%) live in poverty or near poverty as defined by the federal poverty level, are disproportionately from racial and ethnic minority groups (total 63%) and have high rates of chronic conditions compared to the general population [29]. The uptake of patient portals in CHCs is limited especially among individuals with limited English proficiency [25], and few studies have examined specific barriers and facilitators among patients seeking care at these facilities [27]. Given the benefits of patient portals in improving glycemic control, understanding the specific facilitators of and barriers to portal use in this population considered vulnerable is crucial. Such data can aid in the design of interventions to improve access to and use of portals, with the end goal of improving health equity and health outcomes.

Objectives

The purpose of this qualitative study was to explore the barriers to and facilitators of the use of patient portals for managing diabetes in 2 CHCs from the perspective of adults with type 2 diabetes (T2D) and clinicians. Strategies to enhance patient portal use in CHCs were also explored. The data reported in this study were collected as part of a larger study to design and pilot a multilevel, bilingual intervention to improve patient portal use among low-income individuals with diabetes receiving care at CHCs.

Methods

Study Design and Setting

A qualitative description design, a well-established qualitative method, was used to describe the perceptions of adults with T2D and clinicians regarding diabetes self-management and patient portal use [30].

The study was conducted in 2 urban CHCs in Connecticut. Connecticut is a small and densely populated state with prominent health disparities. Black Connecticut residents are nearly 4 times as likely as White residents to have a diabetes-related lower extremity amputation, and the rate is nearly 3 times higher among Hispanic individuals compared to non-Hispanic White individuals [31]. One CHC has 2 clinical sites that provide care to approximately 32,000 residents (including 12,600, adults), 62% Hispanic, 45% Black, 10% report as more than 1 race, and 15% White, with 1763 adults diagnosed with T2D [32]. Similarly, the other CHC has 2 clinical sites that provide care to approximately 20,000 residents, 66% Hispanic, 16% Black, 11% White, 3% Asian, with 2095 diagnosed with T2D [32].

At 1 clinic, most health care providers use the patient portal in some capacity; in the other clinic, few clinicians use the patient portal as they recently changed to a new EHR and patient portal system. Patient portal features at our partner CHCs include the ability for patients to make appointments, refill medications, view test results, and in 1 clinic, securely message clinicians. In both clinics, primary care providers manage T2D, and access to an endocrinologist is available. T2D education is provided by primary care providers and nurses as needed.

Recruitment

We used convenience and purposive sampling to recruit study participants. Participant recruitment and data collection took place toward the end of the COVID-19 public health emergency between October 5, 2022, and March 16, 2023. We recruited participants through Spanish and English flyers in participating clinics, in-person recruitment by research assistants (RAs), and recommendations from clinic leadership and participating stakeholders. Members of the research team assessed eligibility and obtained written informed consent from patients in their preferred language, and clinicians provided verbal consent.

Inclusion criteria for patients were as follows: established patient of 1 of the partner CHCs, aged ≥18 years, diagnosed with T2D ≥6 months, and able to read English or Spanish. For patients, we sought variability in age, sex, race, ethnicity, language (English or Spanish), type of insurance, duration of T2D, and current portal use. Inclusion criteria for clinicians were as follows: clinician or community health worker (CHW) at 1 of our partner CHCs and provided care or services for adults with T2D. For clinicians, we sought variability in age, sex, and type of clinician.

Data Collection

Semistructured interviews were conducted by trained bilingual RAs. Interview guides were collaboratively developed by the research team to assess the individual, social, health care system, and health inequity challenges related to patient portal use for T2D management (Textbox 1). Interviews were conducted via a video call platform (Zoom; Zoom Video Communications, Inc). All interviews were audio-recorded and transcribed verbatim via the video call platform. Spanish transcripts were translated into English, and all transcripts were deidentified and checked or corrected for accuracy by bilingual RAs. Participants also completed a brief demographic questionnaire. All participants were assigned a code number, and names were not transcribed in any interviews to assure confidentiality. Participants continued to be recruited until information saturation was achieved.

Textbox 1. Interview guide.

Interview questions

- What are the most difficult challenges in caring for adults with diabetes in this clinic? (clinicians) What challenges do you have in taking care of your diabetes? (adults with type 2 diabetes)
- Describe your experience and thoughts about using the patient portal.
- What are the barriers and facilitators to your use of the portal? Patients' use of the portal? (clinicians)
- Elicit feedback on the proposed components of intervention.
- How could a nurse help you and your patients (clinicians), using the portal?
- Anything else you would like to share?

Data Analysis

Data were analyzed using a rapid content analysis method [33,34]. A codebook was developed a priori based on the interview guide categories. Research team members, in teams of 2, independently coded and extracted data into the coding categories. Coding discrepancies were resolved within teams or by review by the primary investigator (RW). A second review of the data extraction was conducted by 2 research team members (RW and HNC), who met frequently during the coding process to develop coding categories, memos, and the overarching conceptualization of themes, using Microsoft Word and Excel. Most categories were endorsed by clinicians and adults with T2D; however, there were several subcategories unique to each group. To ensure methodological rigor, we re-examined transcripts to confirm that the coding process was reflective of participants' perspective. We maintained an audit trail of all coding decisions and memos and used a consensus, collaborative approach to finalize the data analysis process and final conceptualization. The results of this study informed the development of an intervention protocol for a multilevel intervention to promote patient portal use in adults with T2D who access care at the partner CHCs.

Ethical Considerations

Institutional Review Board approval was obtained from Yale University (IRB# 2000031753; approved on December 21, 2022). The Consolidated Criteria for Reporting Qualitative Research was used to guide the reporting of this study [35]. Participants received a gift card for US $20.00 for their time.

Results

Sample Description

The sample included 13 (62%) clinicians and 8 (38%) adults with T2D (N=21). All clinicians contacted completed interviews. Of the 14 adults with T2D approached for this study, 4 (29%) declined participation (too busy or not interested), and 2 (14%) were unable to be reached after the initial contact (8/14, 57% participation rate). Participating adults with T2D were aged 61.13 (SD 7.06; range 53 to 72) years and consisted of 62% (5/8) women and 38% (3/8) men. Individuals from minority racial and ethnic groups comprised 88% (7/8) of the sample (Hispanic: n=5, 62%; Black: n=1, 12%; and Asian: n=1, 12%), and 12% (1/8) non-Hispanic White. In addition, 50% (4/8) of participants were interviewed in English and 50% (4/8) in Spanish. Only 25% (2/8) of participants endorsed having medical insurance; 75% (6/8) reported no insurance. Time since T2D diagnosis varied from 6 to 35 years. Self-reported hemoglobin A_{1c} values ranged from 7% to 9% (SD 0.84%). The length of engagement with the CHC spanned from 1 to 17 years. Only 3 (38%) of the 8 participants had ever used a patient portal. For clinicians, age ranged from 25 to 72 years, with a mean of 47.46 (SD 15.93) years, and the majority were female (11/13, 85%). Clinicians were 62% (8/13) non-Hispanic White, with 38% (5/13) Hispanic. The type of clinicians included nurses (5/13, 38%), physicians (n=2, 50%), nurse practitioners (n=2, 50%), and CHWs (2/13, 15%). Interviews ranged from 12 to 32 minutes for adults with T2D and 20 to 54 minutes for clinicians.

Qualitative Themes

Overview

Factors influencing the integration of patient portal use in CHCs included challenges in diabetes self-management, perceived usefulness of the patient portal, and challenges in using the patient portal. Strategies to enhance patient portal use were also identified by clinicians and adults with T2D. Each of these themes is described in more detail in the subsequent sections.

Challenges in Diabetes Self-Management

Clinicians and adults with T2D described numerous general challenges to diabetes self-management. These included addressing social determinants of health (SDOH), complex self-management of T2D, and management of comorbidities, some of which could be improved by greater use of the patient portal. Clinicians and adults with T2D both described SDOH factors of social status, low socioeconomic position, lack of material resources (eg, access to medications and food insecurity), lack of insurance, language, culture, and health literacy as barriers to performing self-management behaviors, including engagement in technology such as a patient portal. Adults with T2D and health care providers also reported that the complex and long-term trajectory of T2D was challenging. Adults with T2D reported difficulty with fluctuating blood glucose (BG) levels and hyperglycemia despite self-management efforts. Several adults with T2D reported that additional health problems or pain made diabetes self-management difficult. In addition, several adults with T2D reported feelings of frustration, being overwhelmed, distress, and depression as a result of diabetes self-management.

Patient Portal Use and Perceived Usefulness (Facilitators)

While both of our CHCs were using patient portals, 1 clinic had recently adopted a new EHR, and the patient portal interface had only been activated in a limited capacity (eg, for making appointments) or with select clinicians. In our sample of clinicians, all (4/4, 100%) physicians currently used the patient portal, only 14% (1/7) of nurses, and no CHW used the portal. Of adults with T2D, 25% (2/8) used the patient portal, and 25% (2/8) had tried to use the patient portal without success. Across our study participants, 33% (7/21) were currently using the patient portal. Despite low use of the patient portal, most adults with T2D and clinicians reported perceived usefulness of the patient portal. Adults with T2D and clinicians reported that access to smartphones and internet capabilities was available to most people, if not individually, then through a shared device or with support from family members. Potential benefits of the patient portal endorsed by adults with T2D and clinicians included the ability to schedule appointments more efficiently, obtain refill prescriptions for medications, and access health information quickly, such as laboratory or test results and health care visit summaries. One adult with T2D stated the following:

> *I can look like the very next day and see my blood results.*

Adults with T2D and clinicians also identified the ability to communicate between health care appointments, ask or respond to a nonurgent question, and have communication in between appointments as clear benefits to the use of the patient portal. As 1 adult with T2D stated the following:

> *The portal would be good, because then you don't have to go stepping out of your house in order to ask a question...you have somebody there to advocate for you.*

Specific to T2D self-management, several adults with T2D and clinicians perceived that the patient portal could be useful for maintaining motivation and having support for the challenges of diabetes self-management. One adult with T2D stated, "It's really good motivation to be aware of what's going on," referring to the patient portal as a way to increase awareness about diabetes care. One clinician stated that through the patient portal, we may be able to address "things that unfortunately the provider and their fifteen minutes may not emphasize, things like behavioral health, immunizations, dental, things that unfortunately often get by the wayside." For example, this clinician indicated that a yearly information sheet could be sent to all patients with diabetes, reminding them to schedule health maintenance appointments. Other educational resources about coping with diabetes and behavioral health resources could also be sent via the portal.

Patient Portal Challenges

Overview

Whereas adults with T2D and clinicians described the potential usefulness of the patient portal as an adjunct to T2D care in a CHC, numerous challenges were identified. This included a lack of engagement in the use of the portal by patients and clinicians, low socioeconomic status, language, literacy (including technical literacy), and patient portal factors related to design, usability, and implementation specific to CHCs. Neither clinic had a current practice for training patients or clinicians in the use of the portal, rather it was clinician-directed.

Lack of Engagement in Portal Use

Adults with T2D and clinicians shared that patient portal use was underused in their health care setting. Clinicians may not recommend use or have experience in patient portal use, and adults with T2D may not be enrolled or, if enrolled, do not use the patient portal consistently. Factors contributing to lack of engagement include perceived clinician burden, competing demands for adults with T2D, or lack of technology support for adults with T2D in patient portal use. One clinician stated the following:

> *Checking a portal twenty-four seven is not something that any of us want to do.*

With regard to engagement, another clinician stated the following:

> *I think the biggest challenge or barrier would be getting the patient engaged to actually download the application and manipulate it and understand how to use it as a tool.*

Adults with T2D reported a lack of time, competing demands, and the need for technology support as barriers to engagement with the patient portal. In reference to navigating the patient portal, 1 adult with T2D stated the following:

> *You have to get over the learning curve.*

Other adults with T2D reported preferring in-person communication with their health care team while clinicians reported that they have other established patterns of communication between health care appointments with phone calls and SMS text messaging.

Socioeconomic Status, Language, and Literacy

Participants reported that although many adults with T2D had access to smartphones and community-based internet, access to the internet at home or tablets or computers with larger screen sizes may not be available at home, limiting timely access or easy reading of small font sizes. One adult with T2D stated the following:

> *I'm drowning with that price for internet and cable.*

Clinicians reported that language or literacy barriers may be exacerbated in patients' understanding and ability to respond to written messages in the patient portal (whether in English or Spanish). Most adults with T2D and clinicians identified challenges associated with technical literacy in using the patient portal which requires downloading the application, creating an account using an email address, creating, and remembering how to enter a password, navigating the patient portal interface, and entering data or written information. As 1 adult with T2D shared the following:

> *I went there to the clinic...they downloaded it for me, they entered an email...I had to enter it for them to download it, but it does not work, it does not show up...I have tried, but no. I cannot use it.*

Another adult with T2D stated the following:

> *I've been left behind with this technology. I haven't learned English well. I've lost all my time working. I've been here for more than 20 years. I've only been dedicated to 2 jobs. I tell my daughters to do it for me.*

Patient Portal Design, Usability, and Implementation Factors

Clinicians shared numerous portal design, usability, and implementation factors that were challenges to the widespread adoption of patient portal use in CHCs (Textbox 2). Patient portal design issues included features and options available. Clinicians reported that the portal's overall design with the requirement for manual data entry, typing of text or BG values, could be challenging for adults who may have low educational attainment. Spelling and grammar to articulate health concerns may be difficult for some patients. Navigating the portal interface to determine how to enter each BG data point may not be user-friendly, all the more for adults with limited health and numerical literacy. Clinicians also reported that patients had difficulty accessing or using patient portal features that allowed them to message their health care team:

> *When I sign off on labs or imaging there is a spot for me to put notes that the patient can view; but there's no opportunity for the patient to ask a question back.*

Textbox 2. Summary of the challenges of patient portal design, usability, and implementation.

Design

- Document upload and data not interoperable for electronic health record
- Unable to upload images
- Requires manual entry
- Limited messaging options (eg, unable to post a question on a test result)
- Cost for certain features to community health centers (eg, alerts)

Usability

- Clinic workflow, linkage between patient and correct clinician for a given message
- Patient users need an alert for when messages or health information sent
- Data entry can be challenging for patient users
- No synthesis of blood glucose data useful for clinicians (eg, data trends or patterns for drug treatment adjustment)

Implementation

- Inadequate staff to triage messages
- Inappropriate message content that cannot be addressed via the portal
- Disparity in the expectation of response time by both users (patients and clinicians)
- Lack of clear procedures for unanswered messages by both users
- Clinician concern about medical decision-making
- Clinician may need objective data or in-person appointment
- Clinician time or burden, currently not reimbursable

Patient portal usability issues included navigation, interface, and tasks required for both users (patients and clinicians). One clinician stated the following:

> *You can only send (a message) to certain providers, and I don't know how do you set it up to send it to a different provider?*

Implementation issues included inadequate staff for triaging messages, inappropriate use of messaging, long response time, decision-making with limited information, clinician time or burden, and the issue of reimbursement for clinician time. For example, 1 clinician stated the following:

> *The patient will say this, and then the provider will send them a message back. But whatever was true three days ago is not true anymore.*

Another clinician stated that she did not make medication changes through the patient portal as she was concerned patients will not see the message.

Strategies to Enhance Portal Use

A total of 3 broad themes emerged regarding strategies to enhance patient portal use in CHCs: (1) standardized clinic- and patient-level implementation strategies to integrate use into clinic workflow, (2) technical modifications tailored for clinicians and adults with T2D, and (3) patient-centered chronic illness management to address SDOH, mental health, and psychosocial support needs.

Standardized Implementation Strategies

Standardized clinic-level strategies included an implementation guide on the specifics of clinic workflow procedures, individual

roles, and responsibilities. Clinicians questioned who would lead clinic-level implementation. For example, 1 clinician stated the following:

> *If we're going to do this, implement this truly,...we do need to rethink our systems and evolve toward systems where we have other people who are...who are triaging those things? I think it's the big thing.*

Personnel challenges at the clinic were identified, such as high turnover for medical assistants or CHWs, registered nurses, and physicians who gain experience and then move on to other settings. One clinician stated the following:

> *It's impossible to hire nurses.*

Despite these challenges, nurses were recognized as a key clinician to triage health-related concerns on the patient portal. For example, 1 suggestion was having a nurse as the initial contact with a decision algorithm detailing: (1) what message to respond to versus route to an appropriate recipient, (2) response time (eg, general questions vs real-time high or low BG), (3) conditions for nurse video visit or other health care provider appointment, and (4) preset templates of messages to be consistent and efficient. One clinician stated the following about the number of messages:

> *How do you handle 3-400 all the time—high volume needs.*

Clinicians felt that an algorithm should give guidance from the beginning of a message to subsequent ones and include how to handle critical laboratories or clinical issues, such as hypoglycemia.

Standardized patient-level strategies included an implementation guide with steps to support patient engagement. The key emphasis was to educate patients about the importance of messaging via the patient portal to build long-term patient-clinician relationships and trust, with regular check-ins. Clinicians recommended that time at the end of clinic visits could be used for specified clinic personnel to teach and show patients how to download and use the patient portal application, allowing enough time for patients to learn the technology. One clinician stated:

> *I think that it's just having a lot of training in that sense and then also when it comes to medical terms on the patient portal, I think that that could get a little tricky for them. It's going to take a lot of kind of reinforcement and just I would think definitely a lot of training for some...individuals.*

Clinicians expressed the need for a training plan for patients and the health care team. There were suggestions for teaching patients about the patient portal, features or navigation, how to use it (login, see laboratories, send, and receive messages), and logistics (eg, who does what on the health care team, how frequently messages are checked or responded to). Training recommendations for adults with T2D included having bilingual personnel and a combination of in-person training with telephone or internet-based training options available to accommodate patient scheduling needs. One clinician stated the following:

> *Here you go...don't go through the whole thing...I think that it would be beneficial to actually have a little bit of time and send a message and show them how to send a message back.*

Reinforcement of training and having technical support staff was also deemed important. One adult with T2D stated that sessions needed to be frequent:

> *Because you can't (have) too much time go in between, because they're going to forget. You have to make it so that it's a cumulative thing of knowledge...so they don't lose anything in the meantime.*

Another adult with T2D stated that "it will maybe take 3 or 4 times" (to learn to use the patient portal).

Technical Modifications

Participants shared their recommendations on key technical designs tailored for clinicians and patients on data sharing, electronic patient-friendly education material, clinic visit items, alerts or reminders set up, social support resources, and behavioral health referrals. Several clinicians expressed that they would like to have easier interfaces for patients to upload BG results and easier access to simple patient education materials electronically on topics such as healthy eating, exercise, glucose targets, laboratory results, hypoglycemia, medication side effects, medication management, insulin use, and recipes. Suggestions were expressed to provide access to prior clinic visit summaries and care plans in the patient portal. Another suggestion among clinicians was having individualized alerts and reminders on sharing BG data, continuous glucose monitoring (CGM) technique, preventive care visits (eg, specialists), responses or nonresponses to patient portal messages, and when a follow-up for laboratory or clinic was past due. One clinician felt that the patient portal could be an efficient and effective tool to follow up on recommendations made in a clinical visit, both for clinicians to remind patients and for patients to report back to clinicians. This clinician stated the following:

> *Patients forget to send in 2 weeks of CGM and glucometer BG readings requested by provider—Need reminders to do action, wished MyChart could send alert to patients to share data.*

A few clinicians suggested a section for social support resources on the patient portal.

Patient-Centered Chronic Illness Management

Most clinicians and adults with T2D expressed a need for patient-centered chronic illness management to address SDOH, mental health, and psychosocial support needs. Adults with T2D expressed that the patient portal held great potential to support regular contact and share concerns, challenges, or successes affecting their health. Adults with T2D also stated that they needed more health education on T2D management that could be done via the patient portal, particularly around glucose variability. One adult with T2D stated the following:

> *It is so tricky, one time it's up, one time it's down...sometimes I'm overwhelmed, and I don't know what to do.*

Spanish-speaking adults with T2D also mentioned that cultural factors, such as foods and celebrations, affected diabetes self-management, and language barriers impacted their understanding of diabetes.

Clinicians felt that the patient portal could be used to provide advice, personal coaching, and encouragement around diabetes self-management or follow up to changes in treatment. Problem-solving for changing health status and mental health were also expressed as challenges that could be addressed on the patient portal. For example, 1 clinician spoke about how the portal could be used to stay connected with patients and identify the need for changes in treatment:

> *Almost everybody (with a chronic illness)...has issues that they need to work through...through a lifetime, because it's dynamic right. Nothing stays the same, your life doesn't stay the same, so nothing is the same.*

This clinician also felt that the patient portal could be helpful to support coping with the challenges of self-management:

> *Whenever, whatever it is, you know, they got a lot of other things going on their lives like everybody else. But...finding a way to cope...and being able to...navigate their chronic illness.*

This clinician went on to state that the portal could also be used to refer and follow-up on referrals to behavioral health:

> *I think...I would include behavioral health...a strong behavioral health program where even the nurse could make a referral.*

Another clinician spoke about the benefit of ongoing connection through the patient portal to "follow up for any previous content/discussion—did it work or not? Were you able to do that? Follow up to affirm or deny, the success of the process. In a supportive way. This is life. This is difficult."

Discussion

Principal Findings

In this study, we identify that both patients and clinicians report that patient portals have the potential to facilitate patient-clinician communication, serving as a mechanism through which the health care team can provide diabetes self-management support. However, numerous barriers to patient portal use were also reported, including language, literacy, and low socioeconomic status of patients, as well as design-related challenges to patient portal use and suboptimal implementation of portals in CHCs. Patients and clinicians shared recommendations to overcome these barriers and facilitate portal use, including providing portal education, hands-on training, ongoing technical support, and having standardized implementation strategies for patients and clinicians.

Although several studies have been published on barriers to patient portal use, the study that is most germane to our findings was published in 2015 [27]. Some improvements have been made in the intervening 9 years since this 2015 study was published. These improvements include a substantial increase in access to both smartphones and the internet in the United States from 59% in 2015 to 85% in 2021 [36]. In addition, patients and clinicians still see the potential for patient portals to improve diabetes self-management and outcomes. Yet, it is important to highlight that many challenges to patient portal adoption in CHCs stubbornly persist. Challenges include the lack of adequate training and technical support for patient portal use, particularly for those with low health or technical literacy and the lack of patient-level and clinic-level standardized and thoughtful implementation strategies to address the unique needs of patients receiving care at CHCs.

Our study extends prior work in several important ways. First, we interviewed both patients and a variety of clinicians (eg, nurses). Whereas patients and clinicians did not contradict each other per se, each group of stakeholders did provide a unique perspective, both of which are important for our understanding of patient portal uptake in CHCs. Second, we included Spanish speakers who may face unique challenges with using patient portals designed in English. Third, we examined patient portals in the context of CHCs where the prevalence of diabetes is higher than the general population (21% vs 11%) [29]. Finally, we elicited strategies to increase patient portal use in a CHC setting which may be different from strategies in other health care settings. The findings from this study have the potential to enhance the development of patient and clinic-level portal implementation strategies and to strengthen other initiatives currently underway in CHCs regarding SDOH screening, referral, and support [37].

Perceived Benefits of Portals

In this study, both clinicians and adults with T2D recognized the usefulness of patient portals in creating an opportunity for adults with T2D to share their successes and nonurgent concerns and for clinicians to provide encouragement or advice on how to address concerns between appointments. In a similar study among adults with diabetes in a safety-net hospital in San Francisco, it was reported that the secure messaging feature of patient portals allowed adults easy access to their health care team and reduced their need for frequent clinic visits [10]. Access to one's health care clinician outside clinic appointments is associated with better patient-clinician communication and a greater likelihood of patients following diabetes self-management recommendations [38]. Consistent with the findings from this study, the ability to contact clinicians outside of clinic appointments is particularly useful given the limited time clinicians have to spend with patients during outpatient visits [39]. Thus, our study affirms that the findings from previous studies regarding the perceived benefits of portals are also recognized in the CHC setting [10,13,14,16,40].

Clinicians and adults with T2D also reported that the ability to view laboratory results and medications, and access health information on patient portals can contribute positively to their self-management. When adults with T2D have access to their personal health information, they are more likely to achieve their glycemic targets, experience greater self-efficacy, and report feeling more empowered to manage their diabetes [41].

In addition, intervention studies have shown that providing patients access to their medical information can result in a greater likelihood of taking medication as recommended [42]. By having access to personal medical information, adults with T2D can review clinicians' recommendations for diabetes self-management as frequently as needed. The importance of having access to health information is underscored by Healthy People 2030, which identifies the provision of online access to EHR and other health information as a critical goal aimed at bolstering health literacy and improving health outcomes [43]. Enhancing patients' access to EHR via patient portals may help address some dimensions of health literacy, which is generally low among individuals who access care at CHCs [44,45]. For example, patient portals may promote patients' information-seeking habits, particularly if information is simplified, in easy-to-understand language. The use of patient portals also facilitates the use of web-based resources, including easy-to-understand videos (eg, resources from CDC [46]). Thus, taken together, patient portals have the potential to facilitate self-management among adults with T2D who access care at CHCs.

Patient-Level Barriers to Portal Use and Recommendations to Address Them in CHCs

Both clinicians and patients in this study reported patient-level barriers, such as limited English language proficiency and low technology literacy that interfere with participants' ability to use portals. These SDOH-related barriers have been well-documented in prior research [4,16,27]. For instance, a recent systematic review of patient portal use among adults with chronic diseases found consistent evidence that individuals with low health literacy and limited access to a computer were less likely to use patient portals [4].

Our study participants proposed several strategies to address these patient-level challenges. Recommendations included addressing SDOH needs prior to initiating patient portal education and training. Providing flexible patient portal education and training with ongoing technical support was deemed essential. These recommendations are consistent with prior studies among adults in non-CHC settings [47]. In 1 study, 48% of patients with chronic conditions who received training on using the patient portal registered for the portal, compared to only 11% of those who did not receive any training [48]. Technical training on patient portals may include setting clearer guidelines on how adults with T2D can use the messaging features [49]. Studies among populations considered vulnerable (such as racial-ethnic minorities and individuals with low literacy) show that providing technical training in patient portal use leads to significant increase in the adoption and use of patient portals [50]. Ongoing technical support may also be required to sustain the continuous use of patient portals among adults with T2D [51]. It should be noted that the population of adults with T2D who access care at CHCs are likely to be socioeconomically disadvantaged individuals who may have barriers to additional clinic visits for training or education [29]. It is, therefore, important for training to be designed and delivered in a flexible manner to accommodate common life circumstances, such as shift work and child or older adult care responsibilities. As suggested by our study participants and in alignment with current literature, strategies may include an initial in-person guide on how to use the patient portal [52], followed by synchronous or asynchronous web-based video tutorials [53,54] phone call and message reminders [55,56], or clinic-specific infographics on patient portal use, problem-solving, and accessing technical support.

In addition, assessing health literacy is important to identify adults with T2D with limited reading or writing literacy who may not benefit from use of the patient portals and to identify adults with T2D who may need additional support or more extensive patient portal training [57]. The health literacy screener question from the Confidence Completing Medical Form tool could be used as a simple and easy-to-use survey to assess health literacy [58] as it can be administered rapidly and has been shown to be sensitive in identifying adults with limited to extremely low health literacy in CHCs [58]. Some practical, evidence-based approaches to accommodate low-literacy adults when delivering patient portal training at CHCs may include avoiding unclear statements or medical jargon, keeping training sessions brief, using bilingual instructors, providing opportunities for patients to practice using the patient portal between sessions, and using a friendly tone [59]. The teach-back method may also be a helpful technique. It involves providing adults with T2D with the most relevant information regarding the topic, with the aid of visual tools, and confirming patients' understanding by having them describe the information they have been taught, using their own words [60]. In the case of patient portal use, it may also involve patients showing that they can execute a specific task. The teach-back method has been effective in improving knowledge recall and retention among adults with low health literacy [61]. For patients with low technical literacy, a strategy to improve portal use, in addition to ongoing technical support, is to provide proxy access of portals to patients' caregivers or family members, as this can potentially lower patients' concerns about self-efficacy in using the portal [57]. However, any concerns about data privacy and control should be carefully navigated when implementing proxy access [62].

Clinic-Level Barriers to Portal Use and Recommendations to Address Them in CHCs

Whereas both clinicians and adults with T2D expressed shared barriers to portal use, such as limited technology literacy and the need for technical support or training, clinicians also reported their own unique barriers. Notably, clinicians expressed concerns about the lack of reimbursement for the time they spend communicating with patients via the patient portal. Indeed, a cross-sectional study among clinicians (physicians, physician assistants, and nurse practitioners, N=59) in a Spanish-speaking safety-net hospital reported that 64% of clinicians were concerned about the lack of reimbursement for using patient portals [63]. However, billing for patient portal messaging is a complex issue [64]. Whereas such billing might help compensate clinicians for their time, it may also present financial barriers to patients with low income who access care at CHCs [65]. Indeed, there is evidence that when patients know that their interactions on patient portals are billed, they are less likely to message their health care team [66]. Practical strategies to equitably introduce patient portal reimbursement may include

waiving copays for sending messages via portals and closely monitoring reimbursement policies to determine their effects on patient experience and health outcomes and making necessary changes as required [64].

In addition, clinicians reported a lack of clear instructions to guide their interaction with patients. Studies have shown that the lack of clear "rules of engagement" when interacting with patients via the patient portal makes it challenging for clinicians to adopt patient portals as a desired platform for communicating with patients [67]. Clinicians in our study suggested that the implementation of patient portals in CHCs should be standardized by providing a clear decision-making algorithm to guide the triaging of messages and clinician responses. The use of an algorithm helps to ensure that adults with T2D have consistent experience with the patient portal regardless of which clinician they are interacting with [57]. In a survey of 1417 frontline workers in 54 CHCs across the United States, about 40% of study participants suggested that having a standardized clinical workflow and operational guidelines can positively contribute to improved care at CHCs [68]. Clinicians may be less likely to find the use of patient portals burdensome if there are clear and easily referenced guidelines for their use.

Staffing challenges and turnover contributing to increased workload are well-documented at CHCs [69] and were reported as a barrier to patient portal use by clinicians in this study. Improving retention of staff can improve care delivery at CHCs [68], yet it remains a challenge. As suggested by our participants, another strategy to reduce clinician workload and burnout in relation to portal use in CHCs is to implement a triaging system to manage messages sent by patients via patient portals. Studies have shown that clinicians can receive excessive messages (eg, form requests and referral responses) via portals that can lead to burnout and contribute to job dissatisfaction [70]. Practical steps to address this information and work overload at CHCs may include having dedicated nursing staff who review messages sent via patient portals, address health questions or concerns within their scope of practice, and forward only messages that require the expertise of primary care providers [71]. In more recent research, artificial intelligence (AI) technology, such as natural language processing, has been used to identify, prioritize, and route urgent patient messages to clinicians. Although natural language processing triaging has been shown to significantly reduce the burden associated with portal use among clinicians [72], the technology is still emerging and requires further testing especially given the concerns of hallucination (a phenomenon where AI generates a convincing but completely fabricated output) in AI technologies and the danger it may pose to patients [73].

Currently, there are a few national interventions, such as the Medicaid EHR Incentive Program, which aims to encourage health facilities to adopt EHR and patient portals [74]. Although this program has contributed to the widespread availability of patient portals across health facilities in the United States [75], it is clear that health facilities that serve underserved populations still face challenges in using this technology in clinical care. Thus, future national programs should prioritize specific incentives and resources that promote equitable access to patient portals for minority populations.

Portal Design Barriers and Recommendations to Address Them in CHCs

In our study, adults with T2D and clinicians reported challenges navigating specific features of the patient portal. These usability challenges, including difficulties in uploading BG results and the lack of notifications when new health information is available, have been reported in previous studies as important design-related barriers to patient portal use [5,13,19]. For instance, in 1 study, adults with T2D reported difficulty in intuitively understanding the patient portal layout and in using its navigation menu to explore features, making it challenging to continue using the patient portal [76]. In addition, the lack of notification features on patient portals can lead to lapses in communication between adults with T2D and their health care team. Customizing patient portal notifications to meet the needs of clinicians and patients is essential. For example, patients may prefer getting SMS text messages for new messages on the patient portal as they do not login regularly or use email, while clinicians may prefer a notification of messages on their clinical dashboard.

Additional recommendations to address patient portal design and usability barriers included the improvement of features for the target population. These improvements include facilitating the seamless upload of BG results, developing alert systems, expanding access to personal medical information such as visit summaries, and increasing access to resources on improving psychosocial well-being. A previous study reported that 86% of adults with diabetes (N=21) rated their ability to record daily glucose log as a "very useful" feature in patient portals [40]. Despite its usefulness, our study participants reported challenges in uploading BG results. While no specific recommendations were provided by study participants to address the challenge of uploading BG results, existing technology could be leveraged to address this problem. We submit that the design and adoption of portal features be expanded to accommodate remote communication and ensure interoperability with existing BG devices to allow for seamless uploading of BG data as well as summary data from widely used apps and wearable devices, such as for physical activity and diet. Linking these devices with patient portals can enhance transparency between clinicians and patients in relation to patients' diabetes management [77]. Although wearable devices are now ubiquitous, linking them with patient portals may present a number of challenges that require creative solutions [78]. A typical challenge is the management of the huge data streams recorded by these devices that may require a substantial bandwidth to transmit and an expanded hospital IT infrastructure to host [79]. AI algorithms have been proposed as a way to extract and generate brief but clinically meaningful summaries from wearables that can be shared with clinicians and linked with portals. Sharing aggregate, preprocessed data as opposed to raw data can reduce clinician burden. In 1 study, informative BG reports from CGM devices were able to be remotely downloaded by clinicians and automatically added to patients' EHR with just a few clicks [77]. While this integration is not currently widespread, it offers promise to address some of the concerns clinicians and patients have raised regarding portal use in adults with T2D. A summary

of patient, clinician, and design-level implementation strategies is presented in Textbox 3.

Textbox 3. Summary of patient-, clinic-, and design-level implementation strategies for community health centers.

Patient level

- Flexible portal training
  - Combine in-person and remote sessions, including the use of prerecorded videos
  - Screen for health literacy using single-item tools and determine the feasibility of using a portal versus other form of communication.
  - Use infographics and simple educational materials for patient portal and type 2 diabetes education.
  - Use the teach-back method for patients to demonstrate the use of patient portal.
  - Encourage the involvement of family caregivers as proxy users, especially for patients with limited technology literacy.
  - Provide easily accessible technical support for patient portal access issues

Clinic level

- Train clinic team to recognize the benefits of patient portal use and encourage them to raise or maintain awareness of patient portal among patients
- Implement a triaging system for patient messages
  - Have a designated support team who is guided by an algorithm to triage new messages
  - Consider incorporating artificial intelligence technology to identify high-priority messages and automatically route messages to the right clinician
- Monitor patient portal use and determine policies for nonuse and nonresponse to messages.
- Implement equitable portal reimbursement policies as relevant.
  - Monitor and evaluate patients' experiences and outcomes following the implementation of any portal billing policies
  - Waive copays for portal-related billing

Portal design level

- Customize portal notifications to meet the needs of clinicians and patients
  - Dashboard notification for clinicians
  - Email or SMS text message notification for patients per preference
- Include language preference options
- Ensure seamless data interoperability with technologies, including continuous glucose monitoring
  - Presentation of clinically meaningful summary of blood glucose data and reports from wearable technologies

Limitations

This study has several limitations. First, our sample size was relatively small, and our sample of adults with T2D had very limited use of the patient portal. For participants without portal experience, we explained the purpose of patient portals to access health information, schedule appointments, obtain medication refills, and communicate with their health care team. In subsequent research, exploring patient portal use among active users with T2D is recommended. Second, our sample was drawn from only 2 clinics, both of which are in Connecticut. Thus, our sample may not be representative of clinicians and adults with T2D who access care in CHCs across the United States. However, our goal was not to achieve representativeness but rather to provide preliminary evidence on the specific challenges to patient portal use in CHCs and how these challenges can be addressed.

Conclusions

Adults with T2D and clinicians at CHCs continue to report pervasive challenges to patient portal use in CHCs. A lack of training and technical support for patients with low literacy to register and use the patient portal coupled with a lack of standardized implementation strategies to address the unique needs of patients receiving care at CHCs continue to impede efforts in achieving health equity in patient portal use. Implementation strategies recommended to improve health equity include portal training for those with low literacy, easily accessible technical support, a nurse triaging system for monitoring and responding to initial messages, algorithms for nurse triaging of chronic conditions, clinic policies for nonresponse to messages and reimbursement, customized notifications for patients and clinicians on new messages, and easy uploading of wearable technology data to the portal.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
BG: blood glucose
CGM: continuous glucose monitoring
CHC: community health center
CHW: community health worker
EHR: electronic health record
RA: research assistant
SDOH: social determinants of health
T2D: type 2 diabetes

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Original Paper

The Development of an Electronic Medical Record System to Improve Quality of Care for Individuals With Type 1 Diabetes in Rwanda: Qualitative Study

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Abstract

Background: Electronic medical record (EMR) systems have the potential to improve the quality of care and clinical outcomes for individuals with chronic and complex diseases. However, studies on the development and use of EMR systems for type 1 (T1) diabetes management in sub-Saharan Africa are few.

Objective: The aim of this study is to analyze the need for improvements in the care processes that can be facilitated by an EMR system and to develop an EMR system for increasing quality of care and clinical outcomes for individuals with T1 diabetes in Rwanda.

Methods: A qualitative, cocreative, and multidisciplinary approach involving local stakeholders, guided by the framework for complex public health interventions, was applied. Participant observation and the patient's personal experiences were used as case studies to understand the clinical care context. A focus group discussion and workshops were conducted to define the features and content of an EMR. The data were analyzed using thematic analysis.

Results: The identified themes related to feature requirements were (1) ease of use, (2) automatic report preparation, (3) clinical decision support tool, (4) data validity, (5) patient follow-up, (6) data protection, and (7) training. The identified themes related to content requirements were (1) treatment regimen, (2) mental health, and (3) socioeconomic and demographic conditions. A theory of change was developed based on the defined feature and content requirements to demonstrate how these requirements could strengthen the quality of care and improve clinical outcomes for people with T1 diabetes.

Conclusions: The EMR system, including its functionalities and content, can be developed through an inclusive and cocreative process, which improves the design phase of the EMR. The development process of the EMR system is replicable, but the solution needs to be customized to the local context.

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KEYWORDS

type 1 diabetes; electronic medical record systems; Rwanda; complex interventions; intervention development; diabetes; diabetic; DM; diabetes mellitus; chronic disease; chronic diseases; qualitative; focus group; quality of care; clinical outcome; clinical

outcomes; public health interventions; public health intervention; design; electronic health record; electronic health records; EHR; medical records; medical record

Introduction

Electronic medical record (EMR) systems are electronic platforms that contain individual health records for patients, maintained by health care professionals (HCPs) and health care organizations. EMRs may include patients' medical history, diagnoses, clinical test results, and treatment plans [1]. Studies from high-income countries (HICs) have shown that the use of EMR systems has the potential to identify and target high-risk patients, autogenerate appointments, and send reminders to patients who do not show up for consultation. Moreover, other potential benefits of the use of EMR include better organization of relevant data and providing HCPs with feedback on their care for individuals with diabetes [2-4]. These features can lead to significant improvements in care and outcomes, as supplies, adjustments to medicines and timely referral can be better ensured [3,5]. Little evidence is available on the development, use, and effects of EMR systems for life-long chronic disease management, such as type 1 diabetes (T1 diabetes), in sub-Saharan Africa [6]. To increase the likelihood of successful implementation, it is crucial to know existing practices and the structure of the current system in order to know what changes are needed and feasible under the local circumstances [7]. However, studies within other disease areas, such as HIV, have shown positive effects on quality of care using EMR systems [8,9]. A study from Kenya showed that the implementation of an EMR system was significantly associated with receiving antiretroviral therapy among patients with HIV and having at least one CD4 test done compared to that before the intervention using paper records [10,11].

Health care systems, access to health care, and health care–seeking behavior differ between countries. Requirements, priorities, and local constraints related to EMR systems in low- and middle-income countries (LMICs) are not well understood [12]. To understand the local context for the people and the health care system involved in the intervention, social practices, needs, possibilities, and potential challenges should be taken into consideration [13]. In this study, we aimed to explore the requirements and needs for improvement in the care processes. This can be facilitated by an EMR system, and these can inform the development of an EMR system for individuals with T1 diabetes in Rwanda. Therefore, the purpose of the design stage was primarily focused on (1) understanding the clinical care context and workflows, (2) defining functional requirements, and (3) defining content requirements.

Methods

Study Participants

The recruitment of study participants was based on a user-centered design approach and therefore included people with (1) significant understanding of the T1 diabetes care pathway and delivery of care, (2) deep experience of receiving T1 diabetes care, and (3) expert knowledge of national digital health strategies or expertise in the design and development of electronic health record platforms (Table 1). Participants were therefore selected to reflect a range of specific characteristics and experiences known to affect the experience and delivery of health care, including gender, years of experience, practitioner role, and diverse patient socioeconomic characteristics. Initially, we identified international expert stakeholders within T1 diabetes and EMR systems (Textbox 1), and meetings were held for inspirational and insight purposes. Thereafter, we identified relevant local stakeholders and conducted the primary data collection for the EMR development (elaborated below).

Table 1. Study participant types in different research activities.

	Focus group discussion, n=10	Workshops, n=8	Patient interview, n=13
Participant type			
Caregiver (nurses and endocrinologist)[a]	7	3	—
Project manager[a]	2	2	—
T1 diabetes individuals[b]	—	—	13
IT expert/software developer[c]	1	2	—
Policy makers[c]	—	1	—
Sex			
Female	3	1	7
Male	7	7	6

[a]Significant understanding of the T1 diabetes care pathway and delivery of care.

[b]Deep experience of receiving T1 diabetes care.

[c]Expert knowledge of national digital health strategies or in the design and development of electronic health record platforms.

Textbox 1. International expert stakeholders within T1 diabetes and electronic medical record (EMR) systems.

SWEET: An international network for paediatric diabetes centers, established in 2008, striving to improve treatment outcomes using standardized documentation and objective comparison of quality indicators.

Life for a Child (LFAC): An NGO established in 2000, providing young people in under-resourced countries with life-saving insulin and supplies and has the vision that no child should die of diabetes.

Changing Diabetes in Children (CDIC): A public-private partnership established in 2009. The partnership provides comprehensive care for children and young people living with type 1 diabetes in low- and middle-income countries.

International Research Institute (IRT): An independent, non-profit institute established in 1958 that provides research, development, and technical services to government and commercial clients. RTI's mission is to improve the human condition by turning knowledge into practice.

World Diabetes Foundation (WDF): An independent foundation founded in 2002 by Novo Nordisk A/S, and is today a leading global funder of diabetes prevention and care projects in low- and middle-income countries.

Data Collection

Researchers with training in qualitative research collected data via 4 activities: technical requirements focus group discussions (FGDs), clinical and contextual observations, patient interviews, and user design workshops. All activities were conducted in English, except for the patient interviews, which were conducted in the local language [Kinyarwanda] and subsequently translated to English by a project manager. The primary data collection was conducted in November 2021 (1 month), mid-February to mid-March 2022 (1 month), and June 2022 (1 month). The different study participant types across research activities are summarized in Table 1.

Semistructured Focus Group Discussion

The purpose of the semistructured FGD was to get a shared understanding of challenges related to current data collection practices and patient monitoring, as well as the needs and requirements for a new electronic system on how to improve follow-up and care for individuals with T1 diabetes. The participants were asked to talk about what data elements and functionalities they would like to see in a new EMR system. The group discussion was chosen to allow a more informal environment where participants could inspire and supplement each other. The participants included nurses (n=7) working at the Rwanda Diabetes Association (RDA), who were familiar with current practices and were expected to use the new EMR system. In addition to this, a few other participants with different professional backgrounds (n=3) were included to get a full understanding of the requirements for the system and contextual insights. The FGD was held after a scheduled meeting at RDA. All participants were either recruited in person at the RDA office or by phone call, and attendance was voluntary. All participants gave signed informed consent prior to the interview. A semi-structured interview guide was used, the session was audio recorded, and an assistant observer was present to take notes during the 2.5-hour interview session. An overweight group of nurses from RDA, representatives of both genders and with a representative age range of 24-54, mean 38.9 (SD 10), were recruited.

Workshops

The workshops served to make room for interaction and discussions about the EMR system requirements among a multidisciplinary group of people. Participants from all 3 stakeholder groups (Table 1) were invited to a joint meeting. Furthermore, 4 physical meetings and 4 web-based sessions with the software developer of the EMR system, a pediatrician from Rwanda Military Hospital, the management team from RDA, and the primary investigator (NB) from WDF were conducted. At the workshops, the software developer presented demo versions of the new software, and the features were discussed. Minutes from all meetings were recorded by NB and distributed for approval. From meeting to meeting, changes were suggested, and subsequently, the EMR system was updated.

Participant Observation and Patient Stories

Participant observations were conducted by the primary investigator (NB) at the RDA clinic in Kigali and at 2 district hospitals; Nemba Hospital and Rumera-Rukoma Hospital. The observations served to better understand the context, the workflow of the HCPs and the RDA staff, current diabetes care processes, and health information collection and recording. In addition to participant observations, patient stories were also collected at the clinic visits. During the clinic visits, 10 individuals with T1 diabetes were informally interviewed (between 15 and 35 min). In addition, 3 individuals were invited by the project manager at RDA to tell their stories about how it is to live with T1 diabetes in Rwanda, and what challenges they face in seeking care and managing their disease.

Analytical Approach

The analysis was inspired by a reflexive thematic approach, focusing on identifying patterned meanings (themes) in data sets [14] related to features and contents. Data triangulation methodology was applied to get a more comprehensive understanding and to enhance the validity of the analyses through the convergence of information from the different data sources and methodologies [15].

The research methodology was guided by the MRC framework related to complex intervention development [16,17]. The approach was partnership-driven but also used a theory of change (ToC) model [17,18]. A ToC model articulates how an intervention is expected to generate outcomes [19], thus, in our case, how the EMR system is expected to link to expected outcomes. Features and content to be incorporated in the EMR system were identified. "Features" encompasses all the functionalities of the system and "content" encompasses all the information and data elements of importance to be included in the EMR system to help the monitoring and care of T1 diabetes individuals. The needs and requirements were combined with

local clinical guidelines based on international standards for T1 diabetes care.

Ethical Considerations

The project was approved by the Institutional Review Board, College of Medicine and Health Sciences, University of Rwanda (FWA assurance number 0001971, IRB 00001497 of IORG 0001100). Informed consent forms were signed for all participants. The consent forms emphasized that participation was entirely voluntary and all data would be kept anonymous. Participants were free to withdraw from the study at any time without further explanation. No compensations for participation were given.

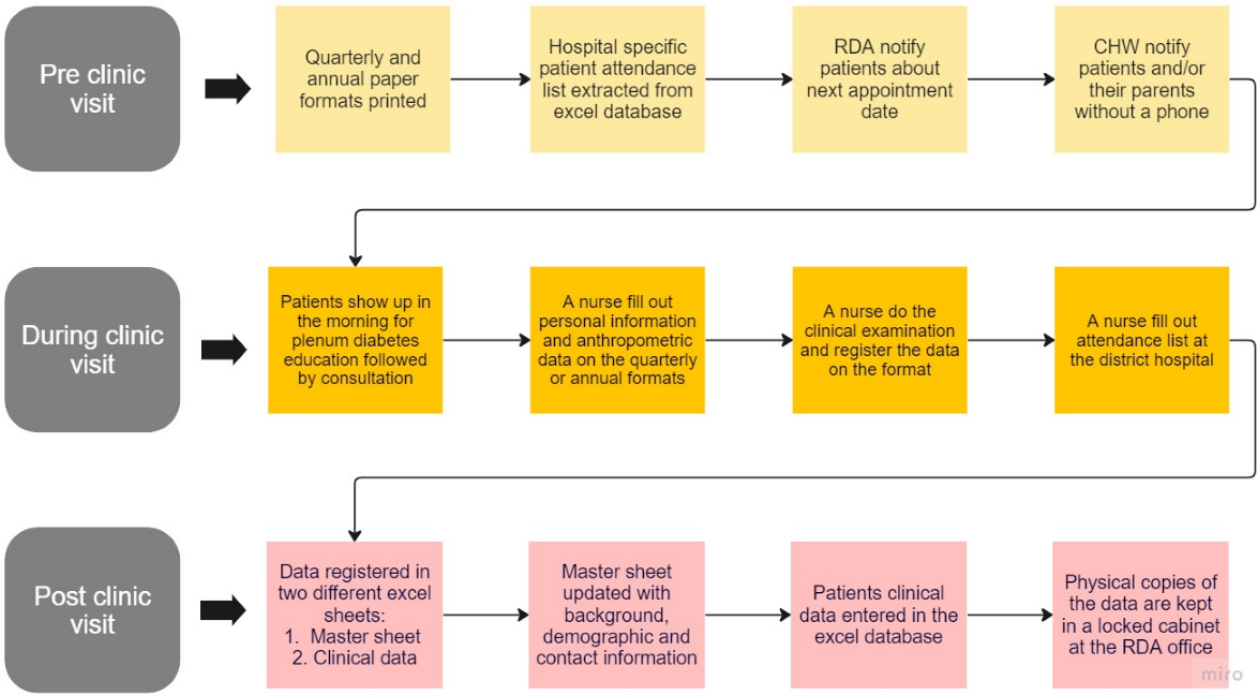
Results

Understanding the Clinical Care Context and Workflows

Since 2009, RDA has been the main health care provider for T1 diabetes in Rwanda, conducting continuous follow-up on children and youth with T1 diabetes for treatment and control purposes. The RDA operates according to national diagnosis and treatment guidelines. Individuals are typically diagnosed with T1 diabetes at the local health facility, the district hospital, a private clinic, or the RDA clinic upon presentation with symptoms of T1 diabetes. Diagnostic confirmation is usually based on glycated hemoglobin (HbA_{1c}) testing, age at diagnosis, response to insulin, presence of diabetic ketoacidosis symptoms, and underweight [20-22].

The RDA has 1 clinic in the capital, Kigali, and works closely with the noncommunicable disease clinics at the district hospitals located throughout the country. Individuals with T1 diabetes living in the Kigali region go directly to the RDA clinic. For individuals with T1 diabetes living outside of Kigali, a team of diabetes nurses and educators from RDA conduct quarterly and annual visits to the district hospitals, providing treatment and care [22,23]. The annual visit is an extensive version of the health examination done at the quarterly visits. Within approximately 3 weeks of the scheduled visit, individuals with T1 diabetes or their legal guardians are notified about the next appointment date, either directly by RDA via phone call, by a nurse from the district hospital, or by the community health worker within the community. On the day of the appointment, T1 diabetes individuals show up in the morning at 9:00 AM for plenum diabetes education, followed by individual examinations conducted by RDA HCPs. All data are collected on paper forms, which are subsequently registered in an Excel spreadsheet database. Transfer of data from paper to spreadsheet is typically carried out at the end of the day, when the nurses have a nightshift or when they have some time left between other tasks. The physical copies are stored in a locked cabinet at the RDA office in Kigali. The follow-up and data collection flow are summarized in Figure 1.

Figure 1. Follow-up and data collection flow. CHW: Community Health Worker; RDA: Rwanda Diabetes Association.



Feature Requirements

The following themes related to the concept of features were identified: ease of use (user-friendly), reporting (automatic report generation), clinical decision support tool (regulation), data validity (data quality), patient follow-up, and data protection and training.

Design: Ease of Use

The structure, design, and interface of the system were identified as important aspects of the new EMR system. It must be user-friendly, intuitive, and developed with a focus on the user (RDA staff). The HCP expressed that the structures and flows of how, and when, the different information should be obtained

needed to be considered, and the data elements should be grouped in a meaningful way, as expressed by one of the project managers:

> *It should be considered how we group and organise the order of the data being collected to improve efficiency. The information collected in the system should match the workflow of RDA.* [Project manager 1 (FGD)]

Participants suggested that patient demographics are only captured one time and recorded in the registration form. Further to this, during the quarterly visit, the most important variables (vitals and results of medical tests) should be captured. Additional information related to patient characteristics that change over time (eg, lifestyle, sociodemographic factors, mental health, etc) and results of microvascular and macrovascular screenings. A balance between "need to know" and "nice to know" should be carefully considered, taking the limited time for consultation per person into account. The less time HCPs spend collecting and registering the data, the more time they have to do more tests, ask more questions, and educate the individual about their disease. Therefore, fewer clicks and time optimizing functions were brought up as important factors, as one project manager explained:

> *The system should have few clicks to ease the data collections processes. The system should not be too complicated to use and therefore the design and structure of the system are important.* [Project manager 1 (FGD)]

Automatic Report Generation

The new EMR could simplify the time-consuming task of generating frequent and routine reports. In the quote below, one manager explains the tedious work of preparing the report:

> *Every month RDA is obligated to upload a report with the status of the T1 diabetes individuals to the MoH. It can take 3-4 days preparing the report. It could be very helpful if the system can generate the data for the reports, including numbers of individuals with newly identified T1 diabetes.* [Project manager 2 (workshop)]

The time gained by using web-based analysis tools for report preparation and outcome monitoring can be used for other important or patient-related tasks. The reports generated by the system should include summary statistics, including graphs and figures giving an overview of incidence and prevalence rates and the health status of the T1 diabetes population. This was expressed by one project manager:

> *It will be useful if the system can provide basic statistics, so it is easier to compare patients across districts and between sex to better target actions and improve care for those who need it most… The reports can be very useful for the management team for control and target purposes.* [Project manager 1 (FGD)]

Clinician Decision Support Tool (Regulation)

The system can generate aggregated reports, which can help track patient outcomes, support clinical management, and improve clinical efficiency. The system can assist in prompt and effective patient management. At point-of-care, the RDA staff can view a summary of the medical records of the individuals with T1 diabetes, showing a chart with clinical and anthropometric measures.

> *Reporting an overview of HbA1c levels, blood glucose levels, height, weight, BMI and diastolic and systolic blood pressure is important to see if the patients improve their glycaemic control and in other relevant factors over time.* [Project manager 2 (workshop)]

The HCPs can track the patient's development in disease management over time as well as identify critical values using real-time data. When key screening tests for comprehensive diabetes care are due or clinical test results are outside the normal range, the RDA staff will receive alerts to facilitate clinical decision-making and considerations for therapeutic interventions. The HCPs can change the treatment regimen according to the recorded blood glucose and HbA_{1c} levels if the values are critically high or low. Not only can the system help provide timely screening and clinical tests, but it can also help avoid unnecessary examinations, saving time and resources. One nurse mentioned how care can be improved and ultimately optimized by providing the right examination in a timely manner:

> *The system should be able to remind the HCPs when it is time for which tests, ensure timely examinations and avoid repeating exams that is not necessary. The system could also alert about critical test results to help the nurses optimizing care.* [Nurse 1 (FGD)]

Using the system and the collected data to guide the HCPs in improving care for individuals with T1 diabetes was a shared belief among the nurses and project managers participating in the FGD.

Data Validity

Since clinical decision-making is based on the data entered and stored in the system, it is critical that the data be as reliable as possible. The EMR system should incorporate multiple functions, helping the RDA staff reduce errors and limit missing information to improve the quality of the data. These include missing data checks, data value checks, and data logic checks. The system should help ensure that meaningless values are avoided, as expressed by a project manager:

> *The system can help reduce human errors. If there are restrictions on some information, it can improve the data. The Rwandan phone numbers have 9 digits—registering more or less than 9 digits should not be allowed by the system.* [Project manager 1 (FGD)]

This does not mean that "free text" boxes must be excluded, as not all data fit into normal and predefined categories or patterns. In the new system, some data elements require further description, necessitating the inclusion of "free text" boxes.

Additionally, information boxes or subtitles should be included for specific data elements to provide clarifying information to the HCPs. For example, how a family size is defined, and the difference between prescribed and self-reported insulin dosage.

Patient Follow-Up

The EMR system should record scheduled visits and send SMS reminders to patients in the local language [Kinyarwanda] reminding them of the date and time of their next visit. This feature is necessary to improve clinic-visit attendance, which can be a challenge for people with T1 diabetes. If a patient does not attend a scheduled appointment, the EMR system should generate a notification so that additional action can be taken to find the patient and reschedule a new appointment. Tracking the number of coherent missed appointments can also help target efforts to find the patients. After several workshops, the clinicians agreed that lost follow-up should be considered after 3 consecutive missed appointments or no-shows for more than a year. This is an arbitrary definition, so it was also agreed that the threshold could be revised after an implementation evaluation. Moreover, it is important to register individuals who have passed away so that follow-up efforts are only targeted at those still alive. The system should also track migration history, easing the process of locating the right individuals. Reliable patient identification can be ensured by autogenerating unique IDs that refer to a numerical code for a specific patient. This feature should help support deduplication and avoid 2 individuals having the same ID, as this confuses the identification of patients. The issue was observed from participant observations in the field:

> *Sometimes when identifying people in the excel database one person was registered more than once with two different ID numbers. Also, in other occasions we found out that two different people has been given the same ID, meaning that the data was mixed.* [Participant observation]

Other relevant, unique national IDs issued to citizens of Rwanda should also be stored to help identify patients and reduce duplication of patient records.

Data Protection

In Rwanda, internet and electricity are available in most places throughout the country, but their quality varies. Connectivity failure can lead to data loss if offline functioning is not in place. Therefore, the EMR system should be able to capture data offline and automatically upload it to a server or cloud-based function after re-connecting to the internet. This concern was raised by several of the nurses:

> *The system cannot work without internet. Sometimes the internet fails at the countryside and in the rural areas, why it would be better if the system can work offline. The system can only be sustainable if the system works offline- offline functioning ensures that no data is lost.* [Nurse 2 (FGD)]

However, this was also discussed with a project manager and the IT expert at one of the workshops, where it was mentioned that internet connectivity rarely fails and is therefore less of a concern. It was further expressed as follows:

> *We needed to consider the pros and cons of including an offline functionality in the system because it might negatively impact the possibility of making adaption and changes in the system as we go into implementation phase.* [Software developer (workshop)]

Moreover, the patient's data should be protected and respected, and therefore the system should comply with Rwanda's National Data Protection law [24]. Patient information should only be released and used by others with the patient's permission, with written informed consent. The data should be secured by giving authorized access to the system with personalized usernames and passwords. Users of the system should have different authorizations depending on their functions, responsibilities, and pre-established role-based privileges. Allowing more HCPs to have access to the data will require additional governmental approvals.

Content Requirements

The following themes related to the concept of content were identified: treatment regimen, complications, mental health, and socioeconomic conditions.

Treatment Regimen

The treatment regimen was mentioned as a complex matter in the care of T1 diabetes, as insulin intake and treatment plans have to be individualized according to the lifestyle and general condition. The RDA staff that participated in the workshop expressed the needs that must be carefully considered when providing care:

> *We experience that many patients have high blood glucose levels and we need to do something about it. The insulin dosage needs to be adjusted according to the blood sugar levels - we need to control and take actions and find the right treatment… also we need to consider the diet, physical activity and other factors that might impact the blood sugar levels.* [Project manager 2 (workshop)]

A lot of different factors might have an influence on how the individual is managing the disease. Even though insulin is a necessity for survival, it is not the only factor contributing to good diabetes management. Many individuals are still in poor control due to other factors than insulin availability and affordability. It is important to adjust and refine the insulin dosage and injections according to the time of day, insulin types, food intake, physical activity level, and insulin storage, as it impacts the effect if it is exposed to high temperatures. It is also crucial that the individual continuously monitors blood glucose levels if self-adjustment of insulin dosage is needed. Sometimes individuals with T1 diabetes did not have access to glucometers for various reasons; the glucometer was lost, out of batteries, or defective.

Complications

Information about self-reported cases of acute complications, such as diabetic ketoacidosis, hypoglycemia, and acute hospitalization, as well as information related to chronic complications, should be obtained and registered in the system.

This includes screening, diagnosing, and referring to treatment for nephropathy (microalbuminuria), retinopathy, and neuropathy. One nurse mentioned:

> *We need to screen the patients for complications to ensure timely referral and treatment... It is critical to investigate if chronic complications have developed so we can either prevent them from occur or take it into account in the care we provide.* [Nurse 1(FGD)]

Mental Health

Mental health problems were mentioned to be an overlooked but serious consequence of T1 diabetes in Rwanda. Individuals are usually missed or underdiagnosed with depression. Thus, additional efforts are needed to ensure a screening process for mental health issues in people living with T1 diabetes. A standardized screening tool for identifying diabetes-related distress should be incorporated into the system with the balance of being able to detect those with mental health issues and not overloading the HCPs with too much additional work. The tool should help guide referrals to a mental health specialist.

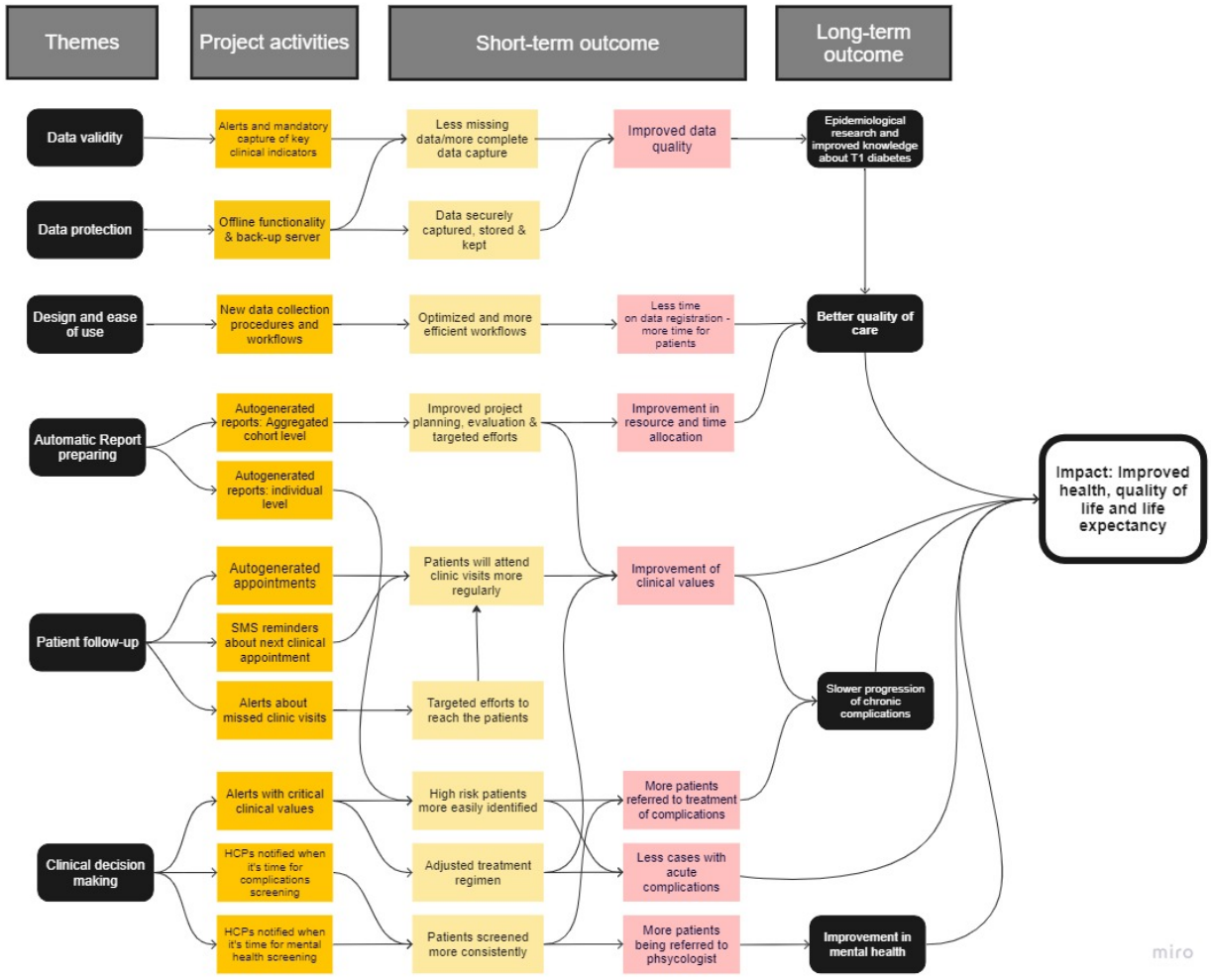
Socioeconomic Conditions

Finally, socioeconomic and demographic information (eg, educational level, job status, insurance, and marital status) were considered important—but particularly whether or not the patient has support from family or friends to manage the treatment regimen.

Theory of Change

The findings from the thematic analysis were used to generate a ToC. The EMR system and its features as well as the data collected are expected to make a change. Figure 2 summarizes how the different themes identified in the analyses relate to project activities, expected output, and outcomes.

Figure 2. Theory of change—a set of assumptions about the relationship between themes, project activities, and expected short- and long-term outcomes. HCP: health care professional.



Discussion

Summary of Main Findings

The features and content of the EMR system were discussed from the perspective of improving clinical outcomes for individuals with T1 diabetes in Rwanda. Improving clinical efficiency through a new EMR system could reduce the time spent on data registration, leaving more time for consultations with individuals with T1 diabetes. Automatic report generation could also reduce time and better inform HCPs and policy makers about the status of T1 diabetes care in Rwanda. This can be used to guide clinical practice, monitor clinical quality, guide service delivery planning, and allocate resources.

Longitudinal data collection at the individual level should be used for tracking patients over time and supporting clinical decision-making. This is in addition to using real-time data to guide the treatment regimen and disease management, all of which can lead to improved clinical efficiency, quality of care, and better outcomes. A fundamental part of improving clinical decision-making and follow-up on individuals with T1 diabetes is the quality of the data. This ensures that the right people are timely identified and that treatment regimens are based on valid information. Moreover, it is critical to capture, store, and ensure good data protection, as well as to comply with national regulations and laws to keep the data safe and confidential. It requires offline functionality in case of internet connectivity failure and a server system to ensure back-up of the data. Finally, it is important to collect the right information (content). In addition to the clinical data, information about treatment regimen, socioeconomic condition, screening for complications, and mental health status were identified as being of great importance to improving the care and clinical outcomes for individuals with T1 diabetes.

Comparison with Prior Work

As research on EMR systems for T1 diabetes in low-income countries has been very limited, we discussed our findings with studies in HICs or other disease areas. In a review by Ali Mohammad et al [25], the enhanced functionalities integrated in the EMR systems were defined as reminders, management prompts, self-care support, provider feedback, and patient report generation. These functionalities are similar to most of the features identified as important in this study: SMS reminders for consultation, reminders for complications screening, management prompts related to critical clinical values, and missed appointments. This was in addition to better self-care support guided by data-informed treatment regimen and autogenerated reports on an aggregated and individual level. Importantly, further discussions are needed on how these standardized values are interpreted in combination with clinical decision-making. Strong clinical competence and not only technical skills are needed to navigate the EMR system without giving too much influence to the individual indicators.

We found that offline functionality was viewed as an important feature related to data protection and ensuring that data are securely captured and uploaded to a backup server. In contrast, the benefits of using a networking EMR system were mentioned in the study by Fraser et al [12]. It was stated that internet access allows a more flexible design, data can be more easily shared at multiple sites, and multiple users can enter the data simultaneously. The study mainly included EMR systems from HICs, where internet failure is considered less of a problem. However, another study reviewing the use of EMR systems in sub-Saharan Africa in other disease areas reported that poor network structure can be a barrier to the adaptation of the EMR systems [8].

Lack of comfort among HCPs to use an EMR system has also been identified as a potential barrier, which can underscore the importance of an easy-to-use system and training of users to increase adaption to the EMR system. In the review by Fraser et al [12], none of the mentioned systems were designed for T1 diabetes, but aligned with the findings of this study, ease of use and training were mentioned as critical factors for a successful implementation. The system should capture the minimum data necessary for the task, and data items should be structured to simplify data entry and optimize use.

In this study, treatment regimen, mental health, and sociodemographic conditions were highlighted as themes of importance for good diabetes management. Khater et al [26] state that living with T1 diabetes, especially in LMICs, can feel overwhelming for both children and parents because constant vigilance and complex and demanding treatment regimen are required for proper care with inadequate resources. It was also found that depression in children and adolescents with T1 diabetes has been associated with suboptimal glycemic control and an increased risk of developing complications and recurrent diabetic ketoacidosis [26]. Therefore, information related to this is critical and aligned with the findings of this study. Screening for diabetes-related distress can help refer patients to a psychologist to get better coping strategies about how to live better mentally with the disease. Moreover, having financial or demographic difficulties, for example, living far from the hospital or having a large household might impact the patients' access to care, for example, by not having enough money for transportation. Furthermore, what factors contribute exactly to good disease management and blood sugar control among Rwandan individuals with T1 diabetes is still not completely clear. Therefore, all the information in the EMR system can be used to further investigate different factors that improve care and outcomes.

Limitations

This study mainly focused on the needs related to features and content and focused less on more technical aspects, such as the data model, network architecture, and software type [8,12]. This limitation could be explained by the characteristics of the study participants, primarily consisting of HCPs and individuals with T1 diabetes. Including more software developers or IT experts might have contributed to the identification of other important themes. Another overlooked topic was the sustainability of the system, including budgeting, timeline, and maintenance of the system. Many IT projects fail due to a lack of continued funding or a good sustainability plan. It is important to consider how the system keeps operating, what will happen in case of staff turnover, and if and when updates are needed in the system. It is also important to consider integration with the national health information and management system, or at least how the systems can support each other instead of operating in parallel and creating double work for HCPs.

Moreover, research must occur concurrently as the pathophysiology of T1 diabetes is not fully understood. Over time, the EMR system will support data for clinical and epidemiological research. We previously investigated the association between HbA_{1c} level and the development of nephropathy among individuals with T1 diabetes in Rwanda, where it was concluded that more data are needed to know what exactly affects the blood glucose levels and the development of diabetes related complications [20].

The suggested EMR system is an early version, and we cannot be sure that we have identified all relevant data elements. Interviewing more individuals living with T1 diabetes or other HCPs from other hospitals could have given other insights. It is understood that updates and revisions will be needed. Nevertheless, it is a strength of this study that triangulation between data sources and methodologies was applied to obtain a comprehensive understanding of the needs and requirements in this specific context [15]. Future research is needed to verify the ToC and analyze whether the system can be used as intended and will lead to the expected improvements in clinical outcomes, as also suggested in the MRC framework.

As shown earlier, many aspects of our study were in accordance with previous research from other settings. Thus, the EMR system and the development process may be replicable in other LMICs and for disease areas other than T1 diabetes, but we recommend taking caution and considering context-specific customization. We are critical of the "one-size-fits-all" approach, but neither do we believe that we have to "reinvent the wheel" if someone wants to adapt an EMR system for better disease management.

Conclusions

This study concludes that themes related to "features" and "content" are important to identify and consider when developing an EMR system for T1 diabetes management in Rwanda. The suggested EMR system is expected to improve data quality, optimize workflows, save more time for patients, improve clinical values, and ensure more patients are referred to treatment of complications in a timely manner. Hopefully, this will lead to a slower progression of chronic complications, more research in the area to further improve and optimize care, and eventually a long-term impact on improving health, quality of life, and reduced mortality rates among individuals with T1 diabetes.

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Conflicts of Interest

NB and MC are employees of WDF; DLC has received payment from Novo Nordisk Mexico for consultancy work; and CG is an employee of RDA. The remaining authors declare that they have no known personal relationships or competing financial interests, which could have influenced the work and results presented in this paper.

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Abbreviations

EMR: electronic medical record
FGD: focus group discussion
HbA1c: glycated hemoglobin
HCP: health care professional
HIC: high-income country
LMIC: low- and middle-income country
RDA: Rwanda Diabetes Association
ToC: theory of change
T1 diabetes: type 1 diabetes

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Comparing Insulin Against Glucagon-Like Peptide-1 Receptor Agonists, Dipeptidyl Peptidase-4 Inhibitors, and Sodium-Glucose Cotransporter 2 Inhibitors on 5-Year Incident Heart Failure Risk for Patients With Type 2 Diabetes Mellitus: Real-World Evidence Study Using Insurance Claims

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is a common health issue, with heart failure (HF) being a common and lethal long-term complication. Although insulin is widely used for the treatment of T2DM, evidence regarding the efficacy of insulin compared to noninsulin therapies on incident HF risk is missing among randomized controlled trials. Real-world evidence on insulin's effect on long-term HF risk may supplement existing guidelines on the management of T2DM.

Objective: This study aimed to compare insulin therapy against other medications on HF risk among patients with T2DM using real-world data extracted from insurance claims.

Methods: A retrospective, observational study was conducted based on insurance claims data from a single health care network. The study period was from January 1, 2016, to August 11, 2021. The cohort was defined as patients having a T2DM diagnosis code. The inclusion criteria were patients who had at least 1 record of a glycated hemoglobin laboratory test result; full insurance for at least 1 year (either commercial or Medicare Part D); and received glucose-lowering therapy belonging to 1 of the following groups: insulin, glucagon-like peptide 1 receptor agonists (GLP-1 RAs), dipeptidyl peptidase-4 inhibitors (DPP-4Is), or sodium-glucose cotransporter-2 inhibitors (SGLT2Is). The main outcome was the 5-year incident HF rate. Baseline covariates, including demographic characteristics, comorbidities, and laboratory test results, were adjusted to correct for confounding.

Results: After adjusting for a broad list of confounders, patients receiving insulin were found to be associated with an 11.8% (95% CI 11.0% - 12.7%), 12.0% (95% CI 11.5% - 12.4%), and 15.1% (95% CI 14.3% - 16.0%) higher 5-year HF rate compared to those using GLP-1 RAs, DPP-4Is, and SGLT2Is, respectively. Subgroup analysis showed that insulin's effect of a higher HF rate was significant in the subgroup with high HF risk but not significant in the subgroup with low HF risk.

Conclusions: This study generated real-world evidence on the association of insulin therapy with a higher 5-year HF rate compared to GLP-1 RAs, DPP-4Is, and SGLT2Is based on insurance claims data. These findings also demonstrated the value of real-world data for comparative effectiveness studies to complement established guidelines. On the other hand, the study shares the common limitations of observational studies. Even though high-dimensional confounders are adjusted, remaining confounding may exist and induce bias in the analysis.

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KEYWORDS

type 2 diabetes mellitus; diabetes; diabetes complications; heart failure; antidiabetic drug; diabetes pharmacotherapy; insulin; GLP-1 RA; DPP-4I; SGLT2I; real-world data; insurance data; claims data; glucagon-like peptide-1 receptor agonist; dipeptidyl peptidase-4 inhibitor; sodium-glucose cotransporter 2 inhibitor

Introduction

Type 2 diabetes mellitus (T2DM) is a major health issue globally and particularly prevalent in the United States. More than 34 million US adults (13%) had diabetes as of 2018, of which 90% to 95% were T2DM, and complication from diabetes was the seventh leading cause of death in the United States in 2017 [1]. Cardiovascular disease (CVD) is a common and lethal complication of T2DM. Among patients with T2DM, the prevalence of heart failure (HF) is between 9% and 22%, which is 4 times higher than that for the general population [2]. Therefore, in addition to apparent short-term disease management goals such as glycemic control, it is important to evaluate the impact of T2DM therapies on long-term health outcomes such as incident HF [2-5].

Insulin therapy has a long history in the management of T2DM and remains one of the most effective and affordable treatments for glycemic control. Insulin is typically initiated after oral medications fail to control glycemia, but it is sometimes used in early-line treatments if a patient has contraindications for oral medications [6]. In recent years, next-generation medications guided by the analysis of disease pathways, such as glucagon-like peptide-1 receptor agonists (GLP-1 RAs), dipeptidyl peptidase-4 inhibitors (DPP-4Is), and sodium-glucose cotransporter 2 inhibitors (SGLT2Is), have become increasingly common alternatives or additions to insulin for second-line T2DM therapy.

Despite insulin's frequent prescription for T2DM management, its impact on long-term incident HF risk has not been thoroughly assessed, especially in comparison to alternative therapy options [2,3]. A study of electronic medical records for nearly 10,000 patients with T2DM and age- and sex-matched controls found that insulin use was associated with a higher risk of both prevalent and incident congestive HF independent of glycemic control, confirming the importance of studying HF beyond successful glycemic control [7]. Several other large observational studies reported the association of insulin with increased risk of CVD-related outcomes, including comparisons across doses of insulin, of insulin monotherapy versus insulin plus metformin, and of insulin versus novel therapies (DPP-4Is or SGLT2Is grouped together) [8]. These studies did not cover all head-to-head comparisons between insulin and alternative therapies. Moreover, many of these studies adjusted for a somewhat limited set of covariates and comorbidities, raising concerns about bias from unmeasured confounding.

Recent evidence suggests that alternative second-line agents may lead to lower CVD risk profiles. For example, comparing the risk of macrovascular CVD outcomes between people with T2DM treated by insulin versus exenatide (a type of GLP-1 RA) in a large ambulatory care dataset, Paul et al [9] found that the risk of incident HF was significantly lower in the exenatide and exenatide+insulin groups compared to the insulin-only group. On the other hand, in a recent systematic review of cohort and nested case-control studies, Alkhezi et al [10] described conflicting evidence, with some studies showing a significantly lower risk of incident HF in GLP-1 RA groups compared to insulin groups and other studies showing no significant differences. Similar studies of SGLT2Is versus GLP-1 RAs and insulin versus DPP-4Is have found that SGLT2Is are associated with a lower risk of incident HF compared to GLP-1 RAs, and DPP-4Is have a significantly lower risk of CVD events than insulin in both a cohort without CVD and the general population (matched on propensity scores [PSs]) [11,12]. However, the outcome definition and inclusion criteria vary between studies, as do the baseline covariates included, making it difficult to directly compare results. Most of the existing studies are based on association studies, which lack causal interpretation. Additionally, insulin is included as a comparison group in very few studies, in part because of the difficulty of fully adjusting for confounding by indication. Patients receiving insulin therapy are generally different from those who are recommended for GLP-1 RAs, DPP-4Is, and SGLT2Is per current treatment guidelines. However, the optimal treatment option remains unclear for patients potentially receiving insulin or alternative therapies based on their predicted HF risks. Consequently, there is a pressing need for a more thorough and robust comparison of the risk of HF between insulin and alternative therapies, accounting carefully for confounding due to differences in patient populations, in order to guide T2DM management recommendations [13-18].

Randomized controlled trials (RCTs) are the gold standard for inferring causal differences in treatment effects, but because the study of HF outcomes requires a very long follow-up time and insulin is a generic medication, there is little incentive for private sponsors to support RCTs comparing insulin to patent-protected agents. Readily available real-world data (RWD), such as electronic health record data and insurance claims data, can be used to generate real-world evidence to fill in the blank. In contrast to highly regimented RCTs, real-world evidence on the therapy may offer both generalizable and personalized guidance for practice as supported by regulatory guidelines [19,20]. The much larger sample sizes and availability of data beyond restrictive RCT inclusion and exclusion criteria allow recommendations based on RWD to apply to a much broader population and to be tailored for specific subgroups. Therefore, our study aims to compare the effect of insulin against GLP-1 RAs, DPP-4Is, and SGLT2Is separately on long-term incident HF risk using real-world insurance claims data, applying a doubly robust estimation method to correct for potential confounding biases across a large set of baseline factors.

Methods

T2DM Data Source

We created the study data from the data factory inside the UnitedHealth Group Research and Development platform. The study period was from January 1, 2016, to August 11, 2021.

Ethical Considerations

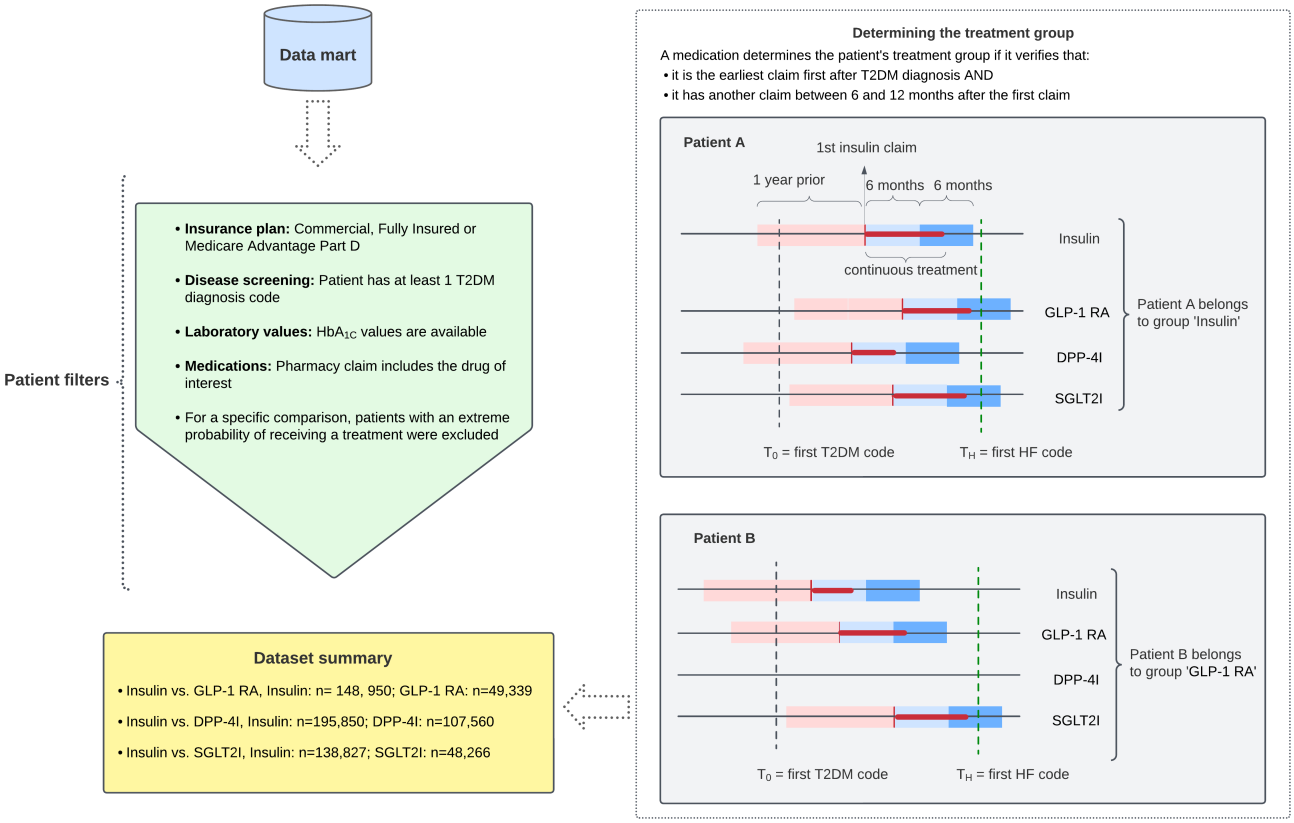
The UnitedHealth Group institutional review board approved the use of the insurance claims and electronic health record data for this study with a waiver of informed consent (RB20-1213: Precision Medicine of Type 2 Diabetes). Data have been deidentified.

Data Curation and Feature Extraction

We identified T2DM diagnoses using a list of *International Classification of Diseases, Ninth Revision* (*ICD-9*) and *International Statistical Classification of Diseases, Tenth Revision* (*ICD-10*) codes related to T2DM and constructed the data mart from patients with these codes in the list. The date of the first T2DM diagnosis was identified. We excluded patients with likely type 1 diabetes mellitus. Inclusion criteria were at least 1 glycated hemoglobin (HbA_{1c}) measurement through the study period (those with zero HbA_{1c} results were considered to have missing data); pharmacy claims for at least 1 of the 4 therapy mechanism groups of interest (insulin, GLP-1 RAs, DPP-4Is, and SGLT2Is); and insurance coverage classified as either "Commercial, Fully Insured (FI)" or "Medicare Advantage Part D (MAPD)" for at least 1 year. Individuals with an HF diagnosis prior to the first prescription of the therapy mechanism groups of interest were excluded. Data on demographics, other medications, laboratory test results, and comorbidities were also extracted for confounding adjustment.

Patients were classified into treatment groups based on their earliest sustained medication among the 4 therapies in comparison. Because a quick switch from a recently prescribed therapy may represent a prolonged treatment decision process between the patient and provider, we required at least 2 insurance claims for the same therapy to indicate sustained use. Specifically, the medication received the earliest after study enrollment, with another claim between 6 and 12 months later, was identified as the patient's treatment group for this study (Figure 1).

Figure 1. Schematic of data generation. Pink: 1-year window before prescription; light blue: 6-month window after prescription; blue: 12-month window after prescription. DDP-4I: dipeptidyl peptidase-4 inhibitor; GLP-1 RA: glucagon-like peptide 1 receptor agonist; HbA_{1c}: glycated hemoglobin; HF: heart failure; SGLT2I: sodium-glucose cotransporter-2 inhibitor; T2DM: type 2 diabetes mellitus.



The outcome of interest was incident HF risk. We identified HF events by a list of *ICD-9* and *ICD-10* diagnosis codes mapped to PheWAS catalog codes (phecodes) [21]: 428.1, congestive HF nitric oxide synthases; 428.2, HF nitric oxide synthases; 428.3, HF with reduced ejection fraction (EF; systolic or combined HF); and 428.4, HF with preserved EF (diastolic HF). The observation time for each patient was the time from the first prescription date to either the first occurrence of an HF event or the last follow-up date, whichever was earlier. The median follow-up time was around 2.4 years. The overall follow-up time was around 5.4 years for insulin, 5.2 years for GLP-1 RAs, 5.4 years for DPP-4Is, and 5.4 years for SGLT2Is.

To account for confounding, we extracted demographic characteristics including age, sex, residential area (urban or rural), Medicaid coverage, socioeconomic index, and disease duration (from the T2DM diagnosis date to the first prescription date), as well as laboratory values for baseline HbA_{1c}, high-density lipoprotein, low-density lipoprotein, and cholesterol up to 1 year prior to the first prescription date. Missing laboratory values were imputed by means. We accounted for confounding from the general health history, summarized by the high-dimensional counts of diagnosis codes in each phecode group during the year prior to treatment initiation [22]. Rare phecode features with less than 5% prevalence were excluded.

Statistical Analysis

The analyses outlined in this section were conducted to compare the treatment effect of insulin versus GLP-1 RAs. The same analyses were repeated for insulin versus DPP-4Is and insulin versus SGLT2Is. We defined the 5-year average treatment effect (ATE) as the difference in HF-free rate (HF survival probability throughout the paper) between treatment groups at 5 years after the first prescription date. Because treatment decisions depend on baseline patient factors that are themselves associated with HF outcomes, adequate adjustment for these confounding biases is critical to infer treatment effects. We, therefore, applied a doubly robust estimation method involving 2 adjustments to account for treatment-by-indication biases, as visualized in Figure S1 in Multimedia Appendix 1. First, for the PS model, we used a logistic regression model with baseline covariates (demographics, laboratory results, diagnoses, and medication). We balanced baseline factors between treatment groups through the inverse probability of treatment weighting (IPW). Second, for the outcome regression (OR) model, we adjusted baseline factors in 2 Cox models (for insulin and GLP-1 RAs, respectively) to assess their association with HF risk. We used an adaptive LASSO (least absolute shrinkage and selection operator) penalized regression to fit both the PS and OR models [23], an approach that shrinks coefficients for uninformative covariates to zero and provides stable effect estimates for the informative covariates. In addition to the baseline covariates, the first 3 principal components of the comorbidities were added as covariates. Within each model, the associations with the covariate *age* can be nonlinear, and the associations with the other covariates are allowed to vary with age. Specifically, we included *g(age)* and the interaction of *g(age)* with other covariates, where *g* is an unknown function. We approximate *g(age)* by splines basis. In practice, we found that the commonly used b-spline or natural splines basis with 3 knots worked well. Equally spaced knots that cover most of the domain of the data for *age* were also desirable. That is, age was represented flexibly using basis splines with 3 equally spaced knots, and all models included the 3 age basis variables and their interactions with other covariates. This resulted in 3 sets of coefficient estimates in the model fitting results.

We also calculated covariate-specific ATEs (CATEs) to study ATEs among different subgroups: score-specific ATE. The score *S* was defined as the survival probability difference based on the 2 Cox models for the 2 treatment groups, where a positive score is in favor of insulin. The score can be considered as the personalized insulin prescription score. All analyses were performed using R software (R Foundation for Statistical Computing).

Results

Insulin Versus GLP-1 RAs

The baseline characteristics of eligible patients in the insulin and GLP-1 RA treatment groups are displayed in Table 1. For the insulin group, the mean age was 66.24 (SD 9.8) years, and 48.06% (71,579/148,950) were male, while for the GLP-1 RA group, the mean age was 62.44 (SD 11) years, and 43.91% (22,664/49,339) were male. As shown in Table 1 and Table S1 in Multimedia Appendix 1, covariate balance after IPW was much improved, with similar distributions of demographic characteristics, average laboratory values, and additional medications between the 2 groups after IPW.

The Kaplan-Meier estimates of HF probability across time, before and after balancing covariates through IPW, are visualized in Figure 2. These show that the HF rate for the insulin group was higher than that for the GLP-1 RA group.

Table 2 presents the doubly robust estimated 5-year HF rate for the 2 treatment groups under comparison, as well as the difference between the 2 rates (the estimated ATE). A positive ATE indicates that insulin group had a higher HF probability compared to the other treatment group. The estimated 5-year HF rate in the insulin group differed across the 3 comparisons due to differences in the populations' distributions of baseline characteristics and the corresponding differences in HF risk, as well as the exclusion of some patients with an extreme probability of receiving a particular treatment due to their inability to be matched with the other treatment group.

Table . Baseline characteristics of patients included in the study (insulin vs GLP-1 RAs[a]).

Baseline characteristics	Before IPW[b]		After IPW	
	Insulin (n=148,950)	GLP-1 RAs (n=49,339)	Insulin (n=148,950)	GLP-1 RAs (n=49,339)
Demographics				
Age at first prescription (y), mean (SD)	66.24 (9.86)	62.44 (11)	65.39 (10.3)	64.79 (10.32)
Disease duration (mo), mean (SD)	2.67 (9.78)	7.45 (14.53)	3.55 (10.9)	4.97 (12.76)
M ale sex, n (%)	71,579 (48.06)	21,662 (43.91)	70,594 (47.39)	22,664 (45.93)
Medicaid coverage, n (%)	1993 (1.34)	474 (0.96)	1923 (1.29)	580 (1.18)
Rural status, n (%)				
Rural	40,693 (27.32)	12,723 (25.79)	40,274 (27.04)	13,284 (26.92)
Urban	42,050 (28.23)	14,046 (28.47)	42,339 (28.43)	13,682 (27.73)
Socioeconomic index, mean (SD)	51.99 (2.95)	52.19 (3.01)	52.01 (2.95)	52.16 (3.01)
Laboratory values, mean (SD)				
HbA_{1c}[c] (%)	8.52 (1.1)	8.25 (1.31)	8.5 (1.14)	8.38 (1.26)
Cholesterol (mg/dL)	170.87 (22.35)	170.91 (26.83)	170.86 (23.29)	170.86 (24.92)
HDL[d] (mg/dL)	45.51 (6.35)	45.46 (7.82)	45.46 (6.64)	45.48 (7.15)
LDL[e] (mg/dL)	90.04 (17.51)	90.17 (21.73)	90.02 (18.26)	90.1 (20.12)
Additional medications, mean (SD)				
Metformin	0.6 (0.82)	0.98 (0.95)	0.69 (0.88)	0.76 (0.88)
Statins	0.73 (0.84)	0.97 (0.94)	0.79 (0.88)	0.84 (0.88)
Sulfonylureas	0.32 (0.68)	0.5 (0.86)	0.36 (0.74)	0.41 (0.77)
Thiazolidinediones	0.07 (0.34)	0.13 (0.47)	0.09 (0.38)	0.1 (0.4)
Other characteristics, mean (SD)				
PC1[f]	−0.02 (2.29)	0.02 (2.22)	−0.02 (2.35)	0.01 (2.21)
PC2[g]	0.1 (0.83)	0.45 (0.92)	0.19 (0.88)	0.25 (0.87)
PC3[h]	0 (0.8)	0 (1)	0 (0.85)	0 (0.9)
S[i]	−0.13 (0.08)	−0.1 (0.08)	−0.13 (0.08)	−0.12 (0.08)

[a]GLP-1 RA: glucagon-like peptide 1 receptor agonist.

[b]IPW: inverse probability of treatment weighting.

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

[d]HDL: high-density lipoprotein.

[e]LDL: low-density lipoprotein.

[f]PC1: the first principal component of the comorbidities.

[g]PC2: the second principal component of the comorbidities.

[h]PC3: the third principal component of the comorbidities.

[i]S: model-based survival probability difference.

Figure 2. HF rates (A) before and (B) after IPW for the insulin versus GLP-1 RA comparison. GLP-1 RA: glucagon-like peptide 1 receptor agonist; HF: heart failure; IPW: inverse probability of treatment weighting.

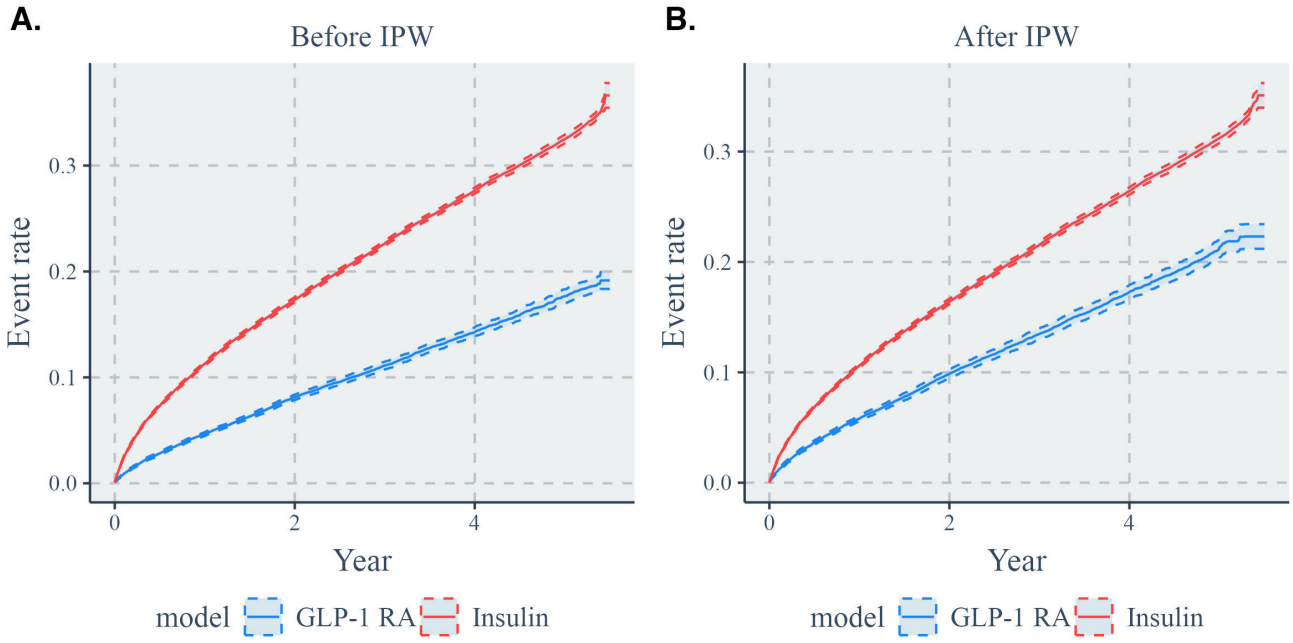


Table . Doubly robust estimates and SE of heart failure (HF) rates for each treatment group and the difference between HF rates (ATE[a]).

Comparison	Insulin group, estimate (SE)	Treatment group, estimate (SE)	Difference (SE)
Insulin vs GLP-1 RA[b]	0.293 (0.002)	0.175 (0.004)	0.118 (0.004)
Insulin vs DPP-4I[c]	0.348 (0.002)	0.229 (0.002)	0.120 (0.002)
Insulin vs SGLT2I[d]	0.281 (0.002)	0.130 (0.004)	0.151 (0.005)

[a]ATE: average treatment effect.

[b]GLP-1 RA: glucagon-like peptide 1 receptor agonist.

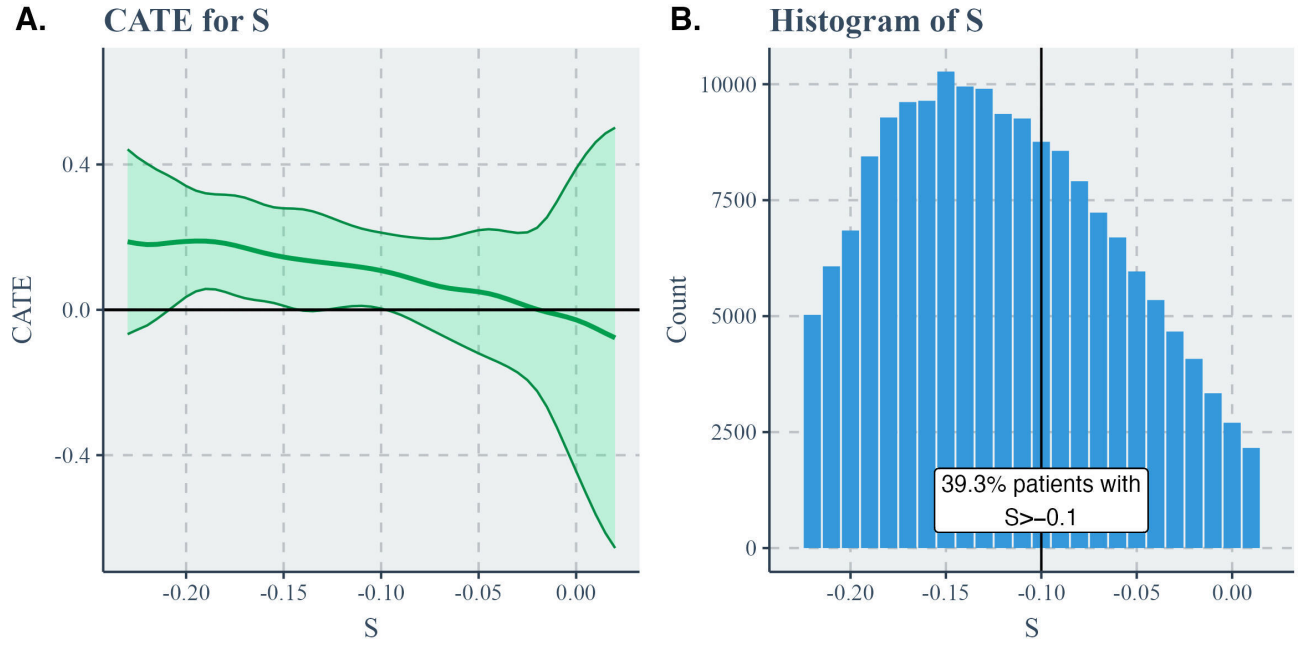
[c]DDP-4I: dipeptidyl peptidase-4 inhibitor.

[d]SGLT2I: sodium-glucose cotransporter-2 inhibitor.

Focusing first on the comparison between insulin and GLP-1 RAs, patients receiving insulin had a higher 5-year HF rate of 29.3% (95% CI 28.9% - 29.7%) compared to patients receiving GLP-1 RAs, whose estimated 5-year HF rate was 17.5% (95% CI 16.8% - 18.2%). Therefore, the estimate of the ATE was 11.8% (95% CI 11.7%-12.7%), suggesting that the probability of having HF 5 years after treatment initiation was nearly 12% higher for patients receiving insulin compared to those receiving GLP-1 RAs.

CATEs, shown in Figure 3, can provide additional detail. The score-specific ATE was significantly positive when the score *S* (model-based survival probability difference) was positive but was no longer significant when *S* was negative. Thus, the score *S* is a relatively good indicator of whether insulin is better than GLP-1 RAs for a patient in consideration of their long-term heart health. Since most patients had positive *S* scores, the score-specific ATE supports the other estimates in suggesting that GLP-1 RAs were related to lower HF risk for most patients. In addition, we identified a substantial subset (nonpositive score) on which insulin had noninferiority compared to GLP-1 RAs.

Figure 3. CATE estimates for the insulin versus GLP-1 RA comparison: (A) CATE for S and (B) histogram of S. CATE: covariate-specific average treatment effect; GLP-1 RA: glucagon-like peptide 1 receptor agonist; S: model-based survival probability difference.



In examining the baseline features selected by the adaptive LASSO procedure to be included in the PS and OR models, we observed confounders with clinical relevance to both treatment assignment and HF outcomes (Table S2 in Multimedia Appendix 1). Covariates associated with treatment assignment were indicated by a nonzero coefficient in the PS model, including age, Medicaid insurance, HbA_{1c} levels, additional medications taken, diabetic retinopathy, electrolyte imbalance, and several other baseline covariates. Fewer baseline covariates were selected in the Cox models for HF outcomes, including demographics, such as Medicaid insurance, and disease diagnoses, such as atrial fibrillation and coronary atherosclerosis. Many of the LASSO-selected features were associated with the treatment group but not HF outcomes, indicated by a nonzero PS coefficient but zero Cox coefficients, or with HF outcomes but not the treatment group, indicated by a zero PS coefficient but nonzero Cox coefficient(s).

Insulin Versus DPP-4Is

Results were broadly similar for the insulin versus DPP-4I comparison. Baseline characteristics are shown Table S3 in Multimedia Appendix 1, and again, covariate balance between the treatment groups was much improved after IPW. The estimated ATE was nearly identical, at 12.0% (95% CI 11.5%-12.4%), although the estimated HF rates were higher in this population than in the previous comparison. In this case, the estimated 5-year HF rate for patients receiving insulin was 34.8% (95% CI 34.5% - 35.2%), whereas the rate for those receiving DPP-4Is was 22.9% (95% CI 22.5% - 23.3%; Figure S2 in Multimedia Appendix 1). The differences in the estimated 5-year HF rate between this analysis and the insulin versus GLP-1 RA analysis were likely due to differences in baseline characteristics. For example, the after-IPW frequency of comorbidities such as chronic renal failure, coronary atherosclerosis, and hypertensive heart or renal disease were all higher in the insulin versus DPP-4I comparison, and the latter was also associated with older age and a higher proportion of Medicaid coverage.

As in the previous comparison, the score-specific ATE (Figure S3 in Multimedia Appendix 1) again suggests that the score could be a useful indicator of optimal treatment, but that in most cases, the insulin group had a higher HF rate than the DPP-4I group. The LASSO-selected coefficients for treatment assignment (PS model) and HF time (Cox model) also included many of the same baseline factors as above (Table S4 in Multimedia Appendix 1).

Insulin Versus SGLT2Is

For the comparison of insulin and SGLT2Is, the estimated ATE was larger, at 15.1% (95% CI 14.3% to 16.0%; Table 2). The 5-year HF rates were also lower than in the prior 2 comparisons (insulin versus GLP-1 RAs and insulin versus DPP-4Is), with the estimated 5-year HF rate reaching 28.1% (95% CI 27.7% - 28.5%) in the insulin group and 13.0% (95% CI 12.3% - 13.7%) in the SGLT2I group (Figure S4 in Multimedia Appendix 1). Baseline characteristics after IPW for this comparison were similar to those for the insulin versus GLP-1 RA comparison (Table S5 in Multimedia Appendix 1), so the comparable HF rates between the 2 analyses were to be expected. The score-specific ATE (Figure S5 in Multimedia Appendix 1) and selected covariates (Table S6 in Multimedia Appendix 1) were also similar to the prior 2 comparisons.

Discussion

Principal Findings

We used an intention-to-treat strategy for medication assignment by assigning patients to the treatment group corresponding to the medication they received the earliest after study enrollment, with another claim between 6 and 12 months later. With more than 1 sustained medication, we defined treatment group based on the earliest one using the intention-to-treat strategy. In

practice, with more than 1 sustained medication, it is hard to distinguish these medications as we do not know which medication takes the main effect. It would be better to include additional exclusion strategies that can reduce bias in assigning treatment groups under the current strategy. On the other hand, future analyses could incorporate additional information about patients switching between treatments over the course of the study, or patients taking multiple study medications simultaneously. As clinical guidelines continue to be clarified, this additional information could also aid in defining relevant medication grouping strategies.

The outcome definition is heterogeneous, which is both a strength and a weakness of the study design. Although HF with reduced EF (code 428.3) and HF with preserved EF (code 428.4) are clinically different in terms of risk factors, prognosis, and treatment [24], we aimed to capture all cardiac-related events through the generic outcome definition. Further research is needed to clarify distinct associations with these 2 diseases.

Further, the use of insurance claims data is limited by data that may be incomplete, especially in those with limited access to health care or who disenroll from the studied insurance plan. For example, the inferred disease duration may not be an accurate measure as people may have received their diagnosis either before the first available data in the system or before they enrolled in this insurance plan. Similarly, because the first prescription date was defined as the earliest prescription after study enrollment, it is possible that patients with "first prescriptions" in the first few months of the study actually started that therapy prior to the study start date, resulting in a longer time to HF than we observed. These covariates curated 1 year prior to the first prescription are also potentially biased due to the potential for an early first prescription (participants enrolled later in the study would have the full year, whereas participants with the first prescription between January 1, 2016, and January 1, 2017, would have proportionally fewer phecode occurrences).

Also, the restriction to those with commercial or Medicare Part D insurance, although necessary to minimize the chance that patients are filling medication prescriptions through another insurance provider, imposes some selection bias. Most Medicare beneficiaries (74.4%) have Part D coverage, and most of the remainder have drug coverage through other providers (16.3% of beneficiaries), but 9.1% of beneficiaries had no drug coverage at all as of 2019. Those with private coverage tended to have higher income, were less likely to be eligible through disability, and were more likely to have attended college compared to other groups; those without drug coverage had characteristics that were between those covered by Part D and those with alternative drug coverage [25].

Although we adjusted extensively for potential confounding effects, the use of real-world (and therefore observational) data still results in the possibility of residual confounding, in particular confounding by indication for the use of insulin, since insulin users are generally "sicker" in many ways than noninsulin users.

By comparing insulin to each of the alternative medications separately, our study aimed to maximize the balance between the treatment groups with respect to baseline covariates using PS modeling and IPW. Studies comparing HF rates among more than 2 therapies can be done with a multinomial regression for the PS model, which is warranted to further guide treatment recommendations.

Conclusion

In this study using real-world, insurance claims data, we compared insulin to other second-line T2DM medications (GLP-1 RAs, DPP-4Is, and SGLT2Is) with respect to incident HF risk. We used a doubly robust, augmented IPW estimation that extensively adjusted for high-dimensional confounding factors in both the PS and OR models, using a data-driven approach for feature selection implemented through a LASSO sparsity penalty in each model. While the results presented above were based on the primary outcome of 5-year HF rate, the results were very similar for 4-year HF rate.

We found that patients with T2DM treated with insulin have a significantly higher risk of 5-year incident HF compared with each of the 3 alternative treatments—GLP-1 RAs, DPP-4Is, and SGLT2Is. The score *S* (model-based survival probability difference) is associated with ATE and may provide treatment guidance. By using RWD with a large sample size and adjusting for a large set of possible confounders using doubly robust estimation, our approach provides potentially clinically applicable estimates of treatment effects on HF rates, particularly in the absence of clinical trial data. The largest difference in HF rates was between insulin and SGLT2Is. This is consistent with prior studies, which broadly conclude that SGLT2Is are associated with reduced rates of HF compared to placebo or other treatments. However, as prior studies have generally been based on association studies and restricted populations (as in secondary analyses of clinical trials) or have adjusted for fewer potential confounders, our results strengthen and generalize these conclusions.

Authors' Contributions

XW and TC contributed to the design and conceptualization of the study. CLB and VP contributed to data collection. XW, AMP, XX, and TC contributed to data analysis or interpretation. All authors contributed to drafting the work or revising it critically for important intellectual content and approved the final version. All authors are responsible for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

A close family member of SJC is employed by the Johnson & Johnson company. JH is a consultant for MediKarma Inc.

Multimedia Appendix 1
Doubly robust estimation scheme, baseline characteristics of patients, variables selected by the propensity score and outcome regression models, and additional results for dipeptidyl peptidase-4 inhibitors and sodium-glucose cotransporter-2 inhibitors.
[DOCX File, 923 KB - diabetes_v9i1e58137_app1.docx]

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Abbreviations

ATE: average treatment effect
CATE: covariate-specific average treatment effect
CVD: cardiovascular disease
DDP-4I: dipeptidyl peptidase-4 inhibitor
EF: ejection fraction
GLP-1 RA: glucagon-like peptide 1 receptor agonist
HbA_{1c}: glycated hemoglobin
HF: heart failure
***ICD-10*:** *International Statistical Classification of Diseases, Tenth Revision*
***ICD-9*:** *International Classification of Diseases, Ninth Revision*
IPW: inverse probability of treatment weighting
LASSO: least absolute shrinkage and selection operator
OR: outcome regression
PS: propensity score
RCT: randomized controlled trial
RWD: real-world data
SGLT2I: sodium-glucose cotransporter-2 inhibitor
T2DM: type 2 diabetes mellitus

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Original Paper

COVID-19 Vaccination Reactions and Risk of Breakthrough Infections Among People With Diabetes: Cohort Study Derived From Community Reporters

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Abstract

Background: This exploratory study compares self-reported COVID-19 vaccine side effects and breakthrough infections in people who described themselves as having diabetes with those who did not identify as having diabetes.

Objective: The study uses person-reported data to evaluate differences in the perception of COVID-19 vaccine side effects between adults with diabetes and those who did not report having diabetes.

Methods: This is a retrospective cohort study conducted using data provided online by adults aged 18 years and older residing in the United States. The participants who voluntarily self-enrolled between March 19, 2021, and July 16, 2022, in the IQVIA COVID-19 Active Research Experience project reported clinical and demographic information, COVID-19 vaccination, whether they had experienced any side effects, test-confirmed infections, and consented to linkage with prescription claims. No distinction was made for this study to differentiate prediabetes or type 1 and type 2 diabetes nor to verify reports of positive COVID-19 tests. Person-reported medication use was validated using pharmacy claims and a subset of the linked data was used for a sensitivity analysis of medication effects. Multivariate logistic regression was used to estimate the adjusted odds ratios of vaccine side effects or breakthrough infections by diabetic status, adjusting for age, gender, education, race, ethnicity (Hispanic or Latino), BMI, smoker, receipt of an influenza vaccine, vaccine manufacturer, and all medical conditions. Evaluations of diabetes medication-specific vaccine side effects are illustrated graphically to support the examination of the magnitude of side effect differences for various medications and combinations of medications used to manage diabetes.

Results: People with diabetes (n=724) reported experiencing fewer side effects within 2 weeks of vaccination for COVID-19 than those without diabetes (n=6417; mean 2.7, SD 2.0 vs mean 3.1, SD 2.0). The adjusted risk of having a specific side effect or any side effect was lower among those with diabetes, with significant reductions in fatigue and headache but no differences in breakthrough infections over participants' maximum follow-up time. Diabetes medication use did not consistently affect the risk of specific side effects, either using self-reported medication use or using only diabetes medications that were confirmed by pharmacy health insurance claims for people who also reported having diabetes.

Conclusions: People with diabetes reported fewer vaccine side effects than participants not reporting having diabetes, with a similar risk of breakthrough infection.

Trial Registration: ClinicalTrials.gov NCT04368065; https://clinicaltrials.gov/study/NCT04368065

(JMIR Diabetes 2024;9:e45536) doi:10.2196/45536

KEYWORDS

COVID-19; diabetes; vaccine; vaccine hesitancy; registry; person-generated health data; patient-reported outcomes; side effects; vaccination; infection; nondiabetic adult; clinical data; fatigue; headache; risk; patient data; medication; community health

Introduction

Recent real-world evidence has demonstrated the overall safety and low risk of serious side effects due to COVID-19 vaccines in the general population including using information from community reporters [1]. People with diabetes are of special interest due to their higher risk of hospitalization and death from COVID-19 [2-5]. Here we use a community-based registry in the United States to describe participant-reported data on COVID-19 vaccine side effects and breakthrough infections in people with diabetes and examine whether diabetes medicine use affects the risk of developing vaccine side effects. As a sensitivity analysis of the accuracy of self-reported medication information, we linked data from these registry participants with their health insurance claims for prescription medications to assess the variation of side effects for those who are known to have filled prescriptions for their self-reported diabetes medicines.

Methods

Study Design

This is a retrospective cohort study conducted using data provided by community-based adults aged 18 years and older who resided in the United States. The IQVIA COVID-19 Active Research Experience (CARE), an online registry, was created as an observational study of people's experience with COVID-19 outside of the hospital setting. The initial study purpose was a 1-time survey, launched on April 2, 2020, to capture COVID-19 exposure, medical history, symptoms, and treatments with the goal of identifying any modifiable events that might reduce the severity of infection with COVID-19, such as the use of a dietary supplement, nonprescription medicine, and so forth. It was quickly expanded to include 3 months of follow-up to evaluate symptom persistence. The protocol has been revised 9 times since its launch, including updates as vaccines and boosters were launched, extending follow-up to 12 months, augmenting the symptom list as new information became available, and streamlining to minimize respondent burden. The most recent version of the questionnaire is available online [6,7]. The enrollment was closed in February 2023 [1,8].

The participants were recruited to CARE via periodic outreach through email and social media (Google, Facebook, and Reddit). For this analytic cohort, we selected respondents who received a COVID-19 vaccine and were not part of a COVID-19 vaccine clinical trial. To enroll, participants provided informed consent online, including consent for their data to be matched with pharmacy claims data using a process of deidentification through a trusted third party. At enrollment and follow-up surveys (weekly after vaccination date for 4 weeks and monthly for months 2-12), participants were asked if they met any of the following criteria: had been exposed to COVID-19, had COVID-19–like symptoms, had tested positive for COVID-19, and whether or not they had sought medical care or been admitted to hospital—either for COVID-19–like symptoms or vaccine side effects—and the dates of any such hospitalizations.

Data Management

The data were extensively curated to eliminate those who were likely to have been under the age of 18 years, were bots, or were such bad typists that the accuracy of their data could not be assured. These data review was performed by looking for patterns where participants consistently chose the first response option to every question, indicated clinically impossible events (eg, pregnant males and height over 7 feet or under 4 feet), or provided nonsensical answers in the free text for side effects), and so forth. The email addresses of volunteers were verified to further rule out attempts at fraudulent data entry.

Since this was designed as an exploratory study, we used all available curated data from CARE. No formal sample size estimates were calculated. There was no imputation of missing data nor was any artificial intelligence, generative or otherwise, used in this data collection or analysis. The gender shown here reflects participants' self-assessment, noting that transgender or other identity were included as response options.

Self-Reported Diabetes and Use of Medications for Diabetes

At enrollment, participants reported their demographics and medical history, including whether they had diabetes (without the differentiation of type 1 and type 2 diabetes or prediabetes) and if so, whether they used any prescription medications to treat their diabetes. Those who indicated that they used prescription medications for diabetes were asked to type in the name of the prescription medication they were using.

People who reported having diabetes were compared with those who did not report having diabetes, with further stratification by the type of diabetes medication used (using the most frequently reported medications, ie, insulin without metformin, insulin and metformin, metformin without insulin, or neither).

The accuracy of self-reported insulin and metformin use was confirmed by comparison with IQVIA Prescription Claims data [9,10], which as of November 2022, included data from roughly 92% of retail pharmacies, 72% of standard mail service, and 76% of long-term care facilities in the United States. Deidentified CARE data were matched with pharmacy claims data (filled within 6 months before or after study enrollment to capture delayed claims and large refill quantities) using the National Drug Code and product name. These linked prescription claims data were used as a sensitivity analysis to examine vaccine side effects for diabetes medications confirmed in pharmacy claims.

COVID-19, Vaccinations, Side Effects, and Breakthrough Infections

At both enrollment and follow-up surveys, participants were asked to report if they had been tested for COVID-19 and, if

so, test dates and results; whether they had been vaccinated against COVID-19; and what prescription and nonprescription medications they used, as well as dietary supplements and complementary medicines [8]. If they reported having been vaccinated against COVID-19, they were asked to report the vaccine manufacturer, date, and lot number. They were also asked if they experienced any side effects after the vaccination and were provided a list of 13 symptoms. They also had the option to insert additional side effects using a free text field for side effects that were not listed.

All CARE participants who reported completion of a COVID-19 vaccine regimen approved by the US Food and Drug Administration (2 doses of Pfizer or Moderna or 1 dose of Johnson & Johnson) between March 19, 2021, when vaccine side effect questions were first added to CARE, and July 16, 2022, were included in this analytic cohort.

Analysis

No statistical tests were used in these exploratory evaluations of diabetes medication-specific vaccine side effects. Vaccine side effects are described based on the total number reported per participant (means and SDs) and percentages for individual side effects. For 2-dose vaccines, each side effect was counted once regardless of whether it was reported at only 1 dose or at both doses. Side effects entered as free text were manually reviewed and grouped into related categories. The distribution of self-reported vaccine side effects by diabetes medications is illustrated graphically to support the examination of the magnitude of side effect differences for various medications and combinations of medications used to manage diabetes.

Incidences of breakthrough infections are described according to whether respondents reported that they had diabetes at enrollment. Breakthrough infections were defined in alignment with the US Centers for Disease Control and Prevention as a positive COVID-19 test, regardless of the type of test, after 14 days post completion of a vaccine regimen [11].

Multivariate logistic regression was used to estimate the adjusted odds ratios (aORs) of vaccine side effects or breakthrough infections by diabetic status, adjusting for age, gender, education, race, ethnicity (Hispanic or Latino), BMI, smoker, receipt of an influenza vaccine, vaccine manufacturer, and all medical conditions.

Ethical Considerations

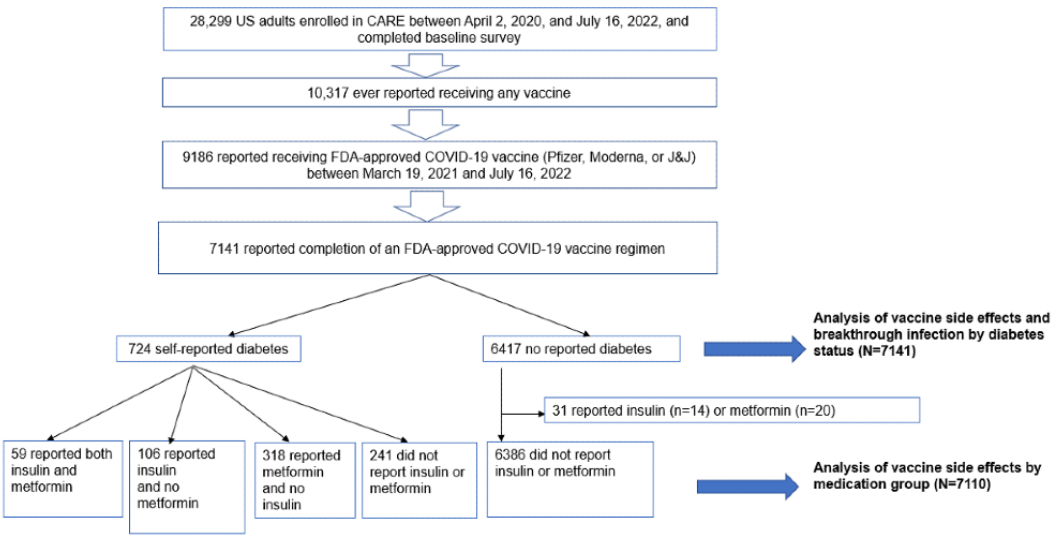
This study was reviewed and approved by an external institutional review board (Advarra; Pro00043030) and registered with ClinicalTrials.gov (NCT04368065) in the spirit of full disclosure, although this was not a clinical trial. This study fully complies with the Declaration of Helsinki.

Results

Study Population

A flowchart describing the study population is shown in Figure 1. The analysis population was composed of 7141 participants who reported having completed a vaccine regimen between March 19, 2021, and July 16, 2022, with 724 reporting they had diabetes and 6417 participants who did not report so (people without any note of having diabetes). The median follow-up time from completion of a vaccine regimen to the last survey submitted was 170 (IQR 38.0-319.5) days and 145 (IQR 37.0-314.0) days for those with and without diabetes, respectively. Most people with diabetes used insulin (n=165, 22.8%), metformin (n=318, 43.9.1%), or both (n=59, 8.1%).

Figure 1. Flowchart of analysis populations from CARE registry. CARE: COVID-19 Active Research Experience; FDA: US Food and Drug Administration.



COVID-19 Vaccinations and Side Effects Among People With Diabetes

In this study population, people with diabetes reported fewer vaccine side effects than those without diabetes (mean 2.7, SD 2.0 vs mean 3.1, SD 2.0, respectively; Table 1), although respondents with diabetes were older than nondiabetics and reported more comorbidities, including hypertension, obesity, depression, and autoimmune disorders.

Table 1. Characteristics at enrollment survey and side effects of COVID-19 vaccines reported by participants at the first or second vaccine dose, by self-reported diabetic status.

	All participants (N=7141)	
	People with diabetes (n=724)	No reported diabetes (n=6417)
Days of follow-up from completion of COVID-19 vaccine regimen (ie, last dose in regimen), n	724	6417
Mean (SD)	182.1 (144.4)	175.0 (143.9)
Median (IQR)	170.0 (38.0-319.5)	145 (37.0-314.0)
Range	0-598.0	0-747.0
Age (years), n	724	6417
Mean (SD)	57.8 (12.04)	47.5 (15.57)
Median (IQR)	60 (51.0-66.0)	46 (34.0-61.0)
Age group (years), n	724	6417
18-29, n (%)	14 (1.9)	767 (12.0)
30-39, n (%)	46 (6.4)	1704 (26.6)
40-49, n (%)	106 (14.6)	1013 (15.8)
50-59, n (%)	193 (26.7)	1104 (17.2)
>60, n (%)	365 (50.4)	1829 (28.5)
Gender , n	724	6417
Self-described as female, n (%)	552 (76.2)	5375 (83.8)
Race, n	724	6409
Black, n (%)	19 (2.6)	100 (1.6)
White, n (%)	651 (89.9)	5793 (90.4)
Other, n (%)	54 (7.5)	516 (8.1)
Ethnicity, n	720	6402
Hispanic or Latino, n (%)	39 (5.4)	369 (5.8)
BMI, n	714	6286
Underweight or normal weight (15.0≤BMI<25.0), n (%)	66 (9.2)	1802 (28.7)
Overweight (25.0≤BMI<30.0), n (%)	150 (21.0)	1825 (29.0)
Obese (30.0≤BMI≤40.0), n (%)	323 (45.2)	2026 (32.2)
Severe obesity (BMI>40.0), n (%)	175 (24.5)	633 (10.1)
Education, n	720	6406
High school or less, n (%)	89 (12.4)	525 (8.2)
Some college, n (%)	273 (37.9)	1845 (28.8)
4 year college degree, n (%)	140 (19.4)	1731 (27.0)
>4 year college degree, n (%)	218 (30.3)	2305 (36.0)
Smoker, n	671	6181
Yes, n (%)	73 (10.9)	571 (9.2)
Vaccinated for influenza, n	721	6358
Yes, n (%)	568 (78.8)	4659 (73.3)
Other medical conditions, n	724	6410
Hypertension, n (%)	409 (56.5)	1286 (20.1)
Depression, n (%)	294 (40.6)	2007 (31.3)
Insomnia or trouble sleeping, n (%)	275 (38.0)	1889 (29.5)
Anxiety, n (%)	272 (37.6)	2515 (39.2)

	All participants (N=7141)	
	People with diabetes (n=724)	No reported diabetes (n=6417)
Autoimmune disease, n (%)	146 (20.2)	732 (11.4)
Cardiovascular disease, n (%)	129 (17.8)	311 (4.9)
Lung disease, n (%)	113 (15.6)	585 (9.1)
Kidney disease, n (%)	70 (9.7)	176 (2.7)
Blood disorder, n (%)	36 (5.0)	150 (2.3)
Manufacturer of COVID-19 vaccine received, n	724	6417
Pfizer, n (%)	327 (45.2)	3124 (48.7)
Moderna, n (%)	317 (43.8)	2502 (39.0)
J&J, n (%)	80 (11.0)	791 (12.3)
Categories of number of side effects to COVID-19 vaccines, n	724	6417
No side effects, n (%)	93 (12.8)	530 (8.3)
1 to 2 side effects, n (%)	300 (41.4)	2186 (34.1)
3 or more side effects, n (%)	331 (45.7)	3701 (57.7)
Number of side effects to COVID-19 vaccines, n	724	6417
Mean (SD)	2.7 (2.0)	3.1 (2.0)
Median (IQR)	2 (1.0-4.0)	3 (2.0-5.0)
Range	0-9	0-10
Specific side effects to COVID-19 vaccines, n	724	6417
Injection site reactions, n (%)	530 (73.2)	4995 (77.8)
Fatigue, n (%)	435 (60.1)	4484 (69.9)
Headache, n (%)	284 (39.2)	3126 (48.7)
New or worsening muscle pain, n (%)	177 (24.4)	1928 (30.0)
Fever, n (%)	171 (23.6)	1938 (30.2)
New or worsening joint pain, n (%)	142 (19.6)	1360 (21.2)
Nausea or vomiting, n (%)	91 (12.6)	1016 (15.8)
Swollen lymph nodes, n (%)	71 (9.8)	724 (11.3)
Chills, n (%)	20 (2.8)	312 (4.9)
Diarrhea[a], n (%)	<10	72 (1.1)
Dizziness[a], n (%)	<10	76 (1.2)
Severe allergic reaction[a], n (%)	<10	35 (0.5)

[a]Percentage not shown for <10 responses.

The aORs for having any or individual vaccine side effects were consistently lower for participants reporting having diabetes compared with those not reporting diabetes, with notable reductions in the risk of side effects such as fatigue and headache (Figure 2). Specific diabetes medications affected the risk of various side effects (Figures 3 and 4), but no consistent patterns of risks were observed between medications or side effects. A similar pattern of vaccine side effects by diabetes medication use was observed in a sensitivity analysis restricted to diabetes drugs that were confirmed in prescription claims (Figure 4).

Figure 2. Adjusted (adjusted for age, gender, education, race, ethnicity, BMI categories, smoking status, receipt of an influenza vaccine, vaccine manufacturer, and all medical conditions) odds ratios comparing COVID-19 vaccine side effects (diarrhea, dizziness, and severe allergic reaction not reported due to small numbers) between people with diabetes (n=724) and without diabetes (reference group, n=6417). aOR: adjusted odds ratio.

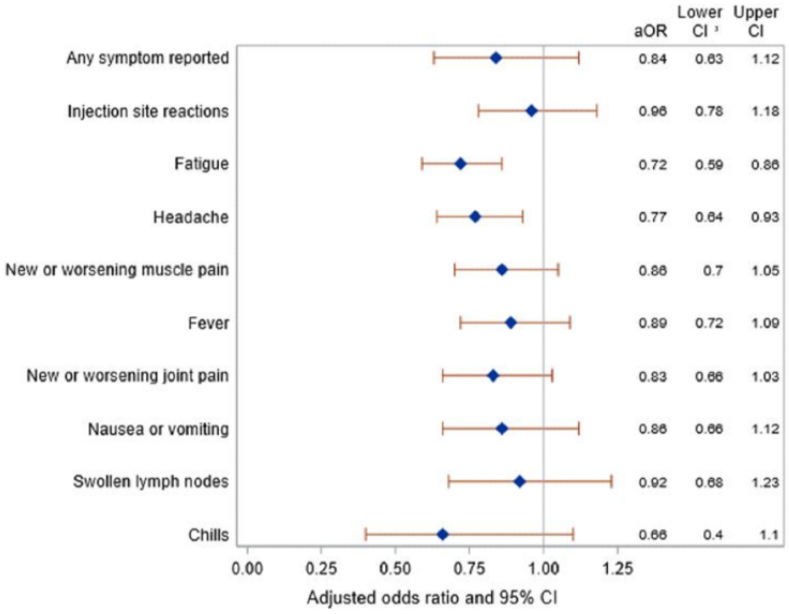


Figure 3. COVID-19 vaccine side effects comparing self-reported diabetes medication use among diabetes to those without diabetes (n=7110). Note that 31 people were excluded here who did not report having diabetes but who did report using insulin or metformin for treatment of another medication condition.

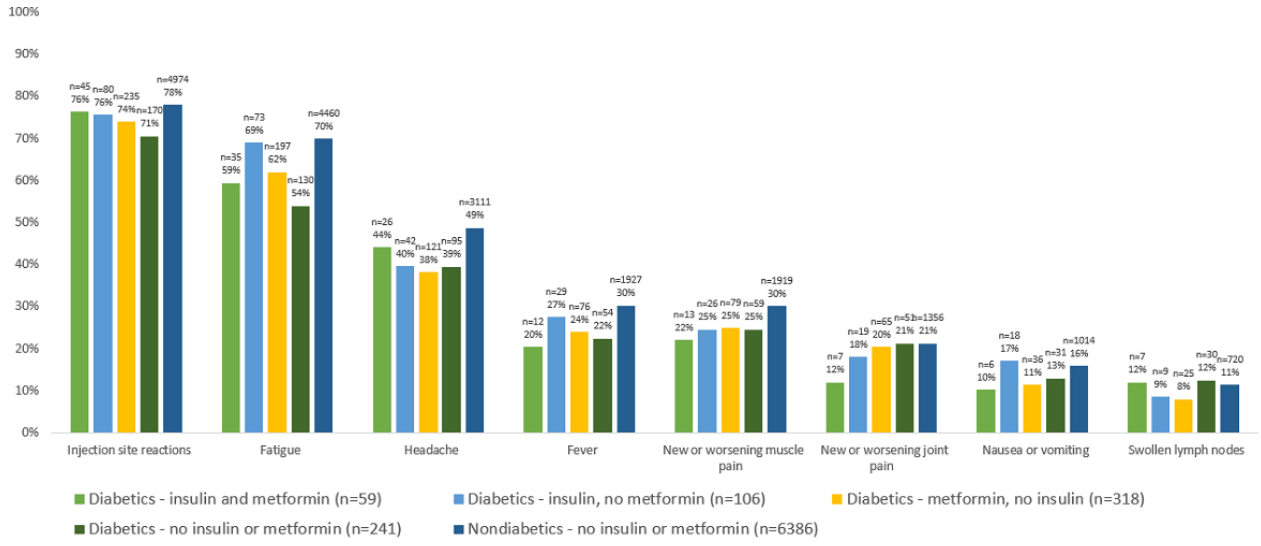
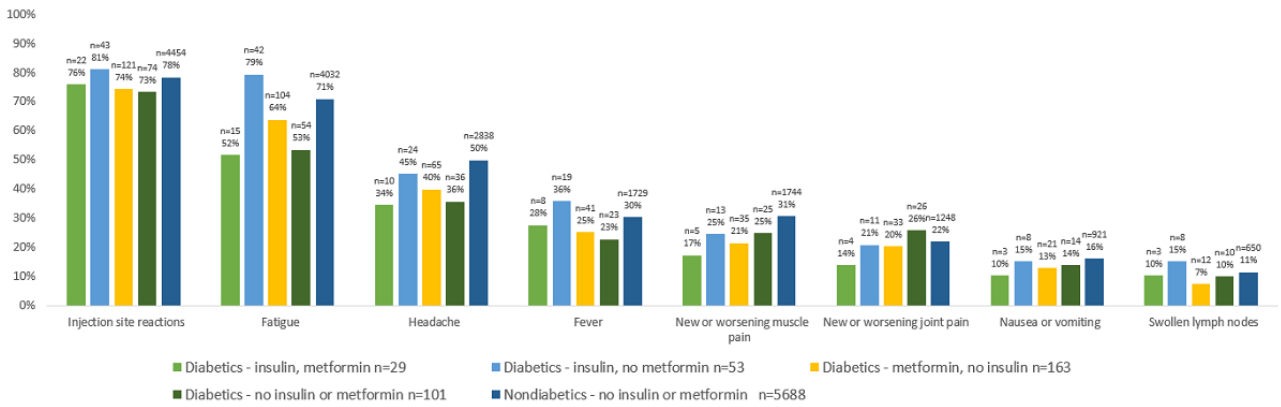


Figure 4. COVID-19 vaccine side effects by diabetes and diabetes medications confirmed through linked pharmacy claims (n=5034).



Accuracy of Self-Reported Medication Use

Most self-reported diabetes medication use was confirmed in prescription claims for participants in the analysis population, who indicated using prescription medications and were linked to pharmacy claims within 6months before or after enrollment in CARE. Specifically, among 142 participants with diabetes who reported using insulin in CARE, 101 had linked prescription claims data available for analysis; using these linked data, 81.2% (82/101) showed at least 1 claim for insulin. Of the 325 participants reporting diabetes who reported using metformin in CARE, 228 had linked prescription claims data and 84.2% (192/228) showed at least 1 claim for metformin.

Breakthrough Infections After Vaccination

Breakthrough infections through participants' last survey were reported by 36 (5.0%) participants reporting diabetes and 396 (6.2%) participants not reporting having diabetes. The median time to breakthrough infection for those who were fully vaccinated was similar between participants reporting diabetes (252, IQR 139-280 days) and participants not reporting diabetes (265, IQR 200-317 days; *P*=.10). When adjusting for other factors, there was no meaningful difference in the risk of breakthrough infections between participants reporting and not reporting diabetes (aOR 0.95, 95% CI 0.65-1.40).

Discussion

Principal Findings

This observational study showed that participants reporting diabetes experienced a lower risk of vaccine side effects than participants not reporting diabetes, even when higher BMI, more frequent comorbidities, and other differential risk factors were controlled statistically. This is similar to findings from another digital real-world study by Beatty et al [12] that showed the presence of self-reported diabetes was not associated with increased risk of COVID-19 vaccine side effects, despite some difference in the time frame of side effects measurement (ie, 2 weeks in CARE vs monthly reporting by Beatty et al [12]).

In general, those who used diabetes medications reported fewer side effects than those who did not report having diabetes or used metformin for any purpose. The most notable exception was evident in the incidence of fatigue; here participants who used insulin reported having levels of fatigue higher than (Figure 4) or equal to (Figure 3) those without diabetes. Analysis of only those medications confirmed by prescriptions also showed slightly higher rates of fever, swollen lymph nodes, and injection site reactions among insulin users compared to those who did not report having diabetes or using metformin, though it is important to emphasize that these are small differences derived from the analysis of relatively small numbers.

The reasonably high correlations between self-reported insulin and metformin with pharmacy claims (81.2%, 82/101 and 84.2%, 192/228, respectively) were similar to findings from other comparisons of adult self-reported prescription data and national pharmacy claims data, noting that even using a national prescription registry in this earlier work, which was presumed to have 100% coverage of the population, did not show 100% agreement with self-reported medication use [13].

Comparison to Prior Work

This level of agreement between self-reported prescription medication use and pharmacy health insurance claims for those medications not only lends more weight to the findings derived from self-reported data but also reinforces the value of participant-reported health data [14].

Some literature shows that people with diabetes have lower neutralizing antibodies after receiving COVID-19 vaccines than the general population [15,16], raising the question of whether people with diabetes are adequately protected by vaccination. However, this study confirms the work of Beatty et al [12] and adds information on breakthrough infections, showing that participants reporting diabetes did not experience any higher rates of breakthrough infections than their counterparts not reporting diabetes, regardless of side effects after vaccination for COVID-19.

Strengths and Limitations

Strengths

This study was designed as an exploratory study of COVID-19 in the community setting, including the risks and benefits of vaccination. Its main strength is bringing the voice of the people to the forefront, without any interpretation or editing by medical care providers.

Limitations

First, voluntary participation in online surveys is susceptible to bias. A fundamental assumption used here is that volunteers will answer honestly, especially since there was no remuneration or other benefit for participation. This study builds on work conducted previously [14] using this methodology where participants from Denmark self-reported prescription medication use was validated through a national prescription registry, with similar levels of reporting agreement shown here. Further, this study also confirms that valuable information can be obtained from laypeople, including information that may not otherwise be available such as perception of vaccine-related side effects. In this study, there was no clinical validation of self-reported side effects nor was proof of test-confirmed COVID-19 requested. These decisions were made to minimize participant burden and to support full reporting of participants' experience about how they felt after vaccination for COVID-19, that is, whether or not they sought medical care. The perception of side effects is important, regardless of how they are viewed by a clinician since they shape personal behavior [17].

Second, we did not differentiate between prediabetes, type 1 and type 2 diabetes, largely since this was a general survey of laymen and we were concerned that not all people would be able to respond accurately. Nor did we seek information about glucose levels due to the broad nature of this study. Instead, we attempted to strengthen our conclusions by analyzing vaccine side effects according to the use of diabetes medications only among those respondents who also indicated that they had diabetes and excluding people from our analysis of diabetes medications who reported using metformin and insulin but did not report having diabetes.

Third, generalizability and missing data are concerns for every observational study. Despite participation from all 50 states, adults who join CARE are not representative of the US population in general or all people with diabetes. The CARE participants are more highly educated than the general population as is common in online research [12,14]. Most described themselves as Caucasian females, aged 30-50 years, and the responses of these unpaid volunteers reflect the experience of people who had both the time and interest to respond to internet advertisements on social media. That said, comparisons within this study population are unlikely to be subject to selection biases that would cause differential reporting between participants reporting or not reporting diabetes. Furthermore, there was no effort to specifically recruit people with diabetes, nor any advance notice of the intent to study vaccine side effects specifically or to compare side effects according to the medication use. However, people who had severe reactions from COVID-19 vaccination may not have participated in this study or may not have provided follow-up due to hospitalization or death.

Finally, most of these data were collected when the predominant COVID-19 variants were the Delta and the original Omicron (BA.1 and BA.2.12.1) variants. The rates of breakthrough infections may differ for other variants [18].

Conclusions

Overall, these results should provide assurance that simply having diabetes does not increase the risk of vaccine side effects compared with those not reporting diabetes. In fact, the risk of developing vaccine side effects in participants reporting diabetes appears lower than in those not reporting diabetes, without any increased risk of breakthrough infections after vaccination.

Acknowledgments

We would like to acknowledge Steven Toovey for his thoughtful medical guidance, Savitha Pallipuram for leading the tech team, and Tom Kown for his program management contributions. This work was supported largely by IQVIA and had support from the US Food and Drug Administration in the development of questionnaires and for work unrelated to the topic of this study. IQVIA was fully responsible for the design, data collection, analysis, and interpretation of the data.

Data Availability

Deidentified data sets generated during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

NAD conceptualized the work, drafted the work, and revised it critically for important intellectual content. KBK and YX performed the data analysis, interpreted the results, reviewed the work, and supported revising the work. MWR, CDM, and NAD contributed to crafting the study design as well as leading project design, implementation, and data collection, and reviewed the work. All authors approved the work to be published. NAD is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

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Abbreviations

aOR: adjusted odds ratio
CARE: COVID-19 Active Research Experience

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Original Paper

Insights Into Sociodemographic Influences on Type 2 Diabetes Care and Opportunities for Digital Health Promotion in Port Harcourt, Nigeria: Quantitative Study

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Abstract

Background: A significant percentage of the Nigerian population has type 2 diabetes (T2D), and a notable portion of these patients also live with comorbidities. Despite its increasing prevalence in Nigeria due to factors such as poor eating and exercise habits, there are insufficient reliable data on its incidence in major cities such as Port Harcourt, as well as on the influence of sociodemographic factors on current self-care and collaborative T2D care approaches using technology. This, coupled with a significant lack of context-specific digital health interventions for T2D care, is our major motivation for the study.

Objective: This study aims to (1) explore the sociodemographic profile of people with T2D and understand how it directly influences their care; (2) generate an accurate understanding of collaborative care practices, with a focus on nuances in the contextual provision of T2D care; and (3) identify opportunities for improving the adoption of digital health technologies based on the current understanding of technology use and T2D care.

Methods: We designed questionnaires aligned with the study's objectives to obtain quantitative data, using both WhatsApp (Meta Platforms, Inc) and in-person interactions. A social media campaign aimed at reaching a hard-to-reach audience facilitated questionnaire delivery via WhatsApp, also allowing us to explore its feasibility as a data collection tool. In parallel, we distributed surveys in person. We collected 110 responses in total: 83 (75.5%) from in-person distributions and 27 (24.5%) from the WhatsApp approach. Data analysis was conducted using descriptive and inferential statistical methods on SPSS Premium (version 29; IBM Corp) and JASP (version 0.16.4; University of Amsterdam) software. This dual approach ensured comprehensive data collection and analysis for our study.

Results: Results were categorized into 3 groups to address our research objectives. We found that men with T2D were significantly older (mean 61 y), had higher household incomes, and generally held higher academic degrees compared to women (P=.03). No statistically significant relationship was found between gender and the frequency of hospital visits (P=.60) or pharmacy visits (P=.48), and cultural differences did not influence disease incidence. Regarding management approaches, 75.5% (83/110) relied on prescribed medications; 60% (66/110) on dietary modifications; and 35.5% (39/110) and 20% (22/110) on traditional medicines and spirituality, respectively. Most participants (82/110, 74.5%) were unfamiliar with diabetes care technologies, and 89.2% (98/110) of those using technology were only familiar with glucometers. Finally, participants preferred seeking health information in person (96/110, 87.3%) over digital means.

Conclusions: By identifying the influence of sociodemographic factors on diabetes care and health or information seeking behaviors, we were able to identify context-specific opportunities for enhancing the adoption of digital health technologies.

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KEYWORDS

type 2 diabetes; digital health; t2d in nigeria; technologies for diabetes; pharmaceutical care for t2d

Introduction

Background

Type 2 diabetes (T2D) is a metabolic condition characterized by elevated blood glucose levels and can lead to complications such as coronary heart disease and kidney failure [1]. Currently, approximately 90% of global diabetes cases are classified as type 2, affecting over 300 million individuals [2]. This represents about 8.3% of the world's population. In Nigeria, a significant percentage of the population is affected by T2D. Similar to the rest of the world, the country is experiencing an increasing prevalence of the condition alongside other noncommunicable diseases [3]. According to the International Diabetes Federation, the estimated number of T2D cases in Nigeria is projected to increase from 3.6 million in 2021 to nearly 5 million by 2045 [4]. However, it is important to note that data regarding its prevalence in Nigeria appear inconsistent, with some research papers reporting rates of 5.7% [5], 4.3% [6], or even 11% [7]. In the South-South geopolitical zone of Nigeria, which includes Port Harcourt, some studies have indicated a prevalence of 9.8% and 6.8% of T2D in Port Harcourt itself, with varying values for other communities [8,9]. The increasing prevalence of T2D coexists with significant rates of communicable diseases, such as HIV [10,11]; infectious diseases, such as malaria [12,13]; and other noncommunicable diseases, such as cardiovascular and renal diseases [14]. The distinction between type 1 diabetes and T2D has also become blurred, and studies have shown that there has been no national consensus on diabetes prevalence since 1992 [15,16]. Given this disease burden and the lack of sufficient epidemiological data, T2D demands significant attention due to its association with distinct complications, many of which result in increased mortality.

Certain risk factors, such as obesity, genetics, sedentary lifestyle, and certain comorbidities, contribute to the incidence and onset of T2D. However, sociodemographic factors, including gender, age, ethnicity, and environmental influences, also play a significant role in increasing T2D risk and influencing the provision of care [17-20]. For instance, studies have shown that people with T2D residing in rural and remote regions face challenges with access to health care [21], such as lacking direct contact with a physician or registered pharmacist [22-24], dealing with unlicensed practitioners or complementary care providers [25], or being unable to manage referrals to secondary or tertiary health care institutions because of their physical inaccessibility [26,27]. Studies show that, globally, Black and Hispanic people face the highest risks of illness and death [28-30]. Another 20-year study found that Asian, Hispanic, and Black women have a much higher risk of T2D compared to White women, with increased BMI being especially harmful for Asian people [31]. Although T2D is mostly linked to wealthier and more developed areas, it is increasingly becoming a significant issue in developing countries like Nigeria [32-34]. This could result from cultural assimilation concerning food and lifestyle behaviors [35], potentially exacerbated by a lack of financial, educational, and infrastructural resources unique to the societal and community context.

T2D Management

The management of the condition involves pharmacotherapy, which includes using hypoglycemic drugs (eg, sulfonylureas and meglitinides) and lifestyle modifications focusing on exercise and diet [36,37]. Digital interventions also play a role across different stages of T2D care, including diagnosis or prognosis with rapid test kits or machine-learning algorithms [38] and providing information, remote monitoring, and lifestyle modifications through mobile apps and websites [2,39,40]. Continuous glucose monitoring systems for blood sugar sensing and personalized medicine [41-43] are also critical components. Because T2D is a long-term condition that requires constant monitoring, its care involves self-management by people with the condition and collaborative care with both caregivers and health care practitioners in both formal and informal settings. However, we recognize that in certain contexts, such as Nigeria, there are limitations affecting the provision of care and the use of digital health technologies. There is also a dearth of contributions providing insight into the scope of T2D care and its intersection with sociodemographic and contextual factors influencing the use of digital health technologies. In light of these observations, we explore the Nigerian landscape by focusing on a notable developing city, Port Harcourt, to achieve the following objectives: (1) to explore the sociodemographic profile of people with T2D and understand how it directly influences their care; (2) to generate an accurate understanding of collaborative care practices, with a focus on nuances in the contextual provision of T2D care; and (3) to identify opportunities for improving the adoption of digital health technologies based on the current understanding of technology use and T2D care.

This was achieved through a quantitative study involving the collection of data from 110 people with T2D using traditional paper surveys and automated WhatsApp (Meta Platforms, Inc) surveys via Twilio (Twilio Inc), a cloud communications platform. We recognized the intersection between self-care and collaborative care practices, contextual influences, and technology use. We propose that insights from our study will contribute to the body of work on T2D incidence and prevalence in Port Harcourt, Nigeria, as well as provide guidance on the design of context-specific digital interventions for T2D care.

Methods

To uncover the influence of contextual factors on T2D care, the current state of technology use for T2D care, and potential design opportunities to improve self and collaborative T2D care, we obtained 110 responses from questionnaires distributed both on paper and via an automated WhatsApp system.

Positionality

The lead researcher, who is also the first author, has a diverse background as a pharmacist, health care manager, and digital

health scholar. Having resided, studied, and practiced in Port Harcourt, Nigeria, for >2 decades, their motivation for undertaking this study is deeply rooted in personal experiences acquired while working as both a hospital and community pharmacist. During this period, they had the opportunity to interact with a wide range of patients, which led to a profound realization of the critical role that cultural diversity plays in the delivery of pharmaceutical care.

The second and third authors, specializing in human-computer interaction, have a collective research focus on the use of health and wellness technologies within various contexts. They bring a valuable interdisciplinary perspective to the study. The fourth author, based in Nigeria, is a pharmacist and academic with a wealth of expertise in the field of T2D research. His work has primarily concentrated on the development of context-specific public health interventions, and he also demonstrates a keen interest in exploring the potential of digital health interventions.

Study Design and Setting

This quantitative cross-sectional study, which was conducted from February through April 2023, involved respondents who were contacted using random and snowball sampling techniques.

Ethical Considerations

The study was made possible by ethics approval from the research ethics committee of the University of Port Harcourt, Nigeria (UPH/CEREMAD/REC/MM85/044). Participants were required to provide informed consent twice, the first being when they signed and filled in the expression of interest form on the web, and the second when they began to answer the questionnaire. Participants were not financially compensated and personal identifiable data such as names were anonymized.

Study Site

Nigeria is currently the most populous country in Africa, with an estimated 223 million people and >371 tribes [44]. This population is expected to grow steadily in the coming years, which will place additional demands on the health care system. Our study was conducted in Port Harcourt, a major developing city in Nigeria with a significant prevalence of T2D [45]. It has a rich colonial history and is a vibrant melting pot of diverse ethnicities, with numerous languages spoken.

Study Population

On the basis of the objectives of this study, the intended questionnaire respondents were people with T2D residing in Port Harcourt, Nigeria. Eligibility criteria required participants to have been diagnosed with T2D for >6 months, be aged >18 years old, and be capable of providing informed consent. We obtained a total of 110 questionnaire responses, comprising 27 valid responses from the automated WhatsApp questionnaires and 83 responses from the questionnaires distributed in person.

Study Instruments

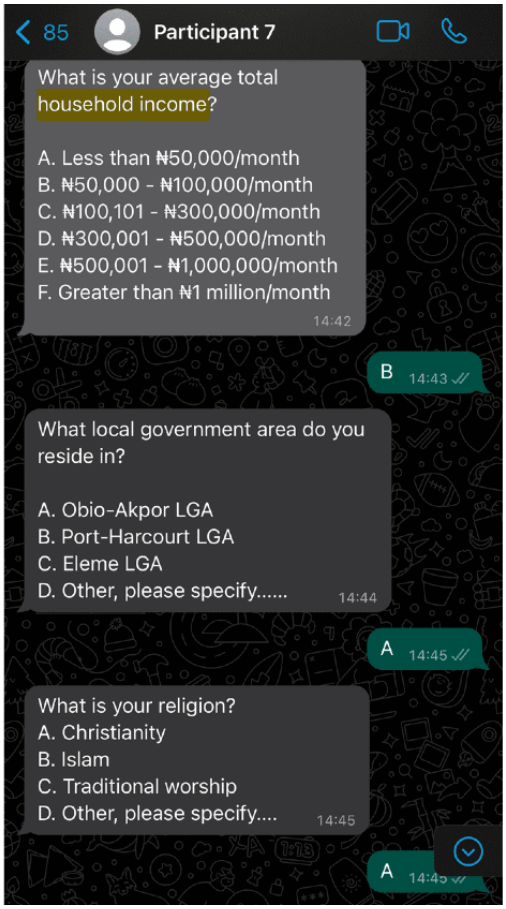
Data were obtained using paper questionnaires and WhatsApp, automated with Twilio. The data were analyzed using descriptive and inferential statistics with the SPSS Premium (version 29; IBM Corp) and JASP (version 0.16.4; University of Amsterdam) software.

WhatsApp for Data Collection

WhatsApp is the most pervasive instant messaging platform in Nigeria, with at least 40% of its population being active users [46]. While quantitative data collection in contexts such as that in Nigeria mostly involves distributing surveys either electronically through Microsoft Forms (Microsoft Corp) or other avenues or in person through paper, the collection of quantitative data using WhatsApp remains underexplored. WhatsApp offers a cost-effective approach for both respondents and researchers. It is user-friendly for people already accustomed to WhatsApp chat functions and ensures sustained participation among mobile populations, as users can retain their WhatsApp number even when changing SIM cards or phones. To recruit WhatsApp respondents, we used a different approach (discussed subsequently) compared to traditional survey distribution methods. This allowed us to reach a hard-to-reach audience, including participants who might otherwise have been unreachable in person. This validates WhatsApp's utility and adds to its list of advantages. However, researchers lacking technical skills or familiarity with web-based recruitment methods may perceive this approach as a limitation.

We obtained quantitative data by automating WhatsApp using Twilio. This approach was a replication of the method used by Fei et al [47] in their work on automated WhatsApp questionnaires in panel surveys. The phone numbers of people who expressed interest via the form we disseminated on social media were securely stored in a password-protected Google Sheet (Google LLC). Subsequently, we created a WhatsApp questionnaire using Twilio's studio dashboard for questionnaire flow. Google Apps Scripts were used for automating questions, allowing participants to respond within the WhatsApp environment. In the Twilio platform, each response from the participants led to the transfer of the response to the password-protected Google Sheet used. On the participants' part, they were instructed to respond using single letters to indicate their chosen answers for each question. Subsequently, this action triggered the presentation of the next question, which also necessitated a single-letter response (Figure 1). This process continued until the questionnaire was completed, and every respondent who expressed interest filled out the WhatsApp questionnaire.

Figure 1. Data collection on WhatsApp (Meta Platforms, Inc) enabled by Twilio (Twilio Inc).



Questionnaire Design

An expert panel consisting of the first author, 2 human-computer interaction experts, and an academic pharmacist residing in Port Harcourt designed the questionnaires in accordance with the research objectives and outcomes derived from preorganized synchronous WhatsApp interviews. To provide context, a total of 36 individuals participated in the preceding WhatsApp interviews, including 15 (42%) people with T2D, 9 (25%) community pharmacists, and 12 (33%) caregivers. Through these interviews, we gathered valuable insights regarding the scope of T2D care in Port Harcourt, the influence of health care providers on community T2D care, potential design opportunities for T2D care, and the role of instant messengers and social media in data collection and T2D care. These insights informed the iterations made to the questionnaire during its design phase. The questionnaires were specifically targeted at people with T2D to obtain statistical information that would answer questions regarding demographics, disease prevalence and coexistence with other morbidities, the role of technology, and how technology is adopted and integrated into their care.

We used a mixed-question format in the design of the questionnaire, incorporating both open-ended questions that required written responses, such as “What approach best describes how you manage your condition?” and closed-ended questions with predefined options, such as “Do you use any form of technology in the management of your condition?” Following the completion of the questionnaire design, we conducted a pilot study involving 6 participants. Among them, 2 (33%) participants resided in the United Kingdom, while the remaining 4 (67%) were based in Nigeria. The 2 pilot participants from the United Kingdom came from diverse backgrounds, including psychology and statistics. Their feedback was invaluable in assessing the questionnaire’s readability and statistical validity. The individuals who participated in the pilot study from Nigeria were primarily pharmacists and academics. They offered insights into the sociocultural relevance of the questions and provided feedback on the questionnaire’s reproducibility and comprehensibility. Following the conclusion of the pilot study, we made iterative improvements to the questionnaires, and the final versions were either printed or manually transferred to Twilio’s dashboard for data collection.

Sample Size Calculation

In the absence of consistent epidemiological data on the prevalence of T2D in Port Harcourt and Rivers state, we used a standard formula to estimate the required sample size based on the established prevalence rate of T2D in Nigeria [9]. The formula required the input of a constant (SD set at 1.96), corresponding to a 95% CI; the estimated proportion of the population with T2D, which was calculated to be 0.036 (3.6% prevalence rate); and a margin of error of 0.05. The ideal sample size for this study was determined to be 55.31.

$$N = [Z^2 \times P\ (1 - p)] / E^2 \textbf{(1)}$$

Using the formula for design effect to calculate anticipated attrition of 10%, we obtained 61 as the recommended number

of responses in the study. Since this systematic sampling technique ensures the appropriate sample size is obtained, but not necessarily an equitable representation of the sample, and due to inconsistencies with data on the prevalence rate of T2D in Port Harcourt or Rivers state, we aimed to double the initially recommended sample size (N×2=110) to achieve an adequate representation of people with T2D.

1 / (1 – adjusted factor) × estimated sample size = ideal number of participants **(2)**

(1 / [1 – 0.1]) × 55 = 61 **(3)**

Data Collection

Participant recruitment was carried out through a combination of random and snowball sampling techniques. For the WhatsApp questionnaires, an expression-of-interest form was created and distributed on social media. An advertisement designed to run for 2 weeks at US $2 per day was created on a designated Facebook (Meta Platforms, Inc) page with no followers for the questionnaire. It featured an image depicting the disease condition in people of color and a concise title: “Have Type 2 Diabetes? Sign up; let’s take action.” A summary of the study was included in the description section, and the advertisement was targeted at people living in Port Harcourt. Although the advertisement reached 3127 individuals and received approximately 46 likes, 10 shares, 2 comments, and 107 link clicks, we excluded 23 invalid responses and obtained only 27 valid responses, as the form was designed to filter out ineligible participants. Out of the 23 invalid responses, 15 (65%) were excluded because the respondents did not have T2D, and 8 (35%) were excluded because they did not provide contact information. Selected participants were contacted using the email addresses or WhatsApp phone numbers they provided on the forms.

Conversely, the distribution of physical questionnaires was facilitated through referrals from pharmacists; nongovernmental organizations, such as The Diabetes Care Network (a Port Harcourt–based nongovernmental organization focused on the provision of diabetes-related health education and digital health care); and random distributions in open markets, academic institutions, and churches. Although we distributed hundreds of questionnaires, we obtained a total number of 87 questionnaires, out of which 83 (95%) were valid. Questionnaires were invalidated for reasons such as being incomplete, ineligible, or suspicious.

Data Analysis

Overview

First, the first author exported the WhatsApp questionnaires as a zip file without any media attachments. The transcripts in the file, in .tex format, were compared to the Google Sheets responses for cleaning and editing. Thereafter, data in the traditional questionnaires were manually transferred to a Microsoft Excel sheet where they were cleaned. Both quantitative data sets were merged as a CSV file before being exported to the SPSS or JASP software for statistical analysis.

Statistical Analysis

Characteristics of people with T2D are reported as mean and SD for continuous variables such as age and duration of stay in Port Harcourt, while they are reported as percentages for categorical variables. These analyses were performed using univariate comparisons. To compare differences in the sociodemographic variables of women and men, we used a chi-square test for categorical variables, such as education, household income, and occupation, and an independent samples 1-tailed t test for continuous variables, such as age and duration of stay in Port Harcourt. To test the relationship between gender and how the condition is managed, either via hospital visits or via pharmaceutical care, we used a logistic regression model. To compare differences in sociodemographic variables using the chi-square test, we organized our data into rows and columns. The data were separated into 2 groups based on gender, and we encoded men and women as 0 and 1, respectively. Subsequently, we assigned numerical values to represent the options for each sociodemographic-related question. Finally, we conducted the relevant analysis using the SPSS software. A similar approach was used for cleaning and organizing data in the independent samples 1-tailed t test, with the difference being the use of continuous variables this time. For the logistic regression model, we organized our data sets into columns representing relevant categorical variables. Thereafter, we encode the responses into numerical values; for example, for the question indicating our independent variable “What approach describes how you manage the condition?” we code option A, which is prescribed medicines, as 0. Other options are coded in an ascending numerical order. For dichotomous responses, such as that observed for the question “Do you have a mobile phone?” we encoded the options yes and no as 0 and 1, respectively. We selected gender as the dependent variable that we want to predict, in comparison with other independent variables, such as the frequency of hospital visits and pharmacy visits, which were categorical variables in the questionnaire. We used the length of the period with T2D and reasons for visiting either the hospital or pharmacy as covariate factors. The data were cleaned and saved in a CSV file, which was analyzed in the JASP software.

Results

Summary of Key Findings

The key findings of this study have been summarized in Textbox 1.

Textbox 1. Key findings.

Findings

1. Cleaning the data resulted in an equal number of men and women in the study. However, people identifying as men were significantly older and had a higher average household income compared to those identifying as women. They also mostly accounted for those recently diagnosed with type 2 diabetes (T2D) and those living with the condition for more than >5 years (Table 1).
2. More than 92.7% (102/110) of people with T2D sampled in this study had tertiary education, resulting in a high literacy rate among our questionnaire respondents. This trend may be attributed to the venues where participant recruitment occurred, referrals from community pharmacists, potential bias in questionnaire distribution, and the assumption that mostly literate individuals would express interest in participating in the recruitment process on the web.
3. Most questionnaire respondents had a hybrid approach to managing their condition, combining prescribed medications with traditional medicines or other lifestyle modifications. Very few respondents admitted to using prescribed medications alone (Table 2).
4. Most questionnaire respondents who admitted to using technology to manage their condition claimed that they were using glucometers. Glucometers provide valuable information that helps people make informed decisions about their diabetes management; however, they are not necessarily interventions for actively managing symptoms, complications, or any indication of the disease (Table 2).
5. Physical contact was the most preferable option for questionnaire respondents for managing the condition and accessing related health information.
6. WhatsApp and Facebook were the most popular instant messaging and social media platforms, respectively, among questionnaire respondents. However, communication with pharmacists over these platforms rarely occurred, and when it did, it was mostly in the form of chats.

Table 1. Sociodemographic profile of men and women with type 2 diabetes in Port Harcourt (N=110).

Variable	Men (n=55)	Women (n=55)	*P* value
Age (y), mean (SD)	61 (1.15)	48 (2.16)	.03
Level of education, n (%)			.04
Secondary school	1 (2)	1 (2)	
College or polytechnic	1 (2)	2 (4)	
University (bachelor's degree [BSc[a]])	35 (64)	40 (73)	
Master's degree (MSc[b])	16 (29)	11 (20)	
Doctorate	2 (4)	1 (2)	
Household income per month ( ), n (%)			.58
<50,000 (US $35.7)	1 (2)	3 (5)	
50,000 (US $35.7) to 100,000 (US $71.4)	15 (27)	19 (35)	
100,000 (US $71.4) to 300,000 (US $214.3)	31 (56)	29 (53)	
300,000 (US $214.3) to 500,000 (US $357.1)	6 (11)	3 (5)	
>500,000 (US $357.1)	2 (4)	1 (2)	
Occupation, n (%)			.09
Student	1 (2)	2 (4)	
Self-employed	19 (35)	22 (40)	
Professional	21 (38)	15 (27)	
Manager or executive	5 (9)	1 (2)	
Housewife or husband	1 (2)	10 (18)	
Religious leader	4 (7)	2 (4)	
Unemployed	1 (2)	1 (2)	
Retired	3 (5)	2 (4)	
Mobile phone type, n (%)			.01
Android	45 (82)	34 (62)	
iPhone	9 (16)	21 (38)	

[a]BSc: Bachelor of Science.

[b]MSc: Master of Science.

Table 2. Current T2D[a] self-care practices, including the use of digital interventions (N=110).

	Men (n=55), n (%)	Women (n=55), n (%)
How long have you been diagnosed with T2D?		
6 months-1 year	20 (36)	15 (27)
1-5 years	27 (49)	37 (67)
>5 years	8 (15)	3 (5)
What approach best describes how you actively manage the condition (select more than one if necessary)?		
Prescribed medications	38 (69)	45 (82)
Traditional medicines	23 (42)	16 (29)
Dietary changes	30 (55)	36 (65)
Exercise	18 (33)	27 (49)
Spirituality (eg, prayers)	9 (16)	13 (24)
Technology	4 (7)	2 (4)
Do you use any form of technology in the management of your condition?		
Yes	12 (22)	16 (29)
No	35 (64)	36 (65)
Unsure	8 (15)	3 (5)
If yes, what best describes the form of technology that you use to manage your condition (select more than one if necessary)?		
Glucometer (the device to check your blood sugar levels)	51 (93)	47 (85)
Websites (eg, offers advice on self-care)	1 (2)	3 (5)
Mobile apps (eg, helps track blood sugar and activity)	3 (5)	5 (9)
If no, what best explains why you do not use any of the above?		
Too expensive	12 (22)	14 (25)
I do not know about them	12 (22)	4 (7)
I prefer physical contact	27 (49)	35 (64)
It is against my religious beliefs	4 (7)	2 (4)
If yes, what best explains why you use any of the above (select all that apply)?		
It is affordable	40 (73)	29 (53)
It is general practice	37 (67)	31 (56)
No reason, I do not think about technology much	4 (7)	5 (9)
I was convinced by someone	8 (15)	11 (20)

[a]T2D: type 2 diabetes.

Sociodemographic Characteristics of People With T2D

Positive Relationship Among T2D Prevalence, Comorbidities, and Age

An equal number of people who identified as men or women actively engaged with the questionnaires (Table 1). The mean age of people who identified as men was 61 (SD 1.15) years, while that of those who identified as women was 48 (SD 2.16) years. It was observed that a substantial percentage of women with T2D (44/55, 80%) ranged between the ages of 40 and 55 years, compared to men with T2D who mostly ranged between 45 and 65 years. A total of 58.2% (64/110) of people with T2D reported that they had been living with the condition for >1 but <5 years. Women had the highest prevalence within this time frame, accounting for 33.6% (37/110) of people living with T2D. However, men accounted for over 55% (11/20) of those recently diagnosed with T2D, that is, within 6 months to a year. While we cannot out rightly state that there is a positive relationship between T2D prevalence and gender because we did not consider confounding factors, we observed that there was a relationship between an increase in age and the prevalence of the condition.

High Household Income Linked to Education and Occupation

Less than 1.8% (2/110) of the questionnaire respondents had no postsecondary school education. However, most respondents possessed some level of education, with 68.1% (75/110) holding bachelor's degrees, 24.5% (27/110) holding master's degrees, and 2.7% (3/110) having doctorates (Table 1). An additional

2.7% (3/110) of the population held various academic certificates, including diplomas and the West African Senior Secondary School Certificate. While no positive relationship was observed between education and the prevalence of the disease, a positive relationship was noted among education, occupation, household income, and the incidence of the disease. It was observed that people with T2D who held Bachelor of Science and Master of Science degrees were mostly self-employed (41/110, 37.3%) or professionals (35/110, 31.8%), such as engineers and lawyers. They predominantly earned between ₦100,000 (US $ 71.4) and ₦300,000 (US $214.3). Finally, most people with T2D who were aged >55 years held managerial positions or served as religious leaders and claimed to earn between ₦300,000 and ₦500,000 (US $214.3-$ 357 at the time of writing).

State of Origin (Cultural Differences) Does Not Influence T2D Prevalence

Participants were asked to indicate their state of origin and how long they had resided in Port Harcourt. A total of 15 states were identified, with Rivers (24/110, 21.8%), Anambra (17/110, 15.5%), and Edo (12/110, 10.9%) states accounting for the top 3, while Kwara (1/110, 0.9%), Plateau (1/110, 0.9%), and Ondo (1/110, 0.9%) states represented the bottom 3. While 32.7% (36/110) of people with T2D noted that they had resided in Port Harcourt for 1 to 10 years, most of them from Anambra, Imo, and Delta claimed to have lived in Port Harcourt for 6 to 10 years. People with T2D who had resided in Port Harcourt for >10 years were mostly from Rivers, Bayelsa, and Abia. As we did not ask about their state of birth, we could not determine whether their residence in Port Harcourt was a result of migration or due to birth. Also, we did not observe any statistical relationship between the state of origin of respondents with T2D and T2D prevalence.

Collaborative T2D Care: Self Practices, Caregiving, and Pharmaceutical Care

Varied Self-Care Practices Influencing Hospital Visits

Most people with T2D (64/110, 58.2%) stated that they had been diagnosed with T2D for 1 to 5 years), while 29.1% (32/110) were diagnosed within the past year (Multimedia Appendix 1). When asked to signify what approach best describes how they manage their condition, most people with T2D noted that they depended on prescribed medications (83/110, 75.5%) and dietary modifications (66/110, 60%). The use of traditional medicines (39/110, 35.5%) and exploration of spirituality (22/110, 20%) in the management of T2D was not left out, as it was observed that they actively combined these approaches with dietary changes and prescribed medications.

We observed no statistically significant relationship between gender and the frequency of hospital (P=.60) or pharmacy visits (P=.48). However, most people with T2D (69/110, 62.7%), including those who depended on prescribed medications claimed to visit the hospital twice a year for care related to their condition. Surprisingly, 7.3% (8/110) admitted to never visiting the hospital, and it was observed that they selected traditional medicines and spirituality as their preferred approach for T2D care. Furthermore, 62.7% (69/110) of people with T2D reported that they visited the hospital only when they had complications, and this accounted for 80% (88/110) of the individuals who claimed to visit the hospital twice a year. In total, 20% (22/110) of questionnaire respondents implied that they visited hospitals, when necessary, in the blank options provided in the questionnaire. However, 15.5% (17/110) of them still indicated that they visited the hospital twice a year. Furthermore, 28.2% (31/110) of questionnaire respondents noted that they visited the hospital majorly for medication refills; however, 70.9% (78/110) of them said that they visited the hospital every 3 months. While university teaching hospitals were the most frequently visited (40/110, 36.4%) and private hospitals were the least frequently visited (3/110, 2.7%), most people with T2D who noted that they visited the hospital majorly for blood glucose and diabetes checkup selected primary health centers as their most frequently visited institutions. We did not ask questions to uncover the reasons behind their hospital choice, but we did observe that the majority of the respondents who claimed to visit the hospital twice a year admitted to visiting the pharmacy every month.

No Relationship Between T2D Prevalence and Caregiving or Pharmaceutical Care

Each person with T2D noted that they visited community pharmacies, albeit with varying frequencies (Multimedia Appendix 2). Most respondents (95/110, 86.4%) indicated that they visited community pharmacies every month, and approximately 1.8% (2/110) noted that they visited community pharmacies twice a year. We did not uncover the factors influencing the frequency of their visits to community pharmacies in the questionnaire; however, we determined the reasons why they chose to visit community pharmacies. They mostly visited community pharmacies for medication refills (74/110, 67.3%) and for disease complications (50/110, 45.5%). We observed that only 80.9% (89/110) of questionnaire respondents admitted to purchasing medications from community pharmacies, including those who indicated that they visited community pharmacies quite frequently. Patent medicine stores (58/110, 52.7%) and health multilevel marketing companies (17/110, 15.5%) accounted for a significant proportion of where T2D medications were routinely obtained from. Communication with pharmacists was mostly in person (98/110, 89.1%), and for people with T2D who engaged with their pharmacists on social media or instant messengers, WhatsApp was the most popularly used platform (85/110, 77.3%). Furthermore, 35.5% (39/110) of people with T2D indicated that they had a caregiver assisting with their disease condition, while 37.3% (41/110) noted that they occasionally had a caregiver. In addition, 69.1% (76/110) of questionnaire respondents indicated that their children were their primary caregivers. Respondents who indicated that they had active caregivers and that they were their children were mostly men (65/110, 59.1%). Women who selected children as their primary caregivers were mostly aged >50 years. We observed that most respondents who indicated that they visited the hospital every 3 months had their children as primary caregivers, were aged >55 years, and earned above ₦300,000 (US $214.2). However,

we could not positively or negatively correlate this observation with the prevalence of T2D.

Management of T2D and Comorbidities Supported by Formal Education

We discovered that people identifying as men generally held higher academic degrees than women (P=.03). However, it is noteworthy that women tended to have more bachelor's degrees than men. This difference might be attributed to the significant age gap between both genders, the nature of participant recruitment, or other sociocultural factors that were not considered. A positive relationship between the level of formal education and approach for the management of T2D was observed. Most people who had a bachelor's degree indicated that they relied on prescribed medications to manage their condition. There was an equal distribution between those who visited the hospital twice a year and those who had scheduled routine visits for medication refills, often associated with comorbidities. We noted the presence of comorbidities such as hypertension (79/110, 71.8% of questionnaire respondents), cardiac related diseases (35/110, 31.8%), kidney diseases (19/110, 17.3%), and cancer (3/110, 2.7%). Finally, individuals with a doctorate degree who were all aged >55 years reported making routine visits to both the hospital and the pharmacy for the management of T2D and coexisting conditions. They were either retired or held executive positions, resulting in higher household incomes. These factors may have contributed to their health-seeking behaviors.

Digital Health Approaches for T2D Care

Most People With T2D Were Familiar Only With Glucometers

Our findings suggest that 64.5% (71/110) of questionnaire respondents did not use any forms of technology to manage their T2D, and 10% (11/110) of questionnaire respondents were unsure about whether they used technology to manage their disease condition. We observed that most respondents who indicated that they use technology to manage their condition had mobile phones with access to the internet. The form of technology being referenced by questionnaire respondents was mostly a glucometer (98/110, 89.2%), as no respondent indicated something different in the blank spaces. The lack of glucometer use was significantly impacted by varying factors, including cost (26/110, 23.6%), ignorance about use (16/110, 14.5%), preference for physical contact (66/110, 60%), and religious preferences (2/110, 1.8%). Finally, we observed that some respondents who selected mobile apps and social media as their source of information did not consider these approaches as forms of technology for managing their disease condition.

Mobile Phones Relevant in T2D Care

Of the questionnaire respondents, 99.9% (109/110) indicated ownership of a mobile phone. However, most users reported having Android phones (79/110, 71.8%), among which 31.8% (35/110) had steady access to the internet, and these users were predominantly men. Unfortunately, we did not observe any significant relationship among the type of mobile phone used, household income, and occupation. Therefore, there is no clear explanation for why iPhones (which are typically more expensive) were owned majorly by women. In addition, considering that we did not probe further to inquire on the model and brand of the respondents' phones and that we did not observe a significant relationship among mobile phone type, household income, and occupation, we cannot infer that Android phones were significantly cheaper, that respondents earned enough to purchase them, or that they were purchased with managing a health condition in mind.

WhatsApp Facilitates Communication, While Facebook Acts as an Information Source

The findings from the questionnaire revealed that both men and women with T2D regularly used WhatsApp for communication (Table 3); however, the focus on its use for T2D care was unexplored. While WhatsApp emerged as the most popular instant messenger, it was not frequently used for communication with pharmacists. According to our findings, men reportedly contacted pharmacists more frequently on WhatsApp compared to women, and they primarily did so through regular chats. By contrast, our questionnaire data showed that women were more likely to collaborate on WhatsApp through conference calls or group chats with family or health care practitioners for health-related reasons. Furthermore, Facebook was reported as the most popular social media network, especially among men with T2D. However, concerning T2D care, few respondents acknowledged its use. An interesting observation was the selection of *word-of-mouth* (62/110, 56.4%) as the most accessible means for obtaining T2D-related health information.

Table 3. Communication and information seeking modalities (N=110).

	Men (n=55)	Women (n=55)
What instant messenger do you use regularly?		
WhatsApp	42 (76)	42 (76)
Telegram	11 (20)	11 (20)
Facebook Messenger	2 (4)	2 (4)
Other	__[a]	—
What social media network do you use regularly?		
Facebook	51 (93)	51 (93)
Instagram	1 (2)	1 (2)
Twitter	3 (5)	3 (5)
TikTok	—	—
Other	—	—
Do you communicate with your pharmacist using WhatsApp?		
Yes	22 (40)	22 (40)
No	33 (60)	33 (60)
If yes, select the way you use WhatsApp to communicate (select more than one if necessary; n=22)		
Video call	1 (4)	1 (4)
Web-based call	4 (18)	4 (18)
Conference call with my family or a physician	—	1 (4)
Group chats with family, a pharmacist, or physician	—	3 (14)
Regular chats (texts)	22 (100)	17 (77)
How do you assess health information related to managing type 2 diabetes (select more than one if necessary)?		
Mobile apps	4 (7)	6 (11)
Social media	12 (22)	17 (31)
Radio	—	—
Television	2 (4)	—
Newspapers	1 (2)	—
Web-based courses	8 (15)	12 (22)
Word of mouth	49 (89)	47 (85)
Other (please specify)	—	—

[a]Not applicable.

Discussion

Principal Findings

Our findings align with global trends suggesting an increasing prevalence of T2D with advancing age, likely influenced by hormonal and lifestyle factors [48,49]. Older individuals tend to have higher educational attainment and increased household income, although this correlation may not always hold true in rural areas. Studies conducted in Nigeria indicate that these factors significantly influence health-seeking behaviors [50,51], including preferences for hospital visits, community pharmacies, or traditional medicine practices. Moreover, our observations reveal that cultural differences based on ethnicity or state of origin do not significantly impact the scope of T2D care, emphasizing the need for nationwide health policies and interventions tailored to address regional disparities. These policies should promote holistic approaches that consider contextual factors influencing health-seeking behaviors [52]. Findings from our study also highlight several opportunities for context-specific health care solutions, such as implementing health literacy programs, developing culturally appropriate diabetes management guidelines, and advocating for policy reforms to ensure equitable health care provision across diverse sociodemographic groups.

Our study indicates that a significant portion (71/110, 64.5%) of respondents do not use any form of technology for managing their T2D, with a notable proportion citing cost, ignorance about technology use, preference for physical contact, and religious preferences as barriers to adopting technologies, such as

glucometers. This finding underscores the need for targeted educational campaigns to address misconceptions and enhance awareness about the benefits of technological tools, for example, large language models, such as Nigerian-owned "Awarri" in diabetes management [53-57]. This could be a significant opportunity for improvement by the Nigeria Digital in Health Initiative focused on transforming the digital health care landscape of Nigeria. Furthermore, the prevalence of mobile phone ownership (109/110, 99.9%) among respondents, predominantly Android phones with internet access, suggests an opportunity to leverage mobile platforms for delivering health information and interventions. Our study, similar to others [6,58,59], reveals that "*word-of-mouth*" is the most accessible source of T2D-related health information for respondents. This preference suggests a reliance on interpersonal networks and community-based information dissemination rather than formal health care channels. Integrating digital health practices and locally relevant health messaging into community networks could enhance the dissemination of digital health information and improve health and technology literacy among person with T2D.

Context-Specific Opportunities for Enhancing the Adoption of Digital Health Technologies

Key findings from this study indicate the need for technological interventions to support T2D selfcare and collaborative care. They are relevant to not only people living with T2D in Port Harcourt but also those in Nigeria as a whole. Opportunities for improvement are summarized in Textbox 2.

Textbox 2. Improvement opportunities.

Opportunities

1. The notable percentage of educated individuals with type 2 diabetes (T2D) represents a promising opportunity to facilitate data-driven approaches, digital health promotion, and co-design activities for a suitable T2D intervention. These can be leveraged and designed to suit the context, as general interactive and personalized resources can be understood by this audience. However, because most respondents were aged >50 years (as some studies have shown that digital literacy is lower in older demographics), they may have limited technological proficiency and could benefit from guidance, assistance, and support [60-62]. Bridging the digital divide by providing sustainable policies and digital health education could go a long way in promoting the use of digital health technologies as well as give users a positive perception about them.
2. Although most questionnaire respondents earned considerably above the average income by Nigerian standards, it may not be a generalizable experience. Considering the indigenous design and deployment of interventions would not only minimize the influx of Western and noncontextual interventions to this populace but also make them more affordable and accessible to Nigerian residents. This is because certain costs, such as incurred taxes, importation fees, distribution, and mark-up fees, would be avoided. In addition, fluctuations in the exchange rate would have minimal influence on domestic prices. This highlights a significant opportunity in the Nigerian market for indigenously designed interventions.
3. Most respondents managed their health based on information that they had learned from social media (presumably Facebook; 83/110, 75.5% general use), their physicians, family members, or other health care providers within their reach. Therefore, relevant interventions should be designed to be integrated with existing routine self-care and collaborative care practices and accessible technologies such as instant messengers and other mobile apps [40]. Given that 61.8% (68/110) of respondents cited "general practices" as a reason for using technology (mostly glucometers), there is a significant opportunity to encourage technology adoption and minimize resistance by integrating these efforts: creating awareness of digital health interventions, improving digital health policies, engaging with end users through design activities, and deploying Nigerian-owned products in general practices.
4. The preference for in-person interactions may be due to a myriad of factors, including cultural influences; expenses; misinformation; and a lack of exposure, awareness, and knowledge about digital interventions. Creating awareness about digital interventions during in-person interactions by health care practitioners; slowly integrating them into health care structures; and leveraging artificial intelligence, virtual reality, and other techniques might be a strategic way to encourage the use and adoption of digital health interventions in this research context [63,64].

Limitations

The limitations of this study are follows. First, we did not inquire about the number of people per household, nor did we consider the purchasing power parity of the Naira to estimate the adequacy of their household income. Our study did not account for the presence of other financially demanding factors or the influx of income through secondary activities. Such considerations would, in turn, have provided a more accurate perception of the affordability of relevant technological interventions. Second, the questionnaire did not include questions about suitable digital alternatives other than WhatsApp for specifically communicating with pharmacists. In addition, there were no questions related to understanding their precise digital health needs. We omitted these questions intentionally to gather initial insights from the questionnaire, which would then inform subsequent interviews involving more in-depth probing. Third, our approach to disseminating the questionnaires may have led to an unfair representation of people with T2D in Port Harcourt, resulting in a high percentage of educated individuals earning above the country's average. In-person questionnaires were likely administered to individuals who appeared literate and were easily accessible. The primary researcher received fewer responses from dissemination campaigns in open markets compared to dissemination campaigns in outpatient primary health diabetes centers, academic institutions, and churches. In addition, it is anticipated that individuals with limited education or restricted access to mobile phones, social media, or the internet would be less likely to express interest in the study on the internet. Fourth, unlike paper questionnaires that can be shared in person, respondents for automated WhatsApp questionnaires need to be recruited beforehand. While this offers the advantage of ensuring that potential participants understand the study and are genuinely interested in participating, it can also be a potentially stressful and expensive process. Researchers would need to learn about the automation of WhatsApp using suitable cloud communication platforms such as Twilio or infobip and run

targeted social media campaigns on designated pages. Considering that we spent approximately US $28 for our campaign and obtained only 27 valid responses, we assume that obtaining a significant amount of data would be costly and potentially stressful using this approach.

Conclusions

On the basis of the scarcity of research addressing sociodemographic factors influencing the use of technology for T2D care in our research context, this study highlights significant opportunities for fostering self-care and collaborative care using technology. This study unveils key relationships between contextual and epidemiological factors of the condition and how they influence health-seeking behaviors and care practices, which, in turn, would inform design decisions. We can assert that people with T2D residing in the city of Port Harcourt are receptive to technological interventions for managing their condition. Although the specific nature of this intervention remains uncertain, we are confident that, with the right approach, issues related to use, adoption, compliance, and referral will not pose significant challenges. We advocate for the replication of this study in similar Global South contexts, incorporating any overlooked questions, exploring alternative platforms to Twilio, and refining sampling or recruitment practices.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Logistic regression model showing the relationship between gender and the categorical frequency of hospital visits.
[PNG File , 244 KB - diabetes_v9i1e56756_app1.png]

Multimedia Appendix 2
Logistic regression model showing the relationship between gender and the categorical frequency of pharmacy visits.
[PNG File , 263 KB - diabetes_v9i1e56756_app2.png]

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Abbreviations

T2D: type 2 diabetes

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Personalized and Culturally Tailored Features of Mobile Apps for Gestational Diabetes Mellitus and Their Impact on Patient Self-Management: Scoping Review

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Abstract

Background: Gestational diabetes mellitus (GDM) is an increasingly common high-risk pregnancy condition requiring intensive daily self-management, placing the burden of care directly on the patient. Understanding personal and cultural differences among patients is critical for delivering optimal support for GDM self-management, particularly in high-risk populations. Although mobile apps for GDM self-management are being used, limited research has been done on the personalized and culturally tailored features of these apps and their impact on patient self-management.

Objective: This scoping review aims to explore the extent to which published studies report the integration and effectiveness of personalized and culturally tailored features in GDM mobile apps for patient self-management support.

Methods: We examined English-language peer-reviewed articles published between October 2016 and May 2023 from PubMed, CINAHL, PsycINFO, ClinicalTrials.gov, Proquest Research Library, and Google Scholar using search terms related to digital tools, diabetes, pregnancy, and cultural tailoring. We reviewed eligible articles and extracted data using the Arskey and O'Malley methodological framework.

Results: Our search yielded a total of 1772 articles after the removal of duplicates and 158 articles for full-text review. A total of 21 articles that researched 15 GDM mobile apps were selected for data extraction. Our results demonstrated the stark contrast between the number of GDM mobile apps with personalized features for the individual user (all 15 mobile apps) and those culturally tailored for a specific population (only 3 of the 15 mobile apps). Our findings showed that GDM mobile apps with personalized and culturally tailored features were perceived to be useful to patients and had the potential to improve patients' adherence to glycemic control and nutrition plans.

Conclusions: There is a strong need for increased research and development to foster the implementation of personalized and culturally tailored features in GDM mobile apps for self-management that cater to patients from diverse backgrounds and ethnicities. Personalized and culturally tailored features have the potential to serve the unique needs of patients more efficiently and effectively than generic features alone; however, the impacts of such features still need to be adequately studied. Recommendations for future research include examining the cultural needs of different ethnicities within the increasingly diverse US population in the context of GDM self-management, conducting participatory-based research with these groups, and designing human-centered mobile health solutions for both patients and providers.

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KEYWORDS

gestational diabetes; pregnancy; cultural tailoring; cultural adaptation; personalization; maternal health; mobile health; mHealth; smartphone; mobile app; mobile phone; self management; social determinants of health

Introduction

Gestational diabetes mellitus (GDM) is an increasingly common high-risk condition in pregnancy that creates potential short- and long-term complications for the mother-child dyad [1,2]. It is defined as any degree of glucose intolerance that begins or is first recognized during pregnancy and resolves postpartum [3]. GDM confers maternal and fetal risks related to the degree of hyperglycemia as well as chronic complications and

comorbidities of the patient [4]. Specific risks to women with prepregnancy diabetes and diabetes developed in pregnancy include preeclampsia, preterm delivery, fetal anomalies (ie, intrauterine growth restriction, small for gestational age, macrosomia, and morphologic anomalies), neonatal hypoglycemia, hyperbilirubinemia, and neonatal respiratory distress syndrome, among others [5,6]. In addition, diabetes in pregnancy may increase the risk of obesity [7], hypertension, and type 2 diabetes in the mother and her offspring later in life [8-10].

Although there is an increasing number of women entering pregnancy with preexisting diabetes, paralleling the global obesity epidemic, there is also concurrently a dramatic increase in the reported rates of GDM [6]. In the United States, ethnic minority women (including Native American, Asian, Hispanic, Latino, and Black women) and women of lower socioeconomic status are often disproportionately affected by both preexisting diabetes and GDM [11-13]. Rates of GDM among minorities have increased in the past 20 years by 10%-100%, making minorities twice as likely as White women to develop GDM [14].

Further, ethnic minority groups in the United States, which are expected to increase from 41.8% of the population in 2019 to 49.3% by 2045 [15], often have higher rates of diabetes-associated morbidity and mortality [16]. Racial and ethnic differences in GDM prevalence and GDM-related adverse perinatal outcomes are well-documented [17]. Even though the prevalence of GDM is higher among Hispanic and Asian women, non-Hispanic Black women have the highest rate of GDM-related adverse outcomes, including preeclampsia, preterm delivery, and neonatal hypoglycemia [18]. Substantial racial disparities in the emergence of type 2 diabetes after GDM show a 4-fold increased risk among Black individuals and 3-fold increased risk among Hispanic and South and Southeast Asian individuals relative to White individuals [19]. Although non-Hispanic Black women have a lower risk of developing GDM during pregnancy, they are 10 times more likely to develop type 2 diabetes following birth [20].

After a GDM diagnosis, a patient is responsible for carrying out complex, daily self-management tasks with close monitoring by a multidisciplinary care team focused on maintaining optimal glycemic control to avoid hyperglycemia, carbohydrate intolerance, and other complications [21]. With proper care and support, approximately 75%-90% of GDM cases can be managed with lifestyle adjustments alone, avoiding the need for pharmacological interventions in the form of medications and insulin [22]. Women from racial and ethnic minorities and vulnerable populations, who already experience greater rates of preterm birth, stillbirth, and maternal mortality, often face additional barriers to GDM self-management, such as language, health literacy, lack of educational materials, and inability to meet the requirements of their nutrition plans [23].

The use of mobile apps for GDM self-management is gaining traction in the United States and globally, with new software entering the market at an increased rate. Despite this, addressing the unique needs of diverse GDM populations is not receiving enough attention. With the rapid growth of mobile health (mHealth) technologies, there is an opportunity to enhance self-management strategies for these women. Features for mHealth, such as personalization and cultural tailoring, are needed to create sustainable behavior changes necessary for successful GDM self-management.

Research that defines personalization and cultural tailoring as 2 distinct concepts and explores their impacts on GDM self-management will help refine and optimize intervention models [24]. Personalization caters to users on an individual level, not at the group, community, or population level [25]. In the context of GDM mobile app design, personalization can be broadly defined as the inclusion of features that customize a user's experience based on health needs, engagement preferences, accepted forms of feedback and communication, and other individualized features (eg, goal setting and appointment reminders). Patient data collected by the app informs treatment plans related to evolving health status (ie, maternal age, gestational age, maternal medical history, comorbidities, medications, and lifestyle) and can be personalized to enhance the user's self-management and the care team's ability to provide feedback on key metrics including blood glucose levels, nutrition plans, and physical activity.

Cultural tailoring (sometimes called cultural adaptation) refers to the adaptation of the intervention design, materials, and other components to reflect the cultural needs and preferences of the priority population. This process requires an understanding of the population's values, attitudes, history, and other influences on behavior. Cultural tailoring is intended to maximize rates of participant recruitment for studies, increase rates of completion or adherence, enhance accuracy in language and understanding in communications, and increase positive outcomes from treatment [26].

Barerra et al [27] identified 2 levels of cultural adaptations: surface structure adaptation and deep structure adaption. Surface structure features include: bilingual and bicultural materials, language translation or back-translation of materials, inclusion of ethnic lifestyle features (eg, food and music), use of community health workers to incorporate traditional healing practices (eg, acupuncture), incorporation of culturally familiar formats and activities (eg, social support structures), and inclusion of same race or ethnicity role models. Deep structure adaptation refers to the incorporation of 1 or more components of cultural values in intervention design or implementation, involvement of the family and possibly peers in the intervention and decision making, adjustment of material to literacy levels of the participants, and use of social support and networks [27]. Culturally adapted interventions have been shown to be effective in promoting health education, healthy eating, and physical activity, specifically among ethnic minorities and underserved populations [28,29].

To the best of our knowledge, this is the first review to examine personalization and cultural tailoring in GDM mobile apps with the goals of: (1) determining the extent to which GDM mobile apps used in published studies provide personalized and culturally tailored features for self-management support for patients and (2) assessing the impact of these GDM mobile apps

with personalized and culturally tailored features on patient self-management.

Methods

Study Design

Overview

We followed Arksey and O'Malley's 6-step methodological framework [30] to conduct this scoping review: (1) clarify the research question, (2) identify relevant studies, (3) select relevant studies, (4) chart the data, and (5) collate, summarize, and report results. We did not include the optional sixth step, a consultation exercise with stakeholders, because we did not engage stakeholders in any stages of this review. Reporting techniques were guided by the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist [31].

Framework Step 1: Clarifying the Research Question

The two research questions for this scoping review were as follows:

1. Do the GDM mobile apps that were utilized in published studies offer patients personalized and culturally tailored features for GDM self-management?
2. Do the personalized and culturally tailored features have a positive effect on patient self-management?

Framework Step 2: Identifying Relevant Studies

To comprehensively identify relevant studies in recent literature, this review conducted search strategies in PubMed, Scopus, CINAHL, PsycINFO, ClinicalTrials.gov, Proquest Research Library, and Google Scholar. English language studies published between October 2016 to May 2023 were eligible for inclusion in the review. We limited our searches to studies published in the last 7 years because software technology evolves at a rapid rate, and we wanted to ensure that the apps were all at a similar level of technological advancement. With Google Scholar, we limited the search to include the top 200 articles ranked by relevance. Our search strategy, developed under the guidance of a research librarian, included "Diabetes, Gestational"[MeSH] OR "Pregnancy in Diabetics"[MeSH] OR "Pregnancy"[MeSH] OR "Postnatal Care"[MeSH] OR "Prenatal Care"[MeSH] OR "Maternal Health Services"[MeSH] OR "Women's Health"[MeSH] OR "Women's Health Services"[MeSH] AND "Diabetes Mellitus"[MeSH] OR "Diabetes Insipidus"[MeSH] OR "Diabetes Mellitus, Type 2"[MeSH] OR "Diabetes Mellitus, Type 1"[MeSH] OR "Blood Glucose/metabolism"[MeSH] OR "Blood Glucose Self-Monitoring"[MeSH] OR "Glycemic Control"[MeSH] AND "Mobile Applications"[MeSH] OR "mobile application*"[tw] OR "mobile app"[tw] OR "mobile apps"[tw] OR "mobile technolog*"[tw] OR "mobile healthcare"[tw] OR "mHealth"[tw] OR "Smartphone"[MeSH]) AND ("Culturally Appropriate Technology"[MeSH] OR "Cultural Characteristics"[MeSH] OR "cultural tailoring" OR "cultural factors" OR "cultural barriers" OR "Culture"[MeSH] OR "Cultural diversity"[tw] OR "Cultural deprivation"[tw] OR "Cultural competency"[tw] OR "Cultural characte*"[tw] OR "cultural sensitivity"[tw] OR "cultural concordance"[tw] OR "Multilingualism"[MeSH] OR sociocultural OR "Hispanic or Latino"[MeSH] OR "Black or African American"[MeSH] OR "Asian American Native Hawaiian and Pacific Islander"[MeSH] OR "American Indian or Alaska Native"[MeSH] OR "Attitude to Computers"[MeSH] OR "Health Literacy"[MeSH] OR "Digital literacy"[tw] OR "Health Liter*"[tw] OR "health knowledge"[tw] OR "health understanding"[tw] OR "Health Knowledge, Attitudes, Practice"[MeSH] OR "Patient Education as Topic"[MeSH] OR "Patient Acceptance of Health Care"[MeSH] OR "Treatment Adherence and Compliance"[MeSH] OR "Patient Compliance"[MeSH] OR "methods"[subheading] OR "psychology"[subheading] OR "education"[subheading] OR "Communication"[MeSH].

Framework Step 3: Study Selection

We used an iterative process to develop inclusion and exclusion criteria to identify articles and research studies relevant to our research questions. Our inclusion criteria for articles were: (1) the study involved a mobile app, and (2) the mobile app used in the study was explicitly designed for GDM self-management. For example, studies that used mainstream mobile apps (eg, WhatsApp or WeChat) to support GDM self-management were excluded from the study. We excluded studies that: (1) did not provide a detailed description of app features, (2) were not yet published or provided insufficient details about the study (eg, poster presentations, unpublished ClinicalTrials.gov studies), (3) were classified as reviews (eg, scoping reviews, systematic reviews, meta-analysis, and editorials), and (4) were not written in English. Two authors (CJ and YC) reviewed the full text of each article independently. A third reviewer (RJ) reviewed the included articles to ensure they met the eligibility criteria.

Framework Step 4: Charting the Data

We created an Excel (Microsoft Corp) file to chart, collate, and summarize the results. We recorded both characteristics of the studies and specific information pertaining to the 2 research questions, including data on author(s), year of publication, country, study design, participants, app name, personalization features, culturally tailored features, and the app's impact on GDM self-management.

Framework Step 5: Collating, Summarizing, and Analyzing the Results

The final process involved collating, summarizing, and analyzing the data and interpreting and reporting the results. The first and second authors independently examined the Excel file for accuracy and to identify common themes. We compared the various features of the mobile apps and the impacts they had on patient self-management in Multimedia Appendix 1. The 15 mobile apps included: Habits-GDM (Singapore) [32,33], SweetMama (United States) [34,35], Mother (Australia) [36], mAPP (Korea) [37], Pregnant+ (Norway) [38,39], myDiabby (France) [40], Dnurse (China) [41], GlucoseBuddy (United States) [42], GDm-Health (United Kingdom) [43], MobiGuide (Spain) [44,45], Stay-Active (United Kingdom) [46], and 4 apps that did not have names, which we refer to as App #1 (Korea) [47], App #2 (Korea) [48], App #3 (Malaysia) [49], and App #4 (New Zealand) [50]. Study characteristics and features of personalization and cultural tailoring in GDM mobile apps

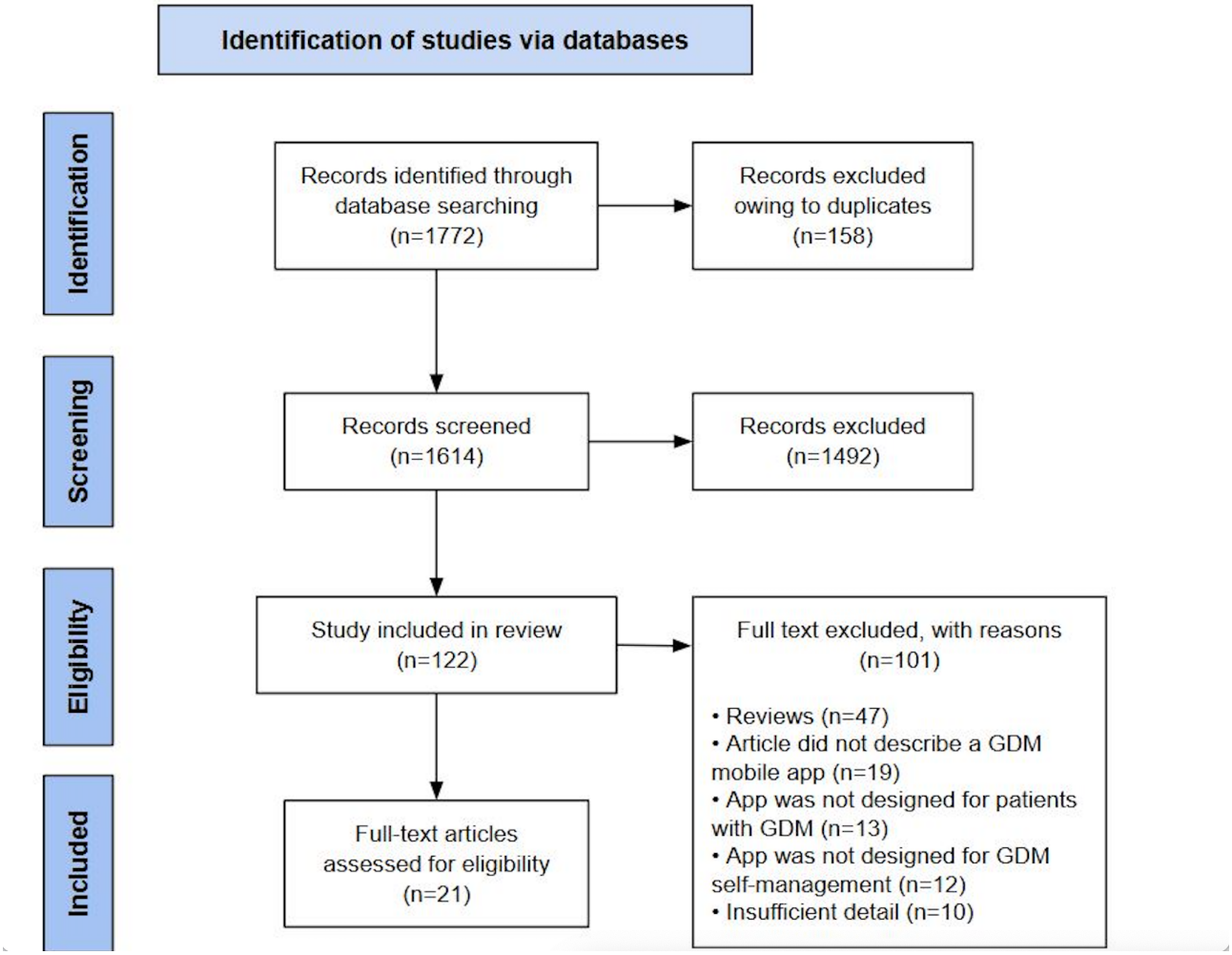
incorporated study design information, stated aims, and lists of personalized and culturally tailored features. The data were analyzed for common themes.

Results

Overview of the Screening Results

The literature searches yielded 1772 records. After removing duplicates, 1614 records were retained for title and abstract review. A total of 122 full-text studies were assessed for eligibility. After completing the study selection process, 21 studies were included in the review, as demonstrated in Figure 1.

Figure 1. PRISMA flowchart. GDM: gestational diabetes mellitus; PRISMA: Preferred Reporting Items for Systematic Meta-Analysis.



The first research question was to determine if and to what extent mobile apps offer patients personalized and culturally tailored features for GDM self-management. Key themes for personalized app features included: live chat (ie, direct communication with a provider to answer patient questions in real time), messaging (eg, educational tips, motivational messages, and reminders, as well as messages to patients when a blood glucose reading was too high), glycemic control, nutrition support (ie, personalized nutritional advice from care teams based on patient logging data such as blood glucose levels), physical activity, medication support, educational materials, and postpartum care. Our findings showed that all 15 mobile apps had some element of personalization, but only 3 of 15 apps included elements of culturally tailored features: Habits-GDM, SweetMama, and Pregnant+.

The second question examined if these GDM mobile apps with personalized and culturally tailored features had a positive effect on patient self-management. Key themes for culturally tailored mobile app features included educational materials, nutritional support (eg, nutritional information adapted or tailored to align with a specific cultural group, including inclusion of an ethnic-focused food database for logging), language, and health literacy level. The results of the 7 studies using the 3 personalized and culturally tailored GDM mobile apps (Multimedia Appendix 2) showed that personalization and cultural tailoring have the potential to positively impact GDM self-management. When combined with personalization, both culturally tailored educational material and nutrition support showed an impact on increased patient motivation for self-management of blood glucose values, while culturally tailored nutrition support showed a positive impact on improved

glycemic control and neonatal outcomes, as well as increased patient motivation and confidence in self-managing GDM. Adjusted health literacy levels showed increased utilization and ease of use, improved user satisfaction, and greater perceived usefulness. The effects of language tailoring were not specifically studied in the articles; therefore, the authors could not draw conclusions about this factor.

Extent of Personalized GDM Mobile App Features

All 15 GDM mobile apps in this scoping review had personalized features, which were grouped in 8 categories. Our results showed that 4 apps offered live chat and all 15 offered patient SMS text messaging on some level. Under the category of glycemic control, all the apps except SweetMama and Stay-Active offered feedback on patient blood glucose logging. In addition, 12 apps offered personalized nutrition support, such as dietary information based on eating preferences, meal logging, and feedback on logging in the form of in-app charts. Of the 15 apps, 11 offered support or tips for physical activity, and 7 offered medication support such as reminders or assistance with dosing insulin. All the apps except MyDiabby, MobiGuide, App #3, and App #4 offered personalized educational materials, such as the ability to choose GDM pregnancy or postpartum messages and what time of day to receive them. There were 4 apps that offered postpartum care tips (eg, breastfeeding encouragement and postpartum weight loss assistance) and encouraged the 6-week postpartum oral glucose tolerance test (OGTT). Table 1 illustrates the 8 categories of personalized mobile app features studied in this review.

Table . Personalized features in mobile apps for GDM.[a]

Mobile app	Personalized mobile app features							
	Live chat	SMS text messages	Glycemic control	Nutrition support	Physical activity	Medication support	Education materials	Postpartum care
Habits-GDM		√	√	√	√		√	
SweetMama		√					√	
Pregnant+		√	√	√	√		√	√
Mother	√	√	√	√	√		√	
mAPP		√	√	√	√	√	√	√
myDiabby		√	√	√		√		
Dnurse	√	√	√	√	√	√	√	
GlucoseBuddy	√	√	√	√	√	√	√	√
GDm-Health		√	√	√	√	√	√	
MobiGuide		√	√					
Stay-Active	√	√			√		√	
App #1 [47]		√	√	√	√	√	√	√
App #2 [48]		√	√	√	√		√	
App #3 [49]		√	√	√				
App #4 [50]		√	√	√	√	√		

[a]GDM: gestational diabetes mellitus.

Extent of Culturally Tailored GDM Mobile App Features

Examining the 3 GDM mobile apps with culturally tailored features showed that 2 apps (Pregnant+ and SweetMama) offered culturally tailored educational materials (ie, self-care educational guidance) and all 3 apps (Pregnant+, SweetMama, and Habits-GDM) offered culturally tailored nutrition support (ie, dietary treatment of GDM for optimal glycemic control). Cultural tailoring by language (patient's ability to select a preferred language) and health literacy level (the degree to which individuals can find, understand, and use information and services to inform health-related decisions and actions for themselves and others) was only available in SweetMama. These results are laid out in Table 2.

Table . Mobile apps for GDM that include culturally tailored educational materials, nutrition support, language, and health literacy levels.[a]

Mobile app	Culturally tailored mobile app features with surface and deep adaptations			
	Culturally tailored educational materials (surface)	Culturally tailored nutrition support (surface)	Culturally tailored language (surface)	Culturally tailored health literacy levels (deep)
Pregnant+	√	√	√	
SweetMama	√	√		√
Habits-GDM		√		

[a]GDM: gestational diabetes mellitus.

Extent of Surface and Deep Structure Adaptations of Culturally Tailored Features

According to Barerra's adaptation model, the 3 categories of culturally tailored app featured in this review can all be classified as surface level. They included bilingual materials (Pregnant+); ethnic lifestyle features, such as nutrition support (Pregnant+, SweetMama, and Habits-GDM); and culturally familiar formats in educational materials (Pregnant+ and SweetMama). The only app that included deep structure adaptation including cultural health literacy levels was SweetMama.

Impacts of Culturally Tailored Educational Materials and Personalization on Self-Management

Pregnant+

Culturally tailored educational materials in this mobile app designed in Norway included information on GDM, physical activity, nutrition, and breastfeeding in 3 different languages: Norwegian, Urdu, and Somali. The physical activity information in Pregnant+ included the benefits of being physically active and examples of healthy activities. Nutrition support included materials on ethnic foods, while general educational materials discussed the importance of check-ups during pregnancy and postpartum, as well as the advantages of breastfeeding. The personalized features in Pregnant+ included messaging in the form of personalized feedback on glycemic control (users received a green smiley face indicating a normal blood glucose value and a red smiley face indicating a high value) and physical activity (users recorded personal goals related to active living), as well as educational materials tailored to pregnancy and the postpartum period. Skar et al [51] conducted a qualitative analysis using semistructured interviews with 17 participants from a previous Pregnant+ randomized control study (RCT) to assess the app users' experience. Results from these interviews showed that Pregnant+ was useful to patients for controlling blood glucose levels and increasing confidence and motivation in overall GDM self-management.

SweetMama

Culturally tailored educational materials in this mobile app designed in the United States included educational resources and SMS text messaging suitable for various health literacy levels. Personalized features included bidirectional messaging with providers through an in-app messaging center, individualized goals, and educational materials tailored to gestational age that were designed to promote health knowledge. Yee et al [35] conducted a study using focus groups with patients and providers to solicit feedback on the app. A total of 16 low-income patients diagnosed with GDM or type 2 diabetes and 29 health care providers with experience treating or educating patients with GDM participated. The qualitative assessment revealed that both patients and providers were satisfied with the information provided in SweetMama. Specifically, participants expressed that the culturally tailored content was easy to understand, practical, and helpful. Content delivery in the form of short text messages (promoting one tip at a time) was seen by patients as an effective way to present information.

Impacts of Culturally Tailored Nutrition Support and Personalization on Self-Management

Pregnant+

Culturally tailored nutrition support in this Norwegian app included information on healthy diets and recommendations for healthy drinks. A link to the Norwegian Diabetes Foundation was provided to give women access to recipes and information related to a GDM pregnancy. A Healthy Diet Score (HDS-P+) was used to assess healthy eating habits based on dietary logging. Borgen et al [39] conducted an RCT with 238 patients to examine the effect of Pregnant+ on the 2-hour postpartum OGTT. All participants in the study received the standard care and the intervention group was given access to Pregnant+. Primary analysis showed no significant difference in 2-hour OGTT at 3 months postpartum between the intervention and control groups (6.7 mmol/L vs 6.0 mmol/L, P=.54). Secondary analysis of HDS-P+ scores showed an overall improvement in patients' healthy eating behaviors from 40.4 at baseline to 56.1 for the control group and 55.34 for the intervention group at the 36-week follow-up. However, no significant difference in average HDS-P+ scores (55.3 vs 56.1, P=.65) was observed. Additionally, there were variations in how patients perceived the culturally tailored dietary information. Some felt it was easy to follow, while others felt it was difficult to maintain decreased amounts of carbohydrates, particularly related to portion sizes for rice and pasta.

Habits-GDM

Culturally tailored nutrition support in the Habits-GDM app, designed in Singapore, included an ethnic food database adapted to incorporate common Singaporean food derived from Chinese, Malay, Indian, and Western cultures. It also provided 12 "bite-sized" interactive lessons on nutrition and physical activity, as well as comprehensive tracking tools for self-monitoring of blood glucose levels, diet, physical activity, and weight gain. The personalized features of this mobile app included messaging

in the form of personalized feedback on glycemic control (automatic messages in response to high blood glucose readings), nutrition support (meal logging), physical activity (tracking the number of daily steps taken using the participants' built-in phone pedometers), and a messaging platform that allowed users to ask questions, schedule appointments, and request blood glucose testing strips from health care professionals. Yew et al [32] conducted an RCT with 340 patients with GDM to evaluate Habits-GDM's efficacy in reducing excessive gestational weight gain. Although no significant difference was observed between participants using the app plus usual care versus those receiving usual care alone, secondary analysis revealed that Habits-GDM led to improvements in glycemic control and neonatal outcomes. Participants using Habits-GDM plus usual care achieved significantly lower average blood glucose readings (mean 5.40, SD 0.53 vs mean 5.54, SD 0.53, *P*=.01) and experienced fewer overall neonatal complications (38.1% vs 53.7%, *P*=.006) when compared to those receiving usual care alone.

In another study, Surendran et al [33] conducted a quantitative analysis of usage data and semistructured interviews with 14 participants from the Habits-GDM RCT by Yew et al [32]. Results showed that diet tracking was the least used app feature, with participants logging only an average of 0.88 meals per week. A majority of participants (12/14) reported negative experiences with diet tracking due to issues with the food database around the limited representation of ethnic food items. Other personalized app features, including the messaging platform, were perceived as useful for GDM self-management by the participants.

SweetMama

Results from a focus group by Yee et al [35] showed that both patients and providers (6/16 patients; 7/29 providers) desired more information on nutrition education and support, including the glycemic index of food items, dietary recommendations for patients, and recipes. Based on these findings, a revised version of the mobile app was created with a library component that included a recipe repository and educational materials from culturally tailored diabetes-specific sources (eg, the American Diabetes Association). The study did not collect any feedback on the SweetMama app with the revised nutrition features.

Impact of Culturally Tailored Language on Self-Management (Pregnant+)

This was the only mobile app that offered culturally tailored language options for users: Norwegian, Urdu, and Somali. The study's authors did not investigate the impact of culturally tailored language on GDM self-management in any of the 3 studies conducted using this app; therefore, the impact of language could not be determined.

Impact of Culturally Tailored Health Literacy Levels and Personalization on Self-Management (SweetMama)

The study participants included 22 low-income pregnant women with GDM or type 2 diabetes. Steinberg et al [34] analyzed app data from a 2-week usability assessment to examine user health and behavioral characteristics including diabetes type, electronic health literacy (computer literacy related to health information processing), general health literacy (ability to obtain and process health information), patient activation (patient engagement in the health care process), and diabetes self-efficacy (psychosocial self-efficacy of individuals with diabetes using the Diabetes Empowerment Scale–Short Form). Results revealed participants with GDM had higher average minutes of use per session (mean 4.0, SD 2.9 minutes vs mean 2.5, SD 0.9 minutes) and total duration of use (mean 28.1, SD 17.0 minutes vs mean 18.2, SD 12.3 minutes) compared to pregnant patients with type 2 diabetes. Participants with greater electronic health literacy, lower patient activation, and higher diabetes self-efficacy also reported greater total duration of use. Study participants expressed that the personalized messaging with content based on gestational age was practical and helpful. Additionally, content delivered in the form of short text messages (one tip at a time) was seen by users as an effective way to present information, improve user satisfaction, and enhance the perceived usefulness of the information received.

Discussion

Impacts of Personalized and Cultural Tailoring Features of GDM Mobile Apps

The use of mobile apps to assist and empower patients to self-manage GDM has shown potential benefits over the traditional model of care that is still in use today, such as logging with paper and pen and communication with doctors and care teams primarily during in-person prenatal and postpartum visits. Despite advances in mobile app technology, patients continue to struggle with daily GDM self-management protocols due to cultural and language barriers, inappropriate health literacy levels, and lack of access to health care providers or the evidence-based interventions they need. One important strategy to overcome some of these hurdles is to personalize and culturally tailor mobile apps for GDM to serve specific racial and ethnic minority groups and vulnerable populations.

This scoping review highlights how important it is to consider individual patient needs as well as the broader context and nuances of the patient's social and cultural environment. Results demonstrated that personalized app features were far more common than culturally tailored features and both types of features were useful in self-managing blood glucose levels, thereby increasing confidence, motivation, and understanding.

Challenges of Culturally Tailoring Features in GDM Mobile Apps

Ultimately, the goal of GDM mobile apps should be to facilitate medical care teams, family, community, and peers to empower patients to produce positive outcomes. The use of cultural tailoring has the ability to leverage cultural strengths by fostering a sense of belonging and community as a means to overcome cultural barriers, stigmas, health disparities, and inequities. Recognizing and respecting cultural identities, languages, ethnic foods, values, and customs, combined with providing culturally appropriate health education, results in patients more likely to feel supported, understood, and motivated, which can lead to increased adoption and sustainability of healthy behaviors during pregnancy and the postpartum period.

Addressing cultural tailoring in the research and development of GDM mobile apps requires raising cultural awareness and knowledge, providing training and education to both health care professionals and IT developers, and allocating the financial and human resources needed to cover additional costs, such as hiring specialists on research teams. Other factors include ensuring diversity among the health care providers who are administering the mHealth intervention and using evidence-based and applicable guidelines to get feedback and tweak features as needed. With these requirements often being a challenge to meet, or completely unattainable, mHealth interventions and programs for self-managing GDM understandably rely on standardized, nontailored approaches and universal guidelines, which do not account for patient diversity, often leading to overlooked or misunderstood needs.

Implications for Future Research and Development

As this review demonstrates, research to effectively measure the impact of cultural tailoring in mHealth is tricky. Joo et al [15] pointed out areas of difficulty researchers might encounter when quantifying the impact of cultural tailoring, including unclear guidelines for cultural tailoring in general; intervention implementation (eg, inadequate training staff, language barriers, cultural competency barriers); low attention and retention rates of participants in research settings; defining measures (eg, process, dosage, fidelity); and defining how to measure the evaluation of care in comparison to standard care [26]. Looking at the study designs of the culturally tailored apps in this review, only 1, Habits-GDM, specifically mentioned cultural tailoring in its study aims.

To advance the understanding of patient engagement and efficacy, future research should include components of Barrera's surface structure and deep structure adaptations developed in iterative stages along with metrics to determine the effectiveness of these adaptations relative to their original versions. A close collaboration should be established between researchers and developers using a human-centered design model, defined as a sociotechnical approach to innovation that considers human activities in a social environment.

Multifaceted social and structural influences, which can intricately shape the course of GDM and patient health outcomes, should also be addressed. In the United States, these multidimensional influences are commonly referred to as social determinants of health, encompassing access to housing, food, education, work, and health care. Structural determinants of health (eg, policies, economic systems, and social hierarchies, such as racism) invariably impact social determinants of health, creating health disparities that are particularly pronounced among racial and ethnic minority groups. Adequately addressing these upstream determinants of health can directly impact personal agency downstream, including the ability to self-manage GDM.

A study by Gonzales et al [52] concluded that co-design with intended users, even small sample sizes of minority populations (often described as participatory-based research), could address and find solutions for challenges, such as barriers relating to digital and health literacy, language, nutrition, education, adherence, trust, and internet access and devices. Inability to access the internet is commonly referred to as the racial digital divide in the United States, which persists despite some advances in access to wireless infrastructure. According to a 2021 Brookings Institution report, 15%-24% of American lack any sort of broadband connection to the internet, limiting their ability to use mHealth technology. This digital divide increases with income disparities in both rural and urban areas [53].

Using an established co-design framework, such as the PRECEDE-PROCEED model, can effectively guide the participatory process of intervention design [54]. This involves conducting formative research, such as focus group discussions and in-depth interviews, with stakeholders throughout the design process and focusing on the constructs of predisposing (eg, health literacy, access to the internet), reinforcing (eg, motivational messages and rewards), and enabling (eg, access to evidence-based content) factors that play a critical role in influencing behavior change among target users. Building iteratively based on feedback from patients and their providers, and any other stakeholders, can improve feasibility and usability, digital literacy, and trust among users. In this review, 2 app studies, Pregnant+ and SweetMama, specifically focused on using an iterative process of patient and provider feedback to dictate design. The bottom line is that even if a mobile app provides high-quality, evidence-based content, the value of an intervention is limited if the information does not adequately match and address the usability, accessibility, readability, engagement, and health literacy needs of the target audience [55].

Strengths and Limitations

The main strength of this scoping study lies in its ability to clearly and comprehensively map out and analyze the field of research on mobile apps for GDM self-management, particularly their inclusion of personalized and culturally tailored app features. Given that cultural tailoring is not widely incorporated into GDM mobile apps, this work has the potential to significantly inform future research and development in this field. By presenting a clear distinction between personalization and cultural tailoring, this study provides a valuable methodological review that can guide future research of mobile apps.

There were numerous limitations to this study. The study's inclusion of only English-language articles may have overlooked GDM research in other languages; however, the review did include mobile apps from 11 countries. There may also be GDM mobile apps in existence that are culturally tailored but that have yet to be used in formal research, or the research may not be published, or the app may currently be in the development process. Although we strove to capture as many articles as possible, we limited ourselves to 5 databases and looked at a 5-year period starting from October 2016 to May 2023 to ensure that the technology being used was not outdated. This may have caused some articles on this topic to be omitted. Recruitment of minorities, ethnic communities, or marginalized groups has been known to be difficult in research, which may have limited the power to detect statistically significant results in certain studies.

The descriptive nature of this review precludes any conclusions about causality, while the absence of a meta-analysis means that findings were not quantitatively synthesized, limiting the ability to generalize results. Future research should address these limitations by incorporating a more detailed analysis and considering the inclusion of non–English language studies and gray literature. Finally, this scoping study concentrated solely on GDM self-management related to the use of mobile apps, a narrow scope that excluded other social and structural influences that can impact a patient's health and health care.

Conclusions

There is a strong need for increased research and development to foster the implementation of personalized and culturally tailored features in GDM mobile apps for self-management designed for patients from diverse backgrounds and ethnicities. Personalized and culturally tailored features have the potential to serve the unique needs of patients more efficiently and effectively than generic features alone. However, their impacts have not been adequately studied. Recommendations for future research include studying the cultural needs of different ethnicities in the context of GDM self-management (particularly in the increasingly diverse US population), conducting participatory-based research with these groups, and designing human-centered mobile app solutions to serve both patients and providers.

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Data Availability

The data supporting the findings of this study will be made available by the corresponding authors upon reasonable request. Requests will be reviewed and, if deemed appropriate, data will be shared in accordance with ethical and privacy considerations.

Authors' Contributions

All authors conceptualized and designed the study. CJ and YC researched and reviewed all the articles, analyzed the findings, and drafted the paper along with the tables. They guided all revisions of the paper. RJ was part of the article review process and edited versions of the paper. EB helped with the tables and editing process. KC assisted with the study design. TM made significant editorial contributions to the paper at all stages. All authors read and approved the final paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Study characteristics and features of cultural tailoring and personalization in gestational diabetes mellitus mobile app.
[DOCX File, 24 KB - diabetes_v9i1e58327_app1.docx]

Multimedia Appendix 2
Presentation of 3 mobile apps for gestational diabetes mellitus used in 7 studies including app name, study and study design, personalized and culturally tailored features, and the impact of gestational diabetes mellitus self-management.
[DOCX File, 18 KB - diabetes_v9i1e58327_app2.docx]

Checklist 1
PRISMA-ScR checklist.
[DOCX File, 24 KB - diabetes_v9i1e58327_app3.docx]

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Abbreviations

GDM: gestational diabetes mellitus
HDS-P+: Healthy Diet Score
mHealth: mobile health
OGTT: oral glucose tolerance test
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
RCT: randomized controlled trial

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Original Paper

Scientific Production Dynamics in mHealth for Diabetes: Scientometric Analysis

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Abstract

Background: The widespread use of mobile technologies in health care (mobile health; mHealth) has facilitated disease management, especially for chronic illnesses such as diabetes. mHealth for diabetes is an attractive alternative to reduce costs and overcome geographical and temporal barriers to improve patients' conditions.

Objective: This study aims to reveal the dynamics of scientific publications on mHealth for diabetes to gain insights into who are the most prominent authors, countries, institutions, and journals and what are the most cited documents and current hot spots.

Methods: A scientometric analysis based on a competitive technology intelligence methodology was conducted. An innovative 8-step methodology supported by experts was executed considering scientific documents published between 1998 and 2021 in the Science Citation Index Expanded database. Publication language, publication output characteristics, journals, countries and institutions, authors, and most cited and most impactful articles were identified.

Results: The insights obtained show that a total of 1574 scientific articles were published by 7922 authors from 90 countries, with an average of 15 (SD 38) citations and 6.5 (SD 4.4) authors per article. These documents were published in 491 journals and 92 Web of Science categories. The most productive country was the United States, followed by the United Kingdom, China, Australia, and South Korea, and the top 3 most productive institutions came from the United States, whereas the top 3 most cited articles were published in 2016, 2009, and 2017 and the top 3 most impactful articles were published in 2016 and 2017.

Conclusions: This approach provides a comprehensive knowledge panorama of research productivity in mHealth for diabetes, identifying new insights and opportunities for research and development and innovation, including collaboration with other entities, new areas of specialization, and human resource development. The findings obtained are useful for decision-making in policy planning, resource allocation, and identification of research opportunities, benefiting researchers, health professionals, and decision makers in their efforts to make significant contributions to the advancement of diabetes science.

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KEYWORDS

competitive technology intelligence; diabetes; digital health care; mobile health; mHealth; scientometrics; mobile phone

Introduction

Background

The number of smartphone users worldwide has been on the rise for years. In 2021, there were 6259 million smartphone users, and this is expected to grow to 7690 million by 2027 [1]. This type of mobile technology requires specific software, commonly referred to as *apps*, according to the features and operating systems (Android or iOS) of smartphones and tablets. These apps are available for download from app stores such as

Google Play Store, Apple App Store, and Amazon Appstore. Worldwide, the number of available apps has experienced an upward trend over the years. By the first quarter of 2022, the Google Play Store had approximately 3.3 million available apps, whereas Apple's App Store had approximately 2.11 million [2]. In 2021, a total of 230 billion mobile apps were downloaded, with >US $613 billion in revenue expected by 2025 [3]. In recent years, health and fitness apps have become increasingly popular. Between the third quarter of 2019 and the second quarter of 2020, approximately 67,748 health and fitness apps were released worldwide [4]. In the third quarter of 2020, apps in the health, fitness, and nutrition category were used by 29.4% of global internet users, making it the ninth most popular app category worldwide [5]. Health care apps improve the delivery of care in a variety of ways, such as symptom assessment, disease information, and treatment progress [6].

The widespread use of mobile technologies, including apps, smartphones, tablets, and wearables, has facilitated access to health care services. Mobile health (mHealth) is a commonly used term that refers to the use of mobile technologies in the health care sector to improve patient conditions by facilitating health care initiatives such as education, intervention, medication adherence, monitoring, and disease management [7]. In addition, mHealth aims to reduce costs, encourage healthy behaviors, and empower patients by providing anytime, anywhere solutions for patients to control and manage their diseases, overcoming geographical and temporal barriers [8]. mHealth technologies, which include apps, smart devices, and sensors, are developing rapidly, supporting patient disease management especially for chronic diseases such as obesity, cancer, heart disease, and diabetes.

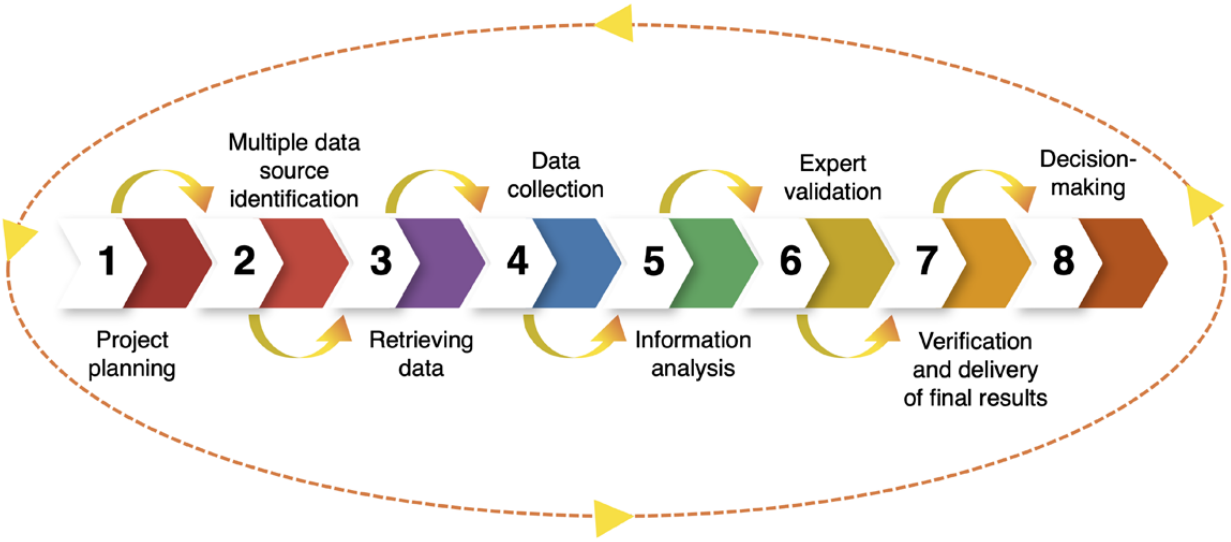
Diabetes mellitus, or simply diabetes, is a chronic disease caused by an abnormal carbohydrate metabolism that results in elevated levels of glucose in the blood and urine [9]. This condition can occur because the body cannot produce enough insulin, cannot produce insulin at all, or cannot effectively use insulin. There are 3 main types of diabetes: type 1, type 2, and gestational diabetes. Currently, 10.5% of the world's population between the ages of 20 and 79 years, approximately 537 million people, are living with diabetes [9]. This number is growing every day, so it is important to empower millions of people with diabetes through the implementation of technology solutions.

Currently, there are several mHealth solution initiatives for diabetes management to support patients in their daily activities. These mainly include guidance on diabetes control, monitoring, food and medication intake, diet and physical activity tracking, and insulin administration, among other general recommendations, alerts, and reminders. However, no research has evaluated the characteristics of scientific production on mHealth for diabetes. In this sense, this study aimed to apply a scientometric analysis through a competitive technology intelligence (CTI) approach to reveal dynamics of scientific publications on mHealth for diabetes and gain insights on who the most prominent authors, countries, institutions, and journals are and what are the most cited documents. CTI adds value to assessing the technological environment, supporting decision makers in identifying opportunities to innovate and anticipate threats that could affect an organization [10]. In addition, it is supported by a methodology that can integrate different tools and disciplines (in this case, scientometrics) to measure the progress of scientific publications considering indexing elements such as authors, affiliations, countries, journal sources, and citations. This study contributes to the decision-making process for research and development (R&D) on mHealth for diabetes, adding value to science and technology output analysis.

CTI Approach

Globalization has facilitated the flow of technology and vast amounts of information, providing opportunities to gain competitive advantages [11]. External information can influence the current and future decisions of any organization by identifying competitors, customers, suppliers [12], markets, collaborations, and disruptive events [13]. Competitive intelligence adds value to organizations in their information strategic management of the external environment [14]. The collected information should be obtained in an ethical manner [15] analyzed through an intelligence approach to identify opportunities for further strategic decisions [16]. The intelligence process involves contextualizing information, applying experience, and understanding using one's knowledge and expertise [17]. In particular, information about the scientific and technological environment under the competitive intelligence approach is commonly known as CTI [18]. Understanding and detecting technological advances is key to identify relevant opportunities for innovation and anticipate threats from technological events [19]. CTI facilitates the technology decision-making process and helps solve the complex challenges associated with implementing or developing new advances. It includes a methodology for properly evaluating scientific and technological progress. There are different methodologies to implement the CTI approach [20], with common stages such as identification of information needs, information collection, information analysis, and information dissemination [21]. This study considered the CTI methodology proposed by Rodriguez-Salvador and Castillo-Valdez [18], which includes eight steps, as shown in Figure 1 [18]: (1) project planning, (2) multiple data source identification, (3) retrieving data, (4) data collection, (5) information analysis, (6) expert validation, (7) verification and delivery of final results, and (8) decision-making.

Figure 1. The 8-step competitive technology intelligence (CTI) methodology. Adapted from Rodriguez-Salvador and Castillo-Valdez [18].



Initially, a planning phase is necessary to identify the needs of the organization and align them with the expected results [22], establishing development activities as well as their timelines. Subsequently, data sources need to be identified. Primary sources are based on a selection of experts, whereas secondary sources are based on reliable documents from information contained mainly in scientific databases. Selecting information involves a careful task aimed at obtaining the most relevant and emerging areas in the field of study [18]. Different types of information can be used, such as scientific literature, patents, social networks, reviews, blog posts, web-based texts, newspaper articles, and policy documents [23]. Designing a research strategy is essential when the main source of information is a scientific database; it requires appropriate queries using the core terms of interest. This is followed by data collection, where the main publications are gathered, and experts are consulted to validate the results. The integration of information should be standardized and classified to obtain a general idea of the documents' topics and facilitate subsequent analysis. Next, in the information analysis phase of the CTI cycle, the goal is to generate intelligence [24]. In this stage, opportunities, challenges, and other critical factors are identified. In the analysis process, different data types and techniques such as scientific literature data mining, specialized patent analysis tools, and data visualization are integrated to gain valuable insights [25]. Specifically, to measure the progress of scientific literature, diverse metrics can be considered, which can be analyzed through a discipline known as scientometrics. Scientometrics aims to understand the distribution patterns of scientific literature and provides researchers with knowledge about the progress and academic impact of any field of study. It is based on a comprehensive analysis to obtain a quantitative view of research outputs, such as most prominent authors, journals, institutions, and countries [26]. The collaborative participation of experts in all steps is essential to validate the research findings through continuous feedback and corroboration of the results. Finally, the reports obtained and verified by the experts are communicated to the stakeholders to support their strategic decision-making process for R&D [18].

Methods

In this study, the CTI methodology proposed by Rodriguez-Salvador and Castillo-Valdez [18] was considered. As was discussed in the previous section (Figure 1) [18], it consists of 8 steps in a cyclical process with continuous feedback between researchers and experts. The application of each step of this CTI methodology is explained in this section.

Steps 1 to 2: Planning and Source Identification

The first step concerned the development of a planning process that included objectives, activities, timelines, and participants and their roles. The second step was to identify primary (experts) and secondary (databases) sources of information. For the primary sources, physicians with significant diabetes expertise from Mexico were identified to participate as experts. Particularly, Mexico ranks among the top 10 countries in the world for this illness, appearing in seventh place with 14.1 million patients with diabetes, with the highest number of adults with diabetes aged 20 to 79 years in 2021; this number is estimated to increase to 21.2 million by 2045 [9]. The selection criteria for experts included medical degrees and medical certificates from prestigious institutions, professional positions in recognized health institutions, and >10 years of experience treating patients with diabetes. A total of 3 physicians were selected, 2 practicing internal medicine and 1 practicing emergency medicine. They work in prestigious health centers in Mexico City with a high level of specialization: the Centro Medico Nacional Siglo XXI, the Instituto Nacional de Rehabilitación, and the Hospital General Regional 1 Carlos MacGregor. These experts were consulted remotely during the various stages of this CTI methodology. On the other hand, the Science Citation Index (SCI) Expanded database from Clarivate Analytics was chosen as the secondary source of information.

This prestigious platform covers >9500 journals, including 182 subject categories and >61 million records [27].

Step 3: Search Strategy and Execution

The third step involved defining the search query to be used in the SCI Expanded database to obtain the data for this study. The journal impact factor (IF) recommends searching SCI Expanded articles after the publication of the journal IF for the year of interest. In this study, the search time frame included all articles published between 1998 and 2021, meaning that the search strategy began after the announcement of the journal IF of 2021 (IF_{2021}). The IF_{2021} was reported in *Journal Citation Reports* (*JCR*) on June 30, 2021. Designing an appropriate query also required identifying appropriate keywords. To this end, terms related to diabetes and mHealth technologies were identified. Quotation marks ("") and the Boolean operator *or* were used to ensure that at least one search keyword appeared in the Topic feature of the SCI Expanded platform. This feature allows for searches of each record in the following sections: title; abstract; keywords named as author keywords; and keywords plus, which includes additional search terms retrieved from the titles of articles cited by the researcher in references and footnotes. All search keywords used in this study were found in the SCI Expanded database. In addition, the results were refined using the Article feature that this database provides in the Document Type option, which includes novel research considered citable that was, for example, published in a journal or presented at a symposium or conference [27]. The identified terms associated with diabetes and mHealth technologies were incorporated into a search query that was validated by experts, and the resulting publications were manually examined to determine whether they were relevant to the mHealth for diabetes topic. Exclusion terms were included to reduce the number of irrelevant publications. Terms associated with *app* that referred to proteins and genes and did not refer to mobile apps were excluded. In addition, terms associated with *tablet* but used for a drug rather than an electronic device were discarded. Terms associated with *wearables* that did not use mobile or wireless technology and terms associated with the materials of the wearables that did not indicate their functionality for smart devices were also excluded. Finally, terms associated with other diseases that superficially mentioned diabetes and terms associated with mHealth as a physical entity rather than mobile technology were excluded. Considering the identified exclusion keywords, the search strategy for this study can be consulted in Multimedia Appendix 1.

A total of 1848 articles from 1998 to 2021 were found in the SCI Expanded database. As Keywords Plus adds keywords that are indexed according to the Institute for Scientific Information database, also known as Clarivate Analytics [28], some publications can be irrelevant to the topic being searched [29]. To prevent this, the research group of Wang and Ho [30] was the first to propose the application of a "front page" filter that includes article titles, author keywords, and abstracts. This filter can prevent the introduction of irrelevant articles for further analysis in the scientometric study [31]. A total of 90.26% (1668/1848) of articles that included search keywords on their front page were found. Finally, the 1668 articles were manually reviewed by the authors, and a total of 1574 (94.36%) articles on mHealth for diabetes research were kept.

Step 4 to 5: Data Collection and Information Analysis

The fourth step involved the collection of data extracted from the previously described research strategy. Data from the 1574 articles identified on mHealth for diabetes research were extracted on September 24, 2022. The full record in SCI Expanded and the number of citations each year for each publication were downloaded into Microsoft Excel 365 (Microsoft Corp), and additional coding was performed manually [32]. Diverse functions in Microsoft Excel 365 were applied, such as CONCATENATE, COUNTA, FILTER, freeze panes, LEN, MATCH, PROPER, RANK, REPLACE, SORT, SUM, and VLOOKUP.

The fifth step concerned information analysis, where the extensive scientific literature obtained was analyzed applying scientometrics. The metrics used included the number of publications and their rate by year, highly cited articles, highly cited authors, and institutions and countries with the most publications, among others. This study focused on seven main topics for the scientometric analysis: (1) publication language, (2) publication output characteristics, (3) Web of Science categories and journals, (4) country and institution publication performance, (5) author publication performance, (6) citation history of the 10 most frequently cited articles, and (7) top 10 articles with the highest impact. As mentioned previously, the journal IFs (IF_{2021}) were obtained following *JCR* for the year 2021. For articles with multiple corresponding authors, all the corresponding authors, institutes, and countries were considered. Articles with corresponding authors who had only the address and no affiliation names were completed by inserting the address into the affiliation name. Author affiliations were also homogenized; for example, England, Scotland, Northern Ireland, and Wales were considered as 1 group under the United Kingdom [33]. Similarly, Harvard Medical School, United States, and Harvard University, United States, were also regrouped under Harvard University, United States. For this research, the *institutions* indicator considered universities or research institutions but not departments or research centers in a university.

Publications were assessed using the following citation indicators: (1) the number of citations from the Web of Science Core Collection in a specific year (C_{year}; eg, C_{2021} describes the citation count in 2021 [34]); (2) the total number of citations received in the Web of Science Core Collection from the year of publication to the end of a specific year (TC_{year}), which in this study was 2021 (TC_{2021}) [35]; (3) the average number of citations per publication (CPP_{year}; CPP_{2021}=TC_{2021}/total number of articles [TP]) [36]; and (4) average number of authors per article (APP).

In addition, six publication indicators were applied to evaluate the publication performance of countries and institutions [37]: (1) TP, (2) number of single-country articles (IP_C) or single-institution articles (IP_I; this indicator provides information about articles written by authors from the same country or institution), (3) number of international collaborative articles

(CP_C) or number of interinstitutional collaborative articles (CP_I; this indicator shows whether the article was written by authors from different countries or different institutions. The institutions can be in the same country or different countries), (4) number of first-author articles (FP), (5) number of corresponding-author articles (RP), and (6) number of single-author articles (SP).

Furthermore, six citation indicators related to the 6 publication indicators (CPP_{2021}) were also used to evaluate the publication impact on countries and institutions [38]: (1) the *Y*-index was used to evaluate the publication performance of authors, which is defined as *Y*-index (*j*, *h*) [34,39], where *j* is a constant related to the publication potential, the sum of the first-author articles, and the corresponding-author articles, and *h* is a constant related to the publication characteristics, the polar angle of the proportion of RP to FP (the larger the value of *j*, the more the first author and corresponding author contribute to the articles); (2) $h=\pi/2$ indicates that an author has only published articles as corresponding author (using this value in the *Y*-index, *j* is the RP); (3) $\pi/2>h>\pi/4$ denotes that an author has more corresponding-author articles than first-author articles (FP>0); (4) $h=\pi/4$ indicates that an author has the same FP and RP (FP>0 and RP>0); (5) $\pi/4>h>0$ indicates an author with more first-author articles than corresponding-author articles (RP>0); and (6) $h=0$ denotes that an author has only published first-author articles (using this value in the *Y*-index, *j* is the FP).

In addition, the most common author keywords were identified to determine current research hot spots. Author keywords reveal the focus that authors transmit to readers. A statistical analysis of the frequency of author keywords in the 1574 documents selected was performed using Microsoft Excel 365 through the functions COUNTA, CONCATENATE, MATCH, VLOOKUP, PROPER, RANK, REPLACE, freeze panes, SORT, SUM, and LEN. Terms related to *diabetes* and *mHealth* were discarded because all articles collected contained these; otherwise, we could erroneously conclude that, for example, the term *diabetes mellitus* was one of the main research topics in diabetes mHealth.

Charts, figures, and tables were created to present the findings of the scientometric analysis, which are described in the Results and Discussion sections.

Step 6 to 8: Expert Validation, Delivery of Results, and Decision-Making

The sixth step of the CTI methodology was the validation of the results obtained, where experts provided valuable feedback during all steps. The seventh step allowed for the integration of the outcomes, which are presented in the Results and Discussion sections. Finally, the eighth step aimed to support the stakeholders in their decision-making process, thus promoting innovation.

Results

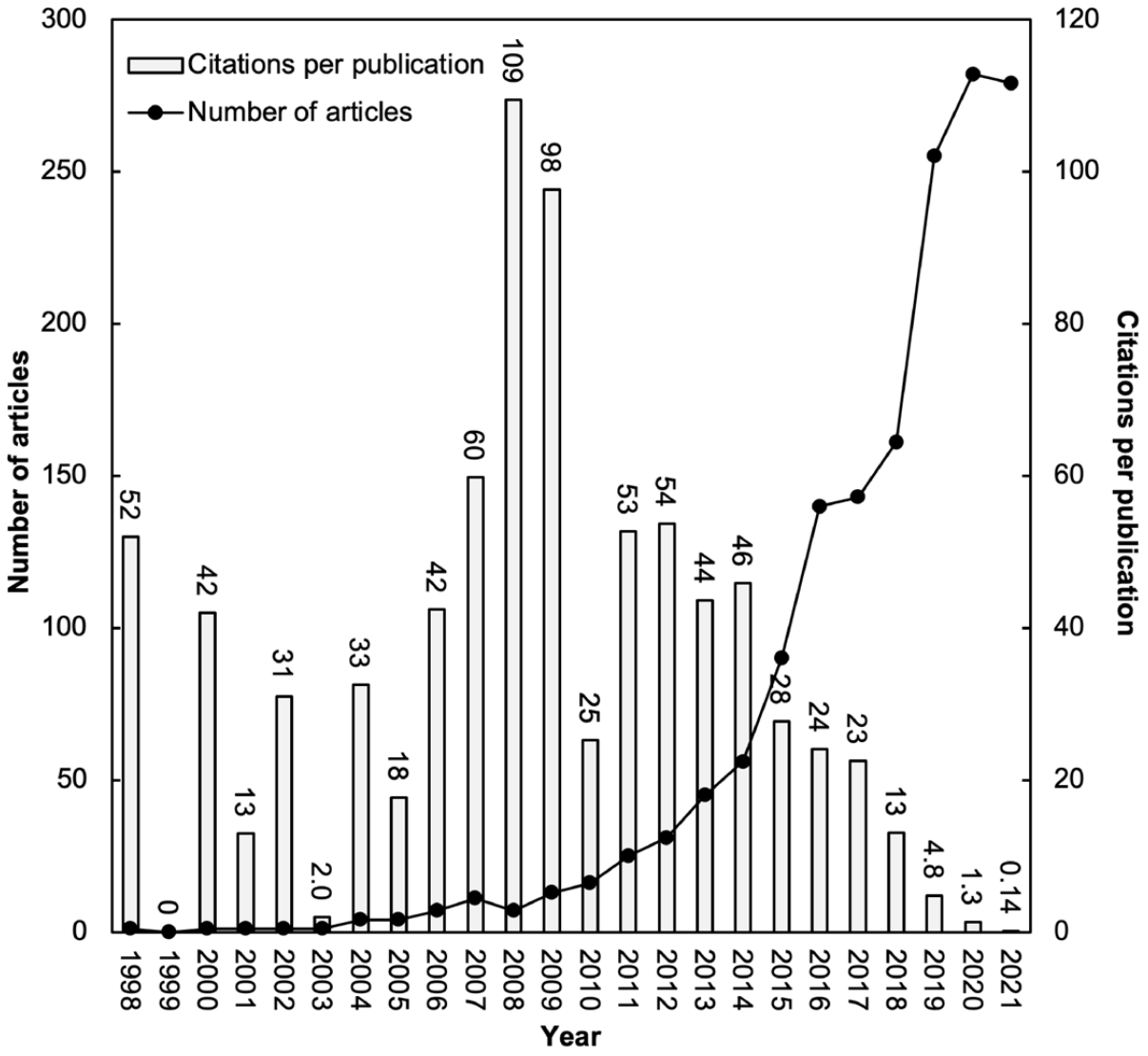
Publication Language

A total of 1574 mHealth for diabetes–related articles were obtained in 7 different languages. The most common language was English with 98.41% (1549/1574) of the articles followed by German with 1.27% (20/1574) of the articles. A total of 0.06% (1/1574) of the articles were published in French, Hungarian, Korean, and Spanish each. In addition, 0.06% (1/1574) of the articles were published in *Trials*, a bilingual (English and Esperanto) journal. Non–English-language articles had fewer citations, with a CPP_{2021} of 1.3 (SD 1.9), while English-language articles had a CPP_{2021} of 16 (SD 38). Non–English-language articles had a lower APP of 3.3 (SD 2.8), whereas English-language articles had an APP of 6.6 (SD 4.4).

Publication Output Characteristics

To understand the trends and impacts of publications on a research topic, Ho [36] proposed a correlation between the annual number of articles (TP) and their CPP by year, which, in the last decade, has been widely applied to several medical-related topics, including dengue [40], Ebola [41], breast reconstruction [42], fracture nonunion [43], keloids [44], and Q fever [45]. Between 1998 and 2021, a total of 1574 articles associated with mHealth for diabetes were published in SCI Expanded. The mean TC_{2021} value was 15, with 705 as the maximum value for an article. The distribution of the annual number of articles and their CPP_{2021} by year is shown in Figure 2. From 1998 to 2008, the number of publications per year ranged from 1 to 11 articles except for 1999, when no articles were published. There was an increase from 7 articles in 2008 to 56 articles in 2014, a total of 282 articles in 2020, and 279 articles in 2021. In 2008, a total of 7 articles with a TC_{2021} of 766 had the highest CPP_{2021} at 109, followed by a CPP_{2021} of 98 in 2009. The second most frequently cited article, titled "Healthcare via Cell Phones: A Systematic Review" [46], in mHealth for diabetes research was published in 2009 with a TC_{2021} of 550. Similarly, in 2008, an article titled "WellDoc (TM) Mobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes And Patient And Physician Satisfaction" [47] ranked ninth with a TC_{2021} of 212. On the basis of Figure 2, it takes approximately 8 years for the CPP to reach a plateau. It took a shorter time to reach a plateau than for other medical topics, such as fracture nonunion (14 years) [43] and breast reconstruction (10 years) [42].

Figure 2. Number of articles and citations per publication by year.



Web of Science Categories

In 2021, *JCR* indexed 9649 journals in all areas with citation references across 178 Web of Science categories in SCI Expanded. For this study, the Web of Science categories were identified based on their CPP_{year} and APP as basic information [38,43]. By 2021, a total of 491 journals published articles related to mHealth for diabetes in 92 Web of Science categories in SCI Expanded. Table 1 shows the top 10 most productive categories, mainly Health Care Sciences & Services (109 journals), Medical Informatics (31 journals), and Endocrinology & Metabolism (148 journals). Comparing the top 10 categories, articles published in the Endocrinology & Metabolism category had the highest CPP_{2021} at 21, whereas Engineering, Electrical & Electronic articles had a CPP_{2021} of 6.7. Articles published in the Medicine, General & Internal category had the highest APP at 7.8.

Table 1. Top 10 most productive Web of Science categories (N=1574).

Web of Science category	TP[a], n (%)	Journals in each category, n	AU[b]	APP[c] (SD)	TC_{2021}[d]	CPP_{2021}[e] (SD)
Health Care Sciences & Services	409 (26)	109	2548	6.2 (4.7)	6952	17 (39)
Medical Informatics	362 (23)	31	2323	6.4 (4.7)	4961	14 (28)
Endocrinology & Metabolism	262 (16.6)	148	1937	7.4 (4.9)	5497	21 (39)
Computer Science, Information Systems	117 (7.4)	164	689	5.9 (7.0)	1647	14 (24)
Public, Environmental & Occupational Health	114 (7.2)	210	778	6.8 (3.4)	1190	10 (22)
Engineering, Electrical & Electronic	108 (6.9)	278	540	5.0 (2.0)	722	6.7 (12)
Medicine, General & Internal	106 (6.7)	172	826	7.8 (5.1)	1677	16 (43)
Chemistry, Analytical	98 (6.2)	87	525	5.4 (2.5)	1394	14 (28)
Instruments & Instrumentation	69 (4.4)	64	370	5.4 (2.7)	587	8.5 (22)
Computer Science, Interdisciplinary Applications	62 (3.9)	113	346	5.6 (2.7)	653	11 (14)

[a]TP: total number of articles.

[b]AU: number of authors in a category.

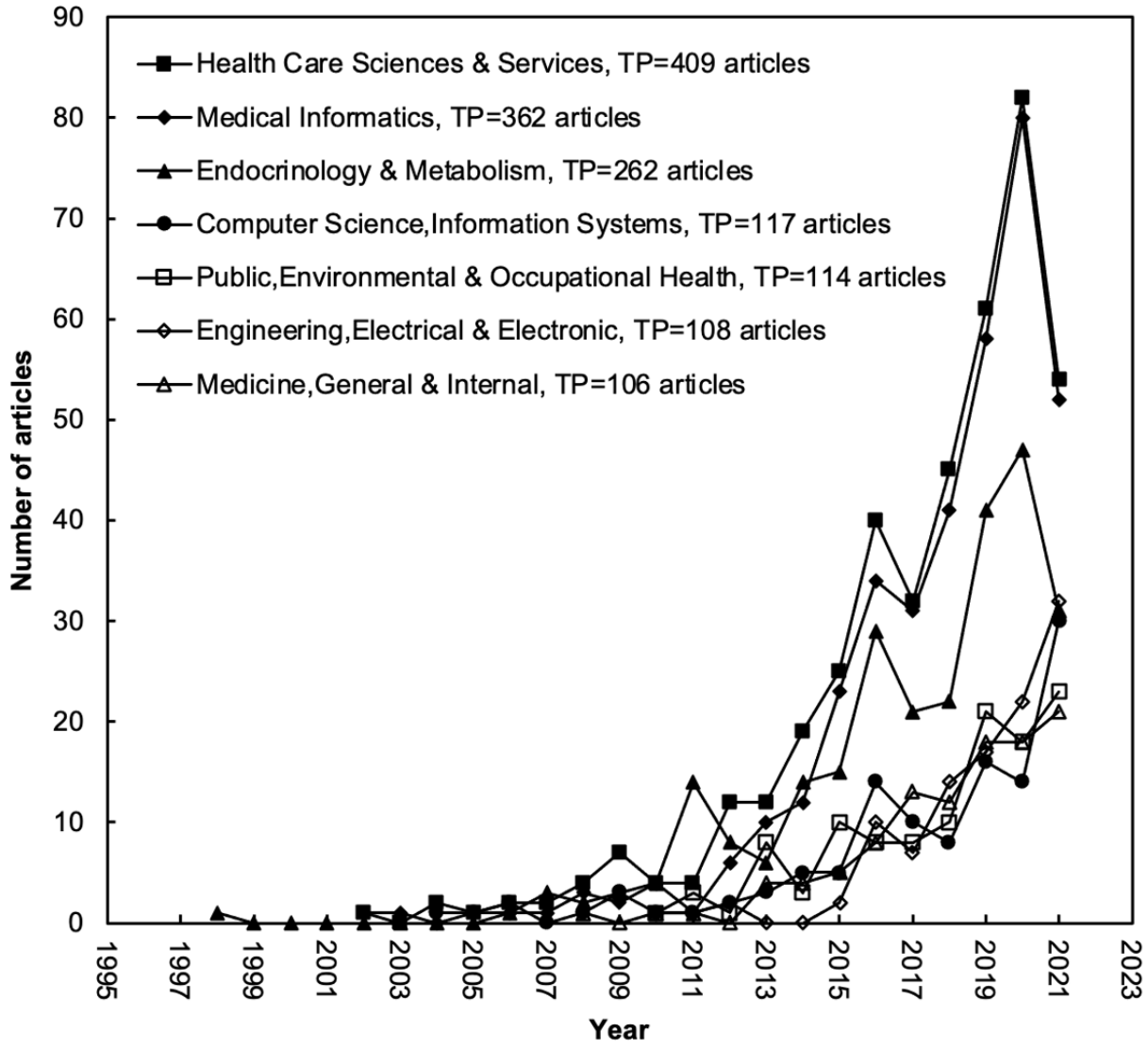
[c]APP: average number of authors per publication.

[d]TC_{2021}: total number of citations from the Web of Science Core Collection from the publication year to the end of 2021.

[e]CPP_{2021}: average number of citations per publication.

The evolution of the top 7 Web of Science categories with >100 articles is illustrated in Figure 3. The Health Care Sciences & Services and Medical Informatics categories have shown a similar trend since 2002. From 2010 to 2021, a total of 108 articles were published in the Engineering, Electrical & Electronic category (ranked sixth), with 32 articles published in 2021. The first article on mHealth for diabetes was published in the Endocrinology & Metabolism category.

Figure 3. Development trends of the top 7 Web of Science categories with a total number of articles (TP) of >100.



Journals

Recently, Ho [48] proposed to measure the characteristics of journals according to their CPP_{year} and APP. Table 2 presents the top 10 most productive journals in terms of journal IFs, CPP_{2021}, and APP. *JMIR mHealth and uHealth* (IF_{2021}=4.947) published the highest number of articles, in this case, 7.94% (125/1574). Comparing the top 10 most productive journals, mHealth for diabetes articles published in *Diabetes Care* (IF_{2021}=17.152) had the highest CPP_{2021} at 59, whereas articles published in *BMJ Open* (IF_{2021}=3.006) had a CPP_{2021} of only 2.8. The APP ranged from 12 in *Diabetes Care* to 4.8 in the *Journal of Telemedicine and Telecare* and *Telemedicine and e-Health*. According to the IF_{2021}, the top 3 journals with an IF_{2021} of >100 were *TheLancet* (IF_{2021}=202.731) with 1 article, the *New England Journal of Medicine* (IF_{2021}=176.079) with 1 article, and the *Journal of the American Medical Association* (IF_{2021}=157.335) with 1 article. These 3 journals were also the top 3 journals among 172 journals in the Web of Science category of General and Internal Medicine.

Table 2. Top 10 most productive journals (N=1574).

Journal	TP[a], n (%)	IF_{2021}[b]	APP[c] (SD)	CPP_{2021}[d] (SD)	Web of Science category
JMIR mHealth and uHealth	125 (7.9)	4.947	6.3 (2.7)	10 (19)	• Health Care Sciences & Services • Medical Informatics
Journal of Medical Internet Research	92 (5.8)	7.076	7.0 (3.3)	21 (41)	• Health Care Sciences & Services • Medical Informatics
Diabetes Technology & Therapeutics	69 (4.4)	7.337	7.2 (4.5)	19 (36)	• Endocrinology & Metabolism
Sensors	34 (2.2)	3.847	5.2 (2.1)	7.3 (10)	• Chemistry, Analytical • Engineering, Electrical & Electronic • Instruments & Instrumentation
BMJ Open	32 (2)	3.006	12 (6.5)	2.8 (3.6)	• Medicine, General & Internal
Journal of Telemedicine and Telecare	30 (1.9)	6.344	4.8 (1.9)	28 (31)	• Health Care Sciences & Services
Telemedicine and e-Health	30 (1.9)	5.033	4.8 (2.3)	21 (27)	• Health Care Sciences & Services
Diabetes Care	27 (1.7)	17.152	12 (7.2)	59 (61)	• Endocrinology & Metabolism
PLOS One	26 (1.7)	3.752	5.7 (2.3)	24 (34)	• Multidisciplinary Sciences
Trials	24 (1.5)	2.728	10 (3.4)	6.4 (8.6)	• Medicine, Research & Experimental

[a]TP: total number of articles.

[b]IF_{2021}: journal impact factor in 2021.

[c]APP: average number of authors per article.

[d]CPP_{2021}: average number of citations per paper (total number of citations/TP).

Country and Institution Publication Performance

It is widely recognized that the first author and the corresponding author are the 2 authors who contribute the most to a research article [49]. At the institutional level, the affiliation specified for the corresponding author might be where they are based or the origin of the article [34]. In this study, a total of 1574 articles were published by authors from 90 countries, 1129 (71.73%) of which were single-country articles with authors from 62 countries and a CPP_{2021} of 15, whereas 445 (28.27%) were international collaborative articles with authors from 83 countries and a CPP_{2021} of 16. The results showed that international collaborative articles slightly increased citations in mHealth for diabetes research. The 6 publication indicators and the 6 related citation indicators (CPP_{2021}) [38] described in the Methods section were applied to determine the top 10 most productive countries, which are presented in Table 3. The United States ranked first in 5 of the 6 publication indicators, with a TP of 566 articles, representing 35.96% (566/1574). These publication indicators were an IP_C of 367 articles, corresponding to 32.51% (367/1129) of the single-country articles; a CP_C of 199 articles, which corresponds to 44.7% (199/445) of the international collaborative articles; an FP of 453 articles, which constitutes 28.78% (453/1574) of the first-author articles; and an RP of 465 articles, equating to 29.54% (465/1574) of the corresponding-author articles. Meanwhile, Germany ranked first in the SP with 8 articles, representing 22% (8/36) of the single-author articles. Among the top 10 most productive countries, South Korea had a TP of 95 articles, an IP_C of 67 articles, a CP_C of 28 articles, an FP of 82 articles, an RP of 85 articles, and an SP of 2 articles. Nevertheless, South Korea had the highest TP-CPP_{2021}, IP_C-CPP_{2021}, CP_C-CPP_{2021}, FP-CPP_{2021}, RP-CPP_{2021}, and SP-CPP_{2021}, with values of 35, 32, 40, 37, 36, and 61, respectively.

Table 3. Top 10 most productive countries.

Country	TP[a], n (%)	TP		IP_C[b]		CP_C[c]		FP[d]		RP[e]		SP[f]	
		Rank	CPP_{2021}[g] (SD)	Rank (%)[h]	CPP_{2021} (SD)	Rank (%)[i]	CPP_{2021} (SD)	Rank (%)[j]	CPP_{2021} (SD)	Rank (%)[k]	CPP_{2021} (SD)	Rank (%)[l]	CPP_{2021} (SD)
United States	566 (35.96)	1	22 (52)	1 (33)	21 (47)	1 (45)	24 (59)	1 (29)	20 (44)	1 (30)	21 (44)	2 (11)	2.8 (2.8)
United Kingdom	172 (10.93)	2	13 (24)	4 (5.2)	15 (28)	2 (25)	12 (22)	3 (6.4)	14 (25)	3 (7.1)	14 (24)	10 (2.8)	0 (n)
China	137 (8.70)	3	11 (28)	2 (7.4)	6.7 (13)	4 (12)	18 (42)	2 (7.6)	11 (30)	2 (7.7)	11 (20)	4 (8.3)	29 (29)
Australia	106 (6.73)	4	10 (20)	5 (4.1)	12 (26)	3 (13)	8.1 (13)	5 (4.3)	11 (22)	5 (4.4)	11 (22)	—[m]	—
South Korea	95 (6.04)	5	35 (85)	3 (5.9)	32 (57)	11 (6.3)	40 (132)	4 (5.2)	37 (91)	4 (5.4)	36 (90)	6 (5.6)	61 (34)
Germany	79 (5.02)	6	9.6 (24)	8 (2.7)	2.5 (4.2)	5 (11)	14 (29)	6 (3.7)	11 (27)	6 (3.7)	8.5 (19)	1 (22)	1.0 (1.9)
India	73 (4.64)	7	13 (26)	7 (3.2)	11 (22)	8 (8.3)	15 (29)	6 (3.7)	13 (27)	6 (3.7)	13 (27)	—	—
Spain	72 (4.57)	8	10 (16)	6 (3.7)	11 (19)	10 (6.7)	8.1 (11)	8 (3.3)	11 (18)	8 (3.5)	10 (18)	—	—
Canada	70 (4.45)	9	21 (45)	9 (2.7)	23 (55)	6 (9.0)	19 (36)	9 (2.9)	26 (53)	9 (2.9)	26 (53)	4 (8.3)	20 (21)
The Netherlands	60 (3.81)	10	22 (29)	14 (1.8)	23 (33)	6 (9.0)	21 (26)	14 (1.7)	25 (36)	14 (1.8)	24 (35)	—	—

[a]TP: total number of articles and percentage of the total number of mobile health for diabetes articles (N=1574).

[b]IP_C: number of single-country articles.

[c]CP_C: number of international collaborative articles.

[d]FP: number of first-author articles.

[e]RP: number of corresponding-author articles.

[f]SP: number of single-author articles.

[g]CPP_{2021}: average number of citations per publication (total number of citations/TP).

[h]Rank and percentage of all single-country articles.

[i]Rank and percentage of all international collaborative articles.

[j]Rank and percentage of all first-author articles.

[k]Rank and percentage of all corresponding-author articles.

[l]Rank and percentage of all single-author articles.

[m]Not available.

Publication trends for the top 4 most productive countries are presented in Figure 4. The United States, the United Kingdom, China, and Australia were the leaders, all with >100 articles. The only article on mHealth for diabetes in the 1990s was published by authors from the United States. Since 2008, the United States has been at the top with a significant upward trend. China and Australia each published their first article in 2011. In 2021, China reached the second position with 41 articles.

In addition, as shown in Table 4, the top 10 most productive countries in terms of publications were compared with respect to diabetes-related health expenditure.

Figure 4. Development trends of the top 4 countries with a total number of articles (TP) of >100. UK: United Kingdom; USA: United States of America.

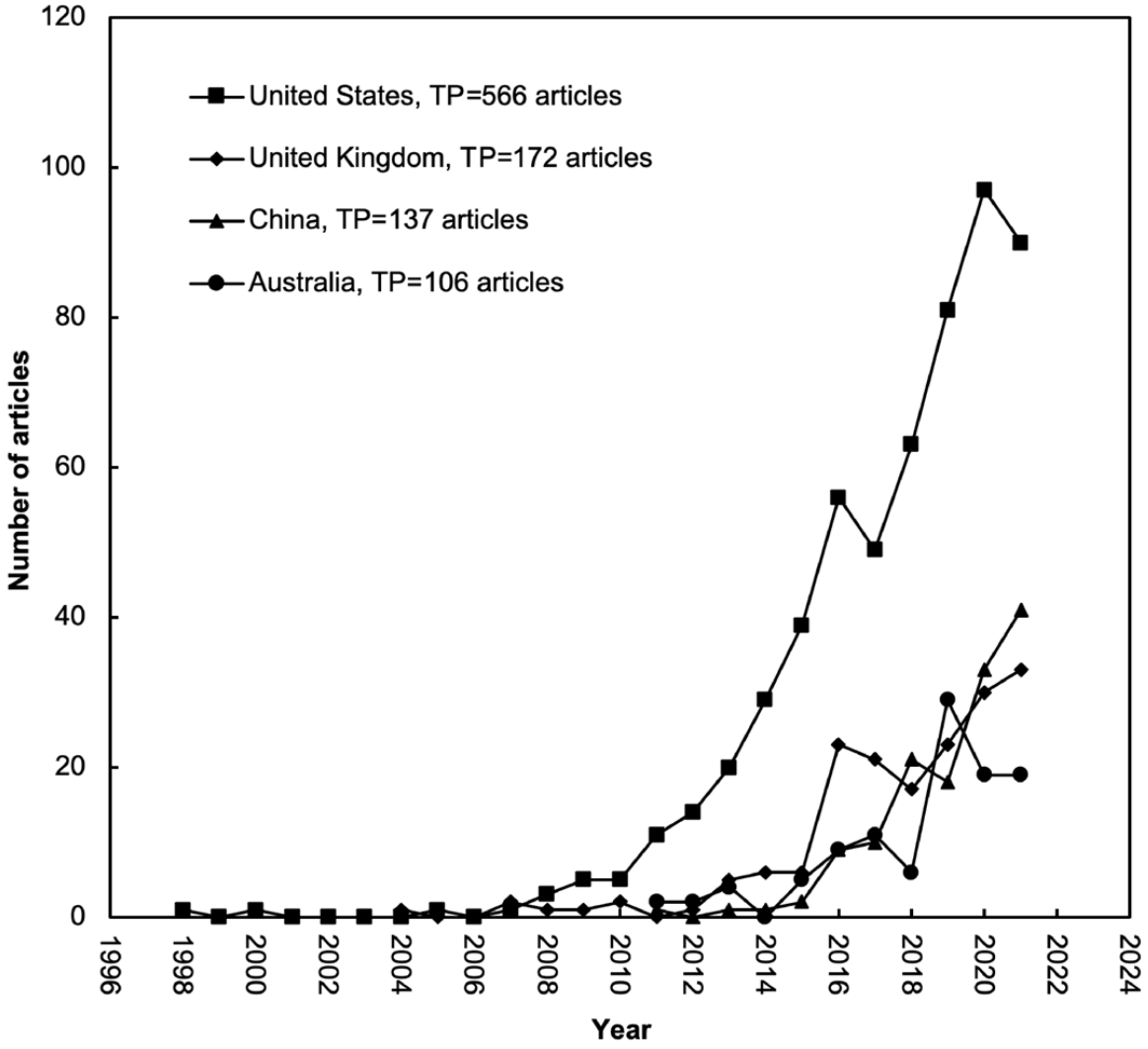


Table 4. Top 10 most productive countries in terms of publications related to mobile health for diabetes and diabetes-related health expenditure (N=1574).

Country	Total number of articles[a], n (%)	Diabetes-related health expenditure (million US $) [50]			Adults aged between 20 and 79 years with diabetes (thousands) [51]			Prevalence of diabetes in adults aged between 20 and 79 years (%) [52]		
		2021	2030	2045	2021	2030	2045	2021	2030	2045
United States	566 (36)	379,470.20	388,934.40	392,537.40	32,215.30	34,755.30	36,289.90	10.7	12.1	12.9
United Kingdom	172 (10.9)	23,415.40	23,815.40	23,949.20	3,996.30	4,140.60	4,408.10	6.3	7	7.5
China	137 (8.7)	165,304.00	185,008.20	193,142.70	140,869.60	164,069.50	174,433.50	10.6	11.8	12.5
Australia	106 (6.7)	8867.10	9588.00	10,405.70	1,491.80	1,693.00	1,935.20	6.4	7.4	8
South Korea	95 (6)	8971.20	9182.80	7807.80	3,511.80	3,934.20	3,860.90	6.8	7.2	7.8
Germany	79 (5)	41,295.80	42,364.90	37,913.80	6,199.90	6,519.70	6,094.40	6.9	7.9	8.4
India	73 (4.6)	8485.80	10,305.50	12,834.30	74,194.70	92,973.70	124,874.70	9.6	10.4	10.8
Spain	72 (4.6)	15,453.60	15,625.30	14,169.20	5,141.30	5,576.00	5,647.60	10.3	11.8	12.7
Canada	70 (4.4)	14,284.10	14,905.90	15,259.40	2,974.00	3,288.20	3,468.50	7.7	8.9	9.6
The Netherlands	60 (3.8)	5523.10	5481.10	5129.20	857	910.4	894.7	4.5	5.3	5.8

[a]Data previously presented in Table 3.

Between 2021 and 2045, the United States, United Kingdom, China, Australia, India, and Canada will increase their diabetes-related health expenditure, whereas South Korea, Germany, Spain, and the Netherlands will decrease it. Trends in diabetes-related health expenditure of the top 4 most productive countries in terms of publications are shown in Figure 5.

Regarding institutions, 23.57% (371/1574) of the mHealth for diabetes articles came from a single institution, with a CPP_{2021} of 14, whereas 76.43% (1203/1574) of the articles were interinstitutional collaborations, with a CPP_{2021} of 16. As before, collaboration slightly increased citations in mHealth for diabetes research. The top 10 most productive institutions and their characteristics are shown in Table 5. Harvard University in the United States ranked first with a TP of 59 articles (59/1574, 3.75%), a CP_I of 57 articles (57/1203, 4.7% of the interinstitutional collaborative articles), and an RP of 18 articles (18/1574, 1.14% of the corresponding-author articles). The University of Michigan in the United States ranked first in first-author articles with an FP of 14 articles (14/1574, 0.89% of the first-author articles). In addition, James Cook University in Australia had a total of 6 articles (ranked 89th), all of which were single-institution articles, obtaining first place for single-institution articles with an IP_I of 6 articles (6/371, 1.6% of the single-institution articles). The University of Toronto in Canada is the only institution with single-author articles in Table 5. Among the top 10 most productive institutions, Seoul National University in South Korea had a TP of 20 articles, a CP_I of 15 articles, and an RP of 17, with the highest TP-CPP_{2021}, CP_I-CPP_{2021}, and RP-CPP_{2021} at 76, 93, and 83, respectively. The University of California, San Francisco, in the United States had an IP_I of 4 articles, with the highest IP_I-CPP_{2021} at 41. Meanwhile, the University of Virginia in the United States had an FP of 8 articles, with the highest FP-CPP_{2021} at 44.

Figure 5. Diabetes-related health expenditure of the top 4 most productive countries in terms of publications. UK: United Kingdom; USA: United States of America.

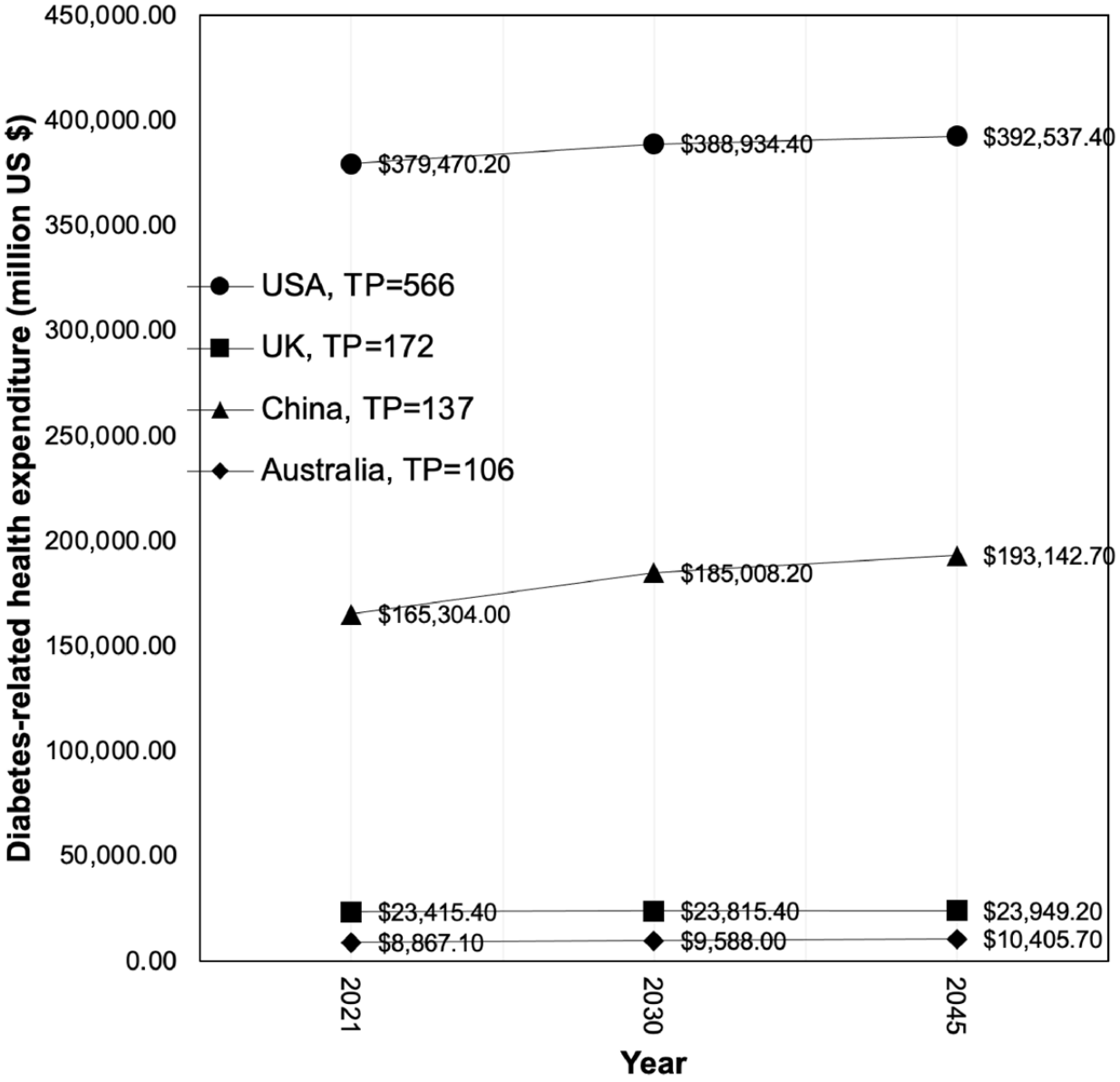


Table 5. Top 10 most productive institutions.

Institution	TP[a], n (%)	TP		IP_I[b]		CP_I[c]		FP[d]		RP[e]	
		Rank	CPP_{21}[f] (SD)	Rank (%)[g]	CPP_{21} (SD)	Rank (%)[h]	CPP_{21} (SD)	Rank (%)[i]	CPP_{21} (SD)	Rank (%)[j]	CPP_{21} (SD)
Harvard University, United States	59 (3.75)	1	22 (46)	16 (0.54)	18 (25)	1 (4.7)	23 (47)	2 (0.76)	18 (22)	1 (1.1)	13 (20)
Stanford University, United States	34 (2.16)	2	23 (41)	16 (0.54)	15 (0.71)	2 (2.7)	23 (42)	5 (0.64)	18 (23)	7 (0.70)	36 (66)
University of Michigan, United States	26 (1.65)	3	31 (39)	16 (0.54)	7.5 (11)	3 (2.0)	33 (40)	1 (0.89)	24 (22)	3 (0.89)	22 (23)
University of California, San Francisco, United States	23 (1.46)	4	21 (27)	8 (0.81)	41 (31)	5 (1.7)	19 (26)	5 (0.64)	27 (29)	4 (0.76)	22 (28)
Duke University, United States	22 (1.40)	5	15 (28)	2 (1.3)	33 (46)	7 (1.4)	9.5 (18)	5 (0.64)	18 (35)	4 (0.76)	18 (32)
University of Toronto, Canada	21 (1.33)	6	35 (72)	—[k]	—	4 (1.7)	35 (72)	48 (0.25)	37 (73)	86 (0.19)	49 (85)
Seoul National University, South Korea	20 (1.27)	7	76 (169)	2 (1.3)	25 (48)	10 (1.2)	93 (192)	2 (0.76)	19 (31)	1 (1.1)	83 (183)
University of Oxford, United Kingdom	20 (1.27)	7	12 (25)	54 (0.27)	15 (—)	6 (1.6)	12 (26)	11 (0.51)	4.1 (5.9)	11 (0.57)	6.2 (8.4)
University of California, San Diego, United States	18 (1.14)	9	16 (28)	6 (1.1)	5.5 (11)	16 (1.2)	19 (31)	8 (0.57)	17 (37)	11 (0.57)	20 (37)
University of Virginia, United States	18 (1.14)	9	51 (40)	8 (0.81)	20 (32)	10 (1.2)	57 (40)	11 (0.51)	44 (48)	27 (0.38)	48 (52)

[a]TP: total number of articles and percentage of all mobile health for diabetes articles (N=1574).

[b]IP_I: number of single-institution articles.

[c]CP_I: number of interinstitutional collaborative articles.

[d]FP: number of first-author articles.

[e]RP: number of corresponding-author articles.

[f]CPP_{21}: average number of citations per publication (total number of citations/TP).

[g]Rank and percentage of all single-institution articles.

[h]Rank and percentage of all interinstitutional collaborative articles.

[i]Rank and percentage of all first-author articles.

[j]Rank and percentage of all corresponding-author articles.

[k]Not available.

Author Publication Performance

The 1574 articles on mHealth for diabetes had an APP of 6.5, whereas the maximum number of authors in an article was 73. A total of 5.59% (88/1574) of the articles had multiple corresponding authors, whereas the maximum number of corresponding authors, institutions, and countries associated with an article were 11, 8, and 4, respectively. Articles published by groups of 3 to 7 authors accounted for 61.94% (975/1574) of the total. These groups consisted of 4, 6, 5, 3, and 7 authors, with 15.5% (244/1574), 13.47% (212/1574), 11.94% (188/1574), 11.05% (174/1574), and 9.97% (157/1574) of the articles, respectively. Table 6 lists the top 20 most productive authors in mHealth for diabetes research considering 4 publication indicators, their corresponding citation indicators, and *Y*-index constants. E Arsand published the most articles with 18. HS Kim published the most first-author articles with 7 and the most corresponding-author articles with 10. Kim was the only author in the top 20 who had single-author articles. Comparing the top 20 most productive authors, A Farret had a TP of 9 articles, with the highest TP-CPP_{2021} at 77. CC Quinn had an FP of 7 articles and an RP of 7 articles, with the highest FP-CPP_{2021} at 83 and the highest RP-CPP_{2021} at 83. Only 5 of the top 20 most productive authors, namely, HS Kim, CC Quinn, CG Parkin,

JD Piette, and J Wang, were among the top 20 publication potential authors according to the *Y*-index.

Authors were extensively studied based on the *Y*-index. The 1574 articles on mHealth for diabetes were produced by 7922 authors. Of these 7922 authors, 5975 (75.42%) had no first-author articles and no corresponding-author articles, with a *Y*-index of (0, 0); 596 (7.52%) published only corresponding-author articles, with $h=\pi/2$; 512 (6.46%) published more corresponding-author articles than first-author articles, with $\pi/2>h>\pi/4$ (FP>0); 263 (3.32%) published the same number of first-author and corresponding-author articles, with $h=\pi/4$ (FP>0 and RP>0); 25 (0.32%) published more first-author articles than corresponding-author articles, with $\pi/4>h>0$ (RP>0); and 551 (6.96%) published only first-author articles, with $h=0$. The polar coordinates are shown in Figure 6, which illustrates the distribution of the *Y*-index (j, h) of the leading 43 publication potential authors in mHealth for diabetes research with $j\geq5$. Each point has a coordinate *Y*-index (j, h), which represents the publication performance of the authors. In some cases, authors can coincide at the same point; for example, R Verwey, S Van Der Weegen, A Torbjornsen, SO Skrovseth, YJH Guo, Fukuoka, AE Carroll, AH Hansen, F Yasmin, I Graetz, I Rodriguez-Rodriguez, and YK Bartlett had a *Y*-index of (6, p/4). The greatest publication potential was found for HS Kim, with a *Y*-index of (17, 0.9601) and a j of 17, followed by CC Quinn with a *Y*-index of (14, $\pi/4$), CG Parkin with a *Y*-index of (13, 0.8622), and JD Piette with a *Y*-index of (12, $\pi/4$).

Table 6. Top 20 most productive authors with ≥9 articles.

Author	TP[a]		FP[b]		RP[c]		SP[d]		*h* [e]	Rank (j[f])
	Rank (TP)	CPP_{2021}[g] (SD)	Rank (FP)	CPP_{2021} (SD)	Rank (RP)	CPP_{2021} (SD)	Rank (SP)	CPP_{2021} (SD)		
E Arsand	1 (18)	29 (29)	157 (1)	51 (—[h])	55 (2)	70 (26)	—	—	1.107	113 (3)
HS Kim	2 (15)	40 (44)	1 (7)	49 (29)	1 (10)	58 (43)	1 (2)	61 (34)	0.9601	1 (17)
X Li	3 (13)	8.3 (20)	—	—	196 (1)	0 (—)	—	—	p/2	910 (1)
E Renard	4 (12)	59 (40)	35 (2)	57 (3.5)	55 (2)	57 (3.5)	—	—	p/4	44 (4)
S Del Favero	4 (12)	58 (42)	18 (3)	60 (4.7)	196 (1)	6.0 (—)	—	—	0.3218	44 (4)
C Cobelli	6 (11)	63 (41)	—	—	12 (4)	51 (18)	—	—	p/2	44 (4)
E Dassau	6 (11)	32 (39)	—	—	12 (4)	18 (15)	—	—	p/2	44 (4)
J Wang	6 (11)	16 (33)	35 (2)	13 (11)	2 (7)	22 (41)	—	—	1.292	8 (9)
N Tandon	6 (11)	13 (21)	—	—	55 (2)	14 (16)	—	—	p/2	169 (2)
D Bruttomesso	10 (10)	71 (34)	—	—	—	—	—	—	0	1948 (0)
FJ Doyle	10 (10)	37 (43)	—	—	—	—	—	—	0	1948 (0)
J Li	10 (10)	10 (16)	10 (4)	1.8 (3.5)	196 (1)	3.0 (—)	—	—	0.2450	31 (5)
A Avogaro	13 (9)	75 (34)	—	—	—	—	—	—	0	1948 (0)
A Farret	13 (9)	77 (48)	—	—	—	—	—	—	0	1948 (0)
CC Quinn	13 (9)	68 (105)	1 (7)	83 (116)	2 (7)	83 (116)	—	—	p/4	2 (14)
CG Parkin	13 (9)	1.7 (3.9)	3 (6)	0.50 (0.84)	2 (7)	2.1 (4.4)	—	—	0.8622	3 (13)
DG Armstrong	13 (9)	14 (12)	157 (1)	14 (—)	196 (1)	8.0 (—)	—	—	p/4	169 (2)
J Car	13 (9)	15 (25)	—	—	—	—	—	—	0	1948 (0)
JD Piette	13 (9)	39 (32)	3 (6)	48 (35)	6 (6)	48 (35)	—	—	p/4	4 (12)
P Keith-Hynes	13 (9)	72 (37)	—	—	—	—	—	—	0	1948 (0)

[a]TP: total number of articles.

[b]FP: first-author articles.

[c]RP: corresponding-author articles.

[d]SP: single-author articles.

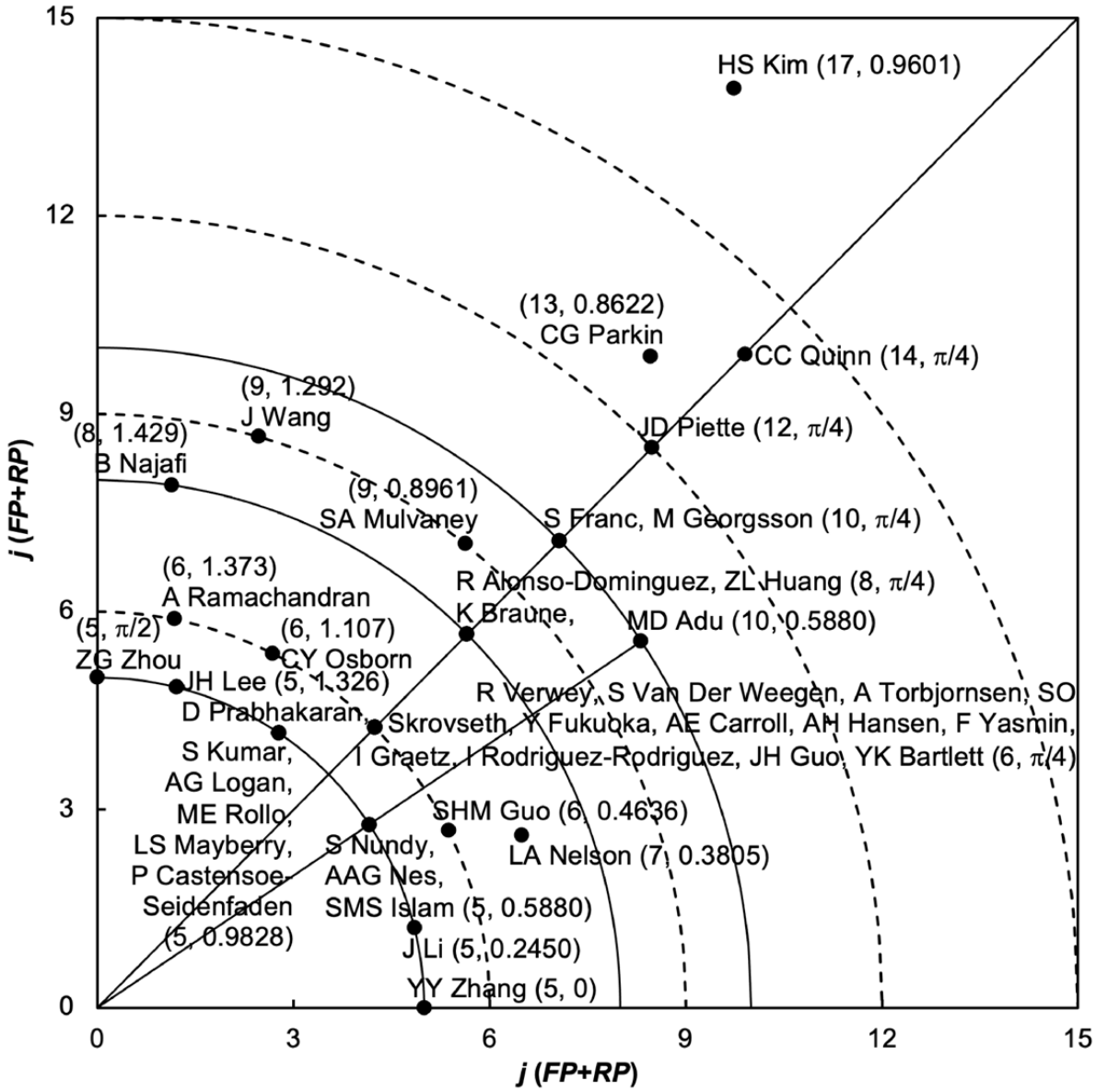
[e]A *Y*-index constant related to the publication characteristics.

[f]A *Y*-index constant related to the publication potential.

[g]CPP_{2021}: average number of citations per publication (total number of citations/TP).

[h]Not available.

Figure 6. Top 43 authors with a Y-index of (j≥5). FP: number of first-author articles; RP: number of corresponding-author articles.



ZG Zhou (5, π/2), D Prabhakaran (5, 1.326), JH Lee (5, 1.326), LS Mayberry (5, 0.9828), S Kumar (5, 0.9828), AG Logan (5, 0.9828), ME Rollo (5, 0.9828), P Castensoe-Seidenfaden (5, 0.9828), SMS Islam (5, 0.5880), AAG Nes (5, 0.5880), S Nundy (5, 0.5880), J Li (5, 0.245), and YY Zhang (5, 0) all had the same *j* of 5. All these authors are located on the same curve (*j*=5) shown in Figure 6, indicating that they had the same publication potential in mHealth for diabetes research but different publication characteristics [53]. ZG Zhou published only corresponding-author articles, with an *h* of p/2. Prabhakaran and Lee had a higher ratio of corresponding-author articles to first-author articles, with an *h* of 1.326, than LS Mayberry, S Kumar, AG Logan, ME Rollo, and P Castensoe-Seidenfaden, with an *h* of 0.9828. The ratio of first-author articles to corresponding-author articles was higher for J Li with an *h* of 0.245 than for SMS Islam, AAG Nes, and S Nundy, who had an *h* of 0.5880. YY Zhang published only first-author articles, with an *h* of 0.

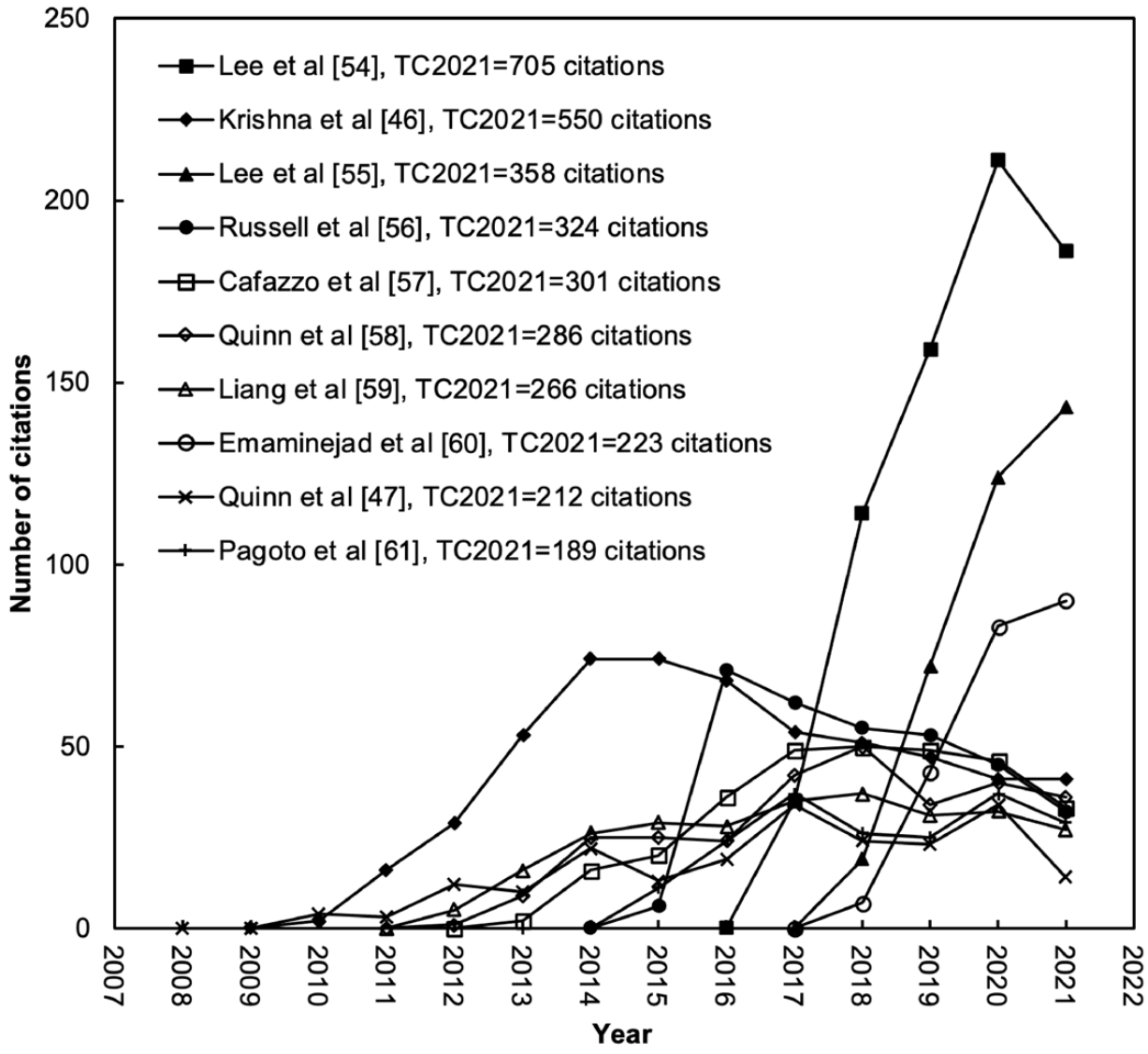
A Ramachandran (6, 1.373), CY Osborn (6, 1.107), R Verwey (6, π/4), and the 11 other authors, as well as SHM Guo (6, 0.4636), are on the same curve (*j*=6) with the same publication potential. However, Ramachandran had a higher ratio of corresponding-author articles to first-author articles with an *h* of 1.373, followed by Osborn with an *h* of 1.107, whereas Verwey and the other 11 authors published the same number of first-author and corresponding-author articles, with an *h* of π/4, and Guo published more first-author articles than corresponding-author articles. Similar behavior was found for authors located at a *j* of 8 and 9. MD Adu (10, 0.5880), S Nundy (5, 0.5880), AAG Nes (5, 0.5880), and SMS Islam (5, 0.5880) lie on a straight line (*h*=0.5880), indicating that they had the same publication characteristics but different publication potentials. Adu had a higher publication potential (with a *j* of 10) than Nundy, Nes, and Islam, who had a *j* of 5. Similar situations for authors located on an *h* of p/4 (the diagonal line) indicate that the authors had the same publication characteristics but different publication potentials. The location on the graph

along the curves represents the publication potential, whereas the location along a straight line from the origin represents the publication characteristics. When authors are located on the same curves, this means that they have the same publication potential, whereas when authors are located on the same straight line from the origin, this means that they have the same publication characteristics.

Citation History of the 10 Most Frequently Cited Articles

The citations of a highly cited article are not always high [39]. It is necessary to understand the citation history of a highly cited article in an area of research. The citation history of the top 10 most frequently cited articles on mHealth for Diabetes is presented in Figure 7 [46,47,54-61]. The article by Lee et al [54] published in 2016 titled "A Graphene-Based Electrochemical Device With Thermoresponsive Microneedles for Diabetes Monitoring and Therapy" was the most frequently cited with a TC_{2021} of 705 (ranked first). The 2009 article by Krishna et al [46] titled "Healthcare via Cell Phones: A Systematic Review" had a high impact from 2011 to 2015 with a TC_{2021} of 550 (ranked second). The 2017 article by Lee et al [55] titled "Wearable/Disposable Sweat-Based Glucose Monitoring Device With Multistage Transdermal Drug Delivery Module" had a similar trend with a TC_{2021} of 358 (ranked third). The rest of the top 10 most frequently cited articles were those by Russell et al [56] (ranked 4th), Cafazzo et al [57] (ranked 5th), Quinn et al [58] (ranked 6th), Liang et al [59] (ranked 7th), Emaminejad et al [60] (ranked 8th), Quinn et al [47] (ranked 9th), and Pagoto et al [61] (ranked 10th).

Figure 7. Citation history of the top 10 most frequently cited articles [46,47,51-58]. TC2021: total number of citations from the year of publication to the end of 2021.



Top 10 Articles With the Highest Impact

The top 10 articles with the highest impact in 2021 are shown in Table 7. These articles had a C_{2021} of ≥46. The top 10 articles were published by 96 authors from 30 institutions in the United States, South Korea, India, Australia, and Germany. The United States published 5 of the top 10 articles. The Institute for Basic Science and Seoul National University in South Korea published

3 of the top 10 articles. The top 3 articles were ranked in both the top 10 most frequently cited articles and the top 10 articles with the highest impact in 2021. These 3 highly cited and most impactful articles are summarized in the following paragraphs, as well as the articles that ranked fourth and fifth.

Table 7. The top 10 articles with the highest impact in 2021 with a number of citations in 2021 (C2021) of ≥46.

Rank: C_{2021}	Rank: TC_{2021}[a]	Title	Country	Reference
1 (186)	1 (705)	"A Graphene-Based Electrochemical Device With Thermoresponsive Microneedles for Diabetes Monitoring and Therapy"	South Korea and the United States	Lee et al [54]
2 (143)	3 (358)	"Wearable/Disposable Sweat-Based Glucose Monitoring Device With Multistage Transdermal Drug Delivery Module"	South Korea	Lee et al [55]
3 (90)	8 (223)	"Autonomous Sweat Extraction and Analysis Applied to Cystic Fibrosis and Glucose Monitoring Using a Fully Integrated Wearable Platform"	United States	Emaminejad et al [60]
4 (75)	14 (154)	"Soft, Smart Contact Lenses With Integrations of Wireless Circuits, Glucose Sensors, and Displays"	South Korea	Park et al [62]
5 (54)	27 (117)	"What Is the Economic Evidence for mHealth? A Systematic Review of Economic Evaluations of mHealth Solutions"	United States	Iribarren et al [63]
6 (53)	25 (121)	"Real-Time Continuous Glucose Monitoring in Adults With Type 1 Diabetes and Impaired Hypoglycaemia Awareness or Severe Hypoglycaemia Treated With Multiple Daily Insulin Injections (HypoDE): A Multicentre, Randomised Controlled Trial"	Germany and the United States	Heinemann et al [64]
6 (53)	72 (72)	"A Longitudinal Big Data Approach for Precision Health"	United States and Australia	Schüssler-Fiorenza Rose et al [65]
8 (49)	37 (110)	"Enzyme-Based Glucose Sensor: From Invasive to Wearable Device"	South Korea	Lee et al [66]
9 (47)	75 (70)	"Automated Diabetic Retinopathy Detection in Smartphone-Based Fundus Photography Using Artificial Intelligence"	India	Rajalakshmi et al [67]
10 (46)	77 (68)	"Cloud and IoT Based Disease Prediction and Diagnosis System for Healthcare Using Fuzzy Neural Classifier"	India	Kumar et al [68]

[a]TC_{2021}: number of citations from the Web of Science Core Collection from its publication year to the end of 2021.

"A Graphene-Based Electrochemical Device With Thermoresponsive Microneedles for Diabetes Monitoring and Therapy" by Lee et al [54] was written by 12 authors from 5 institutions in South Korea and the United States, with a C_{2021} of 186 (ranked first) and a TC_{2021} of 705 (ranked first). In this study, Lee et al [54] enhanced the electrochemical activity of graphene combined with a gold mesh to create a wearable patch useful for determining sweat glucose levels as part of diabetes monitoring. In addition, this wearable can be thermally activated to release drugs according to a feedback strategy as the device can be connected to a wireless unit for data transmission.

"Wearable/Disposable Sweat-Based Glucose Monitoring Device With Multistage Transdermal Drug Delivery Module" by Lee et al [55] was written by 10 authors from 2 institutions in South Korea, with a C_{2021} of 143 (ranked second) and a TC_{2021} of 358 (ranked third). In this article, Lee et al [55] presented a wearable patch using sweat as a noninvasive method to measure glucose levels mainly based on heat, temperature, pH, and humidity sensors with a wireless data communication system for transdermal medication release, which is beneficial for the treatment of patients with diabetes.

"Autonomous Sweat Extraction and Analysis Applied to Cystic Fibrosis and Glucose Monitoring Using a Fully Integrated Wearable Platform" by Emaminejad et al [60] was written by 14 authors from 5 institutions in the United States, with a C_{2021} of 90 (ranked third) and a TC_{2021} of 223 (ranked eighth). In this study, Emaminejad et al [60] developed a wearable platform mainly integrated with sensors and a Bluetooth interface to connect the system to a mobile phone, inducing sweat secretion to provide a sufficient sweat sample to measure various characteristics, especially sweat glucose values. It is useful for the noninvasive continuous monitoring of patients with diabetes or prediabetes.

"Soft, Smart Contact Lenses With Integrations of Wireless Circuits, Glucose Sensors, and Displays" by Park et al [62] was written by 13 authors from 2 institutions in South Korea: Ulsan National Institute of Science and Technology and Sungkyunkwan University. This paper had a C_{2021} of 75 (ranked 4th) and a TC_{2021} of 154 (ranked 14th). The authors developed a smart contact lens to monitor tear glucose levels by integrating sensors, wireless communication components, and a display to visualize the measurement results, which is useful for patients with diabetes.

"What Is the Economic Evidence for mHealth? A Systematic Review of Economic Evaluations of mHealth Solutions" by Iribarren et al [63] was written by 4 authors from 3 institutions in the United States: University of Washington, Columbia University, and New York-Presbyterian Hospital. This paper

had a C_{2021} of 54 (ranked 5th) and a TC_{2021} of 117 (ranked 27th). The authors emphasized the increasing economic evidence for mHealth as a cost-effective way to implement intervention activities, finding that the most common health conditions in the economic evaluations analyzed were outpatient visits, cardiovascular disease, and diabetes.

Top 10 Most Frequent Author Keywords

The keywords used by the authors provide a reasonable description of the topics covered in the articles and indicate the directions in which the researchers are moving. The top 10 author keywords were determined as shown in Table 8.

Table 8. Top 10 most frequent author keywords (N=1277).

Author keywords	TP[a], n (%)	Ranking	Hot spot
Telemedicine	122 (9.55)	1	Remote health care services
Self-management	98 (6.76)	2	Education and self-care activities
Smartphone	85 (6.66)	3	Innovative mobile app solutions
Mobile phone	66 (5.17)	4	Innovative mobile app solutions
Physical activity	52 (4.07)	5	Education and self-care activities
Mobile applications	41 (3.21)	6	Innovative mobile app solutions
Machine learning	37 (2.90)	7	Innovative mobile app solutions
Self-care	33 (2.58)	8	Education and self-care activities
Telehealth	33 (2.58)	8	Remote health care services
Mobile apps	31 (2.43)	10	Innovative mobile app solutions

[a]TP: total number of articles.

The author keywords were manually categorized with the support of the experts mentioned previously, and 3 groups were defined as the main hot spots of mHealth for diabetes: remote health care services, education and self-care activities, and innovative mobile app solutions. The keywords *telemedicine* and *telehealth* in positions 1 and 8, respectively, are the supporting keywords for the first hot spot, named "remote healthcare services." The keywords *self-management*, *physical activity*, and *self-care*, which occupy positions 2, 5, and 8, respectively, are the supporting keywords for the second hot spot, "education and self-care activities." Finally, the keywords *smartphone*, *mobile phone*, *mobile applications*, *machine learning*, and *mobile apps*, occupying positions 3, 4, 6, 7, and 10, respectively, are the supporting keywords for the third hot spot, "innovative mobile app solutions."

Discussion

Principal Findings

The extensive deployment of mobile technologies has simplified access to health care services, especially for diabetes management. mHealth for diabetes is a potential facilitator to reduce costs and overcome geographical and temporal barriers to support people with diabetes in their disease control. Activities such as education, counseling, intervention, monitoring, medication administration, dietary intake, and physical activity can be supported by mHealth for diabetes.

Between 1998 and 2021, a total of 1574 articles on mHealth for diabetes were published in SCI Expanded, 1549 (98.41%) of which were written in English and 20 (1.27%) of which were written in German. The average number of citations for an article from the year of publication until 2021 was 15, and the maximum number of citations for an article was 705. It takes approximately 8 years for the CPP to reach a plateau. In total, 491 journals published articles related to mHealth for diabetes in 92 Web of Science categories. The most productive categories were Health Care Sciences & Services with 25.98% (409/1574) of the articles followed by Medical Informatics with 23% (362/1574) of the articles and Endocrinology & Metabolism with 16.65% (262/1574) of the articles. The most productive journals were *JMIR mHealth and uHealth* with 7.94% (125/1574) of the articles followed by the *Journal of Medical Internet Research* with 5.84% (92/1574) of the articles and *Diabetes Technology & Therapeutics* with 4.38% (69/1574) of the articles. The 1574 articles on mHealth for diabetes were published by authors from 90 countries, of which 1129 (71.73%) were single-country articles with authors from 62 countries, whereas 445 (28.27%) were international collaborative articles with authors from 83 countries.

The most productive countries in terms of publications were the United States with 35.96% (566/1574) of the articles followed by the United Kingdom with 10.93% (172/1574), China with 8.7% (137/1574), Australia with 6.73% (106/1574), South Korea with 6.04% (95/1574), Germany with 5.02% (79/1574), India with 4.64% (73/1574), Spain with 4.57% (72/1574), Canada with 4.45% (70/1574), and the Netherlands with 3.81% (60/1574). Since 2008, the United States has been in the lead with a significant upward trend. This becomes relevant when comparing these countries with respect to the diabetes-related health expenditure. It is estimated that these countries will maintain or slightly increase their diabetes-related health expenditure between 2021 and 2045 and, in some cases, such as South Korea, Germany, Spain, and the Netherlands, decrease it. This may indicate that the measures currently in place are having an impact on preventing new problems arising from the disease and new patients. In fact, it is expected that between 2030 and 2045, the number of adults aged between 20

and 79 years with diabetes in South Korea, Germany, and the Netherlands will decrease.

Regarding institutions, of the 1574 articles, 371 (23.57%) came from a single institution, whereas 1203 (76.43%) came from interinstitutional collaborations. The top 3 most productive institutions came from the United States, led by Harvard University with 3.88% (61/1574) of the articles followed by Stanford University with 2.16% (34/1574) and the University of Michigan with 1.65% (26/1574). The 1574 articles on mHealth for diabetes were written by 7922 authors. The APP was 6.5, whereas the maximum number of authors in an article was 73. The most productive authors were E Arsand with 18 articles followed by HS Kim with 15, X Li with 13, and E Renard and S Del Favero with 12. In terms of publication performance, which considered publication potential and publication characteristics, HS Kim had the greatest publication potential, followed by CC Quinn, CG Parkin, and JD Piette. A potential bias in the authorship analysis can be caused by different authors with the same name or the use of different names by the same author over time [69]. For example, in mHealth for diabetes research, author names such as Hee-Seung Kim, Hun-Sung Kim, Hee-Sung Kim, Hee-Seon Kim, Hyun Seung Kim, and Hwa Sun Kim could be considered as HS Kim. Except for HS Kim, CC Quinn with the *Y*-index (14, π/4) had both the highest publication potential with a *j* of 14 and the highest CPP_{2021} for first-author articles and corresponding-author articles, as previously shown in Table 6.

On the other hand, the most cited articles were the 2016 article by Lee et al [54] titled "A Graphene-Based Electrochemical Device With Thermoresponsive Microneedles for Diabetes Monitoring and Therapy" with a TC_{2021} of 705, followed by the 2009 article by Krishna et al [46] titled "Healthcare via Cell Phones: A Systematic Review" with a TC_{2021} of 550 and the 2017 article by Lee et al [55] titled "Wearable/Disposable Sweat-Based Glucose Monitoring Device With Multistage Transdermal Drug Delivery Module" with a TC_{2021} of 358. The top 10 articles with the highest impact were published by 96 authors from 30 institutions from the United States, South Korea, India, Australia, and Germany. The top 3 articles with the highest impact were "A Graphene-Based Electrochemical Device With Thermoresponsive Microneedles for Diabetes Monitoring and Therapy" by Lee et al [54] followed by "Wearable/Disposable Sweat-Based Glucose Monitoring Device With Multistage Transdermal Drug Delivery Module" by Lee et al [55] and "Autonomous Sweat Extraction and Analysis Applied to Cystic Fibrosis and Glucose Monitoring Using a Fully Integrated Wearable Platform" by Emaminejad et al [60].

Research Hot Spots

The current research hot spots in mHealth for diabetes were determined by analyzing the top 10 most frequent author keywords (Table 8), and 3 hot spots were manually identified with help from experts in the field: remote health care services, education and self-care activities, and innovative mobile app solutions.

Remote health care services describe the delivery of health care services using a variety of mobile technologies, such as mobile apps, smartphones, and videoconferencing. These services include medical consultations, diagnosis, monitoring, and more, giving patients the opportunity to interact with a variety of medical specialists without the need to travel or long waiting times. Telemedicine and telehealth play an important role in the delivery of remote health care services. While telemedicine specifically refers to clinical services delivered remotely, telehealth encompasses a broader range of health care activities, including clinical care, patient education, health promotion, and administrative functions. Telehealth comprises both clinical and nonclinical services. Solutions to improve remote services are rapidly evolving with the support of digital health technologies such as smart devices, digital platforms, and sensors that can work together in a digital framework to simultaneously operate with multiple diabetes control and management activities, such as consultation, monitoring, and interventions. For example, Lian et al [70] demonstrated the effectiveness of a telehealth framework to support diabetes care during the COVID-19 pandemic, becoming an alternative to traditional consultations. In addition, Varnfield et al [71] showed the value of an mHealth platform for women with gestational diabetes mellitus by providing tools for multidisciplinary care coordination, including an app, a clinician portal, and cloud data storage, whereas Spoladore et al [72] presented an ontology-based telehealth platform to promote healthy food intake and physical activity in older adults with chronic diseases, providing appropriate suggestions based on health conditions. Similarly, May et al [73] highlighted the opportunities that digital health technologies offer to clinical practice, improving care delivery and patient engagement.

On the other hand, the education and self-care activities hot spot describes self-management actions that empower patients to take an active role in managing their health, promoting wellness and optimal health outcomes. These actions include a range of behaviors and strategies designed to promote health, prevent diabetes, and effectively manage existing health problems. Educational activities to help patients learn about their health conditions are critical in achieving a healthy lifestyle, promoting adequate physical activity and nutrition as well as treatment options and medications. In addition, it is important to mention that health education empowers patients with the knowledge and skills to make informed decisions about their health and participate effectively in their own care. In this sense, the use of digital technologies, including information and communications technologies, mobile technologies, smart devices, and SMS text messaging, is promoted. For example, Clark et al [74] demonstrated the benefits of using mHealth for diabetes self-management, including education, motivation, and intervention activities for individuals with diabetes distress. The impact of mobile technology interventions has also been evaluated by Chin-Jung et al [75], who found improvements in glucose levels and quality of life. Meanwhile, Whelan et al [76] explored people's engagement in a digital lifestyle in individuals at high risk of developing type 2 diabetes, finding that both real-time behavioral and physiological feedback have a positive impact on health. In addition, Rodriguez et al [77] developed a customized and automated SMS text messaging strategy based on computational tools to involve individuals in a digital diabetes prevention program. Similarly, McGill et al [78] created

an SMS text messaging intervention strategy for adolescents with type 1 diabetes, resulting in improved glycemic control. In addition, Tian et al [79] compared the effectiveness of glycemic control in women with gestational diabetes using social media through a group chat app. They demonstrated the value of instant messaging to improve glycemic control through educational and lifestyle intervention programs. To successfully integrate mHealth into diabetes care activities, changes in health care education and clinical practice are needed [80], and collaboration between patients and health care professionals is fundamental.

Finally, the innovative mobile app solutions hot spot describes the capabilities of mobile technologies such as smartphones and wearables managed by apps to improve diabetes management. These apps integrate advances in artificial intelligence, machine learning, and virtual reality to empower patients to effectively manage their health and help health care professionals improve their services. Furthermore, studies on the economic impact of mobile apps were also present in this hot spot. For example, Ramchandani [81] identified the benefits of internet-based guidance and diabetes-related apps to provide personalized support in real time, reducing the need for health care professionals to assist patients at any time. In addition, Tsuji et al [82] determined a favorable impact on the cost-effectiveness of a mobile app for continuous glucose monitoring using a Markov model to develop a cost simulation, whereas Fu et al [83] evaluated 4 top-rated diabetes apps for patients with type 2 diabetes and found that the future design of diabetes apps should consider patient motivation and a key heuristic design approach with supporting functions. Similarly, Khurana et al [84] validated the reliability of a mobile app to remotely monitor visual acuity and metamorphopsia. In a separate study, Shah et al [85] showed the utility of a direct ophthalmoscope-based smartphone camera for screening diabetic retinopathy. In the same way, Ludwig et al [86] managed to obtain low-resolution fundus images using a mobile phone and an indirect ophthalmoscope lens adapter, which were processed by a deep learning algorithm to detect diabetic retinopathy. On the other hand, diabetic foot ulcers have also been studied. In this context, Oe et al [87] proposed a mobile thermograph attached to a smartphone to prevent diabetic foot ulcers. Furthermore, Goyal et al [88] revealed the efficacy of a robust deep learning model to detect and locate diabetic foot ulcers in real time using a smartphone app, and Lin et al [89] validated the contribution of using wireless wearable near-infrared spectroscopy to predict wound prognosis in diabetic foot ulcers.

Other studies included advances in machine learning to propose solutions for diabetes control. For example, Kumar et al [90] demonstrated the effectiveness of a machine learning model combined with a mobile app to diagnose diseases such as diabetes, heart disease, and COVID-19, facilitating physician disease identification for appropriate treatment. Moreover, Bahadur et al [91] used human activity recognition based on machine learning algorithms to propose an efficient model to recognize and monitor 13 activities associated with diabetes symptoms to determine whether a person has diabetes mellitus. In another study, McVean and Miller [92] reported positive results from an insulin pump system with smartphone connectivity for the treatment of type 1 diabetes.

Conclusions

This study presents the dynamics of scientific publications in mHealth for diabetes through a scientometric analysis based on a CTI approach. CTI added value with a methodology supported by experts who provided feedback during the research process and helped consolidate different elements, including the search queries. The SCI Expanded database was used to collect data and provide insights into the evolution of the field according to the following: publication language, publication output characteristics, Web of Science categories and journals, country and institution publication performance, author publication performance, citation history of the most cited articles, and the articles with the highest impact according to their citation behavior.

This approach provides a comprehensive knowledge panorama of research productivity in mHealth for diabetes, identifying new insights and opportunities for R&D and innovation, including collaboration with other entities, new areas of specialization, and human resource development. It enables the identification of the productivity and impact of the field, comprising leading authors, countries, and journals; focus areas; and highly influential papers. In the top 10 most productive countries in terms of publications related to mHealth for diabetes, the prevalence of adult patients with diabetes will increase slightly by 2045. These countries exhibit strong efforts to discourage diabetes incidence. Researchers can develop collaborations and strategies by identifying key players in countries that contribute significantly to the field of mHealth for diabetes, creating opportunities for better diabetes management.

From a global perspective, the use of digital technologies to improve health conditions and services aims to reduce health disparities. Digital health is evolving rapidly; insights obtained indicate important efforts on health informatics, telemedicine, telecare, and eHealth to improve diabetes care and its prevention. Notable progress has been identified in the opportunities that digital health technologies offer to implement multiple activities to support diabetes management.

In the future, mHealth for diabetes will place the patient at the center of the ecosystem. Apps will provide user-friendly experiences and personalized recommendations based on the patients' specific circumstances and context. The use of machine learning will help prevent the development of diabetes, detect patterns that lead to the disease's development, and optimize treatment plans. The implementation of decision support systems in mobile apps to assist both patients and health care professionals in making informed decisions about diabetes management is a notable development for the future. Physical activity tracking and food plans will be supported using sensors, smartphones, wearables, and machine learning to provide personalized insights and recommendations based on personal health characteristics. Tailored medications for diabetes management are expected to be available through 3D printing technology. Various mobile technologies, electronic health records, the Internet of Things, and other health care

infrastructure will be integrated with a focus on creating interoperable systems that will enable continuous patient monitoring for efficient diabetes management, facilitating timely action in real time. It is expected that future analyses of large data sets generated by mHealth technologies will lead to the inclusion of mental health in the treatment of diabetes. In addition, mobile technology is expected to benefit the patients' caregivers and relatives.

Understanding the research dynamics in mHealth for diabetes, such as the evolution of the field and its current state, as well as providing future insights, enables researchers, health care professionals, and decision makers to focus their resources and efforts on meaningful contributions in which a promising future for mHealth for diabetes science is envisioned. Scholars are encouraged to apply this approach to study the scientific and technological dynamics of this and other fields of study, facilitating a continuous monitoring of the scientific and technological environment, a crucial activity for a strategic vision.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search query.
[DOCX File , 15 KB - diabetes_v9i1e52196_app1.docx]

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Abbreviations

APP: average number of authors per article
CPC: number of international collaborative articles
CPI: number of interinstitutional collaborative articles
CPP: average number of citations per publication
CTI: competitive technology intelligence
FP: number of first-author articles
IF: impact factor
IPC: number of single-country articles
IPI: number of single-institution articles
JCR: Journal Citation Reports
mHealth: mobile health
R&D: research and development
RP: number of corresponding-author articles
SCI: Science Citation Index
SP: number of single-author articles
TC: total number of citations from the year of publication to the end of a specific year
TP: total number of articles

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Original Paper

Care Partner Engagement in Secure Messaging Between Patients With Diabetes and Their Clinicians: Cohort Study

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Abstract

Background: Patient engagement with secure messaging (SM) via digital patient portals has been associated with improved diabetes outcomes, including increased patient satisfaction and better glycemic control. Yet, disparities in SM uptake exist among older patients and racial and ethnic underserved groups. Care partners (family members or friends) may provide a means for mitigating these disparities; however, it remains unclear whether and to what extent care partners might enhance SM use.

Objective: We aim to examine whether SM use differs among older patients with diabetes based on the involvement of care partner proxies.

Methods: This is a substudy of the ECLIPPSE (Employing Computational Linguistics to Improve Patient-Provider Secure Emails) project, a cohort study taking place in a large, fully integrated health care delivery system with an established digital patient portal serving over 4 million patients. Participants included patients with type 2 diabetes aged ≥50 years, newly registered on the patient portal, who sent ≥1 English-language message to their clinician between July 1, 2006, and December 31, 2015. Proxy SM was identified by having a registered proxy. To identify nonregistered proxies, a computational linguistics algorithm was applied to detect words and phrases more likely to appear in proxy messages compared to patient-authored messages. The primary outcome was the annual volume of secure messages (sent or received); secondary outcomes were the length of time to the first SM sent by patient or proxy and the number of annual SM exchanges (unique message topics generating ≥1 reply).

Results: The mean age of the cohort (N=7659) at this study's start was 61 (SD 7.16) years; 75% (n=5573) were married, 15% (n=1089) identified as Black, 10% (n=747) Chinese, 12% (n=905) Filipino, 13% (n=999) Latino, and 30% (n=2225) White. Further, 49% (n=3782) of patients used a proxy to some extent. Compared to nonproxy users, proxy users were older (P<.001), had lower educational attainment (P<.001), and had more comorbidities (P<.001). Adjusting for patient sociodemographic and clinical characteristics, proxy users had greater annual SM volume (20.7, 95% CI 20.2-21.2 vs 10.9, 95% CI 10.7-11.2; P<.001), shorter time to SM initiation (hazard ratio vs nonusers: 1.30, 95% CI 1.24-1.37; P<.001), and more annual SM exchanges (6.0, 95% CI 5.8-6.1 vs 2.9, 95% CI 2.9-3.0, P<.001). Differences in SM engagement by proxy status were similar across patient levels of education, and racial and ethnic groups.

Conclusions: Among a cohort of older patients with diabetes, proxy SM involvement was independently associated with earlier initiation and increased intensity of messaging, although it did not appear to mitigate existing disparities in SM. These findings

suggest care partners can enhance patient-clinician telecommunication in diabetes care. Future studies should examine the effect of care partners' SM involvement on diabetes-related quality of care and clinical outcomes.

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KEYWORDS

caregivers; diabetes; telehealth; secure messaging; patient portal; messaging; diabetes outcomes; family care; clinical care

Introduction

Patient portals are digital platforms that allow patients to securely access their personal health information, request prescription refills, schedule appointments, and communicate with their health care providers [1,2]. Driven in large part by federal meaningful use incentives, portal adoption by health care organizations has accelerated over the past decade [3]. Currently, over 90% of health care organizations offer patient portal access to their patients [4]. Social distancing measures during the COVID-19 pandemic led to restrictions on in-person visits and a dramatic shift to telehealth, making portal platforms and secure messaging (SM) increasingly relevant [1,5]. For patients with chronic diseases, such as diabetes, that rely upon regular intervisit communication with providers to support self-management, patient portals and SM can be critical to ensuring the provision of high-quality care. For example, patients with diabetes depend on communication with their providers to make timely and ongoing adjustments to their medications to avoid adverse events such as hypoglycemia and hyperglycemia [6]. Portal platforms and SM specifically can support this decision-making through asynchronous patient-provider communication. A recent systematic review highlighted significant associations between portal use and increased preventative behaviors, patient satisfaction, and medication adherence [7]. Among patients with diabetes, portal engagement has been associated with better medication adherence and self-efficacy, and SM use has been associated with better glycemic control [8-11].

Yet, many patients with medical and social vulnerabilities who may stand to benefit most from portal and SM use experience barriers to engagement. Several studies have documented substantial disparities in portal use among patients who are older, from diverse racial and ethnic backgrounds, and have lower educational attainment or limited health literacy [12-15]. Despite significant health system investment in patient portals, a recent national study found that only 15%-30% of patients offered portal access logged on [16]. Recent work has found that the reasons patients do not engage with portals likely extend beyond having limited access to technology infrastructure (computers and internet) to portal design features that limit broad accessibility [17]. Prominent features in the design of many patient portals include small font, English-only text, and complex user interfaces that limit access for patients with limited English proficiency, low health literacy, and disabilities [18].

Patients with lower health literacy and limited computer abilities who do manage to access the portal, experience less patient satisfaction than those with higher health literacy and computer abilities [19]. For these patients, care partners (family members or friends who assist patients with their health care needs, including communication) serving as proxies may offer a promising means for increasing portal engagement and accessing the potential benefits of SM. According to national survey data, one-third of caregivers use portals for their caregiving duties and are more likely to do so if they are caring for someone with a chronic condition [20]. Currently, care partners can access the patient portal and message clinicians in one of two ways: (1) *formally*, when a patient designates a registered proxy, who then has their own, linked account, and (2) *informally*, when a proxy logs on as the patient. Prior studies suggest that up to 18% of patient portal users share access with a care partner and anywhere from 25% to 50% of care partners report accessing the portal informally using the patient's account [21,22]. The large proportion of proxies accessing the portal informally using patient credentials is likely due to the inconsistency with which health systems provide care partners portal access and the barriers that exist to registration and use [23]. However, these studies have relied on patient and caregiver self-reported use; fears of reporting unauthorized portal access may lead to an underestimate of actual use.

It is unclear how proxy involvement might influence patients' SM engagement. Understanding the prevalence and characteristics of proxy messaging on behalf of patients is particularly important to inform the provision of patient care for diverse, aging populations. In this study, we leverage a novel computational linguistics algorithm to identify informal proxy involvement in SM among a cohort of older, racially and ethnically diverse patients with type 2 diabetes receiving care in a large, fully integrated health care delivery system with a mature patient portal. We follow this cohort over the course of 10 years, examining all secure messages patients exchanged with their clinicians. The objective of this study is to examine whether SM use varies based on care partner proxy involvement. We hypothesize that the involvement of proxies in SM is associated with increased SM communication and earlier initiation of messaging.

Methods

Study Sample and Setting

This is a substudy of the ECLIPPSE (Employing Computational Linguistics to Improve Patient-Provider Secure Emails) project, which leverages a large data set of secure messages exchanged between a cohort of patients with diabetes and their clinicians to understand the impact of patient health literacy and provider linguistic complexity on diabetes outcomes [24]. The ECLIPPSE cohort was drawn from the Diabetes Study of Northern California (DISTANCE). DISTANCE surveyed a racially or ethnically stratified (African American [n=6781, 17%], Asian [n=11,197, 27%], Latino/a/x/Hispanic hereafter referred to as Latino [n=7018, 17%], and White [n=4233, 10%]) random

sample of patients with diabetes receiving care within Kaiser Permanente Northern California, a large, fully integrated health care delivery system serving over 4 million members in Northern California. In total, 20,188 patients with diabetes completed the survey—fielded in 2005-2006 using a combination of phone, computer, and paper distribution methods—designed to examine social and behavioral factors associated with disparities in diabetes-related care and outcomes [25]. ECLIPPSE included the subset of DISTANCE survey respondents who sent at least 1 secure message to their clinician in over a 10-year period (July 1, 2006, to December 31, 2015).

Kaiser Permanente Northern California launched its patient portal in 1999 and by late 2005, the portal allowed patients to securely exchange messages with providers. In 2006, the portal "Act for a Family Member" feature was activated, which allowed patients to formally designate a proxy (spouse, adult child, friend, or other care partner) to access the portal and send secure messages on their behalf. Outside of "Act for a Family Member," it is not known how often proxy users access the portal and informally perform tasks on behalf of patients without registering as proxies. For this study, we included all patients in the ECLIPPSE cohort who were aged 50 years or older at the start of the observation period (July 1, 2006). We restricted the sample to those who composed English-language messages as the portal was only available in English at the start of this study's period.

Ethical Considerations

The University of California San Francisco and Kaiser Permanente Northern California institutional review boards approved this study (IRB#10-00671). Secondary analysis was permitted without additional consent. All study data were kept secure on password-protected servers to protect the privacy and confidentiality of the patient, care partner, and clinician.

Development and Validation of the ProxyID Algorithm

In addition to formally registered proxies, we also identified those patients who were likely using informal proxies to communicate with providers via SM. We did this by applying *ProxyID*, an algorithm that uses computational linguistics to detect words and phrases more likely to appear in proxy SM compared to patient-authored SM. The development and validation of *ProxyID* has been described in detail previously [26]. Briefly, to develop *ProxyID*, proxy-authored SM written by registered proxy users were identified, then an equal number of presumed patient-authored SM were randomly sampled. Wordsmith Tools 6 was used to identify key n-grams (ie, words and contiguous phrases) significantly more likely than chance to occur in registered proxy SM compared to presumed patient-authored SM [27,28]. Examples of key n-grams included third-person pronouns and phrases such as "I am writing on behalf of." The key n-grams for each secure message were fed into *ProxyID* which, through machine learning, selected likely proxy messages based on these data and patterns of n-grams in the messages. This ultimately enabled the classification of each secure message as likely proxy-authored versus likely patient-authored. To validate these classifications, 3 blinded expert assessors read secure messages from a purposive sample of 200 unique patients (100 secure messages designated by *ProxyID* as likely proxy-authored and 100 designated as likely patient-authored SM) and, based on SM content, categorized these secure messages as proxy-authored or patient-authored. *ProxyID* had moderate agreement with blinded expert categorization (κ=0.58), with a sensitivity of 0.93 (negative predictive value 0.95) and specificity of 0.70 (positive predictive value 0.64). Given the small number of registered proxies compared to informal proxies (see Results, below) identified by *ProxyID*, we grouped registered and informal proxies together for all analyses.

Patient Sociodemographic and Clinical Characteristics

Patients' self-reported sociodemographic characteristics (age, gender, race or ethnicity, marital status, and educational attainment) were obtained via the DISTANCE survey. The patient's most recent hemoglobin A_{1c} (HbA_{1c}) and Charlson comorbidity score before the survey receipt date were derived from the electronic health record [29]. Health care usage (outpatient, inpatient, and emergency room visits) over the 12 months before the survey receipt date was derived from the electronic health record.

SM Characteristics

We examined SM characteristics during active SM use. We defined active SM use as starting from the time at which the patient first sent a secure message to the end of this study's period; we censored due to patient disenrollment from the health plan or death. We defined our primary outcome, secure message volume, as the average secure message count per year during active SM use. We defined our secondary outcomes as (1) initiation: time to first patient-sent secure message from study start and (2) exchanges: average number of unique SM subjects generating ≥1 reply per year during active SM use.

Statistical Analysis

ProxyID was applied to all secure messages sent by each patient to determine which patients had secure messages likely authored by a proxy. Patients with registered proxy-authored secure messages and those found to have one or more secure messages predicted by *ProxyID* to be proxy-authored during this study's period were categorized as "any proxy." Patients without proxy-authored messages over this study's period were categorized as "never proxy." The sociodemographic and clinical differences between "any proxy" versus "never proxy" patients were characterized using bivariate analyses; categorical values were reported as percentages and the Pearson chi-squared test was used to compare subgroups.

For annual SM volume and number of exchanges, we calculated person-years of observation for each patient during their period as active SM users. In a given year, only SM data from active SM users were included. We excluded SM data from patients who disenrolled from the health plan or died. Multivariable negative binomial regression models were specified to examine the association of patient proxy use with the average annual SM volume and number of exchanges. We selected the negative binomial regression as it provided the best fit for modeling count variables that are widely dispersed. The models accounted for repeated measures by patients (eg, some patients contributed up to 10 observations, one for each year of this study). Models

were adjusted for patient sociodemographic (age, gender, race or ethnicity, marital status, educational attainment, and limited English proficiency status) and clinical (HbA_{1c}, comorbidities, outpatient visits, emergency department visits, and hospital admissions) characteristics, as well as proxy use and year of messaging. A Cox proportional hazards regression model adjusted for the same patient sociodemographic and clinical characteristics used in the multivariable negative binomial models above, and proxy use was specified to simultaneously assess the effect of proxy use (reference: no use) on time (in days) to initiation of the first secure message. Model hazard ratios (HRs) of >1 indicated that proxy use was associated with a shorter time to initiation of messaging; HR<1 indicated proxy use was associated with a longer time to initiation of messaging. As all patients sent at least 1 message during this study's period, no observations were censored for this analysis.

We examined whether the relationship between proxy status and SM volume differed by select patient characteristics, by adding interaction terms (proxy status × patient race or ethnicity and proxy status × educational attainment) to the adjusted multivariable regression models.

Statistical significance was defined as 2-tailed $P<.05$. All statistical analyses were performed using Stata (version 16.1; StataCorp).

Results

Cohort Characteristics

In total, 7659 patients met this study's inclusion criteria. The mean age was 61 (SD 7.16) years at baseline, 46% (n=3548) were women, and the majority were married or partnered (75%). Patients self-identified as Black (n=1089, 15%), Chinese (n=747, 10%), Filipino (n=905, 12%), Latino (n=999, 13%), of other races or multiracial (n=817, 11%), and White or non-Hispanic (n=2225, 30%; Table 1). The person-time of observation among active SM users over this study's period was 45,712 person-years (70,812 person-months; Multimedia Appendix 1)

Table 1. Characteristics of patients with type 2 diabetes by proxy engagement over the entire cohort study period, from 2006 to 2015 (N=7659)[a].

Patient characteristics	Total (N=7659), n (%)	Never proxy (n=3877), n (%)	Any proxy (n=3782), n (%)	*P* value
Age (years)				<.001
50-59	3483 (45.5)	1933 (49.9)	1550 (41)	
60-69	2877 (37.6)	1473 (38)	1404 (37.1)	
70-79	1299 (16.9)	471 (12.1)	828 (21.9)	
Women	3548 (46.3)	1752 (45.2)	1796 (47.5)	.04
Race				<.001
Black	1089 (14.6)	587 (15.6)	502 (13.6)	
Chinese	747 (10)	375 (10)	372 (10.1)	
Filipino	905 (12.2)	506 (13.4)	399 (10.8)	
Latino[b]	999 (13.4)	468 (12.4)	531 (14.4)	
Other Asian	663 (8.9)	368 (9.8)	295 (8)	
Other or mixed	817 (11)	388 (10.3)	429 (11.7)	
White	2225 (29.9)	1073 (28.5)	1152 (31.3)	
Married or living with a partner	5573 (75.0)	2838 (75.5)	2735 (74.4)	.28
Education				<.001
Less than high school degree	861 (11.4)	343 (9)	518 (13.9)	
High school	1911 (25.3)	888 (23.3)	1023 (27.5)	
Some college or more	4768 (63.2)	2587 (67.8)	2181 (58.6)	
LEP[c,d]	499 (6.5)	194 (5)	305 (8.1)	<.001
HbA_{1c}[e] ≥8%[f]	1705 (22.3)	871 (22.5)	834 (22.1)	.66
Charlson comorbidity[g]				<.001
1	4075 (53.2)	2225 (57.4)	1850 (48.9)	
2	2152 (28.1)	1011 (26.1)	1141 (30.2)	
3+	1432 (18.7)	641 (16.5)	791 (20.9)	
≥3 outpatient visits[g]	6467 (84.4)	3192 (82.3)	3275 (86.6)	<.001
≥1 emergency department visit[g]	1471 (19.2)	682 (17.6)	789 (20.9)	<.001
≥1 hospital admission[g]	701 (9.2)	315 (8.1)	386 (10.2)	.002

[a]Percentages based on nonmissing values. Missing responses: race or ethnicity (n=214, 2.8%), marital status (n=227, 3%), education (n=119, 1.6%), and limited English proficiency (n=22, 0.3%).

[b]Includes Latino/a/x/Hispanic individuals.

[c]LEP: limited English proficiency.

[d]Respondents were asked, "How often do you have difficulty understanding or speaking English?" Responses were dichotomized as limited English proficiency ("Always," "Often," and "Sometimes") and English proficient ("Rarely" and "Never").

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

[f]Measured closest to study onset.

[g]Usage in the 12 months before this study's entry.

Patient Characteristics by Proxy Status

In total, 49% (n=3782) of patients were categorized as "any proxy" users; 95% (n=3585) were nonregistered proxies, while only 5% (n=197) were registered (Multimedia Appendix 2). In bivariate comparisons, "any proxy" users, when compared to "never proxy" users, were older (aged 70-79 years; 21.9%, n=828 vs 12.1%, n=471; *P*<.001), more likely to be women (47.5%, n=1796 vs 45.2%, n=1752; *P*=.04), have lower educational attainment (less than high school degree, 13.9%, n=518 vs 9%, n=343; *P*<.001), and have limited English proficiency (8.1%, n=305 vs 5%, n=194; *P*<.001). At baseline, "any proxy" users were more likely to have a mean Charlson comorbidity index greater than 3 (20.9%, n=791 vs 16.5%,

n=641; *P*<.001) and more frequent health care usage in the 12 months before survey receipt, including outpatient (≥3 visits, 86.6%, n=3275 vs 82.3%, n=3192; *P*<.001), emergency department (≥1 visit, 20.9%, n=789] vs 17.6%, n=682; *P*<.001), and hospital (≥1 admission, 10.2%, n=386 vs 8.1%, n=315; *P*=.002; Table 1).

SM Patterns by Proxy Status

In unadjusted models, "any proxy" users had nearly twice the volume of secure messages per year compared to "never proxy" users (21.3, 95% CI 20.8-21.8 vs 11.0, 95% CI 10.7-11.3; *P*<.001; Table 2) and double the SM exchanges per year (6.0, 95% CI 5.9-6.2 vs 3.0, 95% CI 2.9-3.0; *P*<.001). These findings were essentially unaltered by adjustment (volume of secure messages per year with any proxy use: 20.7, 95% CI 20.2-21.2 vs never proxy: 10.9, 95% CI 10.7-11.2; *P*<.001); SM exchanges per year (any proxy use: 6.0, 95% CI 5.8-6.1 vs never proxy: 2.9, 95% CI 2.9-3.0; *P*<.001). Compared to "never proxy" users, "any proxy" users had earlier initiation of messaging (unadjusted HR 1.19, 95% CI 1.14-1.25; *P*<.001; adjusted HR 1.30, 95% CI 1.24-1.37; *P*<.001). The relationship between proxy use and annual SM volume did not differ across patient race and ethnicity (*P*=.80) and educational attainment (*P*=.39) over the entire cohort study period.

Table 2. Annual secure message volume by patient characteristics over the entire cohort study period, from 2006 to 2015[a].

Characteristics	Unadjusted hazard ratio (95% CI)	*P* value	Adjusted[b] hazard ratio (95% CI)	*P* value
Never proxy	11.0 (10.7-11.3)	Reference	10.9 (10.7-11.2)	Reference
Any proxy	21.3 (20.8-21.8)	<.001	20.7 (20.2-21.2)	<.001
Age (years)				
50-59	17.0 (16.5-17.5)	Reference	15.9 (15.5-16.3)	Reference
60-69	15.9 (15.4-16.4)	.002	14.8 (14.4-15.2)	<.001
70-79	16.9 (16.0-17.7)	.78	15.7 (15.0-16.5)	<.001
Gender				
Men	16.6 (16.1-17.1)	Reference	15.5 (15.2-15.9)	Reference
Women	16.5 (16.1-17.0)	.87	15.3 (15.0-15.7)	.85
Race or ethnicity				
Black	16.7 (15.8-17.5)	.02	15.6 (14.8-16.4)	.002
Chinese	15.4 (14.5-16.4)	<.001	14.5 (13.7-15.3)	.01
Filipino	14.9 (14.0-15.7)	<.001	14.0 (13.3-14.7)	<.001
Latino	16.1 (15.2-17.0)	.001	14.9 (14.2-15.6)	<.001
Other Asian	15.8 (14.9-16.8)	<.001	14.8 (14.0-15.5)	.009
Other or mixed	16.4 (15.4-17.3)	.005	15.2 (14.4-15.9)	<.001
White	18.0 (17.4-18.7)	Reference	16.8 (16.3-17.3)	Reference
Marital status				
Married or living with partner	16.4 (16.0-16.8)	Reference	15.2 (14.9-15.5)	Reference
Never married or widowed or divorced	17.2 (16.6-17.9)	.03	16.3 (15.7-16.9)	.02
Education				
Less than high school	15.9 (15.0-16.8)	Reference	15.1 (14.3-16.0)	Reference
High school	16.4 (15.8-17.1)	.34	15.4 (14.9-15.9)	.91
Some college or more	16.7 (16.3-17.1)	.11	15.5 (15.2-15.8)	.02
English proficiency				
English proficient	16.7 (16.4-17.1)	Reference	15.6 (15.3-15.9)	Reference
LEP[c,d]	13.3 (12.3-14.4)	<.001	12.7 (11.8-13.6)	<.001
HbA_{1c}[e,f]				
<8%	16.3 (16.0-16.7)	Reference	15.3 (15.0-15.6)	Reference
≥8%	17.4 (16.7-18.1)	.008	16.1 (15.6-16.7)	.02
Charlson comorbidities[f]				
1	15.3 (14.9-15.7)	Reference	14.3 (14.0-14.7)	Reference
2	17.2 (16.5-17.8)	<.001	16.1 (15.6-16.6)	.003
3+	19.4 (18.5-20.2)	<.001	18.1 (17.4-18.8)	<.001
Number of outpatient visits[g]				
<3	13.8 (13.1-14.5)	Reference	13.0 (12.4-13.5)	Reference
≥3	17.1 (16.7-17.4)	<.001	15.9 (15.6-16.2)	<.001
Number of emergency department visits[g]				
None	16.1 (15.8-16.5)	Reference	15.0 (14.8-15.3)	Reference
Any	18.5 (17.7-19.3)	<.001	17.3 (16.7-18.0)	.02

Characteristics	Unadjusted hazard ratio (95% CI)	*P* value	Adjusted[b] hazard ratio (95% CI)	*P* value
Number of hospital admissions[g]				
None	16.4 (16.0-16.7)	Reference	15.3 (15.0-15.5)	Reference
Any	18.5 (17.3-19.6)	<.001	17.4 (16.4-18.3)	.83

[a]Secure message volume: count of annual patient messages sent and received.

[b]Adjusted for age, sex, race or ethnicity, education, marital status, limited English proficiency status, hemoglobin A_{1c}, comorbidities, number of outpatient visits, number of emergency department visits, number of hospital admissions, year of messaging, and proxy use.

[c]LEP: limited English proficiency.

[d]Respondents were asked, "How often do you have difficulty understanding or speaking English?" Responses were dichotomized as limited English proficiency ("Always," "Often," and "Sometimes") and English proficient ("Rarely" and "Never").

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

[f]Measured closest to study onset.

[g]Usage in the 12 months before this study's entry.

SM Patterns by Patient Sociodemographic and Clinical Characteristics

In adjusted multivariable models, patients unmarried or not living with a partner versus married or living with a partner sent and received more messages per year (16.3, 95% CI 15.7-16.9 vs 15.2, 95% CI 14.9-15.5; *P*=.02). Patients with limited English proficiency, compared to those who were English proficient, sent and received fewer messages annually (12.7, 95% CI 11.8-13.6 vs 15.6, 95% CI 15.3-15.9; *P*<.001). Patients with higher baseline HbA_{1c} had greater annual SM volume (16.1, 95% CI 15.6-16.7 vs 15.3, 95% CI 15.0-15.6, *P*<.001). More frequent health care usage in the 12 months before the survey receipt was associated with greater annual SM volume: having ≥3 outpatient visits (15.9, 95% CI 15.6-16.2 vs 13.0, 95% CI 12.4-13.5; *P*<.001) and any emergency department visits (17.3, 95% CI 16.7, 18.0 vs 15.0, 95% CI 14.8, 15.3; *P*=.02; Table 2).

Discussion

Principal Findings

SM is an increasingly important mode of communication in patient care and may have particular relevance for aging patients with chronic illnesses. Such patients often require additional support and can benefit from frequent digital communication for disease management [30-32]. Yet, little is known about how care partners access secure messages on patients' behalf. Among a racially and ethnically diverse older cohort of patients with diabetes, those patients involving proxies in messaging had a greater annual volume of messages, earlier initiation of messaging as well as more message exchanges with their clinicians. However, while involving proxies increased messaging overall, it did not appear to mitigate existing race or ethnic disparities in SM use.

Care partners have key roles in providing support for patients with chronic diseases by taking on responsibilities including coordinating health care tasks, accompanying patients to medical visits, and communicating with clinicians [32,33]. Prior studies suggest that care partners participate in primary care visits for nearly 40% of older adults with chronic illnesses, engaging in conversations and care decisions [34,35]. Given the increasing uptake of telehealth, more of these visit-based conversations are likely to occur remotely and digitally, leveraging platforms such as patient portals. We estimated that nearly half of patients with diabetes in our sample engaged proxies, which is higher than prior estimates [21]. This may be due to this study's health system having a mature patient portal with an early investment in supporting design features, such as ease of use across mobile platforms and a focus on digital accessibility for those with disabilities that allow for wider accessibility for both proxies and patients. Despite having a process for formal proxy registration ("Act for a Family Member"), only 5.2% (n=197) of proxies in our sample were formally registered with the majority, identified using *ProxyID*, likely accessing the portal informally. This suggests that additional exploration is needed to understand design changes that may facilitate proxy registration. Other studies report that 25%-50% of proxies use portals without formally registering [21,22]. These prior estimates rely on self-report and may reflect a reluctance to disclose unauthorized use, thus underestimating rates of informal proxy use. A more recent smaller study focused on dementia care that employed a manual review of message authorship found that care partners overwhelmingly (97%) used patient credentials to access the portal [36]. Prior studies have not focused on large study samples or patients with diabetes, who have self-management support needs that may indicate a reliance on proxies. Designing portals and SM to be easily accessible to all users, can help ensure these communication platforms support patient- and family-centered care.

Patients engaging care partners as proxies were more likely to be older, have less educational attainment, and have limited English proficiency. This is not surprising given the well-documented challenges that older patients and those with communication barriers face in accessing and engaging with health care technology [37,38]. Care partners may be able to support SM engagement for patients who experience barriers to use. Women were more likely to have proxy SM involvement, which may be reflective of women being more likely than men to have a child or child-in-law provide care as opposed to a spouse [39]; younger rather than older generation care partners are more comfortable using technology to support their roles providing care [40]. Patients with more comorbidities and more

frequent health care usage, suggestive of more complex care needs, were also more likely to engage proxies. This finding is consistent with prior work demonstrating that care partner use of technology for health care–related activities is more common when more intensive support is needed [41].

Patients who engaged proxies demonstrated greater SM engagement across several metrics. First, proxy-engaging patients initiated messaging earlier than those without proxy involvement. While it is not clear whether proxies specifically initiated messaging, our findings suggest that care partners assisted patients in the uptake and adoption of SM. Second, patients with proxies had a higher annual volume of messages and number of exchanges with their clinicians. These results are consistent with prior research suggesting that care partners are interested in leveraging health technology to support their loved ones and care-related activities [41]. Importantly, involving a proxy was associated with similar increases in the volume of messaging across patient racial and ethnic groups and levels of educational attainment. This suggests that proxy involvement may enable patient populations who experience barriers to engagement to reap the benefits of this remote technology.

Our study has important limitations. First, we identified patients who engage proxies using a novel computational linguistics algorithm, *ProxyID*, that has been validated in 1 health system. While *ProxyID* has demonstrated high sensitivity in excluding nonproxy messages, its lower specificity suggests that we likely misclassified some patient-authored messages as proxy-authored. This may have led to an overestimation of the number of patients using proxies. Conversely, some “hidden” proxies may have avoided language in secure messages that *ProxyID* could identify, thus leading to an underestimation of proxy engagement. However, the presence of hidden proxies in the sample designated as never proxy users would introduce a conservative bias (ie, underestimation of differences) in our assessment comparing those identified as proxy users versus never proxy users. Patients considered proxy users had varying degrees of proxy engagement in messaging that may have been associated with differences in SM patterns. Additionally, we are reporting data from 1 health system, limiting generalizability. This study’s setting, however, represents a large integrated health care system with advanced and frequent portal use. The sample was socioeconomically and ethnically diverse, except excluding the extremes of income [25]. Study data were gathered before the COVID-19 pandemic, which has been associated with an increase in SM across health systems including within our study setting [42]. Given the large, detailed nature of this study’s data and that the health system was an early adopter of the patient portal, the data set provides a unique opportunity to comprehensively examine broad patient SM patterns and the understudied area of proxy engagement. However, our findings may not reflect current SM patterns. Finally, our study design did not include analyses of SM content, or exploration of how proxy involvement might influence SM content or alter patient care.

Conclusion

To our knowledge, this is the first study to describe how proxy involvement influences engagement with SM for older patients with diabetes. Proxy use was prevalent, with about half of patients engaging proxies to some extent. Proxy engagement was associated with earlier initiation of messaging, a greater volume of messages, and more exchanges with clinicians. Patients engaging proxies represented a more socially and medically vulnerable group. The benefits of proxy involvement were similar across patient race and ethnicity and across levels of educational attainment, thus unlikely to mitigate existing disparities in SM use. These findings suggest that engaging proxies may provide a pathway to increase SM uptake for patients with barriers to use, enabling access to its potential benefits. Modifying portal privacy and security rules may better accommodate proxy portal use on behalf of patients. Future work should explore avenues for identifying patients who may benefit from engaging proxies and determining if proxy involvement in messaging influences patient and care partner outcomes.

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Data Availability

The data sets generated or analyzed during this study are not publicly available due to the need to maintain strict protection of patient and care partner privacy.

Authors' Contributions

This study's concept and design were done by WS, AJK, and DS. The acquisition of subjects or data was performed by WS, AJK, JYL, and DS. Analysis and interpretation of data were completed by WS, AJK, CRL, MER, LK, CK, JYL, JL-T, and DS. Preparation of this paper was by WS, AJK, CRL, MER, LK, CK, JYL, JL-T, and DS. WS had full access to all the data in this study and takes responsibility for the integrity of the data and accuracy of the data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Total person-time of observation among patients with type 2 diabetes who are active users over the entire cohort study period, from 2006-2015 (N=7,659 patients). Active users were defined by starting observation from patient/proxy initiation of first secure message to the end of the study period or to patient leaving the health system if the patient left before the end of the study period.
[PDF File (Adobe PDF File), 42 KB - diabetes_v9i1e49491_app1.pdf]

Multimedia Appendix 2
Type of portal access and proxy authorship for any proxy users on behalf of patients with type 2 diabetes over the entire cohort study period, from 2006-2015 (N=3,782).
[PDF File (Adobe PDF File), 78 KB - diabetes_v9i1e49491_app2.pdf]

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Abbreviations

DISTANCE: Diabetes Study of Northern California
ECLIPPSE: Employing Computational Linguistics to Improve Patient-Provider Secure Emails
HbA_{1c}: hemoglobin A_{1c}
HR: hazard ratio
SM: secure messaging

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Original Paper

Technology and Continuous Glucose Monitoring Access, Literacy, and Use Among Patients at the Diabetes Center of an Inner-City Safety-Net Hospital: Mixed Methods Study

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Abstract

Background: Despite the existence of an increasing array of digital technologies and tools for diabetes management, there are disparities in access to and uptake and use of continuous glucose monitoring (CGM) devices, particularly for those most at risk of poor diabetes outcomes.

Objective: This study aims to assess communication technology and CGM access, literacy, and use among patients receiving treatment for diabetes at an inner-city safety-net hospital.

Methods: A survey on digital technology ownership and use was self-administered by 75 adults with type 1 and type 2 diabetes at the diabetes clinic of Grady Memorial Hospital in Atlanta, Georgia. In-depth interviews were conducted with 16% (12/75) of these patient participants and 6 health care providers (HCPs) to obtain additional insights into the use of communication technology and CGM to support diabetes self-management.

Results: Most participants were African American (66/75, 88%), over half (39/75, 52%) were unemployed or working part time, and 29% (22/75) had no health insurance coverage, while 61% (46/75) had federal coverage. Smartphone ownership and use were near universal; texting and email use were common (63/75, 84% in both cases). Ownership and use of tablets and computers and use and daily use of various forms of media were more prevalent among younger participants and those with type 1 diabetes, who also rated them as easier to use. Technology use specifically for diabetes and health management was low. Participants were supportive of a potential smartphone app for diabetes management, with a high interest in such an app helping them track blood sugar levels and communicate with their care teams. Younger participants showed higher levels of interest, perceived value, and self-efficacy for using an app with these capabilities. History of CGM use was reported by 56% (42/75) of the participants, although half (20/42, 48%) had discontinued use, above all due to the cost of the device and issues with its adhesive. Nonuse was primarily due to not being offered CGM by their HCP. Reasons given for continued use included convenience, improved blood glucose control, and better tracking of blood glucose. The in-depth interviews (n=18) revealed high levels of satisfaction with CGM by users and supported the survey findings regarding reasons for continued use. They also highlighted the value of CGM data to enhance communication between patients and HCPs.

Conclusions: Smartphone ownership was near universal among patients receiving care at an inner-city hospital. Alongside the need to address barriers to CGM access and continued use, there is an opportunity to leverage increased access to communication technology in combination with CGM to improve diabetes outcomes among underresourced populations.

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KEYWORDS

diabetes mellitus; type 1; type 2; digital health; continuous glucose monitoring; mobile phone

Introduction

Background

There has been a marked acceleration in the use of digital communication technology to deliver care since the COVID-19 pandemic [1]. This has further fueled concern that people with diabetes lacking access to and literacy in such technologies may be left behind in an expanding digital diabetes ecosystem [2,3].

Continuous glucose monitoring (CGM) is recognized as an important diabetes management tool leading to clinically meaningful reductions in glycated hemoglobin even among patients with type 2 diabetes (T2D) on less intensive insulin regimens [4]. However, the known benefits of CGM are not evenly distributed, with underresourced populations, particularly African American individuals [5], having lower rates of CGM use and higher rates of discontinuation [6-9].

Several CGM systems have their own proprietary smartphone apps that can be used as an alternative to a stand-alone CGM reader to display CGM data and, like readers, alert patients via alarms to highs and lows [10]. Meta-analyses also suggest that digital apps can facilitate and optimize self-care among people with diabetes [11,12], and some commercial diabetes apps have the capacity to link to popular CGM systems [13,14].

A recent Pew report indicates a marked increase in US cellphone ownership (to approximately 97%) regardless of racial, ethnic, or socioeconomic background. While smartphone ownership has also increased (to approximately 85%), this is lower among older, less educated, and lower-income Americans [15]. A recent survey among vulnerable, primarily Latino, community residents in East Harlem, New York, suggests that the digital divide in access to communication technology is narrowing, and study participants expressed interest in health-promoting apps [16]. However, diabetes health apps are often not accessible to populations vulnerable to the worst diabetes outcomes, namely, minoritized populations with the lowest socioeconomic status and the least education [17,18]. Barriers to access to these apps may include platform (access to recent models of smartphones and data plans); affordability (paywalls or other restrictions); lack of integration with health care; and technology, data, and health literacy (excessive complexity or user burden and limited appeal) [19-21].

Objectives

To explore the feasibility of an app for underresourced patients with type 1 diabetes (T1D) and T2D, we assessed communication technology access, use, and literacy along with CGM use and discontinuation patterns by means of a self-administered survey among patients receiving care at the diabetes center of an inner-city safety-net hospital. We additionally conducted in-depth interviews (IDIs) with a subset of those patient participants and their health care providers (HCPs) to gain insights into their experiences with CGM and app use for diabetes management.

Methods

Overview

Patient participants and HCPs were recruited from the Grady Diabetes Center (GDC) at Grady Memorial Hospital, Atlanta, Georgia.

For the survey portion of the study, efforts were made to ensure recruitment of individuals with and without previous exposure to CGM, with T1D and T2D, as well as male and female participants. Individuals with impaired decision-making capacity or inability to provide consent, including due to an English-language barrier, and minors were excluded from participation. Pregnant individuals were eligible as long as they had a T1D or T2D diagnosis. Data collection took place between June 2021 and December 2021, during which time we enrolled 75 consecutive adult patients currently receiving care at the GDC and its monthly or bimonthly Technology Clinic. Recruitment was first initiated through phone-based contact of individuals with a CGM account linked to the Grady LibreView practice. LibreView is a cloud-based system that allows HCPs to view reports summarizing patients' glucose readings from the FreeStyle Libre CGM system. In response to the limited success of this method (only 4 participants were identified through this strategy), it was replaced with waiting room–based direct contact. Trained study staff members screened participants for eligibility and secured consent either in person at the clinic or by phone. Participants self-administered the survey via tablet-based REDCap (Research Electronic Data Capture; Vanderbilt University) [22] unless they requested study staff assistance in navigating the survey. Questions included ownership and use of communication technology devices (smartphones, tablets, computer, and wearables) and use of media (texting, mobile apps, email, social media, podcasts, web videos, and websites). These items were drawn and adapted from the Technology Access and Competency Scale, an instrument developed by author JE and colleagues that has not undergone psychometric validation but has been used in other technology-related studies [23,24]. Items related to interest in using and intention to use technology for diabetes self-management [25] were also included. Additional demographic (including insurance status) and biometric data were extracted from electronic medical records and used to confirm self-reported diabetes diagnosis (ie, T1D vs T2D). Descriptive statistics (counts and proportions or means and SDs,

as appropriate) were calculated for demographics and technology use and access items using the SAS software (version 9.4; SAS Institute). These were also stratified by diabetes type and age group to elucidate potential within-sample differences.

IDIs were conducted with 12 patient participants and 6 HCPs. Survey participants who indicated willingness to take part in an IDI and met additional eligibility criteria (current or previous CGM use) were contacted for participation in this portion of the study and enrolled consecutively. IDIs focused on patients' experiences with CGM and their use of technology tools for diabetes self-management. HCP IDI participants were selected purposively from among HCPs working at the GDC to cover a range of specializations. These IDIs focused on HCPs' perspectives on their patients' use of technology, particularly CGM, for diabetes self-management and its impact thereon. All IDIs were conducted via Zoom (Zoom Video Communications) and lasted between 30 and 75 minutes. Transcripts of audio recordings were reviewed for accuracy and deidentified before being uploaded into MAXQDA 2022 (VERBI GmbH) for coding and analysis. A codebook of deductive themes focusing on domains addressed in the IDI guides and inductive themes emerging from the transcripts was systematically applied to the transcripts. Thematic analysis of coded segments focused on the challenges of diabetes self-management and opportunities offered by digital technology, along with benefits and difficulties associated with CGM system use as perceived by both patient participants and HCPs. Data were stratified by interviewee group.

Ethical Considerations

This study was approved by the Emory University Institutional Review Board and Grady Memorial Hospital's Research Oversight Committee (IRB#00002376). All participants in the survey and IDI study components were compensated for their time at a rate of US $10 for survey completion and US $25 for IDI participation.

Results

Participant Demographics

Among survey respondents, most were African American (66/75, 88%), and two-thirds were female (50/75, 67%; Table 1). Half (37/75, 49%) had a high school or General Educational Development diploma or a lower educational level; 17% (13/75) were working full time, with 28% (21/75) being retired and 40% (30/75) being unemployed or not working. A total of 55% (41/75) had T2D, and 83% (62/75) reported current insulin use. Most (46/75, 61%) had federal insurance coverage, including Medicare and Medicaid; 29% (22/75) had no insurance coverage.

Table 1. Survey respondent demographics (n=75).

	Total, n (%)	Type 1 diabetes (n=34), n (%)	Type 2 diabetes (n=41), n (%)	Aged <45 years (n=27), n (%)	Aged 45-59 years (n=25), n (%)	Aged >59 years (n=23), n (%)
Female	50 (67)	21 (62)	29 (71)	17 (63)	18 (72)	15 (65)
African American	66 (88)	33 (97)	33 (80)	26 (96)	21 (84)	19 (83)
Educational level						
High school diploma or GED[a] or lower	37 (49)	13 (38)	24 (59)	12 (44)	14 (56)	11 (48)
Some college	21 (28)	13 (38)	8 (20)	10 (37)	6 (24)	5 (22)
College degree	11 (15)	6 (18)	5 (12)	4 (15)	2 (8)	5 (22)
Advanced degree	6 (8)	2 (6)	4 (10)	1 (4)	3 (12)	2 (9)
Employment status						
Retired	21 (28)	4 (12)	17 (41)	1 (4)	3 (12)	17 (74)
Working full time	13 (17)	10 (29)	3 (7)	9 (33)	3 (12)	1 (4)
Working part time	9 (12)	6 (18)	3 (7)	5 (19)	4 (16)	0 (0)
Unemployed or not working	30 (40)	12 (35)	18 (44)	10 (37)	15 (60)	5 (22)
Student	2 (3)	2 (6)	0 (0)	2 (7)	0 (0)	0 (0)
Diabetes diagnosis						
Type 1	34 (45)	34 (100)	—[b]	25 (93)	7 (28)	2 (9)
Type 2	41 (55)	—	41 (100)	2 (7)	18 (72)	21 (91)
Insulin use	62 (83)	34 (100)	28 (68)	27 (100)	21 (84)	14 (61)
Insurance coverage type						
Federal	46 (61)	19 (56)	27 (66)	15 (56)	13 (52)	18 (78)
Private	7 (9)	4 (12)	3 (7)	2 (7)	4 (16)	1 (4)
None	22 (29)	11 (32)	11 (27)	10 (37)	8 (32)	4 (17)

[a]GED: General Educational Development.

[b]Not applicable.

Technology Use, Access, and Literacy

Survey Findings

Smartphone ownership and use were near universal (71/75, 95%), and 88% (66/75) reported using a smartphone daily (Table 2). Most participants (42/75, 56%) had Android devices, and 84% (54/64) of those who provided a model name that could be dated owned models that had become available in the last 5 years. A total of 89% (67/75) of the participants accessed the internet on their phones, 73% (55/75) had unlimited data plans, and 93% (70/75) had Wi-Fi access at home. Ownership and daily use of devices was generally highest among younger participants and those with T1D, who also rated all devices as easier to use than their older counterparts and those with T2D. Smartphones were deemed the easiest to use (68/75, 91% found them “very easy” or “somewhat easy” to use), and wearables were deemed the least easy to use (21/75, 28%).

Of the media types presented in the survey (texting, mobile apps, email, social media, podcasts, web videos, and websites), texting was the medium most commonly used (63/75, 84%), and 73% (46/63) of texters indicated that they used it daily (Table 3). Email use was as common as texting, although it was used less frequently. Social media was used by 65% (49/75) of participants, 63% (31/49) of whom reported daily use. Over 50% of participants reported use of web videos (43/75, 57%), mobile apps (53/75, 71%), and websites (55/75, 73%). Podcasts were used by a minority of participants, and daily use was very low. In general, use and daily use of media was highest among younger participants; however, a larger proportion of participants aged >59 years used email daily than their counterparts aged 45 to 59 years; daily video use was similar across age groups. Daily use of media was more common among those with T1D (who were overall younger) for everything except videos, websites, and podcasts. With the exception of podcasts, all forms of media were rated as “somewhat easy” or “very easy” to use by at least 65% (49/75) of users. The 2 older age groups rated texting, email, and web videos as similarly easy to use, and websites notably scored better among the oldest age group than among the middle one.

Approximately 70% of the participants indicated that they used some type of device (53/75, 71%) and some form of media (51/75, 68%) to manage their health (Table 4). Despite a majority of participants (57/75, 76%) owning a computer or tablet, few reported using these for health or diabetes

management. Participants with T1D used smartphones and wearables (not including CGM devices) for health and diabetes management more than those with T2D. The media tool most commonly used for health management was websites, used by 37% (28/75) of participants for both health and diabetes management, followed by email (25/75, 33% for health management and 22/75, 29% for diabetes management). Texting was used for diabetes or health management by 24% (18/75) and 25% (19/75) of the participants, respectively, and apps were used by 20% (15/75) of the participants for diabetes management and 27% (20/75) of the participants for general health management. Only 5% (4/75) of the participants reported leveraging social media for diabetes management, 9% (7/75) reported using it to manage their health, and none were in the oldest age group.

Most participants indicated that they would find an app to help them manage their diabetes interesting (58/75, 77%), helpful (58/75, 77%), and time saving (50/75, 67%), with a higher proportion of those with T1D than T2D responding positively (Table 5). Interest in and perception of this app as useful or interesting also decreased with age. Four-fifths (60/75, 80%) of the participants indicated that they would feel confident using a mobile app to help them with their diabetes, and a similar proportion (58/75, 77%) indicated that they would likely use such an app. Similarly to participants' perception of the app, younger participants and those with T1D were more confident in their ability to use and their likelihood of using such an app than their older counterparts. While 93% (25/27) of participants aged <45 years indicated that they felt confident that they could use an app to help with their diabetes management, that proportion fell to 84% (21/25) in the middle age group and 61% (14/23) among those aged >59 years. The oldest age group was also the least likely to use an app to help them manage their diabetes, with just over half (12/23, 52%) indicating that they were likely to do so compared to 80% (20/25) of those aged 45 to 49 years and all but one of those in the youngest age group (26/27, 96%).

Features selected as being of interest included tracking blood sugar levels (64/75, 85%); communication with health professionals (60/75, 80%); diet (57/75, 76%) and physical activity (57/75, 76%) planning or tracking; SMS text message monitoring, notifications, and reminders (57/75, 76%); and communication with others who have diabetes (45/75, 60%). Some differences existed in participants' interest in each proposed app feature by age and diabetes type. While all age groups expressed the most interest in an app that tracked blood sugar levels, physical activity planning or tracking was equally appealing to the youngest age group (25/27, 93%), whereas the middle age group indicated equal interest in blood sugar level tracking and communicating with health professionals (21/25, 84%). For the oldest age group, diet planning or tracking was tied for second place with "text message monitoring, notifications, and reminders" (17/23, 74%). For all age groups, the least attractive feature proposed was communicating with others who have diabetes. For those living with T1D, relative interest mirrored that of the youngest age group, whereas participants with T2D found diet planning or tracking as interesting as blood sugar tracking (34/41, 83%), followed by communicating with health professionals (31/41, 76%) and SMS text message monitoring, notifications, and reminders (30/41, 73%).

Table 2. Device ownership, daily use, and usability (n=75).

	Total, n (%)	Type 1 diabetes (n=34), n (%)	Type 2 diabetes (n=41), n (%)	Aged <45 years (n=27), n (%)	Aged 45-59 years (n=25), n (%)	Aged >59 years (n=23), n (%)
Device ownership and daily use						
Smartphone ownership	71 (95)	33 (97)	38 (93)	25 (93)	25 (100)	21 (91)
Daily use for smartphone owners[a]	66 (93)	32 (97)	34 (89)	24 (96)	22 (88)	20 (95)
Tablet ownership	40 (53)	22 (65)	18 (44)	19 (70)	11 (44)	10 (43)
Daily use for tablet owners[a]	12 (30)	6 (27)	6 (33)	7 (37)	2 (18)	3 (30)
Computer ownership	53 (71)	28 (82)	25 (61)	22 (81)	17 (68)	14 (61)
Daily use for computer owners[a]	8 (15)	5 (18)	3 (12)	5 (23)	1 (6)	2 (14)
Wearable ownership	20 (27)	14 (41)	6 (15)	11 (41)	7 (28)	2 (9)
Daily use for wearable owners[a]	10 (50)	9 (64)	1 (17)	6 (55)	3 (43)	1 (50)
Device usability						
Smartphones very or somewhat easy to use	68 (91)	34 (100)	34 (83)	26 (96)	23 (92)	19 (83)
Tablets very or somewhat easy to use	38 (51)	25 (74)	13 (32)	22 (81)	10 (40)	6 (26)
Computers very or somewhat easy to use	48 (64)	28 (82)	20 (49)	23 (85)	14 (56)	11 (48)
Wearables very or somewhat easy to use	21 (28)	15 (44)	6 (15)	12 (44)	7 (28)	2 (9)
Internet access using smartphone	67 (89)	34 (100)	33 (80)	27 (100)	22 (88)	18 (78)
Unlimited smartphone data plan	55 (73)	26 (76)	29 (71)	22 (81)	17 (68)	16 (70)
Location of Wi-Fi access						
Home	70 (93)	33 (97)	37 (90)	27 (100)	22 (88)	21 (91)
School	9 (12)	9 (26)	0 (0)	8 (30)	1 (4)	0 (0)
Work	20 (27)	15 (44)	5 (12)	14 (52)	4 (16)	2 (9)
Library	9 (12)	5 (15)	4 (10)	3 (11)	4 (16)	2 (9)
Friends' or relatives' homes	30 (40)	16 (47)	14 (34)	10 (37)	12 (48)	8 (35)
Coffee shops, restaurants, and other businesses with free Wi-Fi	25 (33)	15 (44)	10 (24)	10 (37)	10 (40)	5 (22)

[a]The denominator for the percentages in these rows is the numerator from the row above.

Table 3. Media type use, daily use, and usability (n=75).

	Total, n (%)	Type 1 diabetes (n=34), n (%)	Type 2 diabetes (n=41), n (%)	Aged <45 years (n=27), n (%)	Aged 45-59 years (n=25), n (%)	Aged >59 years (n=23), n (%)
Media use and daily use						
Texting users	63 (84)	31 (91)	32 (78)	24 (89)	22 (88)	17 (74)
Daily texting for users[a]	46 (73)	26 (84)	20 (62)	22 (92)	15 (68)	9 (53)
Mobile app users	53 (71)	28 (82)	25 (61)	23 (85)	15 (60)	15 (65)
Daily app use for users[a]	36 (68)	20 (71)	16 (64)	16 (70)	11 (73)	9 (60)
Email users	63 (84)	30 (88)	33 (80)	23 (85)	21 (84)	19 (83)
Daily email use for users[a]	37 (59)	19 (63)	18 (55)	15 (65)	11 (52)	11 (58)
Social media users	49 (65)	25 (74)	24 (59)	22 (81)	16 (64)	11 (48)
Daily social media use for users[a]	31 (63)	17 (68)	14 (58)	15 (68)	11 (69)	5 (45)
Podcast users	14 (19)	8 (24)	6 (15)	7 (26)	6 (24)	1 (4)
Daily podcast use for listeners[a]	2 (14)	1 (12)	1 (17)	1 (14)	1 (17)	0 (0)
Video users	43 (57)	19 (56)	24 (59)	16 (59)	15 (60)	12 (52)
Daily video use for users[a]	23 (53)	10 (53)	13 (54)	9 (56)	8 (53)	6 (50)
Website users	55 (73)	26 (76)	29 (71)	23 (85)	16 (64)	16 (70)
Daily website use for users[a]	26 (47)	12 (46)	14 (48)	11 (48)	4 (25)	11 (69)
Media usability						
Texting very easy or somewhat easy to use	64 (85)	32 (94)	32 (78)	25 (93)	20 (80)	19 (83)
Apps very easy or somewhat easy to use	51 (68)	30 (88)	21 (51)	24 (89)	15 (60)	12 (52)
Email very easy or somewhat easy to use	66 (88)	33 (97)	33 (80)	27 (100)	20 (80)	19 (83)
Social media very easy or somewhat easy to use	50 (67)	27 (79)	23 (56)	23 (85)	16 (64)	11 (48)
Podcasts very easy or somewhat easy to use	20 (27)	13 (38)	6 (15)	11 (41)	7 (28)	1 (4)
Web videos very easy or somewhat easy to use	49 (65)	24 (71)	25 (61)	19 (70)	16 (64)	14 (61)
Websites very easy or somewhat easy to use	57 (76)	28 (82)	29 (71)	24 (89)	16 (64)	17 (74)

[a]The denominator for the percentages in these rows is the numerator from the row above.

Table 4. Device and media type use for health and diabetes management (n=75).

	Total, n (%)	Type 1 diabetes (n=34), n (%)	Type 2 diabetes (n=41), n (%)	Aged <45 years (n=27), n (%)	Aged 45-59 years (n=25), n (%)	Aged >59 years (n=23), n (%)
Device use for health and diabetes management						
Smartphone use for health	51 (68)	26 (76)	25 (61)	19 (70)	16 (64)	16 (70)
Smartphone use for diabetes	51 (68)	28 (82)	23 (56)	21 (78)	16 (64)	14 (61)
Tablet use for health	7 (9)	3 (9)	4 (10)	3 (11)	1 (4)	3 (13)
Tablet use for diabetes	7 (9)	3 (9)	4 (10)	3 (11)	1 (4)	3 (13)
Computer use for health	21 (28)	9 (26)	12 (29)	5 (19)	8 (32)	8 (35)
Computer use for diabetes	18 (24)	6 (18)	12 (29)	3 (11)	7 (28)	8 (35)
Wearable use for health	8 (11)	7 (21)	1 (2)	4 (15)	3 (12)	1 (4)
Wearable use for diabetes	7 (9)	6 (18)	1 (2)	4 (15)	2 (8)	1 (4)
Media use for health and diabetes management						
Texting use for health	19 (25)	13 (38)	6 (15)	8 (30)	6 (24)	5 (22)
Texting use for diabetes	18 (24)	11 (32)	7 (17)	6 (22)	6 (24)	6 (26)
Mobile app use for health	20 (27)	14 (41)	6 (15)	9 (33)	7 (28)	4 (17)
Mobile app use for diabetes	15 (20)	12 (35)	3 (7)	8 (30)	5 (20)	2 (9)
Email use for health	25 (33)	14 (41)	11 (27)	8 (30)	11 (44)	6 (26)
Email use for diabetes	22 (29)	12 (35)	10 (24)	6 (22)	10 (40)	6 (26)
Social media use for health	7 (9)	5 (15)	2 (5)	6 (22)	1 (4)	0 (0)
Social media use for diabetes	4 (5)	3 (9)	1 (2)	3 (11)	1 (4)	0 (0)
Podcast use for health	4 (5)	2 (6)	2 (5)	2 (7)	4 (16)	0 (0)
Podcast use for diabetes	1 (1)	1 (3)	0 (0)	1 (4)	0 (0)	0 (0)
Web video use for health	19 (25)	6 (18)	13 (32)	3 (11)	8 (32)	8 (35)
Web video use for diabetes	15 (20)	4 (12)	11 (27)	1 (4)	8 (32)	6 (26)
Website use for health	28 (37)	10 (29)	18 (44)	7 (26)	9 (36)	12 (52)
Website use for diabetes	28 (37)	12 (35)	16 (39)	9 (33)	9 (36)	10 (43)

Table 5. Perceived value of a digital app to help with diabetes management (n=75).

	Total, n (%)	Type 1 diabetes (n=34), n (%)	Type 2 diabetes (n=41), n (%)	Aged <45 years (n=27), n (%)	Aged 45-59 years (n=25), n (%)	Aged >59 years (n=23), n (%)
Mobile app would be interesting	58 (77)	31 (91)	27 (66)	26 (96)	18 (72)	14 (61)
Mobile app would be helpful	58 (77)	30 (88)	28 (68)	25 (93)	18 (72)	15 (65)
Mobile app would be time saving	50 (67)	25 (74)	25 (61)	21 (78)	16 (64)	13 (57)
Confident that they could use an app	60 (80)	32 (94)	28 (68)	25 (93)	21 (84)	14 (61)
Likely to use an app	58 (77)	33 (97)	25 (61)	26 (96)	20 (80)	12 (52)
App features participants were interested in						
Tracking blood sugar levels	64 (85)	30 (88)	34 (83)	25 (93)	21 (84)	18 (78)
Communicating with health professionals	60 (80)	29 (85)	31 (76)	24 (89)	21 (84)	15 (65)
Diet planning or tracking	57 (76)	23 (68)	34 (83)	21 (78)	18 (72)	17 (74)
Physical activity planning or tracking	57 (76)	30 (88)	27 (66)	25 (93)	17 (68)	15 (65)
SMS text message monitoring, notifications, and reminders	57 (76)	27 (79)	30 (73)	22 (81)	18 (72)	17 (74)
Communicating with others who have diabetes	45 (60)	21 (62)	24 (59)	18 (67)	16 (64)	11 (48)

Qualitative Findings Related to Technology Use

Individuals who participated in the IDIs included 83% (10/12) female and 17% (2/12) male patient participants and 6 HCPs. Patient participant ages ranged from 21 to 66 years; 58% (7/12) were aged <40 years. Of the 12 participants, 11 (92%) had been diagnosed with T1D, and 1 (8%) female patient participant had a T2D diagnosis; all used insulin. While 17% (2/12) of the patient participants had private insurance, 25% (3/12) were uninsured at the time of the study, and the rest (7/12, 58%) had federal insurance coverage. The HCPs represented a range of specialists who are instrumental in the care of people with diabetes, including an endocrinologist, certified diabetes educator, certified medical assistant, and pharmacist (additional demographics are not provided to avoid identifying participants).

During the IDIs, patients and HCPs were asked about the use of apps for diabetes self-management. A total of 67% (4/6) of the HCPs and half (6/12, 50%) of the patient participants discussed the use of apps, with CalorieKing, MyFitnessPal, and Noom being mentioned by name. In total, 50% (3/6) of the HCPs indicated that they recommend use of CalorieKing to their patients, which can help with nutrient and meal tracking, including carbohydrate counting. One patient participant who was using CalorieKing at the time of the interview found it useful to be able to access existing food nutrition references for each serving and restaurant menu item rather than inputting all the information for her meals by hand. Another app, MyFitnessPal, was mentioned by 33% (2/6) of the HCPs as being sometimes recommended by themselves or their colleagues. One patient interviewee particularly enjoyed its barcode scanner feature to log nutrition information automatically. Some patient participants reported having used other apps specifically for diabetes self-management (eg, MyDiabetes); however, while they remembered features that allowed them to track blood glucose levels, meals, and physical activity, they could not remember the names of the apps, nor were they still using them. In addition, those who used CGM systems referred to using the associated CGM apps to review and share data with HCPs.

CGM Use

Survey Findings

A total of 56% (42/75) of the participants reported having used a CGM device, but only 29% (22/75) were using one at the time of data collection (Table 6). The most commonly tested CGM model was Abbott's FreeStyle Libre (no distinction was made during data collection between the different FreeStyle Libre models, namely, the 14-day system and FreeStyle Libre 2, the models available at the time of data collection), which was used by 81% (34/42) of all individuals with a history of CGM use and was most common across diabetes types and age groups. However, our initial use of phone-based recruitment of individuals with a LibreView profile may have led to a minor oversampling of participants with experience using the FreeStyle Libre. Dexcom's G5 or G6 models were used by 8% (6/75) of the participants, all with T1D. On the basis of the estimated age of the smartphones that participants reported having and release dates of compatible operating systems, it seems unlikely that compatibility between CGM systems and phones would have been a barrier to use for many. CGM use history and current use differed by diabetes type and age—CGM use was more common among individuals with T1D (29/34, 85% had a history of use, and 18/34, 53% reported current use) than among those with T2D (13/41, 32% had ever used CGM, and 4/41, 10% reported current use). For those reporting current CGM use (22/75, 29%), the most commonly selected reason for using a CGM was "to instantly check my blood sugar" (19/22, 86%), followed by "helps me to have better control over blood glucose levels (by looking at trend arrows)" (17/22, 77%) and "to prevent low/high blood sugar faster" and "to see my sugar levels

at times when checking may be harder (e.g. while sleeping)" (15/22, 68% in both cases).

The most common reasons for discontinuation of use centered on cost and issues with the sensor adhesive. Of the 20 individuals who reported reasons for discontinuing CGM use, 7 (35%) indicated that the device was too expensive, and 2 (10%) indicated that their insurance would not cover CGM (the latter was reported through an open-ended "specify other reasons" answer option). For 30% (6/20) of participants who had discontinued using a CGM, the device did not stick to the skin or caused a rash. Technical issues such as the device losing signal or malfunctioning accounted for the remaining barriers to continued use.

Among individuals who had no experience with CGM (33/75, 44%), the most common reason given was that they had never been offered the option (21/33, 64%). Other reasons given were the prohibitive cost of the device (4/33, 12%), not finding a comfortable and discrete place on the body for the sensor (1/33, 3%), a concern about infection for one individual who reported having a high risk of infection, finding the device too complicated to use (1/33, 3%), not being "technology savvy" (1/33, 3%), and "monitoring myself" (1/33, 3%).

Table 6. Self-reported continuous glucose monitoring (CGM) use and reasons for use and nonuse by diabetes type and age (n=75).

	Total, n/N (%)	Type 1 diabetes, n/N (%)	Type 2 diabetes, n/N (%)	Aged <45 years, n/N (%)	Aged 45-59 years, n/N (%)	Aged >59 years, n/N (%)
History of CGM device use	42/75 (56)	29/34 (85)	13/41 (32)	22/27 (81)	13/25 (52)	7/23 (30)
Used Abbott FreeStyle Libre model	34/42 (81)	23/29 (79)	11/13 (85)	19/22 (86)	10/13 (77)	5/7 (71)
Used Dexcom G5 or G6	6/42 (14)	6/29 (21)	0/13 (0)	1/22 (5)	3/13 (23)	2/7 (29)
Current CGM use	22/75 (29)	18/34 (53)	4/41 (10)	13/27 (48)	5/25 (20)	4/23 (17)
Reasons for current CGM use						
Respondents, n	22/75 (29)	18/34 (53)	4/41 (10)	13/27 (48)	5/25 (20)	4/23 (17)
To instantly check my blood sugar	19/22 (86)	15/18 (83)	4/4 (100)	12/13 (92)	4/5 (80)	3/4 (75)
Helps me have better control over my blood glucose levels (by looking at trend arrows)	17/22 (77)	15/18 (83)	2/4 (50)	10/13 (77)	4/5 (80)	3/4 (75)
To prevent low/high blood sugar faster	15/22 (68)	14/18 (78)	1/4 (25)	8/13 (62)	4/5 (80)	3/4 (75)
To see my sugar levels at times when checking may be harder/ (eg, while sleeping)	15/22 (68)	14/18 (78)	1/4 (25)	9/13 (69)	4/5 (80)	2/4 (50)
My health care provider recommended I use it	14/22 (64)	13/18 (72)	1/4 (25)	9/13 (69)	3/5 (60)	2/4 (50)
Helps me lower my glycated hemoglobin levels	13/22 (59)	12/18 (67)	1/4 (25)	7/13 (54)	4/5 (80)	2/4 (50)
Makes me feel safer	13/22 (59)	12/18 (67)	1/4 (25)	9/13 (69)	2/5 (40)	2/4 (50)
Gives me/my health care provider useful information that can help make insulin requirements more accurate	12/22 (55)	12/18 (67)	0/4 (0)	7/13 (54)	3/5 (60)	2/4 (50)
To have a better understanding of how insulin, food, or physical activity change my blood sugar	11/22 (50)	10/18 (56)	1/4 (25)	6/13 (46)	2/5 (40)	3/4 (75)
Gives me more motivation to make healthier choices	11/22 (50)	11/18 (61)	0/4 (0)	6/13 (46)	3/5 (60)	2/4 (50)
Reasons for discontinuation of use						
Respondents, n	20/75 (27)	11/34 (32)	9/41 (22)	9/27 (33)	8/25 (32)	3/23 (13)
Device is too expensive	7/20 (35)	3/11 (27)	4/9 (44)	2/9 (22)	4/8 (50)	1/3 (33)
Device/adhesive gives me a rash or other skin problem	1/20 (5)	1/11 (9)	0/9 (0)	1/9 (11)	0/8 (0)	0/3 (0)
Device/adhesive does not stick to my skin	5/20 (25)	4/11 (36)	1/9 (11)	3/9 (33)	2/8 (25)	0/3 (0)
Device loses signal/does not function well	4/20 (20)	2/11 (18)	2/9 (22)	1/9 (11)	2/8 (25)	1/3 (33)
Insurance issues	2/20 (10)	0/11 (0)	2/9 (22)	0/9 (0)	1/8 (13)	1/3 (33)
Reasons for no previous CGM use						
Respondents, n	33/75 (44)	5/34 (15)	28/41 (68)	5/27 (19)	12/25 (48)	16/23 (70)
Never been offered to me	21/33 (64)	1/5 (20)	20/28 (71)	1/5 (20)	9/12 (75)	11/16 (69)
Device is too expensive	4/33 (12)	3/5 (60)	1/28 (4)	3/5 (60)	1/12 (8)	0/16 (0)
Hard to find a comfortable and discrete place on my body to place the device	1/33 (3)	1/5 (20)	0/28 (0)	1/5 (20)	0/12 (0)	0/16 (0)
Device is too complicated to use	1/33 (3)	0/5 (0)	1/28 (4)	0/5 (0)	1/12 (8)	0/16 (0)
Concerned about contracting an infection	1/33 (3)	0/5 (0)	1/28 (4)	0/5 (0)	0/12 (0)	1/16 (6)
Was just offered one	1/33 (3)	1/5 (20)	0/28 (0)	1/5 (20)	0/12 (0)	0/16 (0)

	Total, n/N (%)	Type 1 diabetes, n/N (%)	Type 2 diabetes, n/N (%)	Aged <45 years, n/N (%)	Aged 45-59 years, n/N (%)	Aged >59 years, n/N (%)
Not technology savvy	1/33 (3)	0/5 (0)	1/28 (4)	0/5 (0)	0/12 (0)	1/16 (6)
I monitor myself	1/33 (3)	0/5 (0)	1/28 (4)	0/5 (0)	0/12 (0)	1/16 (6)

Qualitative Findings Related to CGM Use

During interviews, the overwhelming sense across both patients and HCPs was that CGM devices were highly beneficial additions to the suite of diabetes self-management tools. All patient participants referenced how easily they could check their blood glucose repeatedly during the day, even discretely in public. They mentioned the convenience of the device allowing them to check their blood glucose at strategic time points (eg, on waking, before and after meals, and when periodically alerted to potential hypo- and hyperglycemic events by alarm notifications), which made it possible for them to take preventive measures to avoid their blood glucose rising or falling too much. Patients also took advantage of the added convenience by simply checking their glucose more frequently throughout the day as they did not need to carry additional supplies or stick their finger to obtain a reading.

Despite checking their readings more often with their CGM system than when using finger sticks, only 33% (4/12) of the patient participants, all female, aged <40 years, and covered by federal insurance, mentioned leveraging the data to track patterns in their blood sugar levels. Each described different reasons for doing so. For example, one female participant in her late 30s with T1D generally liked having "more insight into what's going on," even at night. Another female participant of the same age with T1D talked about reviewing her data to understand her responses to certain foods and plan for her meals as she could anticipate how her body would react. A younger woman with T1D indicated that the data (supported by the alarms) had helped her significantly in taking preventive measures when her blood sugar level was decreasing. She indicated that she had learned about target time in range and used the summary data to make sure that she was keeping within her target percentage time in range.

Patient participants also highlighted the system's ability to support their communication with HCPs by making their longitudinal data available to their care teams. This helped streamline some of the conversations during appointments as HCPs could review data ahead of time, and patient participants also appreciated the ability to obtain insights from HCPs when they saw unusual glucose activity and needed clarification between appointments.

The challenges to CGM use discussed by patient participants mirrored those reported in the survey—58% (7/12) of the participants mentioned the lack of insurance coverage rendering CGM use prohibitively expensive, and 33% (4/12) indicated that the adhesive failing to keep the sensor on the skin or the sensor falling off when bumped made its use impractical and the financial burden even larger. Others mentioned that the alarms waking them up at night or being loud and not shutting off quickly could be annoying, although one did note that the new model of the sensor she had previously used had optional alarms, which addressed her one complaint with the device.

HCPs echoed these sentiments as well, noting the barrier of cost and lack of insurance coverage. This was due to some patients' individual treatment plans (eg, not using insulin) rendering them ineligible for continued insurance coverage for CGM systems and related supplies. However, they also mentioned that some patients, if they were financially able to, chose to pay for CGM supplies out of pocket due to the value they placed on the devices. HCPs were not asked to elaborate on the reasons why patients might not be offered CGM.

Among HCPs, the same benefits of reducing the burden of finger pricks and streamlining the process of checking blood glucose levels were echoed. One noted that the convenience was especially useful for individuals who need more frequent monitoring, such as those at higher risk of hypoglycemia, as the CGM allowed them to feel more confident taking their insulin while avoiding their blood glucose dropping too low. Other groups considered to particularly benefit from CGM included individuals with challenging-to-manage diabetes (often due to high glycemic variability); those with hypoglycemia unawareness; and, more generally, individuals with a T1D diagnosis.

Another benefit discussed by HCPs, which aligned with patient participants' comments, was the value of being able to add explanatory notes to specific times of day or events to help HCPs and patients themselves better understand the reports generated by the CGM systems. The data helped fill in gaps for HCPs and support clinical decision-making for patients who might not normally check their blood sugar frequently. Although this value of the data was universally discussed by HCPs, they did agree that patients generally checked the main glucose reading at individual time points rather than engaging with the patterns that emerged over longer use. One HCP reported that some of her patients did "their own little experiments" when they changed their eating or exercise habits and tracked the effects via the CGM data.

In addition, according to HCPs, patients tended to prefer the convenience of using a phone-based CGM app rather than a separate reader; however, they pointed out that, for patients without a compatible phone or without a reliable internet connection, the ability to share data with an HCP or to track trends was reduced as they could not easily upload the data before appointments, nor could they leverage the longitudinal data themselves between health care visits.

Discussion

Principal Findings

This study found that patients receiving care for diabetes at an inner-city safety-net hospital had access to a range of technology

communication devices, with almost universal smartphone and home Wi-Fi access. While some also had access to other types of communication devices and used a range of media platforms and two-thirds of the participants (51/75, 68%) reported use of their smartphones for general health or diabetes management, the use of specific digital tools for those purposes remained low. CGM systems were seen by patient participants and HCPs as positive enhancements to diabetes self-management, helping patients take preventive measures and better achieve glycemic control. There remain opportunities for patients to better leverage their access to both digital communication technologies and, when available, CGM to enhance their diabetes self-management.

Comparisons With Prior Work

While innovative technologies continue to transform diabetes care and self-management, equity concerns persist. Pilot studies have demonstrated the potential of mobile apps to improve diabetes outcomes [26]; however, concerns have been raised about the risk of increasing digital marginalization and health disparities if efforts are not made to ensure equitable access for socially disadvantaged groups [27].

Our findings align with those from other studies that have reported a reduction in the digital divide in terms of access to devices connected to the internet (particularly smartphones) [16]. We found that the vast majority of patients receiving care at an inner-city safety-net hospital in Atlanta, Georgia (71/75, 95%), owned a smartphone compared to 85% of the US population (where rates are lowest among those aged >65 years, 61%; those with the lowest socioeconomic status, 76%; and educational levels, 75%; and those living in rural areas, 80%) [15].

However, the use of available technologies for health management appears to be limited among underresourced patients. For example, the use of apps for health purposes among participants in our study was low (20/75, 27%). According to a 2015 Pew Research Center study, over half of mobile phone users have downloaded a mobile health (mHealth)–related app, with fitness and nutrition apps being the most popular [28].

Interest among participants in our study in an app to help them manage their diabetes was high, along with related self-efficacy and perceived likelihood of using such an app. Three-quarters of the participants had an unlimited smartphone data plan (55/75, 73%), and 89% (67/75) had internet access at home, suggesting that logistical barriers to app use would be limited.

Our findings echo those from a community-based survey of a vulnerable, low-income, predominantly Latino population (n=104) in East Harlem, New York [16], which found the digital divide to be narrowing. While a higher proportion of smartphone owners (39%) in the New York study than in our study reported using health apps, those who had graduated high school were 7 times more likely to use health apps than those who had not, suggesting a potential link to income or health literacy. Our study did also observe higher app use and interest in a diabetes self-management support app among high school graduates. As in our study, participants in the study by Vangeepuram et al [16] expressed interest in a health promotion app. Our data also align with findings from an earlier study focused on the appeal of an mHealth diabetes app and conducted in both a medically underserved area and a more affluent suburb [29]. That 2015 study also found that younger individuals were more likely to be interested in mHealth solutions than their older counterparts while also providing support for people from underserved communities being particularly interested in using mHealth apps.

Participants in our study who had experience with CGM reported high levels of satisfaction with the experience. However, most participants in our study (53/75, 71%) did not have the opportunity to benefit from CGM, either because they had not been offered CGM by HCPs (as noted, we did not explore reasons for this with HCPs during IDIs) or had had to discontinue use due to a lack of insurance coverage and the prohibitive cost of the sensors. These factors, in conjunction with previously reported data indicating lower rates of CGM use and high rates of discontinuation among African American individuals, our primary population in this study, point to a need to increase the accessibility and affordability of these tools [5-9,30]. In parallel, it is crucial to address well-documented implicit HCP biases resulting in lower rates of CGM recommendation and prescription to patients from racial or ethnic minority groups and other populations vulnerable to health disparities [6,31-33]. There have been efforts to expand the use of CGM, and the evidence for its use among different demographics, including those with T2D, is growing [34-39]. Health systems, payers, and policy makers should continue efforts to increase technology access for underresourced communities to promote more equitable access to the diabetes digital ecosystem [40].

In addition to patients having limited access to CGM systems, there is an underuse of CGM data and visualizations by those who do use CGM. HCPs in this study discussed their patients making little use of CGM data, and only a minority of the patient participants indicated that they engaged with the data patterns. While it is unclear whether this was due to a lack of interest in the patterns or a gap in knowledge about the data, other studies have found that, without additional support, CGM data remain challenging to interpret by users [34], reducing the potential of these data to effect behavior change and lead to glycemic control among users, even with increased access to CGM systems. This and existing studies of CGM training programs demonstrate the important role of increasing educational resources related to the use of CGM data to enhance and support glycemic control [41-46].

Our participants' expressed willingness, confidence, and self-efficacy for the use of a diabetes management app point to the likely acceptability and feasibility of such an app to increase diabetes self-management skills among low-income individuals with diabetes. However, to ensure uptake and maximize the effectiveness of such an app, it is imperative that it be designed in tandem with people living with diabetes, their HCPs, and other relevant stakeholders. This would also help avoid the current challenges of existing commercially available diabetes management apps, many of which are overly complex or unappealing [19-21]. While alternatives to an app, such as a website or informational web-based portal, exist, as current

CGM systems report data through apps, we anticipate that this platform may be more familiar and integrate better into participants' lives.

Limitations

Limitations of the study include the relatively small convenience sample, the disproportionate number of female participants despite efforts to enroll male participants, and potential bias toward those more comfortable with technology. Individuals who felt less technologically literate may have been less interested in completing a survey about technology, especially as the survey itself was either offered via emailed link to those recruited by phone or presented on a tablet to those recruited on-site at the clinic. Offering a paper version of the survey may have increased the representation of individuals less at ease with technology. In addition, our initial phone-based recruitment of individuals with a LibreView profile may have led to a minor oversampling of participants with experience using the FreeStyle Libre relative to other CGM systems, although only 5% (4/75) of participants from our sample were recruited via this method. Finally, while the most common reason patients gave for never having used CGM was lack of HCP recommendation, their eligibility for CGM was not validated through medical record review, nor was this topic explored with HCPs.

Conclusions

Although access to digital communication technologies was widespread among patients receiving care for diabetes at an Atlanta, Georgia, safety-net hospital's diabetes center, those same patients were not taking full advantage of those technologies to support their diabetes care. Among participants with experience using CGM systems, satisfaction was high, although there was potential to further increase the benefits of this technology through additional support to boost CGM access and diabetes technology literacy. There was strong acceptability and likelihood of use of a digital app for diabetes management support. These findings, in combination with the anticipated increased access to smartphones and CGM systems, support further research into the development of innovative digital solutions to support diabetes management.

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Authors' Contributions

GS analyzed the data and collaborated on study design and manuscript drafting. CT collected and reviewed the data and reviewed and edited the manuscript. MM collaborated on study design and reviewed and edited the manuscript. WSZ contributed to data analyses and reviewed and edited the manuscript. JCE reviewed and edited the manuscript. FJP and KW oversaw study design and data analysis and collaborated on manuscript drafting. GS is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

FJP has received research support from Dexcom, Ideal Medical Technologies, Tandem Diabetes Care, Insulet, and Novo Nordisk and consulting fees from Dexcom. JCE is a paid consultant for Sanofi. All other authors declare no other conflicts of interest.

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Abbreviations

CGM: continuous glucose monitoring
GDC: Grady Diabetes Center
HCP: health care provider
IDI: in-depth interview
mHealth: mobile health
REDCap: Research Electronic Data Capture
T1D: type 1 diabetes
T2D: type 2 diabetes

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Original Paper

Development and Validation of a Measure for Seeking Health Information in the Diabetes Online Community: Mixed Methods Study

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Abstract

Background: Individuals with chronic diseases often search for health information online. The Diabetes Online Community (DOC) is an active community with members who exchange health information; however, few studies have examined health information brokering in the DOC.

Objective: The aim of this study was to develop and validate the Attitudes Toward Seeking Health Information Online (ATSHIO) scale in a sample of adults with type 1 diabetes (T1D).

Methods: People with T1D were recruited through the DOC, specifically Facebook and Twitter. They were provided with a Qualtrics link to complete the survey. This was a mixed methods study that used thematic analysis along with existing theory and formative research to design the quantitative ATSHIO scale.

Results: A total of 166 people with T1D participated in this study. Confirmatory factor analyses determined a 2-factor scale (*Trusting and Evaluating Online Health Information in the DOC* and *Engaging With Online Health Information in the DOC*) with good convergent validity and discriminant validity. Correlations were found between social support, online health information–seeking, diabetes distress, and disease management.

Conclusions: The ATSHIO scale can be used to investigate how people with diabetes are using the internet for obtaining health information, which is especially relevant in the age of telehealth and Health 2.0.

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KEYWORDS

online health information; health information seeking; digital health; digital technology; digital intervention; social support; social media; diabetes distress; diabetes; type 2 diabetes; type 1 diabetes; scale development; chronic disease; telehealth

Introduction

As health information is readily accessible on the internet, there has been a shift in how individuals with chronic diseases are acquiring information about their condition [1]. People with type 1 diabetes (T1D) typically seek health information online from their peers and share anecdotal evidence and published articles [2]. However, health practices that work extremely well for one person may be ineffective or even detrimental for another person. People with T1D are also encouraged to engage in social support [3], which can exert a positive effect on disease management and is a key factor for psychological adjustment [4], health information–seeking [5], and maintaining mental health [6] and physical health [7,8]. In addition, for individuals

with T1D, this social support is often experienced on social media platforms such as Facebook and Twitter/X [9]. More recently, the Diabetes Online Community (DOC) has emerged as a network of individuals with diabetes to engage in discussion on various social media platforms, including Reddit, YouTube [10], Instagram [11], and TikTok [12]. There are many psychosocial benefits to participating in online chronic disease groups such as the DOC [13]. Individuals with diabetes who participate in online support groups report increased empowerment [14], as well as increased positive emotional experiences, positive attitudes toward T1D, and engagement in T1D management behaviors [2].

In this study, we sought to clarify several gaps in the literature due to the nature of existing health information–seeking measures not being tailored to individuals with chronic conditions. In particular, various existing psychological assessment tools do not consider whether an individual has a chronic condition. The Krantz Health Opinion [15], the Miller Behavioral Style scale [16], Threatening Medical Situation [17,18], and the Autonomy Preference Index [19,20] are assessment tools that do not lend themselves to chronic conditions, as these measures propose a hypothetical medical condition and prompt responses based on these hypothetical conditions. Moreover, few studies have been performed in the context of the DOC to collect data on online health information–seeking [13,21].

Health information–seeking is most often studied in three contexts: a hypothetical threatening health situation, behavior change, and prevention. The Krantz Health Opinion [15] focuses on decisions that are actively occurring in a hospital room. The reliability for the item scores ranges from poor to acceptable. The Miller Behavioral Style scale [16] is a widely used measure that assesses coping, specifically monitoring and blunting behaviors. This scale poses four hypothetical threatening situations followed by four monitoring and blunting options for participants to choose from for each provided scenario. This scale has displayed poor to acceptable reliability. Lastly, the Threatening Medical Situation [17,18] measures monitoring and blunting during a medical threat presented using four vignettes (eg, headache, hypertension diagnosis, potential heart surgery, and appendicitis).

Therefore, this study can fill these gaps through the development and validation of a scale that measures seeking health information online for individuals with T1D and examining the relationships between key constructs.

Methods

Mixed Methods Framework

This study used a mixed methods approach for scale development [22], involving feedback and inductive and deductive information in a strictly online setting. Items for the developed Attitudes Toward Seeking Online Health Information (ATSHIO) scale were established in previous studies [23-25]. A qualitative pilot study found that participants were using online peer-to-peer–provided health information to decide whether they would seek health care [23]. The scale was then developed based on the pilot study results and a review of the literature. Subsequent studies then focused on investigating the constructs and gaining feedback on the scale [24,25]. Participants provided feedback on the wording of the items; thus, the scale used in this study included the edited and refined items based on this feedback.

Participants

Participants were eligible for the study if they met the following criteria: (1) 18 years or older, (2) identifying as a member of the DOC, and (3) having been diagnosed with T1D by a doctor. Participants were recruited from the DOC via Facebook posts; tweets using the hashtags #doc, #type1 diabetes, and #dsma; and peer-to-peer referrals.

Ethical Considerations

This study was approved by the Institutional Review Board at the University of Texas at El Paso (1216875-1). Participants received a US $10 tango gift card upon completing the study.

Measures

Participants were provided access to a link to the Qualtrics survey where they responded to questions on demographics, a health questionnaire, the eHealth Literacy scale [26], the Social Provisions scale [27], the Treatment Adherence scale [28], and the Diabetes Distress scale [29]. Participants also provided qualitative feedback on the clarity, esthetics, relevancy, tone, and cultural competence of the ATSHIO scale, along with the length of time needed to respond. The scale items are provided in Table 1.

Table 1. Items of the Attitudes Toward Seeking Health Information Online scale.

Item number	Item description
1	I frequently use the internet to gain health advice in the Diabetes Online Community.
2	I review multiple internet sources in the Diabetes Online Community before making a health decision for myself.
3	I do not follow the health information that I find on social media in the Diabetes Online Community.[a]
4	I trust the health information that I find in the Diabetes Online Community.
5	I feel comfortable receiving health advice in the Diabetes Online Community.
6	I trust the health information that my friends on social media (Facebook, Twitter, Instagram, discussion forums) provide in the Diabetes Online Community.
7	I feel confident in my knowledge of the available online health resources in the Diabetes Online Community.
8	It is difficult for me to find health information online in the Diabetes Online Community.[a]
9	I feel confident in my ability to find accurate health information in the Diabetes Online Community.
10	When I am confronted with a health problem, I can usually find several solutions via advice in the Diabetes Online Community.
11	I prefer to get advice about medical devices (insulin pumps and CGMs[b]) from the Diabetes Online Community instead of my doctor.
12	When trying to understand my symptoms, my first resource is social media in the Diabetes Online Community.
13	I share health articles on my social media account(s) in the Diabetes Online Community.
14	I do not post health-related items on social media (Facebook, Twitter, Instagram, and/or discussion forums) in the Diabetes Online Community.[a]
15	I prefer to read the health information that I find on social media websites but not engage in online conversations about the health information in the Diabetes Online Community.[a]
16	I feel comfortable providing advice to others in the Diabetes Online Community.

[a]Item is reverse-coded owing to the negative phrasing.

[b]CGM: continuous glucose monitor.

Data Analysis

Confirmatory factor analysis (CFA) was performed using Mplus 7.11 [30]. Following the suggestions of Brown [31], a variety of plausible models were tested, including a 3-factor model and a 2-factor CFA model, each with 16 items. Robust maximum-likelihood estimation was used in these models. The absolute fit indices included the Satorra-Bentler scaled χ^2 statistic and the standardized root mean square residual (SRMR). The relative fit indices included the Tucker-Lewis index (TLI) and the comparative fit index (CFI). Following factor analysis and model fit comparison guidelines [32], the CFA results were compared to assess the model fit according to a threshold of SRMR<0.09 in combination with either a TLI or CFI<0.96 or root mean square error of approximation (RMSEA)>0.06.

Results

Descriptive Statistics

A total of 175 people with T1D agreed to participate in the study. Nine participants were excluded due to not meeting the inclusion requirements. Of the 166 participants included in this sample, 89.8% (n=149) identified as female with an average age of 34.33 (SD 11.249) years. The majority (149/166, 89.8%) of sample participants were living in the United States. Approximately 86.1% (143/166) of participants identified their race as White. The average household income was US $85,425.28 (median US $74,500). Most participants (133/166, 80%) reported obtaining additional education after high school. The average hemoglobin A_{1c} was 7.3% (SD 1.36%) and more than half of the participants (88/166, 53%) reported using an insulin pump. Of note, 81.9% (136/166) of the participants indicated that they take additional medications beyond insulin. Table 2 summarizes the main demographic and health-related characteristics of the sample.

Table 2. Demographic and health-related characteristics of the sample (N=166).

Characteristics	Participants, n (%)
Race/ethnicity	
White	143 (86.1)
Black/African American	3 (1.8)
Mexican American	6 (3.6)
Hispanic or Latino	5 (3)
Comorbidities	
Anxiety	44 (26.5)
Celiac disease	8 (4.8)
Depression	55 (33.3)
Eating disorder	24 (14.3)
Eye disease	14 (8.4)
Gastroparesis	11 (6.6)
Graves disease	6 (3.6)
Hashimoto disease	12 (7.2)
Renal disease	3 (1.8)

Qualitative Assessment of the ATSHIO Scale

Participants provided many detailed responses from questions that should be added to the ATSHIO scale and overall general comments for improvement:

> *The questions reflect an understanding of what t1s typically do in the online space. One question I would have liked to see, or at least something I'd add, is that my decision to follow advice in the DOC often depends on how well I feel I "know" the person giving the advice. (i.e, is he/she active in DOC, have I interacted with him/her in DOC, etc).* [ID 110]

Participants were also asked to address the cultural competency of the ATSHIO scale: "Each question was something someone living with type 1 diabetes could answer or relate to" [ID 129]. One participant identified how the items correctly reflected what individuals with T1D experience: "They understood the DOC is able to help through the disease, especially to avoid an appointment with the endo since those are hard to get sometimes" [ID 179]. Participants stated that the survey used participant-endorsed terminology and that questions seemed to indicate that the research team had knowledge of T1D, largely due to the level of detail.

Reliability of Measures

Reliability Based on the Cronbach α Coefficient

The reliability of the quantitative scales was assessed using the Cronbach α coefficient. Every scale exhibited good to excellent reliability (see Table 3).

Table 3. Scale and subscale reliability.

Scale	Reliability (Cronbach α)
eHealth literacy	0.897
Social provisions	0.936
Attachment	0.845
Social integration	0.796
Reassurance of worth	0.687
Reliable alliance	0.828
Guidance	0.854
Opportunity for nurturance	0.802
Treatment adherence	0.889
Diabetes distress (T1-DDS[a])	0.937
Powerlessness	0.820
Management distress	0.760
Hypoglycemia distress	0.860
Negative social perceptions	0.841
Eating distress	0.766
Physician distress	0.883
Friend/family distress	0.860
Attitude toward seeking health information online	0.839
Trusting and evaluating online health information in the DOC[b]	0.789
Engaging with online health information in the DOC	0.746

[a]T1-DDS 1: Type 1 Diabetes Distress Scale.

[b]DOC: Diabetes Online Community.

Reliability Based on CFA

Three-Factor Model With 16 Items

First, we used CFA to evaluate a 3-factor model with 16 items (see Table 4 for factor loadings). A high correlation was found between factor 1 and factor 2 (r=0.942), with moderate correlations found between factor 1 and factor 3 (r=0.364) and between factor 2 and factor 3 (r=0.492). The following indices did not demonstrate a good model fit: Satorra-Bentler χ^2_{101}=271.026, RMSEA=0.101 (90% CI 0.086-0.115), CFI=0.748, Akaike information criterion (AIC)=8667.727, and SRMR=0.086. In this model, there was a high correlation between factors 1 and 2 (r=0.997), but not between factors 1 and 3 (r=0.618) or factors 2 and 3 (r=0.591).

Table 4. Factor loadings (λ) for the 3-factor model with 16 items.

Item number	Item description	Factor	λ (SE)	*Z*-score
1	I frequently use the internet to gain health advice in the Diabetes Online Community.	1	1.00 (0.0)	999.0
2	I review multiple internet sources in the Diabetes Online Community before making a health decision for myself.	1	–0.494 (0.180)	2.741
3	I do not follow the health information that I find on social media in the Diabetes Online Community.[a]	1	0.951 (0.215)	4.412
4	I trust the health information that I find in the Diabetes Online Community.	1	1.127 (0.222)	5.083
5	I feel comfortable receiving health advice in the Diabetes Online Community.	1	1.531 (0.295)	5.184
6	I trust the health information that my friends on social media (Facebook, Twitter, Instagram, discussion forums) provide in the Diabetes Online Community.	1	1.503 (0.289)	5.203
7	I feel confident in my knowledge of the available online health resources in the Diabetes Online Community.	2	1.000 (0.0)	999.0
8	It is difficult for me to find health information online in the Diabetes Online Community.[a]	2	0.496 (0.180)	2.760
9	I feel confident in my ability to find accurate health information in the Diabetes Online Community.	2	0.803 (0.169)	4.737
10	When I am confronted with a health problem, I can usually find several solutions via advice in the Diabetes Online Community.	2	1.074 (0.150)	7.145
11	I prefer to get advice about medical devices (insulin pumps and CGMs[b]) from the Diabetes Online Community instead of my doctor.	2	0.783 (0.210)	3.729
12	When trying to understand my symptoms, my first resource is social media in the Diabetes Online Community.	2	1.143 (0.203)	5.625
13	I share health articles on my social media account (s) in the Diabetes Online Community.	3	1.00 (0.0)	999.0
14	I do not post health-related items on social media (Facebook, Twitter, Instagram, and/or discussion forums) in the Diabetes Online Community.[a]	3	1.093 (0.108)	10.144
15	I prefer to read the health information that I find on social media websites but not engage in online conversation about the health information in the Diabetes Online Community.[a]	3	0.730 (0.124)	5.904
16	I feel comfortable providing advice to others in the Diabetes Online Community.	3	0.583 (0.14)	5.098

[a]Item is reverse-coded owing to the negative phrasing.

[b]CGM: continuous glucose monitoring.

Two-Factor Model With 16 Items

The high correlation between factors 1 and 2 violated the discriminant validity of the measure. For this reason, factor 3 was removed from the list of items and we next evaluated the 2-factor model with CFA. Factor 1 is composed of items 1-12 and factor 2 is composed of items 13-16 (see Table 5 for factor loadings). The following indices presented a good model fit: χ^2_{103}=163.672, RMSEA=0.060 (90% CI 0.042-0.076), CFI=0.906, AIC=8631.384, and SRMR=0.072. In addition, the interfactor correlation between factors 1 and 2 was r=0.401.

Table 5. Factor loadings (λ) for the 2-factor model with 16 items.

Item number	Item description	Factor	λ (SE)	*Z*-score
1	I frequently use the internet to gain health advice in the Diabetes Online Community.	1	1.00 (0.0)	999.0
2	I review multiple internet sources in the Diabetes Online Community before making a health decision for myself.	1	0.499 (0.175)	2.848
3	I do not follow the health information that I find on social media in the Diabetes Online Community.[a]	1	0.917 (0.203)	4.514
4	I trust the health information that I find in the Diabetes Online Community.	1	1.087 (0.204)	5.337
5	I feel comfortable receiving health advice in the Diabetes Online Community.	1	1.457 (0.264)	5.515
6	I trust the health information that my friends on social media (Facebook, Twitter, Instagram, discussion forums) provide in the Diabetes Online Community.	1	1.440 (0.267)	5.40
7	I feel confident in my knowledge of the available online health resources in the Diabetes Online Community.	1	1.037 (0.184)	5.632
8	It is difficult for me to find health information online in the Diabetes Online Community.[a]	1	0.492 (0.186)	2.639
9	I feel confident in my ability to find accurate health information in the Diabetes Online Community.	1	0.851 (0.205)	4.159
10	When I am confronted with a health problem, I can usually find several solutions via advice in the Diabetes Online Community.	1	1.107 (0.161)	6.889
11	I prefer to get advice about medical devices (insulin pumps and CGMs[b]) from the Diabetes Online Community instead of my doctor.	1	0.845 (0.216)	3.912
12	When trying to understand my symptoms, my first resource is social media in the Diabetes Online Community.	1	1.187 (0.211)	5.631
13	I share health articles on my social media account (s) in the Diabetes Online Community.	2	1.105 (0.0)	999.0
14	I do not post health-related items on social media (Facebook, Twitter, Instagram, and/or discussion forums) in the Diabetes Online Community.[a]	2	1.00 (0.112)	9.885
15	I prefer to read the health information that I find on social media websites but not engage in online conversation about the health information in the Diabetes Online Community.[a]	2	0.728 (0.123)	5.914
16	I feel comfortable providing advice to others in the Diabetes Online Community.	2	0.578 (0.114)	5.086

[a]Item is reverse-coded owing to the negative phrasing.

[b]CGM: continuous glucose monitoring.

Correlations

Importantly, several factors of diabetes distress were correlated with factors of the ATSHIO (Table 6): powerlessness and factor 1 (r=0.198, P=.01), hypoglycemia distress and factors 1 and 2 (r=0.153, P=.05 and r=0.158, P=.04, respectively), management distress and factor 2 (r=0.169, P=.03), physician distress and factor 1 (r=0.204, P=.008), and family distress and factor 2 (r=0.219, P=.005).

Table 6. Correlations of various scale items with Attitudes Toward Seeking Health Information Online factors for validation.

Scale items	Factor 1		Factor 2	
	r	*P* value	*r*	*P* value
Diabetes distress				
Powerlessness	0.198	.01	NS[a]	—[b]
Hypoglycemia distress	0.153	.05	0.158	.04
Management distress	*NS*		0.169	.03
Physician distress	0.204	.008	NS	—
Friend/family distress	NS		0.219	.005
Social provisions				
Attachment	0.183	.02	0.269	<.001
Social integration	0.260	.001	0.276	<.001
Reassurance of worth	0.251	.001	0.353	<.001
Reliable alliance	0.273	<.001	0.264	<.001
Guidance	0.341	<.001	0.314	<.001
Opportunity for nurturance	0.172	<.001	0.324	<.001
eHealth literacy	0.413	<.001	0.197	.01
Hemoglobin A_{1c}	NS	—	–0.358	<.001
Age	NS	—	–0.156	.04

[a]NS: not significant.

[b]Not applicable.

Discussion

Principal Findings

In this study, a scale examining online health information–seeking for individuals with T1D was developed and validated. This scale measures multiple types of peer-provided social support and examines how peers broker health information. Scale development was necessary due to the lack of existing scales addressing real-world experiences of seeking chronic disease–related information. We developed a reliable 2-factor, 16-item scale. Furthermore, this project examined the relationships between the measure of seeking health information online and the scale items of eHealth literacy, social provisions, and diabetes distress to establish validity by demonstrating the magnitude of these relationships.

Regarding CFA model comparison, the 2-factor, 16-item scale had small standardized residuals [32] and provided a good model fit. The majority of the project's scales had excellent reliability, whereas a few scales used to validate the measure demonstrated adequate reliability, as indicated by the Cronbach α coefficient, including Social Provisions-Social Integration, Social Provisions-Reassurance of Worth, Diabetes Distress-Management Distress, Diabetes Distress-Eating Distress, and Attitudes Toward Seeking Health Information Online (factor 1), and fair reliability for Attitudes Toward Seeking Health Information Online (factor 2). The findings from this study will contribute to the knowledge base of the health care of adults with T1D. Participants were forthcoming about the items of the scale and provided recommendations, as they are a very active and communicative population in the context of social media.

As expected, both factors were positively related to eHealth literacy. Additionally, the Trusting and Evaluating Online Health Information factor was positively related to the Social Provisions factors (Attachment, Social Integration, Reassurance of Worth, Reliable Alliance, Guidance, and Opportunity). Thus, this study extends what is known about informational support, as a type of social support, in the context of online health information–seeking. The factor Engaging with Online Health Information in the DOC was also found to be positively related to several Social Provisions items (Attachment, Social Integration, Reassurance of Worth, Reliable Alliance, Guidance, and Opportunity for Nurturance). These relationships are to be expected, as informational support is a type of social support.

Diabetes Distress

Of interest, Trusting and Evaluating Online Health Information (factor 1) was positively related to multiple types of Diabetes Distress items (Powerlessness, Hypoglycemia Distress, Physician Distress). These findings are a unique contribution to the T1D literature because they provide support that key diabetes-related constructs impacting health behaviors also impact health information–seeking. These findings are significant because, to the best of our knowledge, this study is the first to assess these relationships. These findings are a unique contribution to the T1D literature because they provide support that with more feelings of distress toward managing T1D, hypoglycemia-related distress, and diabetes-related distress related to friends and family, individuals are engaging more

with online health information in the DOC. With more diabetes-related distress comes more engagement in the DOC and more trust in the information found online.

Clinical Implications

This study highlights that with more distress toward managing T1D, hypoglycemia-related distress, and diabetes-related distress related to friends and family, people with T1D are engaging more with online health information in the DOC. This is important because instead of seeking support from their health care team, they are seeking support from the DOC (which is available 24 hours a day, 7 days a week). Clinicians may be able to use this scale as a starting point for a discussion with their patients with T1D about how they seek information online and how their clinicians can better support them when they need information quickly. This is especially poignant for the current generation of clinicians who are using telehealth.

Limitations and Future Directions

Although this study provides an innovative, valid, and reliable scale, there are a few important limitations from which future research may build upon. The sample mostly comprised female participants of White race who were well-educated. Future research in this area should also seek to collect data from minority populations because much of the existing DOC research does not represent the diversity that exists in the online community. Similar research considering and incorporating caregivers for adolescents with T1D would be beneficial because these individuals also engage in the DOC. The developed ATSHIO scale was created for the T1D community but could be tailored for other chronic disease groups who seek health information online.

Future research should be performed based on the feedback provided in this study for the ATSHIO scale to further confirm the findings, further validate its factor structure, and establish reliability of those factors. Future research should also aim to increase the reliability of both factors of the ATSHIO scale. Due to the nature of potential biases inherent to self-reported data, future research should seek to incorporate other sources of data beyond self-reported data, including electronic medical record data.

Conclusions

These findings provide support for the relationships between ATSHIO, social provisions, diabetes distress, and T1D-related health outcomes and behaviors. With a better understanding of the roles of online social support and seeking health information online on disease management, this project serves as the first of several series of studies to improve use of the DOC and facilitate constructions of interventions that encourage or discourage specific aspects of each behavior. From these results, clinicians may encourage people with diabetes to seek social and informational support online. People with diabetes should be educated on health literacy to safely navigate the diabetes online community.

Conflicts of Interest

None declared.

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Abbreviations

AIC: Akaike information criterion
ATSHIO: Attitudes Toward Seeking Health Information Online
CFA: confirmatory factor analysis

CFI: comparative fit index
DOC: Diabetes Online Community
RMSEA: root mean square error of approximation
SRMR: standardized root mean square residual
T1D: type 1 diabetes
TLI: Tucker-Lewis index

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Original Paper

New Approach to Equitable Intervention Planning to Improve Engagement and Outcomes in a Digital Health Program: Simulation Study

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Abstract

Background: Digital health programs provide individualized support to patients with chronic diseases and their effectiveness is measured by the extent to which patients achieve target individual clinical outcomes and the program's ability to sustain patient engagement. However, patient dropout and inequitable intervention delivery strategies, which may unintentionally penalize certain patient subgroups, represent challenges to maximizing effectiveness. Therefore, methodologies that optimize the balance between success factors (achievement of target clinical outcomes and sustained engagement) equitably would be desirable, particularly when there are resource constraints.

Objective: Our objectives were to propose a model for digital health program resource management that accounts jointly for the interaction between individual clinical outcomes and patient engagement, ensures equitable allocation as well as allows for capacity planning, and conducts extensive simulations using publicly available data on type 2 diabetes, a chronic disease.

Methods: We propose a restless multiarmed bandit (RMAB) model to plan interventions that jointly optimize long-term engagement and individual clinical outcomes (in this case measured as the achievement of target healthy glucose levels). To mitigate the tendency of RMAB to achieve good aggregate performance by exacerbating disparities between groups, we propose new equitable objectives for RMAB and apply bilevel optimization algorithms to solve them. We formulated a model for the joint evolution of patient engagement and individual clinical outcome trajectory to capture the key dynamics of interest in digital chronic disease management programs.

Results: In simulation exercises, our optimized intervention policies lead to up to 10% more patients reaching healthy glucose levels after 12 months, with a 10% reduction in dropout compared to standard-of-care baselines. Further, our new equitable policies reduce the mean absolute difference of engagement and health outcomes across 6 demographic groups by up to 85% compared to the state-of-the-art.

Conclusions: Planning digital health interventions with individual clinical outcome objectives and long-term engagement dynamics as considerations can be both feasible and effective. We propose using an RMAB sequential decision-making framework, which may offer additional capabilities in capacity planning as well. The integration of an equitable RMAB algorithm further enhances the potential for reaching equitable solutions. This approach provides program designers with the flexibility to switch between different priorities and balance trade-offs across various objectives according to their preferences.

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KEYWORDS

chronic disease; type-2 diabetes; T2D; restless multiarmed bandits; multi-armed bandit; multi-armed bandits; machine learning; resource allocation; digital health; equity

Introduction

Chronic diseases, while obviously heterogeneous in their physiology, pose a series of common management challenges. One of them is that, by the very nature of these conditions, interventions have to impact multiple aspects of the patient's daily living to be effective. This scenario is propitious for the implementation of digital health programs (via wearables, mobile apps, or virtual care), such as vida (Vida) and welldoc (Welldoc), that provide patient-centric support between in-clinic visits. These digital health programs may lead to improved clinical outcomes [1-3].

The success of digital health programs, however, hinges on the dynamic balance of several factors. The ultimate metric of success of any program is always the improvement of the individual health outcomes of participants in the program. However, these programs need to sustain participant engagement to be effective [4]. The importance of patients engaging with specific intervention points is clear since only the interventions that patients receive can have an effect. However, sustained engagement over time is a critical success factor in itself, as it can mediate enduring and (potentially) disease-modifying long-term shifts in patients' attitudes and perceptions about the management of their own health and lifestyle [5]. Yet, attrition and dropout across programs are estimated to be as high as ~50% [6], representing a major barrier to optimal effectiveness. Moreover, these programs may have capacity limitations (eg, the volume of coaches or health counselors) and need to allocate intervention resources proactively. The options for resource management in digital health programs can vary widely, depending on the metrics and time horizon on which success is measured. In that context, it can be challenging to estimate which approach will be the most effective for a given set of goals.

Our focus is on type 2 diabetes (T2D), which is a representative chronic disease condition. T2D is a high-prevalence, high-burden disease. In the United States, 30 million people are estimated to live with diabetes, the 8th leading cause of mortality [7], and it is estimated to account for over US $300 billion of economic cost [7-9]. The physiologic hallmark of the disease is elevated blood glucose, and success in clinical management is monitored by testing the levels of hemoglobin A_{1c} (HbA_{1c}) tests [10]. T2D can lead to organ damage, but it is manageable through medication and lifestyle changes. Our work is based on a digital program that supports patients through a mobile app, virtual coaching (web-based and app-based), and integration of sensor-collected information.

Our digital program of interest contacts patients to maintain engagement and direct and support specific patient actions. Resource investment into those outreach interventions often relies on an intuitive strategy guided by a present clinical state (eg, in this case, giving preference to patients with the highest HbA_{1c}). However, such engagement-agnostic strategies may not lead to the best possible health outcomes at the population level, since reactive strategies that only prioritize immediate clinical improvements may do so at the expense of future engagement, reducing the ability to deliver interventions to patients who have dropped out.

Digital programs that consider the joint dynamics of engagement and clinical status may arrive at better determinations about intervention strategies. This is a problem that entails long-term planning usually in resource-constrained settings, therefore it can naturally be cast as a restless multiarmed bandit (RMAB) framework, of the type used for studying resource allocation in the context of stochastic scheduling problems [11]. Recent examples of applying RMABs to health-related problems include computing optimal cancer screening regimens [12], improving maternal health through telehealth [13], and planning hepatitis-C treatment delivery [14].

RMAB frameworks generate sequential resource allocation strategies in pursuit of desired outcomes (in our case it would be optimal health status and engagement) but may be prone to maximizing system-level rewards by sacrificing certain groups to favor the "most promising" ones, hence leading to inequities [15]. In a disease-management context, these (potentially) inequitable policies would translate into disparate outcomes across demographic groups, potentially exacerbating existing systemic inequities in health care [15]. To mitigate this issue, there have been recent studies of fairness in RMAB, in the sense of generating resource allocation strategies with a degree of distributive fairness, where all arms have an opportunity to receive the intervention of interest (in this case resources). Specifically, some works view fairness from the lens of equality, guaranteeing a lower bound of receiving an intervention for all groups [16,17]. Fairness has also been set by modulating risk sensitivity, encoding risk-averseness or risk-prevalence levels to shape the reward functions [18].

In this work, we aimed to develop a resource allocation strategy for a digital health app to support patients with T2D applying an RMAB framework. We intentionally sought to incorporate equity as a desirable feature of our approach, aiming to leverage recent innovations in health care, such as the emergence of digital health, without perpetuating systemic flaws in care delivery, such as societal inequities [15]; moreover, T2D represents an unfortunate example where the presence of systemic inequities continues to have a negative impact in care [19]. We introduce a new solution, equitable RMAB (ERMAB), which requires that allocation policies take affirmative steps to distribute resources in a way that equalizes outcomes across prespecified groups. That is, we focus on fairness through the lens of achieving equitable outcomes in resource allocation. We applied this paradigm to the resource allocation of outreach interventions in our program, evaluating an engagement-health dynamics model and an equitable intervention planning approach via an extensive simulation study using publicly available statistics about digital T2D management. Subsequently, we

carried out a Pareto analysis to further study the interplay of engagement-clinical outcome dynamics under different intervention strategies, and perform sensitivity analyses to demonstrate our framework's robustness across RMAB parameter settings.

Methods

Model

Overview

Our model needed to simultaneously address the following facets essential to digital health programs: (1) evolution of clinical outcomes per patient, (2) joint engagement-health dynamics per patient, (3) limited observability of clinical outcomes, and (4) limited resource availability.

We model the problem as a restless bandit with n ∈ 1, . . . , N arms representing each patient, discrete per-arm state space S_n, per-arm action space A_n = {User self-care, Intervention} (equivalently {U, I}), per-arm transition functions P_n defining the probability of arm n transitioning from state s to state s′ given action a, per-arm reward function R_n (s) defining the reward for an arm being in state s, time horizon H, and action budget B. For ease of exposition, S_n, A_n, and $R_n(s)$ are the same for all arms, so we drop the subscript n from these, but our methods apply to the general setting where arms have different state, action, and reward functions. Let s^t be the N-length vector of arm states at time t, indexed as s^t_n, and let a^t be an N-length 1-hot encoding of the arms that receive interventions from the program in time period t. The planner must take actions to maximize their objective, subject to a per-round budget constraint, $|a^t|_1 \leq B \; \forall t \in 1, \ldots, H$.

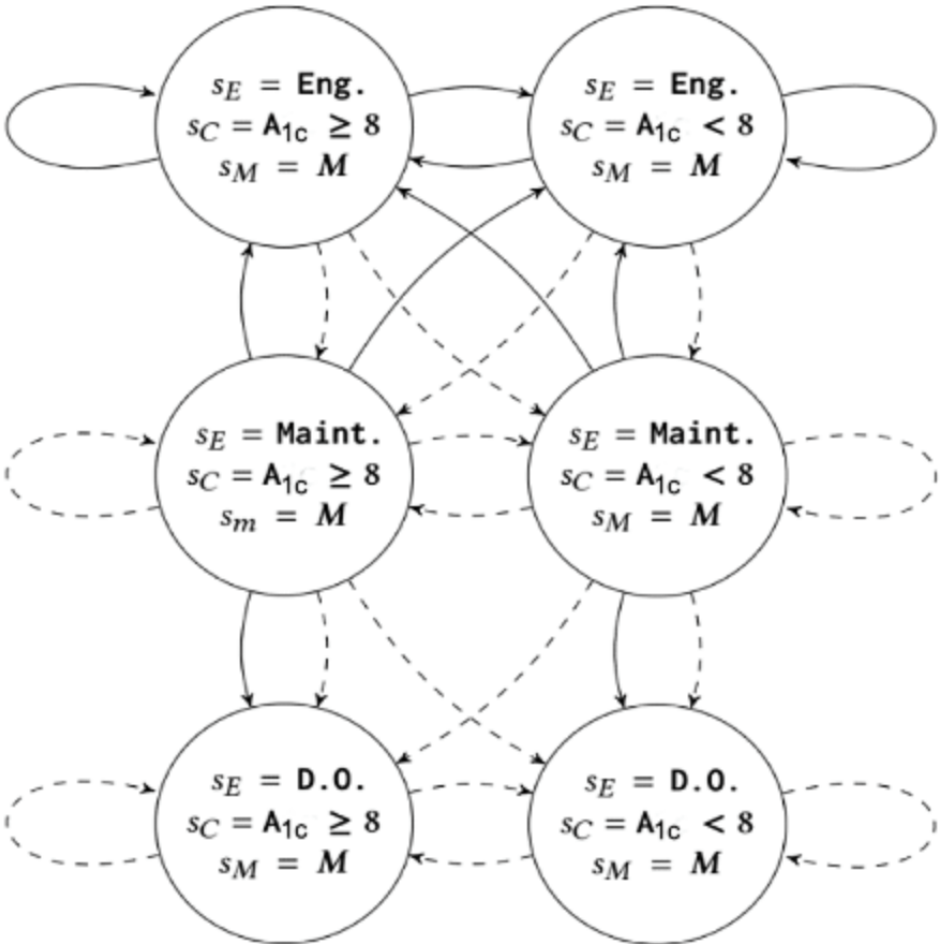
To capture the joint dynamics of engagement and health in digital health programs, we included a dimension for each factor in our state space. For the T2D domain, we also include a dimension for memory, since intervention effects have a delayed impact on clinical outcomes. We represent this 3D state space S by a 3-tuple (s_E, s_C, and s_M), where s_E captures the arm's engagement, s_C captures the arm's clinical (ie, health) state, and s_M is a 2-length memory vector. All dimensions of the state space are modeled as discrete, where continuous spaces are discretized via threshold rules, described next.

The engagement dimension, s_E, has 3 states: {*Engaged*, *Maintenance*, and *Dropout*}. A patient is *Engaged* if they received an intervention from the care team and they responded to the team within the app in the current time period. A patient is in the *Maintenance* state if they have produced any interactions within the app, but did not respond to an intervention if it was attempted in the current time period. A patient is in the *Dropout* state if they have not produced any interactions in the app in the current time period and will no longer do so in any future time period (eg, they have deleted the app). These states are chosen to capture the primary high-level engagement dynamics seen in our digital program.

The clinical dimension, s_C, captures a user's HbA_{1c} value (via 2 states: {$HbA_{1c} < 8$, $HbA_{1c} \geq 8$}. This threshold was chosen to model the clinical outcome target for app users in publicly available data, that is, reducing their HbA_{1c} below 8. Finally, the memory dimension, s_M, is a 2-length vector for recording previous values of s_E, so its entries can take the same values as the s_E dimension. The memory serves to implement a 3-month delay between an intervention and its impact on the clinical state. This effect is observed in data and is due to the biological nature of HbA_{1c} progression, that is, it is a summary measure of the body's blood sugar over the previous 3 months. Let s_{Mi} reference the ith entry of the 0-indexed, 2-length memory vector.

Transition dynamics are summarized below (Figures 1 and 2).

Figure 1. State transition diagram for 1 arm. Bold arrows are transitions when a = intervention and dotted arrows represent transitions when a = user self-care. Eng: engaged; Maint: maintenance.



Engagement Dynamics

The engagement model is made up of 4 main effects. First, each patient has their own independent probability of responding to an intervention and transitioning to the *Engaged* state from either the *Engaged* or *Maintenance* states. Second, the probability of a patient responding to an intervention if they were previously in the *Engaged* state is higher than if they were previously in the *Maintenance* state. Third, the probability of a patient transitioning to a *Dropout* state is lower if the patient receives an intervention, than if they do not. Lastly, patients in the *Dropout* state will never respond to an intervention. In summary, this corresponds to 4 open parameters for the engagement dynamics, p^{I}_{MtoE}, p^{I}_{EtoE}, p^{I}_{MtoD}, *and* p^{U}_{MtoD}, where superscripts, *I* or *U*, denote the action.

Clinical Dynamics

There are 2 meaningful clinical dynamics, corresponding to the clinical evolution of patients who did and did not respond to an intervention. Specifically, we assume that patients who received and responded to an intervention (ie, were in the *Engaged* state) will have a higher probability of transitioning to a healthy clinical state than a patient who did not receive or respond to an intervention. In addition, all effects are delayed by 3 months via the memory states as described in the equations below (Figure 2). Note that we assume that HbA_{1c} progression is the same for users who were in the *Maintenance* and *Dropout* states. We show the evolution of the clinical state s'_C, given the memory state s_{M1} (ie, clinical state 3 months ago), and the current clinical state s_C, in Table 1. Row 1 of Table 1 represents users who received and responded to an intervention 3 months ago, whereas row 2 represents users who did not receive or respond to an intervention 3 months ago. Note that this requires estimating only 4 parameters for clinical progression, that is, $p^{E}_{A_{1c}\geq 8}$, $p^{E}_{A_{1c}<8}$, $p^{\bar{E}}_{A_{1c}\geq 8}$, *and* $p^{\bar{E}}_{A_{1c}<8}$, all of which encode the probability of having an HbA_{1c} level less than 8 in 3 months.

Figure 2. Construction of the delayed intervention effect on clinical state, sC, via zoomed in view of Figure 1. Each transition (arrow) in Figure 1 encodes 2 transitions with different probabilities (the dashed and dotted arrows in this figure), each of which depend on the engagement state of the user 3 months ago, that is, the last entry of the memory state M. Specifically, the probability of transitioning to a better clinical state will be larger if the user was in the engaged state 3 months ago. Eng: engaged.

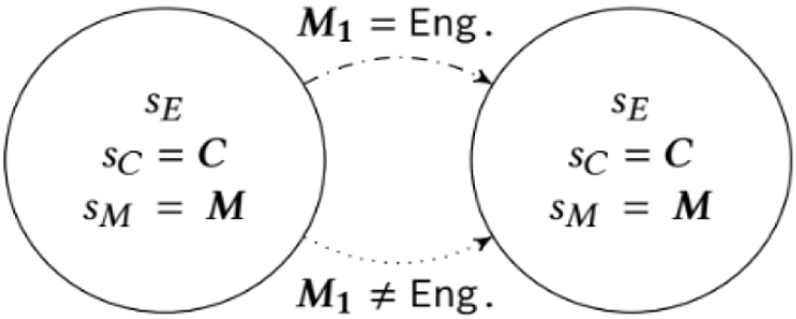


Table 1. The table shows the evolution of clinical state P (s′C = HbA_{1c} < 8|r, c) where r represents the memory state s_{M1} and c represents the current clinical state sC.

Evolution of clinical state P (s'_C = HbA_{1c} < 8|*r*, *c*)	s'_C = HbA_{1c} ≥ 8	s'_C = HbA_{1c} < 8
s_{M1} = Eng[a]	$p^E_{A_{1c}\geq 8}$	$p^E_{A_{1c}<8}$
$s_{M1} \neq$ Eng	$p^{\bar{E}}_{A_{1c}\geq 8}$	$p^{\bar{E}}_{A_{1c}<8}$

[a]Eng: Engaged.

Memory Dynamics

The memory dimension is a sliding window to record the engagement state of the previous 3 months:

P (s′M0 = sE, s′M1 = sM0 | sE, sM0) = 1

Finally, note that the arrows in Figures 1 and 2 represent joint engagement-clinical-memory transition probabilities. These are obtained by multiplying the engagement, clinical, and memory transition rules.

Observability

By definition, the engagement state s_E, and thus memory state s_M, are fully observable. However, the clinical state s_C relies on a patient collecting a measurement of their HbA_{1c} in a given time period. We assume that users in the *Engaged* state have fully observable s_C, for example, they will measure their HbA_{1c} upon request from the program, patients in the *Maintenance* state have a partially observable HbA_{1c}, for example, they will measure their HbA_{1c} in a given round with probability q^{Obs}_{Maint}, and users in the *Dropout* state have an unobservable HbA_{1c}. To handle this partial observability in a computationally scalable way, we convert the partially observable system via a belief-state conversion which allows us to treat the converted system as fully observable [20]. The main benefit is that it allows us to use more efficient optimization tools, at the cost of having a slightly larger state space in the converted system.

Rewards

We assign rewards based on the current state of each patient and represent them as *R(s)*. In general, our objective is to jointly boost engagement and clinical state. To capture that objective, we define rewards for each state dimension independently as:

The reward for a patient's full state is then computed as $R([s_E, s_C, s_M]) = \alpha r_E(s_E) + (1 - \alpha)\, r_C(s_C)$.

Thus the parameter α represents the relative weight on the engagement reward and it can be tuned based on the planner's desired objective.

Equitable Restless Bandit Problem

Overview

We model the problem as an RMAB, a framework for finding optimal allocations of constrained resources across many Markov Decision Processes and across time. In this work, we enforce that solutions must also be equitable across *groups* of arms, introducing a new class of ERMAB. Here, we give a brief overview of the ERMAB framework and the equitable objectives considered for our simulation analysis. For full technical background on restless bandits and full derivations of ERMABs and their solutions, please see Killian et al [21].

Preliminaries

We consider predefined groups of arms (patients) G, indexed by g. Let M-1(g) be the set of arms in group g. Given a time horizon *H*, a start state s^0_g, and per-round budget b_g, a reward-maximizing allocation policy for a group of arms can be found by computing the value function $V^0_g(s^0_g, b_g)$, where:

and $V^H_g(\cdot) = 0$. However, solving this exactly is PSPACE-Hard [22], due to the coupling between arms imposed by the budget constraint. Thus, it is more common to work with objectives that relax the budget constraint equation 4 in a Lagrangian fashion, trading some solution quality for computational tractability. Solutions to the relaxed value functions are denoted $L^t_g(s^t_g, b_g)$, rather than $V^t_g(s^t_g, b_g)$.

Equitable Objectives

In ERMABs, our objective is to both maximize reward and ensure that rewards are distributed equitably across groups of arms. Below, we give 2 objectives for planning such policies.

Maximin Reward

Maximin reward (MMR) is a robust objective that maximizes the minimum prospective total reward of any group.

where B is the total per-round budget constraint over all groups. This objective takes a bottom-up approach to equity, ensuring that the groups that are the worst-off are prioritized for resources. However, since the objective focuses only on maximizing the worst case, on some data distributions, it may over-commit resources to a subset of groups with very low potential for improved outcomes, at the expense of potential gains to other groups, which may be undesirable. To account for this, we also consider a second equitable objective that is sensitive to gains across the distribution of groups, while still prioritizing the worst-off.

Maximum Nash Welfare

The maximum Nash welfare (MNW) objective gives diminishing returns as the prospective total reward of a group becomes larger. This leads to prioritizing allocations that improve the rewards of all groups more equitably. However, if 1 or a subset of groups have little potential for gains, the allocations will go to the next-worst-off groups which may see some meaningful utility increase from the allocation.

Both objectives represent a natural bilevel optimization problem, where the inner problem solves for the value function *within* 1 group, and the outer problem solves for the equitable distribution of resources *across* groups. To solve equation 5, we use algorithm 1 (Figure 3 [21]), an efficient water filling procedure that incrementally assigns a budget to the group with the smallest long-term value *L*, until the total budget *B* is exhausted. To solve equation 6, we use algorithm 2 (Figure 3 [21]), an efficient greedy approach that incrementally assigns a budget to the group that will see the largest marginal (log) increase in its long-term value *L*, until the total budget *B* is exhausted. The algorithm also includes nuance which corrects for computational biases that occur in the presence of unequal group sizes. To take actions (assign resources) in the simulations, we follow the actions implied by the value functions $L^t_g(s^t_g, b_g)$ output by algorithms 1 or 2 (for complete algorithm derivation, with additional proofs and technical detail, see Killian et al [21]).

Figure 3. Algorithms. ERMAB: equitable restless multiarmed bandit.

Algorithm 1: ERMAB water filling: maximin reward

Data: $\mathcal{G}, B, \boldsymbol{s}, h$
$\boldsymbol{b} = 0$ // $|\mathcal{G}|$-length vector, of budgets
for $g \in \mathcal{G}$ **do** // Initialize
  $L(\boldsymbol{s}_g, b_g) = \textsc{InnerOpt}(g, b_g, \boldsymbol{s}_g, h) / |M^{-1}(g)|$
for $b \in [1, ..., B]$ **do**
  $g^\star = \textsc{ArgMin}(L(\boldsymbol{s}_g, b_g))$
  $b_{g^\star} \mathrel{+}= 1$
  $L(\boldsymbol{s}_{g^\star}, b_{g^\star}) = \textsc{InnerOpt}(g^\star, b_{g^\star}, \boldsymbol{s}_{g^\star}, h) / |M^{-1}(g)|$
return L, $\boldsymbol{b}$

Algorithm 2: ERMAB greedy: max Nash welfare

Data: $\mathcal{G}, B, \boldsymbol{s}, h$
$\boldsymbol{b} = 0$ // $|\mathcal{G}|$-length vector, of budgets
$\theta = \max_g\{|M^{-1}(g)|\}$
for $g \in \mathcal{G}$ **do** // Initialize
  $\textsc{UpSample}(g, \theta)$ // Resample arms, until g has size θ
  $L_0(\boldsymbol{s}_g, b_g) = \textsc{InnerOpt}(g, b_g, \boldsymbol{s}_g, h)$
  $L_1(\boldsymbol{s}_g, b_g) = \textsc{InnerOpt}(g, b_g + 1, \boldsymbol{s}_g, h)$
  $L_\Delta(\boldsymbol{s}_g, b_g) = \log(L_1(\boldsymbol{s}_g, b_g)) - \log(L_0(\boldsymbol{s}_g, b_g))$
for $b \in [1, ..., B]$ **do**
  $g^\star = \textsc{ArgMax}(L_\Delta(\boldsymbol{s}_g, b_g))$
  $b_{g^\star} \mathrel{+}= 1$
  $L_0(\boldsymbol{s}_{g^\star}, b_{g^\star}) = L_1(\boldsymbol{s}_{g^\star}, b_{g^\star})$
  $L_1(\boldsymbol{s}_{g^\star}, b_{g^\star}) = \textsc{InnerOpt}(g^\star, b_{g^\star} + 1, \boldsymbol{s}_{g^\star}, h)$
  $L_\Delta(\boldsymbol{s}_{g^\star}, b_{g^\star}) = \log(L_1(\boldsymbol{s}_{g^\star}, b_{g^\star})) - \log(L_0(\boldsymbol{s}_{g^\star}, b_{g^\star}))$
$\textsc{Rescale}(\boldsymbol{b}, \mathcal{G}, \theta)$ // Rescale budgets proportional to original group size
return L, $\boldsymbol{b}$

Simulation

MarketScan Datasource

To derive baseline statistics on clinical evolution, we relied on the widely used Truven Health MarketScan Commercial Database [23], a convenience sample of medical insurance claims from patients who are privately insured in the United States over the years 2018 to 2020, which includes measurements of HbA_{1c}. We consider users enrolled for more than 6 months that have T2D only, that is, excluding those with hypertension, depression, heart failure, or cancer. We then group users by age, gender, and starting HbA_{1c} to derive statistics per group on monthly HbA_{1c} change (full details in Multimedia Appendix 1). These provide values of $p^{\bar{E}}{}_{A_{1c} \geq 8}$ and $p^{\bar{E}}{}_{A_{1c} < 8}$ of approximately 7.5% and 0.5%, respectively, with about 1% variation across groups. The MarketScan data set is publicly accessible and provides a reasonable estimate for the background rate of HbA_{1c} change for users not in a specific digital health program, but receiving standard care. It provides a conservative baseline for our experiments.

For the engagement dynamics, statistics on monthly dropout rates by demographic groups from digital health programs are not readily available. Therefore, we use age and gender-based monthly dropout statistics published by the National Diabetes Prevention Program (NDPP) lifestyle change program, primarily made up of in-person meetings [24]. With monthly dropout rates near 10%, this again forms a reasonable conservative baseline for experiments, serving as a proxy for patients' willingness to engage with T2D-related ongoing behavior change coaching. These statistics populate $p^{U}{}_{MtoD}$ in our model, with about 4% variation between groups.

The remaining parameters require estimates from digital health program data which are not readily available publicly. Thus we make the following assumptions to instantiate their values. For $p^E_{A_{1c}\geq 8}$ and $p^E_{A_{1c}<8}$, that is, the clinical probabilities of patients who received and responded to intervention, the patients in age ranges of aged 30-44, 45-54, and 55-64 years receive 25%, 50%, and 75% boost in their clinical probability of transitioning to $HbA_{1c} < 8$, respectively. We found that this leads to clinical trajectories in line with 1 published observational study of a digital diabetes management program [25], and included age-based variation to align with variation observed in NDPP's monthly dropout statistics. For p^I_{EtoE} and p^I_{MtoD}, we assign values of 99% and 3%, respectively, encoding an assumption that patients are more likely to stay in the program if intervened or if already engaged. For p^I_{EtoE}, we assign values with a mean of 75%, but with the same group variation as was present in the data for NDPP's dropout statistics.

Finally, we set the probability of observing the clinical state of a patient in the maintenance state, that is, q^{Obs}_{Maint} to 30%, in line with statistics from MarketScan.

MMR Counterexample Data

Since MMR objectives are prone to "getting stuck" on unmovable targets, we include a domain to serve as a counterexample that induces this effect. To achieve this, we adopt the probabilities of the MarketScan data, but change the probabilities of 1 group such that interventions are barely effective. Full details are given in the Multimedia Appendix 1.

Analyses

Our simulation analyses quantify the extent to which target clinical outcomes are achieved by calculating the numbers and proportions of patients reaching target HbA_{1c} levels (< 8). For all simulation experiments, we started with all patients in the *Engaged* state, with $HbA_{1c} \geq 8$, and a memory state of [M, M]. We divided data sets by 3 age ranges (aged 30-44, 45-54, and 55-64 years) and 2 genders (man and woman), creating 6 groups in total. The 6 groups had relative sizes of 0.175, 0.15, 0.2, 0.15, 0.125, and 0.2. To ensure each patient followed a unique behavior profile in simulation, for each patient in a group, we instantiated their transition probabilities by sampling each parameter from a normal distribution using the group value as the mean and $\sigma = 0.05$ SD.

Policies were optimized with $\alpha = .0$ unless otherwise noted.

We generated simulation results based on our 2 new equitable policies, MMR and MNW-EG which implemented the MMR and max Nash welfare (with equalized groups) policies, respectively.

We compared simulation results against 2 baselines that served as proxies for how our digital health program of interest, and similar ones, assign intervention resources, that is, based only on the current clinical state. Specifically, allocating interventions randomly each round on patients who are "High Risk," that is, patients with $s_C = HbA_{1c} \geq 8$ (termed high-risk random allocation), and a round robin approach which prioritized acting on patients with both $s_C = HbA_{1c} \geq 8$ *and* with the longest time period without an intervention (termed high-risk round robin allocation).

Additionally, we included a No Action baseline which simulated without assigning any intervention resources, to generate a lower bound of expected outcomes, that is the outcomes observed if individuals were not enrolled in a digital health program, but solely passively seeking care from the traditional primary care system.

We also compared against a state-of-the-art baseline (termed Opt), which assigns resources according to the asymptotically optimal utility-maximizing Whittle index policy [11,26].

Ethical Considerations

This is a simulation study, without human subject participation. World Medical Association Helsinki Declaration and informed consent guidelines are not applicable.

Results

Overview

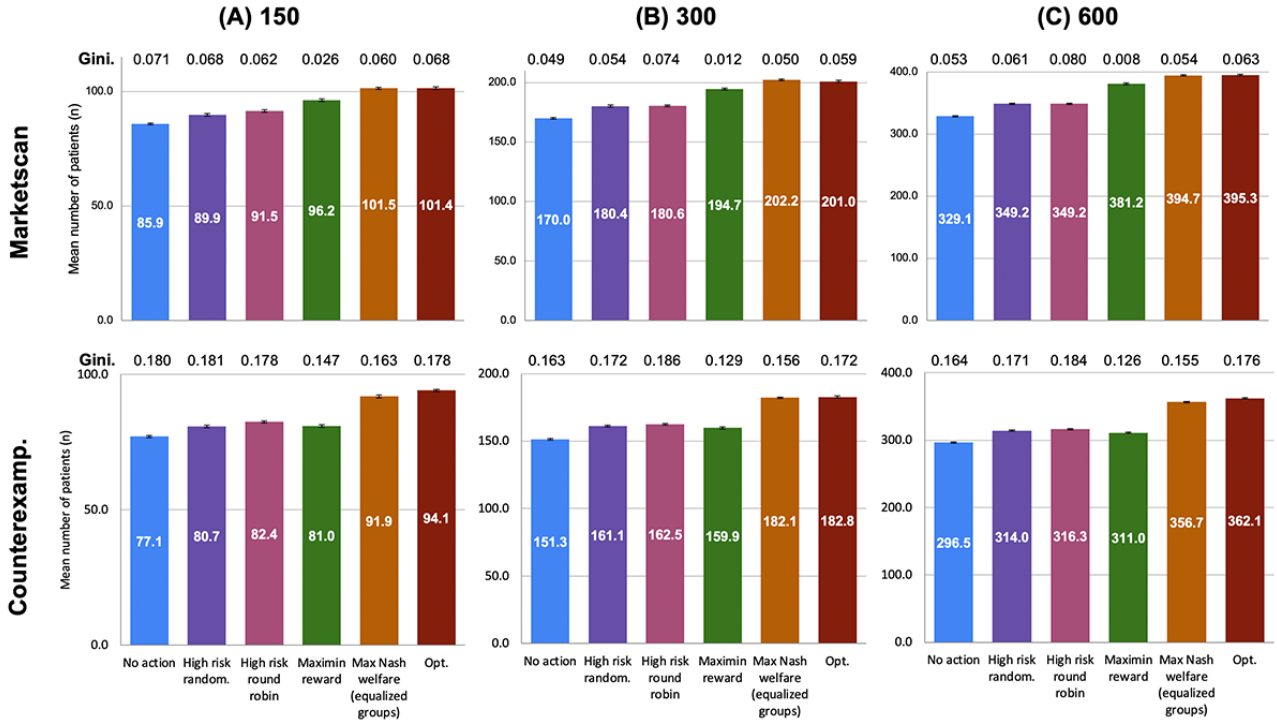
We evaluated our modeling and algorithmic contributions in simulation environments with data derived from publicly available sources on diabetes progression and health program engagement.

We ran experiments for $N \in \{150, 300, 600\}$ patients, horizon of $H = 18$ months, for budget values $B \in \{30, 60, 75, 100, 150\}$ and $\alpha \in \{0, .25, .50, .75, 1.0\}$. To simulate gradual patient enrollment over time, a real-world consideration raised by our digital program, 20% of patients are randomly added to the simulation in each of the first 5 months. Final statistics are all reported based on the health state of each patient after their 12th month in the simulation. We use the Gini coefficient [27] concerning each group's average final reward to measure the equity of each policy applied to each data distribution. Each combination of parameters was run for 50 random seeds, and the results show the average and SE over the seeds.

Achievement of Target Individual Health Outcomes

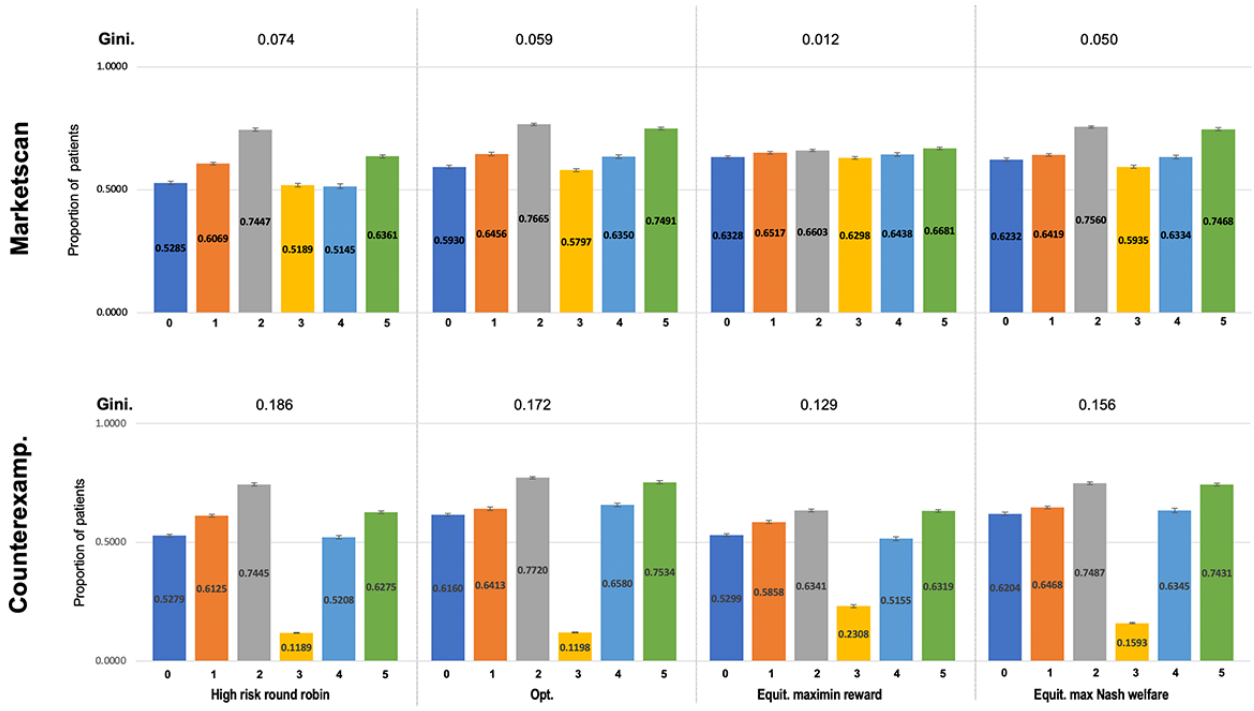
After 12 months, the Opt, MMR, and MNW-EG policies produced better individual clinical outcomes (measured by number of patients reaching healthy HbA_{1c} levels) and engagement than the baselines (Figure 4). The baselines increased the number of users with healthy HbA_{1c} after 12 months by roughly 5%, whereas at the same budget level, assignment policies considering joint clinical-engagement dynamics, that is, the Opt, MMR, and MNW-EG RMAB policies, could double this improvement, up to a further 10% on the MarketScan data set simulation analysis. MMR finds policies nearly 4-times more equitable, for little system-level cost. On the counterexample, MNW-EG avoids the pitfalls of maximin approaches, achieving more equity for little system-level cost.

Figure 4. Individual clinical outcomes (average number of patients reaching healthy HbA_{1c} level) with each policy after 12 months, with a monthly intervention budget of B = N 10. Bars show average proportions by policy. Gini coefficient is displayed atop each policy (lower is better). Top: MarketScan. Bottom: MMR-Counterexample. Panels A, B, and C: analyses with N ∈ [150, 300, 600] patients, respectively. Counterexamp: counterexample; Max: maximum; Opt: baseline policy that assigns, based on the optimal utility-maximizing Whittle index policy; random: randomization.



MMR and MNW-EG achieved their lift in the proportion of patients with healthy HbA_{1c} while ensuring greater equity of outcomes across the groups (Figure 5). Specifically, MMR reduced inequity by nearly a factor of 4, at only a slight performance cost. In the counterexample domain (bottom row in the figure), we found that the overly conservative (by design) MMR over-committed resources to improving outcomes of the unmovable group, at the expense of the performance of all other groups. However, in this case, MNW-EG maintained performance as good as Opt, while achieving the most equitable outcomes of any non-MMR policy. We included additional results in the Multimedia Appendix 1 that show analogous results when policies optimize strictly for engagement (ie, α = 1.0), conclusions held similarly, although the fair policies were able to achieve even greater improvements to equity over baselines.

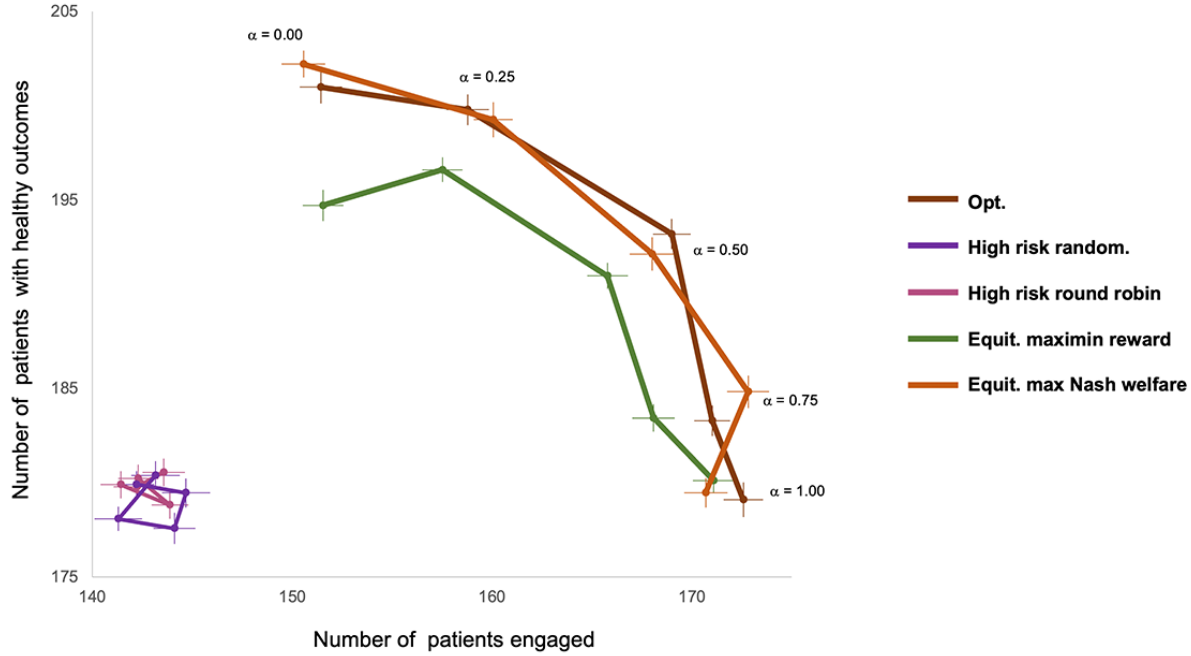
Figure 5. Individual clinical outcomes (proportion of patients reaching healthy HbA_{1c} level) across demographic subgroups. Bars show average proportions by group (0-5) and policy. Gini coefficient is displayed atop each policy. N = 300, B = 30. Top: MarketScan. Bottom: MMR-Counterexample. Counterexamp: counterexample; Equit: equity; Max: maximum; Opt: baseline policy that assigns, based on the optimal utility-maximizing Whittle index policy.



Policy Performance Under Different Preferred Specifications (Pareto Analysis)

Pareto analyses (Figure 6) showed that, even with the choice of $\alpha = 0$ (ie, optimizing only for health), MNW-EG and MMR approaches could achieve both improved health and improved engagement compared to clinical-only baselines. Interestingly, for the MarketScan data set, optimizing with $\alpha = 0.25$, that is, a quarter of reward weighted by engagement, could lead to roughly a 10% total reduction in 12-month dropout compared to baselines, while maintaining the 10% boost in 12-month HbA_{1c} targets. We hypothesize that this is due to the "sticky" nature of healthy HbA_{1c} in the MarketScan data set, that is, patients with $HbA_{1c} < 8$ have a <1% chance of flipping back to $HbA_{1c} > 8$ in the next month. We give additional results in the Multimedia Appendix 1 for more values of the monthly budget B, and with the Gini index as an axis—the equitable policies remained fairer than Opt across choices of α and B.

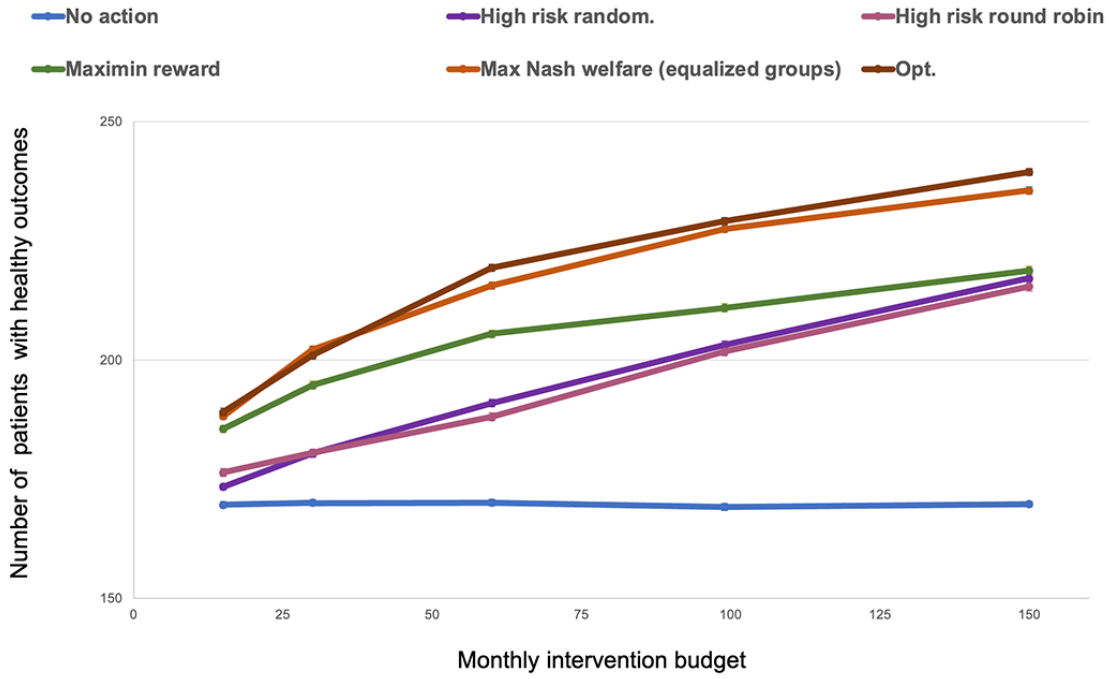
Figure 6. Pareto curve for each policy as α varies from 0 to 1, with number of engaged patients after 12 months (ie, in E or M states) on the x-axis and number of patients with healthy clinical outcomes (HbA_{1c} < 8) on the y-axis. The results are shown for the MarketScan data set with N = 300 and B = N 10. Equit: equity; Max: maximum; Opt: baseline policy that assigns, based on the optimal utility-maximizing Whittle index policy; random: randomization.



Clinical Outcomes According to Resource Allocations: Capacity Planning

Using the MarketScan data set, we performed analyses to estimate the clinical outcomes resulting from different levels of intervention resource allocations. These analyses demonstrated the capability to perform resource capacity planning for prospective cohorts using our MNW-EG and MMR approaches (Figure 7). For example, if the 12-month target was to reach 200 users with HbA_{1c} < 8, this analysis suggested that roughly 30 intervention resources would be needed if following the Opt policy or MNW-EG policies and 45 resources if following the MMR policies. In contrast, the use of our baseline approaches to reach comparable goals would nearly double the budget, up to 100 monthly intervention resources. Additional results for the counterexample domain, and for α-weighted targets, found similar conclusions (Multimedia Appendix 1). These capacity planning plots allowed us to compute the "cost of fairness," that is, the additional monthly intervention resources required for a more equitable policy to achieve the same total system-level return as the unfair optimal one, by estimating the horizontal difference between where each policy's line intersects with the target dashed line. In our analysis, the cost of fairness for MNW-EG was negligible, but it was roughly 15 monthly resources for MMR.

Figure 7. Analysis of individual clinical outcomes according to resource allocation, MarketScan data set, N = 300. In this case, clinical outcomes are measured as the number of patients with healthy outcomes (ie, with $HbA_{1c} < 8$). Max: maximum; Opt: baseline policy that assigns, based on the optimal utility-maximizing Whittle index policy; random: randomization.



Discussion

Principal Findings

In this study of a digital health program in T2D, we used a simulation exercise to present a methodological approach to allocate resources in a digital health program with the potential to balance optimization of clinical outcomes, engagement of participants, and distribution of resources in an equitable fashion across participant subgroups. As an example of that potential, in our simplified simulation exercise, optimized intervention policies based on our proposed ERMAB framework led to 10% more patients reaching a healthy clinical outcome (defined by target HbA_{1c} levels) after 12 months, with a 10% reduction in program engagement dropout compared to standard-of-care baselines. Further, these new equitable policies reduced the mean absolute difference (a common equity measure) of engagement and health outcomes across 6 demographic groups by up to 85% compared to the state-of-the-art. We also demonstrated a new capability for a principled capacity planning system. That is, our system allows planners to estimate the required number of intervention resources needed for this digital health program to support a prospective cohort of patients, each with unique support needs and starting state, in reaching target HbA_{1c} levels. While this study was performed in a T2D setting, we believe that the general tenets of our observations may have applications across a spectrum of chronic diseases. Note that, for simulation, we streamlined our modeling approach, with simplified health goals and demographic groups based on age. Therefore, our quantitative results are merely illustrative, but the principles of this approach could be applied and enriched with more sophisticated modeling and other criteria, such as race or ethnicity, geographic location, or other salient sources of existing inequity (as documented in diabetes care [19]), when information about those factors is available.

Comparison to Other Work

This work is related to a wide literature on using machine learning to make predictions in support of the delivery of digital health. Examples include predicting mood and depression [31], predicting medication adherence [32], ranking the efficacy of smoking cessation messages [33], and predicting heart arrhythmias from smart watches [34]. There are, however, several elements that contrast this study from others. While other works make predictions about the current or future states of a patient's health, they do not offer tools for planning the allocation of resources. Our work focuses on building up the algorithmic tools required for the long-term planning of allocations of limited resources in ways that will benefit the digital health system as a whole.

This study is also the first to formulate an RMAB model of digital health which has the novel characteristic of a multidimensional state space that encodes the joint dynamics of engagement and clinical health, giving the problem a relevant new structure, but increasing the computational complexity over previous domains.

Furthermore, we had equity-focused objectives, which viewed fairness through the lens of taking affirmative steps toward equitable outcomes. Overall considerations of equity in digital health are an underdeveloped area of study; prior or ongoing studies are still trying to measure the inequality problem in digital health in terms of usability, access, or feedback opportunities [35-39]. Most results show that societal inequalities at large have a reflection in the field of digital health, compounded by the issue of uneven technical access. These findings lend more urgency to the development of

optimizing strategies that tackle the problem of inequality intentionally and proactively. Our work is novel in that it proposes to formulate digital health programs to achieve outcome-based fairness. To our knowledge, this is the first study of its kind leveraging restless bandits and the first to give a principled framework for solving the problem of equitable outcomes with guarantees, in contrast to previous work on probabilistic fairness, which merely guaranteed each arm a lower bound of being considered for an intervention [16,17].

Specific Strengths

In addition, we demonstrated a key new capability of interest to digital health program administrators, namely the ability to perform resource capacity planning for prospective cohorts. This feature allows, for instance, to answer the question of whether the digital health program needs the same number of intervention resources to support a cohort of people aged 55-64 years from a particular region as it does to support a cohort of people aged 35-44 years from a different location. Given estimates of each cohort's clinical and engagement behaviors derived from historical data, one can simulate their preferred intervention policies to understand how many resources are needed to reasonably expect each cohort to reach their clinical goals. Capacity planning analysis, coupled with group-level evaluations of policy equity should allow planners to make principled decisions about resource needs for different populations.

Limitations

We acknowledge that this study also has limitations. As reported in this paper, we have only conducted simulation exercises with the analytical framework that we are proposing. We found the simulated results encouraging regarding the potential of our approach to achieve the objectives of allocating digital health program resources in a manner that is effective for reaching individual target clinical outcomes, and for maintaining patient engagement and population-level equitable care delivery throughout the process. However, further research applying this ERMAB framework in a real-world context is warranted to confirm the upside potential shown in simulations. In addition, our T2D model is simplified and we used claims data for our simulations; claims have limitations as sources when inquiries go beyond information directly related to medical procedures, thus we opted for a simplified strategy accordingly. First, we are modeling a binary distinction for HbA_{1c} outcomes (< 8 or ≥ 8); while there is precedent for this approach, this simplification is still a limitation of the model. This cutoff point may not be optimal for all patients [40]. Second, the model does not consider comorbidities, which are highly relevant in diabetes, and chronic conditions in general, and could have meaningful effects on outputs, particularly the individual health outcomes. However, this model can be expanded with more granularity, as long as it can learn additional parameters from more sophisticated real-world data sets. These considerations (more individualized HbA_{1c} outcomes, comorbidities, and relevant subcohorts to the investigation of inequity) will all be important for future research based on other sources (such as electronic health records or clinical registries), to determine to which extent increasing complexity in the desired outcomes may affect the model's performance, and the practical implementation of the results.

Conclusions

In conclusion, our work showed the potential feasibility of planning interventions in digital health attending to several important factors in today's societal environment and resource-constrained systems. Our approach to intervention planning accounts not only for individual clinical outcome objectives but also for long-term participant engagement dynamics, using an RMAB sequential decision-making framework. We were able to simulate more equitable policies that could jointly improve engagement as well as clinical outcomes and demonstrated how the RMAB simulation framework could also provide key new capabilities in capacity planning, and objectively analyze how to trade-off between different program outcomes. Finally, we make a key new algorithmic contribution by introducing ERMABs and designing an efficient and fair approach for reaching population-level equitable solutions. We hope that ERMABs will add to the arsenal of tools available to practitioners addressing resource allocation problems in ethically sensitive domains.

Acknowledgments

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Authors' Contributions

Study concept and design, draft writing and review, and draft approval for submission were done by all authors. Data collection was by JA. Data analysis and interpretation were performed by JAK, YJ, EH, and MJ.

Conflicts of Interest

This study was sponsored by Verily Life Sciences and Google Health. YJ, EH, and JA report employment and equity ownership in Verily Life Sciences. JAK was a student researcher at Google LLC and Verily Life Sciences. MJ and MT are employees of Google LLC and own Alphabet stock.

Multimedia Appendix 1

Additional description of methods.
[PDF File (Adobe PDF File), 1237 KB - diabetes_v9i1e52688_app1.pdf]

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Abbreviations

ERMAB: equitable restless multiarmed bandit
HbA_{1c}: hemoglobin A_{1c}
MMR: maximin reward
MNW: maximum Nash welfare
NDPP: National Diabetes Prevention Program
Opt: baseline policy that assigns, based on the optimal utility-maximizing Whittle index policy
RMAB: restless multiarmed bandit
T2D: type 2 diabetes

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Original Paper

Inequalities in the Ability for People With Type 2 Diabetes and Prediabetes to Adapt to the Reduction in In-Person Health Support and Increased Use of Digital Support During the COVID-19 Pandemic and Beyond: Qualitative Study

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Abstract

Background: The COVID-19 pandemic created unprecedented challenges for people with type 2 diabetes (T2D) and prediabetes to access in-person health care support. Primary care teams accelerated plans to implement digital health technologies (DHTs), such as remote consultations and digital self-management. There is limited evidence about whether there were inequalities in how people with T2D and prediabetes adjusted to these changes.

Objective: This study aimed to explore how people with T2D and prediabetes adapted to the reduction in in-person health support and the increased provision of support through DHTs during the COVID-19 pandemic and beyond.

Methods: A purposive sample of people with T2D and prediabetes was recruited by text message from primary care practices that served low-income areas. Semistructured interviews were conducted by phone or video call, and data were analyzed thematically using a hybrid inductive and deductive approach.

Results: A diverse sample of 30 participants was interviewed. There was a feeling that primary care had become harder to access. Participants responded to the challenge of accessing support by rationing or delaying seeking support or by proactively requesting appointments. Barriers to accessing health care support were associated with issues with using the total triage system, a passive interaction style with health care services, or being diagnosed with prediabetes at the beginning of the pandemic. Some participants were able to adapt to the increased delivery of support through DHTs. Others had lower capacity to use DHTs, which was caused by lower digital skills, fewer financial resources, and a lack of support to use the tools.

Conclusions: Inequalities in motivation, opportunity, and capacity to engage in health services and DHTs lead to unequal possibilities for people with T2D and prediabetes to self-care and receive care during the COVID-19 pandemic. These issues can be addressed by proactive arrangement of regular checkups by primary care services and improving capacity for people with lower digital skills to engage with DHTs.

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KEYWORDS

diabetes; diabetic; DM; diabetes mellitus; type 2 diabetes; type 1 diabetes; prediabetes; prediabetic; COVID-19 pandemic; COVID-19; SARS-CoV-2; coronavirus; severe acute respiratory syndrome; coronavirus infections; novel coronavirus; motivation; health inequalities; self-care; mHealth; mobile health; app; apps; application; applications; digital health; digital intervention; digital interventions; telemedicine; telehealth; virtual care; virtual health; virtual medicine; remote consultation; telephone consultation; video consultation; remote consultations; telephone consultations; video consultations

Introduction

Type 2 diabetes (T2D) is a chronic disease that affects a large number of people and creates a significant burden for patients and the health services that support them. In the United Kingdom, 1 in 10 people older than 40 years now has T2D and around a third of adults living in England have prediabetes [1]. Prediabetes puts individuals at high risk of developing T2D and the associated health complications [2], including cardiovascular pathologies, kidney disease, eye problems, and foot ulcers [3].

The COVID-19 pandemic created unprecedented challenges for people with T2D and prediabetes to access in-person health care and self-care support in the United Kingdom [4,5]. Routine checkup appointments and nonurgent hospital care were cancelled due to government-implemented social distancing rules and the reallocation of health services and personnel to manage COVID-19 patients [6]. There was a 77% reduction in the number of tests for hemoglobin A_{1C} in the United Kingdom between March and December 2020, which provides an objective marker of glycemic levels and diabetes disease status [7]. Primary care teams were required to accelerate plans to increase the implementation of digital health technologies (DHTs), such as remote consultations and digital self-management [5]. Concurrently, face-to-face community-based interventions (eg, Healthier You service) transitioned to fully remote digital delivery [8].

There is conflicting evidence about the impact of the reduction of in-person health care and increased digital support on health inequalities during the COVID-19 pandemic. In this paper, we use the term "health inequality" in the sense used by Marmot [9,10] in his key papers on this topic to denote differences in health due to social determinants such as neighborhood deprivation. There is qualitative evidence that people in the United Kingdom with T2D faced varied challenges in health care access; some struggled to contact health care professionals (HCPs), while others noticed no change [11]. The difference in experience accessing care may relate to the individuals' ability to adjust to the increased delivery of health care through digital and remote approaches. In a qualitative study with HCPs working in primary and secondary care during the COVID-19 pandemic, the HCPs felt that while most of their patients were able to adapt to the change in the delivery of services (because they had no alternative options), they had concerns about digital exclusion for those who were older, less physically fit, or from lower socioeconomic groups [12]. A YouGov survey from 2020 indicated that older individuals (older than 55 years), those with a carer, or those who were unemployed were more likely to have negative experiences with DHTs than the general population [13]. A qualitative study found no barriers to DHT use among people with T2D during the COVID-19 pandemic [11]. Conversely, they reported that several had felt that their skills and confidence to use digital platforms to communicate with HCPs increased during pandemic, due to the increased prevalence of these digital tools in all areas of life (eg, work, social, and health) [11]. However, the study had limitations, as the sample were younger (79% were younger than 65 years) than the overall UK population (47% were younger than 65 years), and no information was provided about socioeconomic status (SES) [11].

As we move beyond the COVID-19 pandemic, we will also move into a new chapter in the delivery of in-person health care and self-care support and the use of DHTs [14]. The pandemic accelerated innovation in health care, and a Department of Health and Social Care white paper proposed that these advances should be made permanent [15]. Primary care clinicians have cited concerns that the lack of face-to-face appointments during the lockdown phases of pandemic resulted in poorer control of blood glucose and resulted in many people with prediabetes crossing the threshold into a T2D diagnosis [14]. Health services recovery plans have sought to address the backlog in care by retaining some digitally led tools that were used during the pandemic, including blended digitally enabled triage (remote tools and digital methods) [16], blended consultations (remote and face-to-face) [17,18], digital self-care tools such as remote-monitoring devices, and web-based support tools including the Healthy Living platform [14]. However, it is widely reported that there are continued challenges for patients accessing health care services, particularly in primary care [16]. It is essential that we understand the barriers that patients face when accessing and using these DHTs. This will support the identification of those who may need support to benefit from increasingly digitally led health care services.

We conducted a qualitative interview study to explore how people with T2D and prediabetes adapted to the reduction in in-person health and self-care support and the increased provision of support through DHTs during the lockdown stages of the COVID-19 pandemic and beyond. The interviews were conducted in April 2022, a total of 8 months after the final lockdown concluded in the United Kingdom (July 2022) and after emergency measures had been relaxed. This allowed us to capture reflections on experiences of the emergency stage of the COVID-19 pandemic and the transition into the recovery stage for health services, with the associated shifts in provision of services through DHTs. We wanted to explore issues with inequalities in access to support and any barriers or supporting factors to individuals with T2D and prediabetes adapting to the changes in access to support.

Methods

A qualitative interview design was used [19]. We have adhered to the COREQ (Consolidated Criteria for Reporting Qualitative Research) reporting checklist [20].

Ethical Considerations

All activities were approved by and conducted in accordance with the Health and Social Care Research Ethics Committee B, who granted a favorable ethical opinion on January 11, 2022 (reference 21/NI/02022), and the Declaration of Helsinki. The participants received both written and verbal information about the research. Informed consent was collected from all participants. Interview participants provided written consent before the interview was arranged, which was confirmed with verbal consent immediately prior to the interview.

Participant Recruitment

A purposive sample of patients with T2D and prediabetes was recruited, which was diverse with respect to SES, gender, ethnicity, and age. Two primary care practices were selected to ensure access to a diverse patient population. Eligible patients were identified by staff in the recruited primary care practices by searching patient records for adults who were recorded as having a T2D or prediabetes diagnosis. A text message was sent out to eligible patients through the practice messaging system inviting them to enter the study. More than 90 potential participants expressed an interest in being interviewed. Interviewing continued until data saturation was reached and no new data arose in relation to the key themes, with a final sample of 30 participants.

Data Collection Procedure

Participants were provided with written information about the study in advance and either completed the eConsent form or provided detailed verbal consent that was audio recorded before beginning the interview.

The interviews were semistructured and conducted by 1 researcher (ST). The topic guide (available in Multimedia Appendix 1) was developed by ST and CC, informed by the literature and the authors' prior qualitative work on access to DHTs for people with T2D [21,22]. There were 3 iterations of the topic guide, with minor changes to questions about the potential of an intervention to reduce inequalities in access to DHTs, and around any unmet information needs they had about their condition. Field notes were taken during and after interviews. Participants were asked to describe their age range, gender, ethnicity, and occupation (or most recent employment if they were not currently employed). Their SES was determined by coding the occupational group using the Office of National Statistics Standard Occupational Classification 2020 [23] and mapping them to the 3 National Statistics Socio-economic Classification (NS-SEC) categories using the guidelines provided by the Office of National Statistics [24]. Interviews were recorded with consent on an encrypted audio-recorder and transferred to the University of Bristol secure servers. They were transcribed and uploaded to NVivo (Version 1.6.2; Lumivero) for analysis [25].

Analysis

Thematic analysis was used [26], and data collection and analysis was iterative to allow emerging themes to be explored in subsequent interviews. ST initially took an inductive approach, allowing the themes to emerge from the data, and then took a deductive approach, organizing the themes into 2 broad preconceived concepts related to the study aims of exploring challenges in accessing health care and changes in the use of DHTs [19]. The codes were developed by 2 researchers working independently with the data to ensure a robust analysis. ST developed the initial coding structure, which CC then applied to a sample of transcripts independently. The final coding structure was agreed by consensus and applied to the whole data set (the coding tree is available in Multimedia Appendix 1). Participants were provided with a summary of the findings.

Research Team and Reflexivity

Personal Characteristics

ST is a mixed-methods researcher with a BSc degree in psychology, MSc degree in neuropsychology, and a PhD degree in the impact of digital interventions on health inequalities for chronic conditions. CC is a senior researcher with a PhD degree in social anthropology and research projects in the fields of primary care, social care, and global health.

Relationship With Participants

There was no prior relationship with the study participants before the study commenced. All but 1 of the interviews were conducted over the phone, so participants would not have had any awareness of ST's physical characteristics. They would have known that ST was a female researcher working at the University of Bristol. The participants knew that the study was about how people who are at risk or diagnosed with T2D use technology to help them with their health, fitness, or well-being. The position taken by the ST was that DHTs have the potential to improve access to health care support, but that it is likely that not all social groups will be able to benefit from these types of innovations in health care without support. This may have influenced the conduct of the interviews and interpretation of findings. However, care was taken to phrase questions openly and avoid leading participants, and we therefore believe these findings to be a credible representation of participants' views.

Results

Sample

A total of 30 people were interviewed, who were diverse with respect to gender, age, type of T2D (diagnosed with T2D or prediabetes), ethnicity, and SES (Table 1). Although the majority (23/30, 77%) felt that they were able to navigate technology, the sample included those with no internet access and those with low digital skills (Table 1). Interviews lasted between 14 minutes and 1 hour 15 minutes.

Table 1. Sample sociodemographic information.

Sociodemographic information	Participants (n=30), n (%)
Gender	
Female	15 (50)
Age range (years)	
20-29	1 (3)
30-39	1 (3)
40-49	8 (26)
50-59	7 (23)
60-69	8 (26)
70-79	2 (6)
80-89	3 (10)
Ethnicity	
African	1 (3)
Asian British	2 (6)
British African	1 (3)
Indian	3 (10)
White British	19 (63)
White European	2 (6)
White Irish	2 (6)
Type of diabetes	
T2D[a]	12 (40)
At risk of T2D	18 (60)
NS-SEC[b] 3 classes based on current or previous occupation	
1. Managerial, administrative, and professional occupations	6 (20)
2. Intermediate occupations	7 (23)
3. Routine and manual occupations	12 (40)
Unemployed or long-term sick	4 (13)
Not possible to classify (religious sister)	1 (3)
SES[c] group	
Low	14 (47)
Medium	9 (30)
High	6 (20)
Not possible to classify (religious sister)	1 (3)
Digital skills and access	
Generally confident using technology	23 (77)
Temporarily did not have access to the internet but had good digital skills	1 (3)
Not confident using technology but had devices they could use	5 (17)
Did not have internet connection or devices to access the internet and felt like they were unable to learn about new technology	1 (3)
Did not have internet connection or devices to access the internet and knew about bursaries they could use to access devices and the internet but felt that they were getting everything they needed without it	1 (3)

[a]T2D: type 2 diabetes.

[b]NS-SEC: National Statistics Socio-economic Classification.

[c]SES: socioeconomic status.

Results From Thematic Analysis

There were 2 broad groups of themes: challenges with accessing health care, and changes in the use of DHTs during and beyond the pandemic lockdown periods. An outline of the themes and subthemes is available in Table 2.

Table 2. Themes and subthemes.

Theme	Subtheme
Accessing health care services	• Accessing primary care • Perceptions of changes support for T2D[a] and prediabetes • Impact of patient engagement strategy on access to care • Differences between people with prediabetes and T2D
Changes in the use of DHTs[b]	• Impact of previous experience of DHTs on engagement • Capability to use DHTs • Opportunity to access DHTs

[a]T2D: type 2 diabetes.

[b]DHT: digital health technology.

Accessing Health Care

Overview

Participants described a reduction in access to primary care services and increased provision of remote services. They had different perceptions of how support for their T2D or prediabetes had changed and used either passive or active engagement strategies in response to the changes in care, which impacted the level of support they received from primary care. Those with prediabetes appeared to experience a greater reduction in support, which led to increased engagement and interest in DHTs.

Access to Primary Care: "I Just Give Up. I Don't Bother Anymore..."

Participants described difficulties in accessing primary care since the beginning of the pandemic. Some described how the phone triage systems setup during the pandemic had led to primary care feeling like "a complete closed-door system," because trying to get an appointment "could take between 80 and 100 phone calls, whilst getting cut off" (ID A, male, T2D).

Those who reported having less free time or flexibility to call the practices in the morning and wait in a queue reported having challenges booking checkups, appointments, or blood tests using the total triage system:

> *...it's just such a nightmare at the moment, trying to get an appointment...you have to ring at 8:00 in the morning...I'm just a bit hectic at the moment, I've got a new-born baby...* [ID B, male, prediabetes]

Perceptions of Changes in Health Care Support for T2D and Prediabetes

Participants had different perceptions of how support from HCPs for T2D and prediabetes changed during the pandemic. For some, diabetes support from HCPs continued as before and they "never had any problems" accessing care (ID R, female, T2D). Others spoke about how their health care support did continue, but checkups were "not as regular" (ID E2, male, prediabetes).

Others described how health support from the National Health Service (NHS; eg, diabetes nurses and dieticians) completely stopped during the pandemic:

> *...[care] was really excellent up until the pandemic...everything got cut off as soon as lockdown started.* [ID J2, male, prediabetes]

Impact of Patient Engagement Strategy on Level of Health Care Support

Whether the participants had a passive or active engagement strategy with health services determined the level of care they received during the pandemic. The strategy was determined by their beliefs about how they should engage with the NHS during the pandemic and their entitlement to care. Those who took a passive approach (rationing or delaying seeking support) held the belief that they should not burden the NHS with non–COVID-19–related issues. They were "embarrassed to ring up the doctor because they're so busy with important stuff...like COVID" (ID J, female, prediabetes). A man with T2D spoke about how he felt that access was limited, and he needed to ration requests for support for the care he needed most help with:

> *...didn't feel my situation was important enough...the access was limited, so I had to be very picky about keeping up with my medication reviews, my physical review. I just felt like I needed to keep those going and not put any more pressure on the NHS.* [ID A, male, T2D]

Others took an active approach and requested appointments. They described contacting the practice due to the belief that if they were "not determined enough" (ID N2, male, prediabetes), they would not receive support for their condition. One woman described how her role in social care has meant she knew what help she was entitled to, which meant she proactively sought the care she felt she deserved:

> *...I am the one who pushes it, you see? I am the one who insists that I want support, because I know the system...because of social care [job] I know what is*

happening and what I can get or what I can't get. [ID D, female, T2D]

Differences Between People With Prediabetes and T2D

Participants with both T2D and prediabetes experienced a reduction in health care support during the pandemic. However, those diagnosed with prediabetes around the beginning of the pandemic described how they had "no follow-up visit, appointments, information, nothing" (ID M, male, prediabetes). This led to confusion about how they should manage their condition and whether they still had the diagnosis.

Several of the participants with prediabetes spoke about how they wanted to have a blood glucose monitor at home, to keep track of their condition and so that they were no longer reliant on the health service to understand how their health condition was progressing:

> *I want to get one [blood glucose monitor] because I want to know what my level is, and then I can check in, in a couple of weeks to see if it's actually going down or going up...instead of waiting however long to get an appointment with the doctor...* [ID S, male, prediabetes]

Changes in the Use of DHTs

Participants described how positive or negative experiences of using DHTs and capability to use DHTs influenced their engagement with DHTs following the removal of in-person health care and self-care support.

Impact of Experience of DHTs on Engagement

Some participants had positive experiences of remote or web-based health care or exercise support, which supported further engagement. For example, a woman described how she "found it easier" requesting support through eConsultations, because she was able to write about her multiple and complex issues in her own time: "they only get five minutes with you face-to-face, but online, you can write down whatever you want" (ID F, female, prediabetes). Some participants reflected on how closures of gyms had prompted them to buy fitness watches "to monitor [their] fitness level" (ID D, female, T2D), or to seek out web-based fitness classes to keep them motivated to exercise. A woman with T2D spoke about how having access to some web-based support from her tai chi instructor led her to explore other support for her diabetes online: "I went on to look at something that he [tai chi instructor] had set for us to do, I then found other things and thought, 'Oh, that looks interesting,' and then I went on from there" (ID G2, female, T2D).

Negative experiences were linked to disengagement from DHTs. Participants stopped using DHTs because they hurt themselves, preferred in-person support, felt demotivated by the feedback from DHTs, or lost money by accidently subscribing to services they did not want. A woman with prediabetes explained that she had received remote support from a personal trainer, but "when you're not face to face and we're going on a video, you can't do it...they gave me backache. So I've stopped" (ID C, female, prediabetes). She also reflected that remote support could not replace the in-person support in gyms "Because it's in a group and it's a lot of motivation...you push yourself...going to the gym and in itself is good because you know...it releases endorphins..." (ID C). Another woman with prediabetes described how there was no time to prepare for the shift to digital support from her exercise class, and she was not interested in replacing in-person with digital support: "I don't use that kind of technology" (ID Q2, female, prediabetes). One man with prediabetes stopped tracking his exercise and movements during the pandemic using his fitness watch, because he was moving less and found the feedback highlighted "the lack of progress" (ID J2, male, prediabetes). A woman with T2D had a fall pendant and started receiving calls she had not asked for: "I was receiving calls [fall service] twice a week. They'd go, 'Are you fine' 'Yes, I'm fine.' And when I got my bank statement I found they took £60 out of my account for every phone call. They were ringing up, and I didn't authorise it..." (ID K, female, T2D).

Capability to Use DHTs

Several participants described barriers to accessing and using DHTs caused by their capability (skills) to use these technologies. These included challenges finding web-based support that suited their individual needs, low digital skills, and the absence of good-quality support to use DHTs. Participants spoke about how they "get in a terrible mess" (ID Q2, female, prediabetes) when trying to use technology generally and did not know how to use emails, apps, or navigate the internet. One woman spoke about how the absence of good-quality instructions created a barrier for her taking her own blood pressure reading during the pandemic in her general practitioner practice:

> *[I] just kept reading the leaflet there, and then I just couldn't—I just could not. I had a go at wrapping it, and the lady said, "No, you've got to do it yourself."...I just walked out the building and I cried...That was the worst feeling I've had, like illiterate feeling, at 60.* [ID J, female, prediabetes]

The majority of participants who struggled with digital skills described how they were able to overcome issues by being shown how to use DHTs through videos or in-person support: "I'd got to ask my niece how to download the COVID-19 app for me because I couldn't do it, I couldn't understand it" (ID K, female, T2D). A young woman with prediabetes spoke about how she struggled to "access it [digital support] until I've been explained how to use it...if you can send me a video, show me how to do it before I do it, then it would be easier" (ID V, female, prediabetes). Another woman with T2D spoke about the importance of being shown how to use DHTs rather than having it done for them, so they could learn for themselves: "...[young people] don't show you. They do it for you...But of course, where does that leave you? You're going to ask all over again" (ID H, female, T2D). One man felt that he was not able to learn how to use technology generally or DHTs, even with support from others: "I haven't got the brain to use it...The people are trying to teach me...I just give up" (ID F2, male, T2D).

The capacity to use DHTs was also impacted by a lack of awareness of what DHTs were available. For example, none of

the participants who had been told that they were at risk of T2D spoke about being offered the web-based Healthier You program and were not aware of it when they were explicitly asked.

Opportunity to Access and Use DHTs

There were barriers related to the opportunity for participants to use DHTs caused by the cost of the internet access and DHTs. Two men spoke about how they were "not online" because they were retired and the internet was "just another bill..." they could not afford because they have other priorities, such as running a car (ID E2, male, prediabetes). A woman with prediabetes spoke about how she wanted a blood glucose monitor but "can't afford that..." (ID F, female, prediabetes).

Discussion

Summary of Findings

There was evidence of inequalities in the ability for people with T2D and prediabetes to adapt to the reduction in access to in-person health care and self-care support and increased implementation of DHTs during the pandemic. There was an indication that those with prediabetes were more likely than those with T2D to feel that they had a lack of support from HCPs, particularly those who received their diagnosis near the beginning of the pandemic.

There was a near universal perception of a reduction in access to primary care services and a mixed perspective of the change in NHS support to manage T2D and prediabetes. Barriers to accessing primary care were greater for those who had less free time or flexibility to call the practices in the morning and wait in a queue for an appointment. The level of support provided for people with T2D or prediabetes was determined in part by the engagement strategy used by the patient. Those who contacted their health care provider about needing more support subsequently received it, while those who waited to be contacted received a lower level of support. Participants with both T2D and prediabetes experienced a reduction in health care support during the pandemic. However, those who were diagnosed with prediabetes around the beginning of the pandemic described how they had not received any follow-up care from health professionals. This led to confusion about how they should manage their condition and whether they still had the diagnosis. They spoke about wanting to have an at-home blood glucose monitor so that they would not be reliant on the NHS to track the progress of their condition. Prior positive or negative experiences of using DHTs impacted motivation to engage in this support during the COVID-19 pandemic. Those with less opportunity (eg, financial resources) and capability (digital skills, knowledge of what was available, and support to use DHTs) struggled to engage in health services delivered through technology.

Strengths and Weaknesses

Several qualitative studies have explored the impact of COVID-19 lockdowns on people with T2D's access to health care support [11,27-29]. However, none have explored the perspectives of people with T2D as we move beyond the emergency to the recovery stage of the pandemic, or the perspectives of people with prediabetes.

In this study, we explored inequalities in access to support to adapt to the changes brought about by the COVID-19 pandemic and therefore purposively recruited people with lower SES. People with lower SES have a higher incidence and severity of T2D [1,30,31]. They also faced greater barriers accessing in-person support [10-12] and DHTs prior to the pandemic [32-36]. Therefore, we selected a recruitment method that would increase the chance of including people from these groups. We asked 2 practices serving lower-income areas in Bristol to identify adults with a T2D or prediabetes diagnosis from their patient database and to send them a text message invitation. More than 90 people contacted the study team to express an interest in being involved. This study successfully recruited a sample that was diverse in respect to SES, gender, age, type of T2D (diagnosed or at risk), ethnicity, and digital skills. Just less than half (14/30, 47%) of the sample were from the low SES group, using the NS-SEC 3 classes of SES based on current or previous occupation [24]. Those with lower digital skills reported that the reason they engaged with the study was because the invitation text message included a phone number to contact the study team.

We acknowledge that this method of recruitment is biased toward people who have some interaction with primary care services. However, for this project, we wanted to recruit people who had been diagnosed with T2D or prediabetes to establish how support from primary care changed throughout the pandemic and how people responded to a shift in delivery of care through DHTs. Although we had planned resources for a translator, none of the participants requested this support. The study invitations were sent in English and did not include details about the availability of a translator due to limited space to include study details in the text message invitation. This may have acted as a barrier to participating in the study for people whose first language is not English.

Participants were offered interviews by video call and telephone. All but 1 participant selected telephone interviews. Complete audio data were recorded for all interviews, and there were no issues with lost data. In 2 of the telephone interviews, other people were present in the room where the interview was taking place, and 1 interview was conducted while the participant was driving. This could have impacted the interview content. The participants were not asked to comment on the transcripts. Multiple views of the data were conducted to promote confidence in the credibility of the findings [37]. To ensure that the coding scheme was robust, CC double coded a subset of interviews and ongoing discussion about coding structure was conducted. The authors ensured that a diverse range of experiences and opposing sides of arguments were identified and presented.

Interpretations in the Context of Existing Literature

The findings from this study agree with previous evidence that during the emergency stage of the COVID-19 pandemic, people with T2D perceived primary care support to be less accessible (UK survey) [38] and had mixed experiences of access to health care support for diabetes (UK qualitative study) [11].

Our study adds to the mixed evidence of the acceptability and accessibility of increased delivery of health care through DHTs

during the pandemic. A UK-based survey of patients with a range of conditions indicated that those from underserved populations (older, unemployed, with a carer) were more likely to report negative experiences of using DHTs during the pandemic [13]. A qualitative study found that some people with T2D had reported increased digital skills acquired through the pandemic due to the pervasive nature of digital platforms to communicate in all areas of people's lives [11]. None of their participants in this study reported barriers to accessing DHTs. This may have been related to their sample being younger (79% were younger than 65 years) than the overall UK population (47% were younger than 65 years). A measure of SES was not provided, but it may be possible that the sample were from higher SES groups, which is associated with higher level of digital skills [39]. Our study agreed with the finding by Morris et al [40] that people with chronic conditions with greater access to resources (social, financial, digital skills, and knowledge) were better able to adapt their self-care routines to the reduction of support and the increased delivery of services through DHTs during the pandemic.

This replicates the authors' prepandemic qualitative study of people with T2D, which found that technical proficiency and cost were barrier to the use of self-care DHTs, but that participants were able to draw from resources in their social networks to overcome these barriers [22]. This study also confirms findings of a qualitative study conducted prior to and during the pandemic with primary and secondary care clinicians, where they had concerns that some of their patients were excluded from support delivered by DHTs during the pandemic due to lower digital skills or lack of affordability of internet access [12].

Although we did not set out to apply the COM-B model in analysis, the 3 elements that are needed for behavior change proposed in the COM-B model have been identified in our study as important influences for adapting to the changes of the COVID-19 pandemic [41]. The COM-B model specifies that capability, opportunity, and motivation have to be present for a behavior to occur [41]. Those who had the opportunity and capability to engage with the total triage systems to access health care, or who were highly motivated to ensure that they received a higher level of health care support, were able to access greater support from health care services during the COVID-19 pandemic. Negative experiences of using DHTs reduced participants' motivation to use web-based tools, and a lower capacity to use DHTs prevented participants from being able to use them.

Implications for Practice and Policy

Improving Equality in Access to Health Care

The findings from this study have highlighted how procedures implemented during the pandemic created uneven access to health care. Participants described the "total triage" model system making primary care feel like a "closed door system" where some patients have given up seeking support. They described waiting in phone lines all day and not being able to access appointments, and a system where those who are able to phone early or who are most persistent are able to get appointments. Moving beyond the emergency stage of the COVID pandemic, the total remote triage is being replaced with a blended model where traditional methods are being used alongside digital tools [14,42]. The addition of digital triage may reduce barriers to accessing primary care services by providing those who are unable to wait in phone queues with an alternative method of seeking support. However, this will be beneficial only for those who are willing and able to use digital tools.

Improving Access to Monitoring of Disease Progression

There are concerns about the significant reduction in hemoglobin A_{1C} tests in the United Kingdom (77% between March and December 2020) during the pandemic and how this may result in suboptimal management of T2D [7]. Population-based studies have found that the completion of a higher number of primary care–based process checks for people with T2D results in lower rates of mortality, amputations, and emergency hospital admissions [43]. There were indications in this study of unequal access to care and checkups for people with T2D and prediabetes. This seemed to have a particular impact on those who had been diagnosed with prediabetes around the beginning of the pandemic, with no follow-up support from primary care. Some subsequently purchased their own blood glucose monitors, but others were not able to afford them. The COVID-19 pandemic has galvanized the push to supply more continuous blood glucose monitors to people with type 1 diabetes; however, this is not yet the case for people with T2D [14]. It is therefore essential that regular checkups are uniformly reestablished for people with both T2D and prediabetes as soon as possible to prevent the widening of health inequalities [43]. Those with prediabetes in this study did not report being aware of or offered access to the Healthy Lives program. Greater dissemination of the Healthier Lives program and other self-care support to people with prediabetes may reduce confusion around how to self-manage their condition [14].

Improving Access to DHTs

The Department of Health and Social Care plans to make the increased use of digital innovations since the beginning of the pandemic permanent [15]. The NHS Long Term Plan also laid out the ambition to provide a "digital first" health care service within the next 10 years [44]. Although many participants in this study responded positively to the increased use of DHTs to deliver health care, some reported barriers to accessing this support, caused by negative experiences of using DHTs, lower levels of digital skills, lack of access to the internet, and a preference for in-person support. It is essential that unliteral adoption of DHTs by patients is not assumed, and face-to-face services are still offered for those who are not able or willing to use DHTs. There is evidence that engagement with DHTs can be improved in lower SES groups using multimodal content and the provision of in-person support [45,46]. This was supported by our findings, where participants spoke about how support being shown how to use DHTs through videos, or in-person reduced barriers to use for those with lower digital skills. A scheme piloted by NHS digital found that the digital champions successfully supported people with lower digital skills to access to DHTs [47,48]. This model shows promise as a route to tackle inequalities in access to DHTs in the future.

Conclusions

There was evidence of inequalities in the ability for people with T2D and prediabetes to adapt to changes in health care support and increased implementation DHTs during the pandemic. Those who reported having challenges accessing to health care support had greater barriers engaging with the total triage system, a passive interaction style, or a prediabetes diagnosis at the beginning of the pandemic. Adaptation to the increase in provision of support through DHT was determined by whether the participants had previous positive or negative experiences of DHTs, and whether they had the capacity (eg, digital skills, finances, and technical support) to access and use DHTs. Inequalities in motivation and opportunity to self-care can be addressed by increasing the visibility of self-care support and proactive arrangement of regular checkups by primary care services (thereby avoiding the use of triaging systems) for people with prediabetes and T2D. Digital champions show promise for improving capacity for people with lower digital skills to engage with DHTs.

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Data Availability

Anonymized data sets used and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

ST drafted the manuscript. ST and CC were involved in the conception, study design, analysis, and interpretation of the findings. ST conducted the interviews and coded the interviews. Both authors read and approved the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Topic guides and coding tree.
[DOCX File , 27 KB - diabetes_v9i1e55201_app1.docx]

Multimedia Appendix 2
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 415 KB - diabetes_v9i1e55201_app2.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
DHT: digital health technology
HCP: health care professional
NHS: National Health Service
NS-SEC: National Statistics Socio-economic Classification
SES: socioeconomic status
T2D: type 2 diabetes

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Original Paper

Exploring the Impact of Device Sourcing on Real-World Adherence and Cost Implications of Continuous Glucose Monitoring in Patients With Diabetes: Retrospective Claims Analysis

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Abstract

Background: Insurance benefit design influences whether individuals with diabetes who require a continuous glucose monitor (CGM) to provide real-time feedback on their blood glucose levels can obtain the CGM device from either a pharmacy or a durable medical equipment supplier. The impact of the acquisition channel on device adherence and health care costs has not been systematically evaluated.

Objective: This study aims to compare the adherence rates for patients new to CGM therapy and the costs of care for individuals who obtained CGM devices from a pharmacy versus acquisition through a durable medical equipment supplier using retrospective claims analysis.

Methods: Using the Mariner commercial claims database, individuals aged >18 years with documented diabetes and an initial CGM claim during the first quarter of 2021 (2021 Q1, index date) were identified. Patients had to maintain uninterrupted enrollment for a duration of 15 months but file no CGM claim during the 6 months preceding the index date. We used direct matching to establish comparable pharmacy and durable medical equipment cohorts. Outcomes included quarterly adherence, reinitiation, and costs for the period from 2021 Q1 to the third quarter of 2022 (2022 Q3). Between-cohort differences in adherence rates and reinitiation rates were analyzed using *z* tests, and cost differences were analyzed using 2-tailed *t* tests.

Results: Direct matching was used to establish comparable pharmacy and durable medical equipment cohorts. A total of 2356 patients were identified, with 1178 in the pharmacy cohort and 1178 in the durable medical equipment cohorts. Although adherence declined over time in both cohorts, the durable medical equipment cohort exhibited significantly superior adherence compared to the pharmacy cohort at 6 months (pharmacy n=615, 52% and durable medical equipment n=761, 65%; *P*<.001), 9 months (pharmacy n=579, 49% and durable medical equipment cohorts n=714, 61%; *P*<.001), and 12 months (pharmacy 48% and durable medical equipment n=714, 59%; *P*<.001). Mean annual total medical costs for adherent patients in the pharmacy cohort were 53% higher than the durable medical equipment cohort (pharmacy US $10,635 and durable medical equipment US $6967; *P*<.001). In nonadherent patients, the durable medical equipment cohort exhibited a significantly higher rate of therapy reinitiation during the period compared to the pharmacy cohort (pharmacy 61/613, 10% and durable medical equipment 108/485, 22%; *P*<.001).

Conclusions: The results from this real-world claims analysis demonstrate that, in a matched set, individuals who received their CGM through a durable medical equipment supplier were more adherent to their device. For individuals who experienced a lapse in therapy, those whose supplies were provided through the durable medical equipment channel were more likely to resume use after an interruption than those who received their supplies from a pharmacy. In the matched cohort analysis, those who received their CGM equipment through a durable medical equipment supplier demonstrated a lower total cost of care.

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KEYWORDS

diabetes; diabetic; adherence; medical costs; continuous glucose monitor; propensity score matching; CGM; glucose; cost; costs; claim; claims; insurance; economic; economics; finance; financial

Introduction

In 2021, an estimated 29.7 million people (8.9% of the US population) in the United States were living with diabetes [1]. Despite the availability of effective treatments, nearly half of all individuals with diabetes fail to achieve good glycemic control. According to US Centers for Disease Control and Prevention, an estimated 47.4% of adults with diabetes had a glycated hemoglobin (HbA_{1c}) value of 7% or higher during the period of 2017-2020 [1], which is higher than the recommended HbA_{1c} goal of <7% for most nonpregnant adults with diabetes without significant hypoglycemia [2].

As a natural corollary of insufficient management, uncontrolled diabetes imposes substantial health consequences for patients in the form of cardiovascular complications, nephropathy, retinopathy, neuropathy, diabetic foot ulcers in advanced diabetes, and reproductive issues. Hyperglycemia has been associated with the spread of cancer cells, osteoarthritis, and an increased risk of infection [3]. These negative health outcomes impose a substantial burden on the health care system. In 2022, the estimated total direct and indirect costs of diabetes in the United States reached US $413 billion [4].

Managing diabetes involves consistent and ongoing care due to its chronic nature, and blood glucose monitoring has long been the gold standard for patients with diabetes to self-monitor their blood glucose levels for decades [5]. A successor to the familiar periodic fingerstick monitoring technique, continuous glucose monitoring enables individuals with diabetes to self-monitor their blood glucose continuously day and night, eliminating the burden of frequent, unpleasant finger pricks [5]. Continuous glucose monitors (CGMs) generate detailed reports that enable health care providers and individuals with diabetes to determine time in range, calculate glycemic management index, and evaluate hypoglycemia, hyperglycemia, and glycemic variability with certainty [6,7].

The effectiveness of CGMs is reflected in the 2023 American Diabetes Association Standards of Care, which included recommendations for using CGM in diabetes management [8]. Previous studies have shown that adherence to a CGM is significantly associated with reductions in HbA_{1c}, medical costs, and health care use [9-12]. While CGMs have been a significant breakthrough in managing diabetes, work is needed to increase their use among the clinically appropriate population. The predictors of CGM adherence are well studied and include age, percentage of time in glucose target, the perceived necessity of CGM, BMI, and gender [13].

Another potential factor influencing adherence may be the dispensing source from which patients receive their CGM device. Depending on the benefits offered by a health plan, a physician's prescription for CGM can be filled by a durable medical equipment supplier or a pharmacy. When a patient has a choice in dispensing source, the channel decision may be influenced by physician or patient preference, differences in patient out-of-pocket financial responsibility, or other factors.

No studies have been published examining the impact of the CGM device dispensing source on device adherence and costs, to the authors' knowledge. To begin closing that knowledge gap, this retrospective analysis of insurance claims data assessed differences in adherence rates and costs among patients with diabetes obtaining CGM supplies through durable medical equipment providers and those using pharmacy services.

Methods

Data Source

Administrative claims data (January 1, 2021, to September 30, 2022) were obtained from the Mariner commercial claims database, which represents 75.7 billion claims of all payer types across 161 million unique patients across the United States.

Population Analyzed

Patients with a diagnosis of type 1 or type 2 diabetes were identified using *International Classification of Diseases, Ninth Revision* (249.00-250.99, 790.2, 790.21, 790.22, 790.29, 791.5, and 791.6) and *Tenth Revision* (E08.0 through E13.9) codes. Eligible patients were aged 18 years or older with an initial CGM claim in the first quarter of 2021, the exact date of which served as the index date. Patients with diagnosis codes for renal failure or cancer were excluded. Patients were required to have continuous enrollment for 6 months before and 15 months after their index date without evidence of CGM claims before the index date.

Two diabetes patient cohorts were identified by direct matching. The first cohort, the pharmacy cohort, was composed of patients who received their CGM device and subsequent supplies over the next 12 months through their pharmacy benefit. These patients were identified using the billing codes for the CGM devices and supplies. The second cohort, the durable medical equipment cohort, consisted of patients with diabetes who received their CGM device and supplies from a durable medical equipment provider over the same 12-month period. Patients in both cohorts were identified using the prespecified CGM and supply codes (Table S1 in the Multimedia Appendix 1). Patients from the durable medical equipment and pharmacy cohorts were matched directly based on Charleson Comorbidity Index scores, age range, gender, diabetes type, and insurance plan type.

Outcome Measures

The 3 outcome measures were adherence, medical costs, and reinitiation.

Adherence

Adherence was assessed after each patient's index data at month 3, month 6, month 9, and month 12. These time points coincided with the prescribed 3-month ordering interval for CGM supplies. Patients were deemed adherent if they made all scheduled reorders, which served as a proxy for adherence. Any patient without evidence of a reorder during the study period was classified as nonadherent.

Costs

Total medical costs, assessed throughout the 12-month follow-up period, included any medical or pharmacy claim reimbursed during the 12-month study period after each patient's index date.

Reinitiation

The reinitiation of CGM device use was assessed in any patient who became nonadherent during the 12-month study period. Reinitiation was defined as the resumption of CGM following a gap of ≥1 calendar quarter with no CGM codes occurring after a patient's index date. Nonadherent patients were followed for 3 months after the 12-month assessment (15 months) to assess reinitiation in patients first showing nonadherence at 12 months. To be considered to have reinitiated CGM, the patient was required to resume the same type of device from the original device acquisition channel they had been using before the gap in therapy.

Statistical Analysis

Cohort Assignment

Subjects were assigned to their respective cohorts by direct matching on the following matching variables: Charleson Comorbidity Index score (calculated using all existing claims for each patient over a 2-year period from the index date), age, gender, diabetes type, and insurance plan type.

Adherence Algorithm

The adherence algorithm uses the Medication Possession Ratio model, which is defined as the sum of the number of days supplied for all fills divided by the number of days in the given time. For the durable medical equipment cohort, supplies are assumed to be billed in a way that allows for a comparable analysis of prescription adherence.

More specifically, on the adherence calculations for both pharmacy and durable medical equipment cohorts, the patient must have at least 2 relevant claims; the numerator was the sum of units provided from all relevant claims; the denominator was calendar days from the chronologically first to the chronologically last claim in the time frame coded.

Differences in adherence and reinitiation rates between the durable medical equipment and pharmacy cohorts were examined using *z* tests, with the significance level set at $P<.05$.

Cost Analysis

Total medical costs included all allowable costs across pharmacy and medical benefits for patients with at least one medical claim in 2021 Q1. Pharmacy costs included all allowable costs for patients with at least one pharmacy claim in 2021 Q1. Outlier values for both total medical and pharmacy costs were removed by excluding data points that were 1.5 SDs above the average allowable cost for that service.

Differences in mean costs between the durable medical equipment and pharmacy cohorts were examined by 2-tailed *t* tests, with the statistical significance level set at $P<.05$.

Ethical Considerations

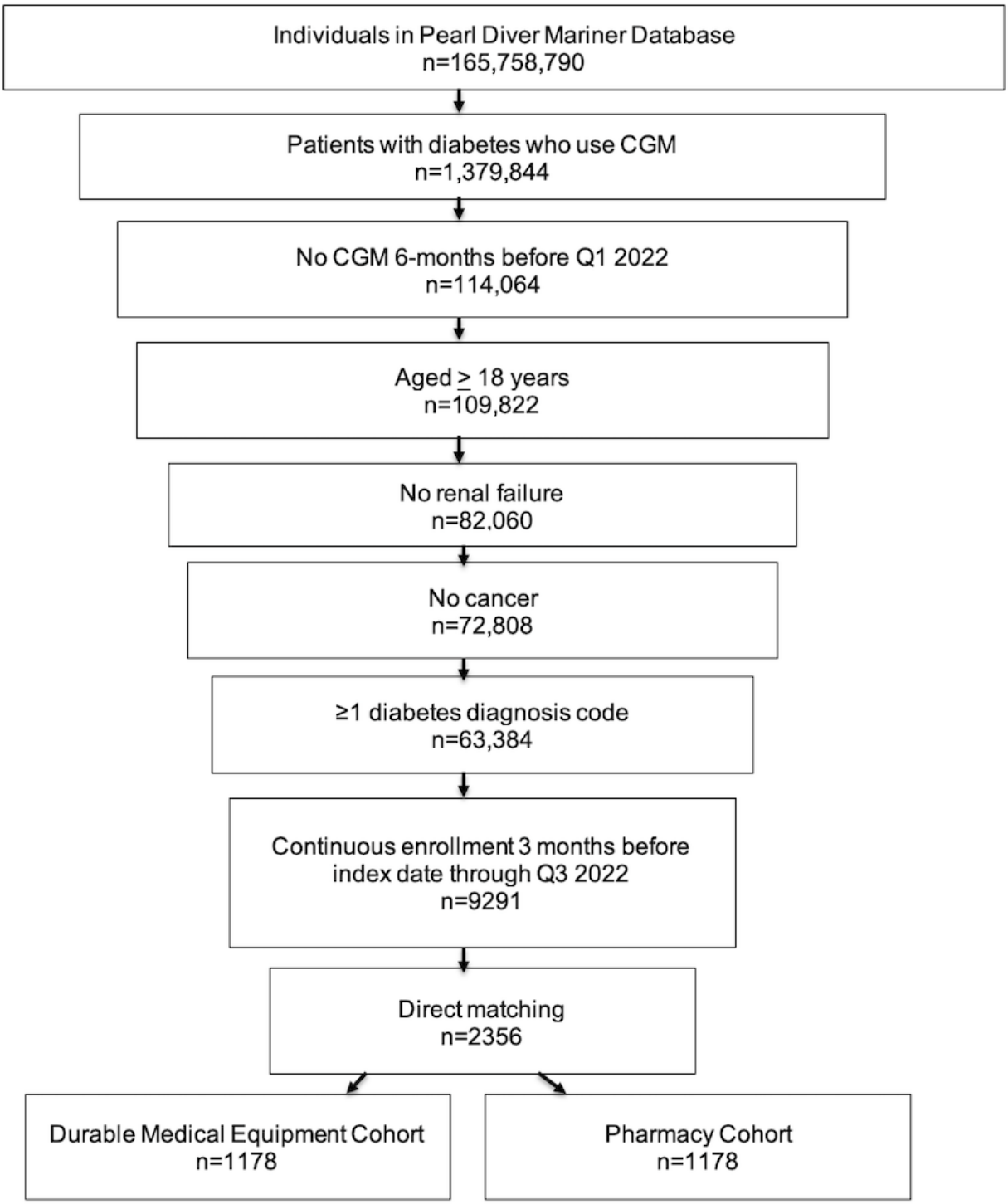
Data were de-identified and comply with the patient requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996; therefore, no review by an institutional review board was required per Title 45 of CFR, Part 46.101(b)(4) [14]. The authors obtained permission to use the data from PearDiver.

Results

Study Cohorts

Records for 165,758,790 individuals in the Mariner database were screened. Of these, 1,379,844 patients had diabetes and used CGM. After applying inclusion and exclusion criteria, 9291 patients (aged ≥18 years) with diabetes, an index CGM claim, no CGM claim in the 6 months before their index claim, and continuous enrollment 15 months after the index date were identified as individuals new to the use of CGM during the index period (Figure 1).

Figure 1. Sample selection.



Direct matching generated two 1178 patient cohorts from these individuals. The first cohort, the pharmacy cohort, included patients who received their CGM device and subsequent supplies over the next 12 months through their pharmacy benefit.

The final study sample consisted of 2356 individuals with diabetes (pharmacy cohort=1778 and durable medical equipment cohort=1778) who were direct-matched and newly prescribed a CGM device. The mean age of both cohorts was 48.8 (SD 17.4) years. Patients' baseline characteristics are presented in Table 1.

Table 1. Patient characteristics.

Characteristics	Durable medical equipment cohort (n=1178)	Pharmacy cohort (n=1178)	Total sample (N=2356)
Age (years), mean (SD)	48.9 (17.5)	48.7 (17.3)	48.8 (17.4)
Gender, n (%)			
Man	591 (50.2)	591 (50.2)	1456 (49.7)
Woman	587 (49.8)	587 (49.8)	1476 (50.3)
Payer, n (%)			
Commercial	1106 (93.9)	1104 (93.7)	2210 (93.8)
Medicare	27 (2.3)	27 (2.3)	54 (2.3)
Medicaid	36 (3.1)	36 (3.1)	72 (3.1)
Other or unspecified[a]	9 (0.8)	11 (0.9)	20 (0.8)
Diabetes type			
Type 1, n (%)	760 (64.5)	760 (64.5)	1520 (64.5)
Type 2, n (%)	132 (11.2)	132 (11.2)	264 (11.2)
Other or unspecified[b], n (%)	86 (24.3)	286 (24.3)	572 (24.3)
CCI[c], mean (SD)	1.19 (1.07)	1.19 (1.07)	1.21 (1.27)

[a]Other payers or payments include cash, employer groups, government, pharmacy benefit managers, processors, third-party administrators, or workers compensation.

[b]Others or unspecified may include diabetes of indeterminant etiology or rarer conditions, such as gestational diabetes mellitus, monogenic diabetes, or secondary diabetes.

[c]CCI: Charleson Comorbidity Index.

Adherence

The percentages of patients who were adherent within each quarter of the 12-month follow-up period are presented in Table 2. Adherence in the first 3 months was similar in the 2 cohorts. In both cohorts, adherence rates decreased over time; however, adherence rates were higher at 6, 9, and 12 months for the durable medical equipment cohort relative to the pharmacy cohort (P<.001).

Table 2. Adherence rate by diabetes cohort.

Time point, n (%)	Durable medical equipment cohort (n=1178)	Pharmacy cohort (n=1178)	*Z* score	*P* values
3 months	620 (52.6)	635 (53.9)	–0.06	.54
6 months	761 (64.6)	615 (52.2)	6.10[a]	.01
9 months	714 (60.6)	579 (49.2)	5.59[a]	.01
12 months	693 (58.8)	565 (48)	5.29[a]	.01

Health Care Costs

For adherent patients, the mean (SD) total allowable medical costs across the 12-month follow-up for the durable medical equipment cohort was US $6967 (SD US $5405). For the pharmacy cohort, it was US $10,635 (SD US $9095); the difference between the cohorts was statistically significant ($t_{1568.7}$=–12.15; P<.001).

Reinitiation

In the durable medical equipment cohort, 22% (108/485) nonadherent patients resumed CGM, compared with 10% (61/613) nonadherent patients in the pharmacy cohort. The reinitiation rate was significantly higher in the durable medical equipment cohort (z=5.62; P<.001).

Discussion

Overview

Results of this retrospective insurance claims analysis indicate that patients who obtained their CGM device and supplies from a durable medical equipment cohorts supplier exhibited better adherence and incurred lower health care costs than patients who did so through a pharmacy. Despite a decline in adherence rates for both cohorts after the index CGM orders, adherence remained consistently higher in the durable medical equipment cohort than in the pharmacy cohort across subsequent assessments at 6 months, 9 months, and 12 months. The lower adherence seen in the durable medical equipment cohort at 3 months is the result of patients waiting longer for their second fill, resulting in an adherence lull at 3 months. The durable

medical equipment cohort adherence rate increases at 6 months and aligns with expected patterns since most patients have gone through the refill process. Significant differences in medical costs accompanied differences in adherence between the durable medical equipment and pharmacy cohorts. For adherent patients, total medical costs were 53% higher in the pharmacy cohort relative to the durable medical equipment cohort.

Nonadherent patients were more likely to resume CGM if they received their device and supplies through a durable medical equipment supplier. After combining patients who were CGM adherent throughout the entire 12-month analysis period (durable medical equipment: n=693 and pharmacy: n=565) with those who resumed CGM after an interruption (durable medical equipment: n=108 and pharmacy: n=81), substantially more patients in the durable medical equipment cohort (801/1179, 68%) than in the pharmacy cohort (626/1179, 53.1%) were using their CGM device at the end of the analysis period. Although costs in patients who reinitiated CGM were not assessed, a higher overall rate of CGM use is likely to be accompanied by additional positive effects on resource use, but that remains a topic for future research.

While numerous analyses have described the positive impact of CGM on clinical outcomes and costs [10,15-17], as well as the severe negative consequences of nonadherence on costs [9,18,19], this analysis is the first to examine whether the distribution channel for CGM devices and supplies influences adherence and costs. A single study found that patients who received their CGM through their pharmacy had a faster time to initiate their CGM compared to patients who received their device through a durable medical equipment [20]. However, that study did not examine device adherence over time. Furthermore, no previous study has compared differences in costs between patients who received their CGM through pharmacy benefits or a durable medical equipment supplier.

Patients with diabetes not only face challenges associated with the correct use of CGM devices and CGM data interpretation but also frequently report psychological barriers to CGM use, such as not wanting to wear a device on their body, drawing unwanted attention, or losing privacy [21,22]. Parents of children with young children with type 1 diabetes report reluctance to use CGM devices due to painful insertions, problems with skin or adhesives, and the need to apply multiple devices to small bodies [22].

The difference in adherence between the 2 cohorts may be attributed to the extended services durable medical equipment suppliers provide. Durable medical equipment suppliers provide specialized support and personalized training on device usage, including initial setup, troubleshooting during ongoing use, and interpretation of data generated by the device. Durable medical equipment suppliers may also possess specialized expertise in specific disease states, such as diabetes, or have patient support staff capable of guiding clinicians and patients. This expertise allows them to promote increased patient awareness about CGM equipment and supplies, onboard new CGM users, explain subtle differences between CGM brands, discuss insurance benefits and medical policies specific to diabetes care, and address reorder objections. In contrast, while retail pharmacies can provide valuable information on multiple medications and supplies that a patient may be prescribed, they may not have the time or expertise to become experts in all aspects of care related to CGM devices and supplies or how to integrate CGM into a patient's overall care plan, such as integrating CGM with insulin pump use. Finally, the high volume demands on pharmacy staffing may limit their ability to interact with patients or provide the ongoing equipment support a patient might need at home. Simply receiving a prescription can be a passive event, and it does not guarantee that the patient will receive the support needed to effectively use their CGM. With these services, patients ordering CGM directly from a durable medical equipment supplier may experience fewer disruptions in CGM and order CGM devices more consistently, potentially affecting adherence and costs.

Public insurance has very different rules for reimbursement relative to commercial insurance. Traditional Medicare only allows patients to access CGM from a durable medical equipment supplier, but Medicare Advantage plans frequently provide a choice between channels. When patients have a choice, improved outcomes and lower costs may encourage provision through a durable medical equipment supplier. Low-income households face additional challenges. All payers, especially state Medicaid agencies, have sought ways to manage expenses, and some have moved to provide CGM through the pharmacy channel to capture the rebates provided by manufacturers. If, as indicated by the current analysis, dispensing through a durable medical equipment supplier improves adherence and lowers costs, then obstacles to coverage for CGM in general and limiting distribution to pharmacies appear misguided.

The declining adherence over time observed in both cohorts is concerning and worthy of discussion. Strategies to improve adherence require a multifaceted approach that addresses both practical and psychological factors. These strategies should include patient education, personalized care, regular follow-ups, and addressing insurance coverage [21-24]. Providing education on the long-term benefits of consistent monitoring and CGM usage, including proper insertion techniques and data interpretation, can increase user confidence and comfort. Additionally, a personalized approach with regular follow-ups to set realistic goals, tailor the CGM regimen to their lifestyle, and provide feedback can motivate patients to stay on therapy. Lastly, insurance policies may dictate how patients can obtain their diabetes supplies, which often impacts patient cost-sharing, potentially creating financial barriers to adherence. The results of this analysis should prompt policy makers to advocate covering the cost of CGM devices and associated supplies to make them more accessible to patients from a source that promotes adherence. By implementing these strategies, patients can better manage their diabetes and avoid complications associated with poor adherence.

Limitations

The results from this analysis should be considered alongside some caveats. First, while well-suited for evaluating health care resource use and costs, retrospective administrative claims data lack clinical detail, such as reasons for selecting a therapy, the brand or type of device and chosen sensors, and the specific

clinical response. As a result, the analysis may not fully account for relevant clinical factors that contributed to outcomes. Second, the data for this study come from individuals with commercial health coverage or private Medicare supplemental coverage; therefore, the results of this analysis may not be generalizable to all CGM patients with other insurance or without health insurance coverage or to patients outside the United States. Third, because adherence was based on reorder rates, it is unknown whether patients used their devices correctly or at all.

Lastly, due to the nature of the claims data, it was not possible to determine why durable medical equipment patients had better adherence and lower costs. With respect to the latter caveat, it can be hypothesized that the reason for higher adherence among durable medical equipment patients centers around the operating business model durable medical equipment providers use, which is based on constant contact with the patient to obtain consent to ship or deliver equipment and supplies. Commercial payor durable medical equipment medical claim rules usually require consent to ship a CGM order. That, combined with the need to collect deductibles and coinsurance, results in a significant amount of patient contact. For commercial pharmacy refills, the automated process allows for quick refills that patients pick up or have delivered through a mail-order pharmacy. This nuance can result in faster device acquisition through a pharmacy, but followed by a progressive decline in adherence over time due to a lack of active patient engagement [20]. This may explain why the reinitiation rate in the durable medical equipment channel was significantly higher than in the pharmacy channel.

Future Research

Future research should explore the potential impact of durable medical equipment supplier or patient interactions on psychological barriers to CGM. This would be an interesting area for future research. Nonetheless, previous research has shown a positive association between CGM uptake and patient education with a clinical diabetes educator [20]. In addition, studies should be conducted to evaluate adherence based on geographic differences in therapy availability and prescribing patterns. Additionally, geographic differences can influence device availability. Therefore, it is crucial to consider these factors while evaluating adherence.

Conclusions

Results from this real-world, retrospective claims analysis demonstrate that greater patient adherence to CGM and lower health care costs significantly favor the acquisition of CGM devices and related supplies through a durable medical equipment provider instead of through a pharmacy. Given the effectiveness of CGM devices, the increasing prevalence of diabetes in the United States and worldwide, and the ever-shifting insurance landscape, further education of both providers and insurance plans is needed to ensure that patients receive and use CGM devices and supplies in the most cost-effective way.

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Authors' Contributions

JCA and CD contributed to conceptualization, data curation, and writing the original draft. CD contributed to data interpretation. AM contributed to conceptualization. SW and AM contributed to the reviewing and editing, supervision, and data interpretation.

Conflicts of Interest

JCA has received consulting fees from CCS Medical. CD and AM are employees of CCS Medical. SW has no conflicts to report.

Multimedia Appendix 1
Cohort and CPT and NDC Codes.
[DOCX File , 14 KB - diabetes_v9i1e58832_app1.docx]

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Abbreviations

CGM: continuous glucose monitor
HbA1c: glycated hemoglobin
HIPAA: Health Insurance Portability and Accountability Act

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Original Paper

Moderating Effect of Depression on Glycemic Control in an eHealth Intervention Among Black Youth With Type 1 Diabetes: Findings From a Multicenter Randomized Controlled Trial

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Abstract

Background: Black adolescents with type 1 diabetes (T1D) are at increased risk for suboptimal diabetes health outcomes; however, evidence-based interventions for this population are lacking. Depression affects a high percentage of youth with T1D and increases the likelihood of health problems associated with diabetes.

Objective: Our aim was to test whether baseline levels of depression moderate the effects of a brief eHealth parenting intervention delivered to caregivers of young Black adolescents with T1D on youths' glycemic control.

Methods: We conducted a multicenter randomized controlled trial at 7 pediatric diabetes clinics located in 2 large US cities. Participants (N=149) were allocated to either the intervention group or a standard medical care control group. Up to 3 intervention sessions were delivered on a tablet computer during diabetes clinic visits over a 12-month period.

Results: In a linear mixed effects regression model, planned contrasts did not show significant reductions in hemoglobin A_{1c} (HbA_{1c}) for intervention adolescents compared to controls. However, adolescents with higher baseline levels of depressive symptoms who received the intervention had significantly greater improvements in HbA_{1c} levels at 6-month follow-up (0.94%; *P*=.01) and 18-month follow-up (1.42%; *P*=.002) than those with lower levels of depression. Within the intervention group, adolescents had a statistically significant reduction in HbA_{1c} levels from baseline at 6-month and 18-month follow-up.

Conclusions: A brief, culturally tailored eHealth parenting intervention improved health outcomes among Black adolescents with T1D and depressive symptoms.

Trial Registration: ClinicalTrials.gov NCT03168867; https://clinicaltrials.gov/study/NCT03168867

(JMIR Diabetes 2024;9:e55165) doi:10.2196/55165

KEYWORDS

adolescents; black; depression; eHealth; family intervention; randomized clinical trial; randomized controlled trial; T1D; type 1 diabetes

Introduction

Adolescence is a period of risk for youth with type 1 diabetes (T1D), as the transition to independent diabetes management is challenging for families to navigate [1], affecting glycemic control [2]. Black adolescents with T1D are at even higher risk for diabetes-related health disparities, such as elevated blood glucose levels [3], hospital admissions [4], and diabetes distress [5]. Given the critical protective role played by families in the health of adolescents with T1D, a variety of family-based interventions have been developed. Such interventions have used multiple strategies to target the family process related to youth diabetes health, such as improving diabetes-related family communication and reducing conflict [6]. However, despite the extensive literature documenting health disparities, few randomized controlled trials have included adequate samples of Black adolescents with T1D [7]. Almost no clinical trials have tested interventions designed and tailored for Black adolescents and their families [8,9].

eHealth interventions have shown promising effects for a number of health conditions, including T1D [10], and circumvent many of the barriers that prevent successful behavioral interventions from being adopted [11]. Behavioral health services are also limited in many pediatric diabetes care settings by the lack of trained mental health specialists [12], despite widespread acknowledgment of their value [13]. Furthermore, as family-centered care approaches have been shown to improve health outcomes in youth with T1D, there have been a growing number of calls to leverage technological advancements to promote the use of family-centered care through internet-based or other similar eHealth tools and interventions [14]. As regular attendance at diabetes clinics is part of the recommendations for the care of adolescents with T1D [15], such visits may provide a natural opportunity to deliver such eHealth interventions.

In collaboration with Black adolescents with T1D and their caregivers, we previously developed and tested the feasibility of a brief, culturally tailored eHealth intervention (The 3Ms) [16,17], aimed at increasing a critical protective parenting practice: daily parental monitoring of adolescent diabetes care [18-20]. While parents often reduce involvement in diabetes care during adolescence, decreased involvement is associated with suboptimal glycemic control [21,22]. Therefore, the intervention was developed for primary caregivers of young Black adolescents with T1D transitioning to independent self-care to decrease parental disengagement from diabetes management during this high-risk developmental period.

Depression, including symptoms of hopelessness and helplessness, affects approximately 20% of youth with T1D [23]. Multiple studies have shown that depression is a significant predictor of health outcomes in youth with T1D, as it may affect health through either suboptimal self-management [24] or physiological mechanisms such as metabolic abnormalities and systemic inflammation [25]. Cross-sectional and longitudinal studies have shown that youth with T1D and depression are also more likely to report family conflict and low levels of parental involvement in diabetes care [26,27]. Such findings suggest that elevated depressive symptoms may identify youth who are more likely to be treatment responders in behavioral studies aimed at increasing family support for diabetes management [28]. In order to determine how to most effectively tailor treatments and develop the best decision rules for choosing between treatment alternatives, it is crucial for moderator variables to be identified that predict for whom a particular intervention is most likely to succeed. While there is limited information on such moderator variables from previous trials of health behavior change interventions for adolescents with T1D, a clinical trial testing a web-based diabetes coping intervention found that adolescents with higher levels of depression at baseline had more improvements in quality of life at the conclusion of the study [29]. Other clinical trials testing health behavior change interventions for Black families have likewise shown that the baseline level of depression in adolescents is related to treatment response [30].

The purpose of this study was to investigate the effects of depression in adolescents as a potential moderator of the efficacy of The 3Ms to improve glycemic control in a randomized controlled trial.

Methods

Ethical Considerations

This study was approved by the institutional review board of the first author's university (IRB# 015117B3E) using a single institutional review board agreement covering all participating institutions. The primary caregiver and adolescent provided informed consent and assent to participate. Participants were provided with US $50 at each study visit to compensate them for their participation. The trial was registered at ClinicalTrials.gov (NCT03168867).

Procedures

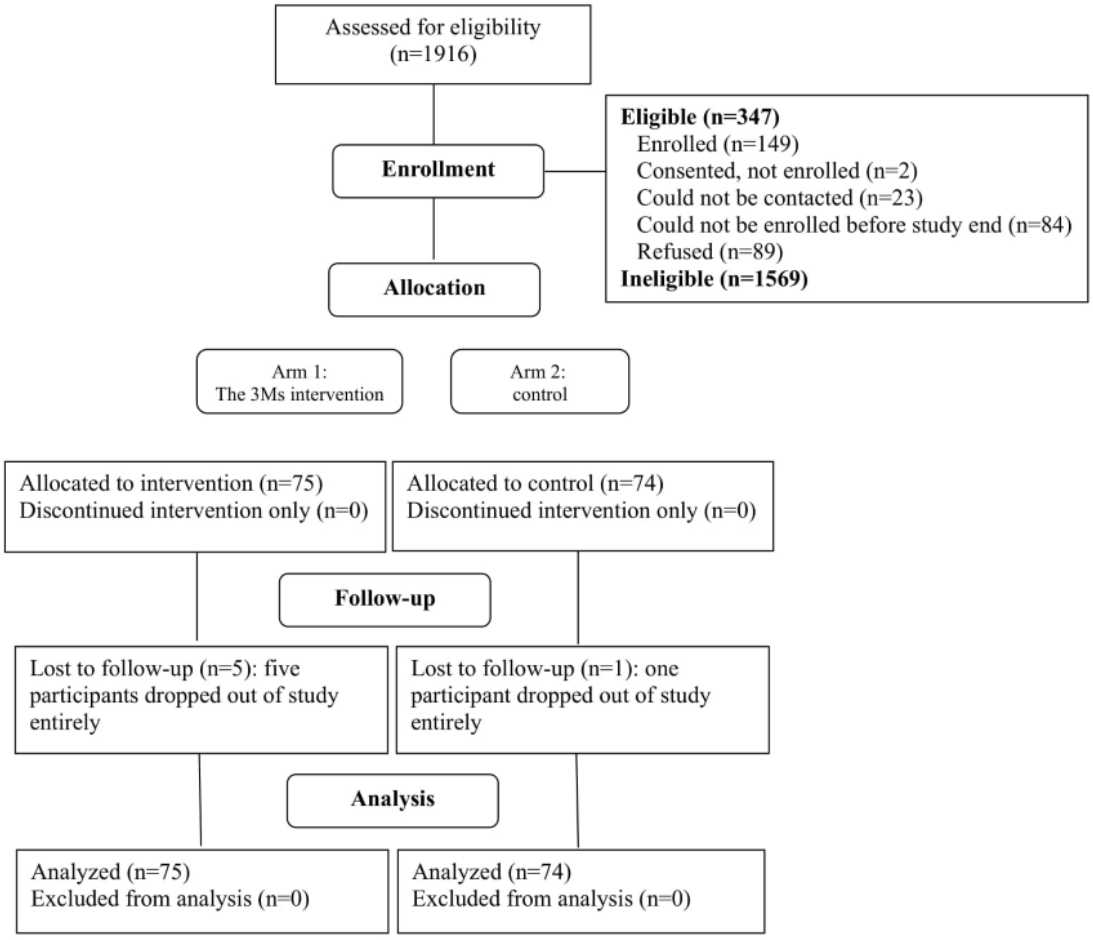
Adolescent participants and their primary caregivers were recruited from 3 pediatric diabetes clinics located in the greater metropolitan Detroit area and 4 in the Chicago area. The study took place from 2017 to 2021. Eligible adolescents had to be aged between 10 years, 0 months, and 14 years, 11 months, diagnosed with T1D for at least 6 months, self-identify as Black, and be residing with a caregiver who was willing to participate in the study. Study exclusion criteria were psychiatric diagnoses, such as suicidal ideation or psychosis, cognitive impairments that limited the ability to complete study measures, not being able to speak in English, or having an additional medical diagnosis leading to atypical diabetes management.

The data regarding study eligibility (based on adolescents' age, race, and medical diagnosis) were obtained from the electronic medical records of the participating diabetes clinics, along with

their contact information. Families were first sent an introductory letter describing the study. Subsequently, study research staff contacted the adolescent's primary caregiver by phone or at a clinic visit to provide more information and screen interested families for additional eligibility criteria.

Of the 1916 families screened for participation, 1569 were ineligible, and 23 could not be contacted. Of the remaining 324, a total of 89 (27.5%) declined to participate, citing lack of interest or time. An additional 86 (26.5%) expressed an interest in the study but did not enroll before the closure of recruitment. A total of 149 families were enrolled (89 from Detroit clinics and 60 from Chicago clinics), of whom 75 were assigned to The 3Ms and 74 to standard care. A total of 5 of The 3Ms families and 1 of the standard care families dropped out of the study and did not complete follow-up data collection. The overall study retention rate was 96% (143/149). Enrollment and flow through the study are shown in Figure 1.

Figure 1. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



The study was a multicenter controlled trial using a randomized, controlled, parallel arm design. Participants were allocated to either The 3Ms plus standard medical care or standard medical care control in a 1:1 ratio using block randomization within 14 strata defined by the 7 sites and hemoglobin A_{1c} (HbA_{1c}) level (most recent HbA_{1c} <9.5% vs ≥9.5%) after baseline data collection. The allocation sequence was generated by the study statistician using randomization software. Assignment to condition was completed by study research staff immediately after baseline by opening a sequentially numbered, sealed envelope with the allocation.

This study was designed as an effectiveness trial to test the effects of The 3Ms under "real-world" conditions. Caregivers who were randomized to receive The 3Ms completed between 1 and 3 intervention sessions, depending on the number of diabetes clinic visits attended by the family during the 12-month intervention window. A maximum dose of 3 sessions was chosen based upon routine practice in the care of youth with diabetes [15], as standards of care include quarterly visits to a diabetes specialty care center. The first intervention session was delivered after the baseline data collection to ensure all caregivers received at least 1 intervention session. The subsequent 2 sessions were completed during any clinic visit that occurred during the 12 months after baseline.

The planned study design called for follow-up data collection visits to be completed in the family home to minimize study attrition. T2 data collection visits were completed 6 months after baseline, T3 data collection visits were completed 13 months after baseline (1 month after the 12-month intervention window was complete), and T4 data collection visits were completed 18 months after baseline (6 months after intervention completion). However, the COVID-19 pandemic caused the study's institutional review board to place restrictions on all face-to-face contact with trial participants in March of 2020, which precluded any subsequent in-home data collection. For

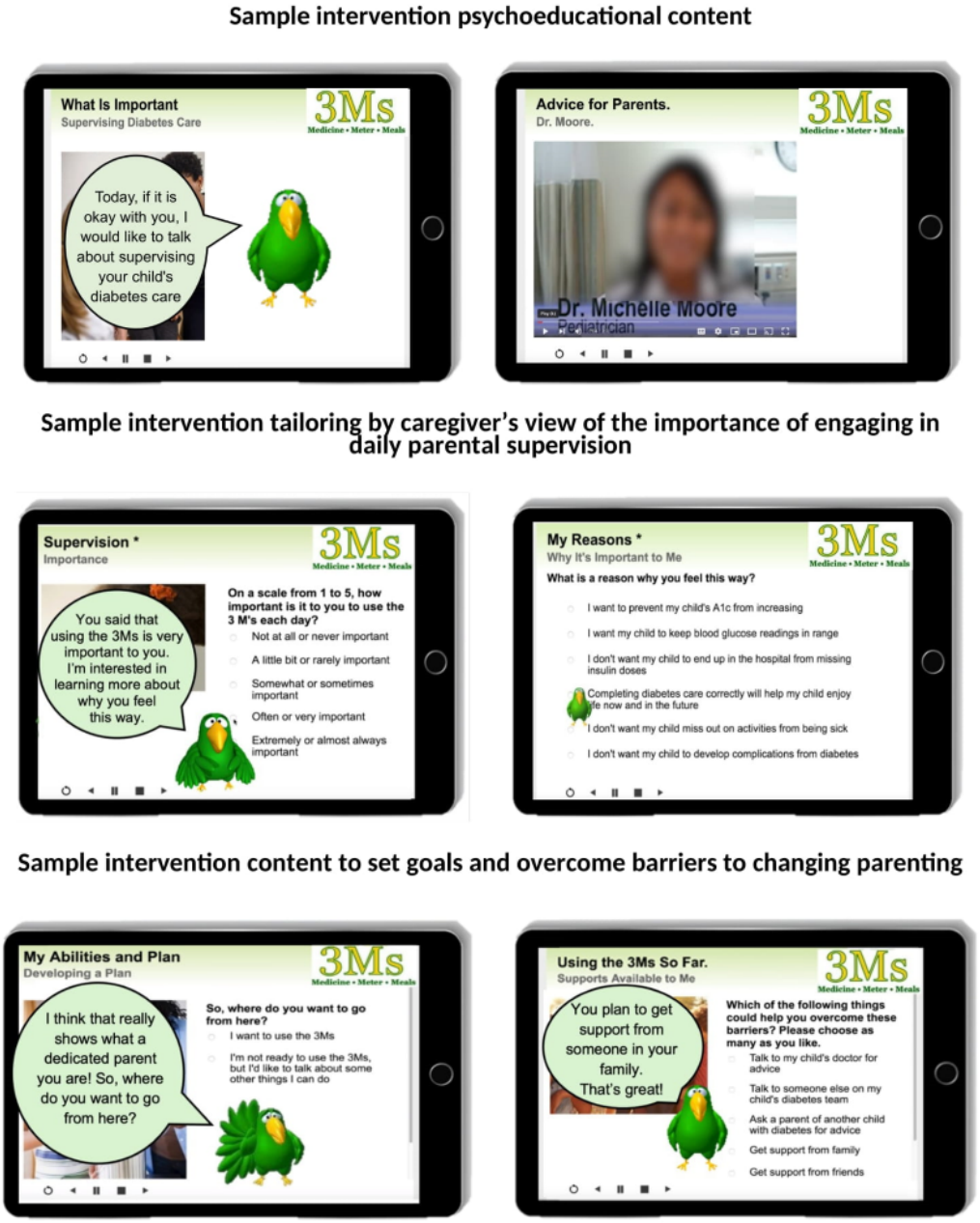
follow-up data collections completed after this date, participants either had HbA_{1c} test kits dropped at their home or were mailed the test kit to complete and return. In both cases, study staff watched the adolescents complete the test during a videoconference call to ensure reliable collection of the specimen. Due to the difficulties associated with the completion of study follow-up visits during the pandemic, the planned study design, in which follow-up data were only collected within narrow study windows (±2 weeks from the planned visit date, or 30 days in total), were modified to obtain data whenever possible within 18 months after baseline. About 87.3% (124/142), 86.7% (118/136), and 87.4% (106/121) of data collection visits were within a 45-day window of the planned visit dates at T2, T3, and T4, respectively. Study staff were not blinded to the treatment conditions; however, the objective nature of the HbA_{1c} measure mitigated the risk of bias.

The 3Ms intervention was delivered using Computer Intervention Authoring Software, an internet-based, interactional software [31]. Session content was delivered by an interactional and emotive 3-dimensional narrator that reads, speaks aloud, reflects participant responses, and functions as an engaging guide throughout the intervention. This approach is particularly useful in populations such as those for whom the present intervention was designed, where challenges with health literacy could affect engagement with the eHealth intervention [32]. Caregivers used a tablet computer provided to them at the diabetes clinic visit by research staff to complete The 3Ms.

The early development process for The 3Ms intervention has been reported elsewhere [17], as have the results of pilot testing [16]. In brief, The 3Ms was based on the "Information-motivation-behavioral Skills" model of behavior change [33], which posits that health behavior change is driven by 3 critical components: "accurate information" about both risk behaviors and their replacement health behaviors (eg, benefits of daily parental monitoring), "motivation" to change behavior, and "behavioral skills and confidence" (eg, self-efficacy) necessary to perform the behavior. As The 3Ms was designed to be delivered during regular diabetes clinic visits, each session lasted approximately 15-20 minutes. To ensure the cultural relevance of The 3Ms for Black caregivers, the early intervention development process included input and review of intervention content and language from Black pediatric researchers and beta-testing by caregivers of Black adolescents with T1D.

The intervention's informational content encouraged parents to use 3 strategies for increasing parental supervision and monitoring of adolescent diabetes management. Called "The 3Ms," the strategies were (1) watch your child give as many doses of insulin each day as possible (medicine), (2) check your child's glucose monitor at least once a day (monitor), and (3) eat at least 1 meal each day with your child so carbohydrate counting can be assessed (meals). This informational content was delivered through psychoeducational video clips where a Black endocrinologist and a Black caregiver provided advice regarding these parenting behaviors and encouragement to use them. To increase caregivers' motivation and self-efficacy to engage in daily supervision of adolescent diabetes management, the intervention used multiple strategies consistent with motivational interviewing [34], including evoking change talk and commitment language (ie, statements regarding desires, reasons, needs, and abilities to make behavior change) and eliciting the pros and cons of behavior change. Intervention content was tailored based on caregivers' ratings of the importance of engaging in daily parental supervision and their ratings of self-efficacy for parental supervision. Tailoring also included the completion of different content in follow-up sessions based on caregiver appraisals of their success in completing daily parental supervision, as well as the completion of optional goal-setting activities at the end of each session (Figure 2 provides sample intervention content).

Figure 2. Sample intervention content for The 3Ms.



Measures

HbA_{1c} level was used to evaluate glycemic control. Values were obtained during data collection visits using the Food and Drug Administration (FDA)–approved Accubase fingerstick capillary blood collection test kit. Due to the COVID-19 pandemic and higher than expected missed data collection visits, these data were also obtained from the clinic medical record for follow-up points if a clinic visit fell within ±30 days of data collection and data were otherwise missing. A total of 88.5% (485/548) of follow-up HbA_{1c} measurements were obtained using the Accubase test kit, and 11.5% (63/548) were obtained from the medical record. Previous studies have shown high comparability between samples collected using methods similar to those of the Accubase kit compared to venous samples [35].

A self-report questionnaire was used to obtain information from the adolescent's primary caregiver on demographic variables. The adolescent's medical chart was reviewed to obtain clinical information such as the duration of diabetes and insulin delivery method.

Adolescent depressive symptoms were measured at baseline using an adapted version of the 8-item Patient-Reported Outcome Measurement Information System Pediatric Short Form Depressive Symptoms (PROMIS-D; version 1.0) [36]. The self-report scale assesses mood, positive or negative affect, and views of self. Items were rated from 1 to 4, with higher scores reflecting more depression. The internal consistency of the measure in this study was high (α=.94). For the analyses, PROMIS-D was dichotomized at a score of 1 SD above the sample mean (<23 vs ≥23). This approach is similar to using a

T-score of 60 or higher; PROMIS-D T-scores in this range indicate mood-related difficulties [37].

Statistical Analyses

Analyses were conducted using a repeated-measures linear mixed effects (LME) regression model. The LME model included 3 fixed factors and 4 fixed covariates. The fixed factors were treatment group (The 3Ms vs control), data collection point (at baseline, 6 months, 13 months, and 18 months), and treatment moderator (PROMIS-D ≥23 vs <23). The 4 covariates were age, income, and 2 dummy codes for insulin delivery method. These covariates were selected from medical and demographic characteristics (Table 1). A correlation below the threshold value of P=.10 with either the treatment group variable or HbA_{1c} determined selection. The intercept and study site were random factors. The treatment effects were evaluated with change-from-baseline–planned comparisons in HbA_{1c} levels at 6-, 13-, and 18-month follow-up. Planned comparisons were statistically evaluated with a 2-sided P<.05 for significance. Moderation effects were investigated with post hoc simple effect tests.

Table 1. Demographic characteristics of adolescents and primary caregivers.

Variable	Total sample (N=149)	The 3Ms group (n=75)	The control group (n=74)
Adolescent age (years), mean (SD)	13.4 (1.7)	13.1 (1.8)	13.7 (1.5)
Adolescents' sex, n (%)			
Male	63 (42.3)	29 (38.7)	34 (45.9)
Female	86 (57.7)	46 (63.1)	40 (54.1)
Duration of diabetes (years), mean (SD)	5.8 (3.9)	5.6 (3.9)	6.1 (3.8)
HbA_{1c}, mean (SD)			
%	11.5 (2.7)	11.5 (2.7)	11.5 (2.8)
mmol/mol	102.1 (29.7)	102.3 (29.1)	102.0 (30.5)
Insulin delivery, n (%)			
Basal bolus injection	98 (65.8)	53 (70.7)	45 (60.8)
Basal bolus pump	41 (27.5)	17 (22.6)	24 (32.4)
Other	10 (6.7)	5 (6.7)	5 (6.8)
Caregivers' age (years), mean (SD)	42.4 (8.7)	42.3 (9.0)	42.5 (8.5)
Caregivers' sex, n (%)			
Female	134 (89.9)	67 (89.3)	67 (90.5)
Male	15 (10.1)	8 (11.7)	7 (9.5)
Caregivers' race, n (%)			
Black	139 (93.3)	72 (96.0)	67 (90.5)
Other	10 (6.7)	3 (4.0)	7 (9.5)
Caregivers' education (years), mean (SD)	13.4 (2.3)	13.2 (2.3)	13.6 (2.2)
Number of caregivers in the home, n (%)			
2	74 (49.6)	46 (61.3)	28 (37.8)
1	75 (51.4)	29 (39.7)	46 (62.2)
Yearly family income (US $), mean (SD)	34,933 (27,076)	36,644 (26,511)	33,889 (27,961)

Analyses were intent-to-treat, and all randomized cases were included. Of the 149 enrolled cases, 122 cases provided complete HbA_{1c} data across 18 months. Under the assumption that data are missing at random, the LME model used all available data to estimate model parameters. Explicit data imputation was not required.

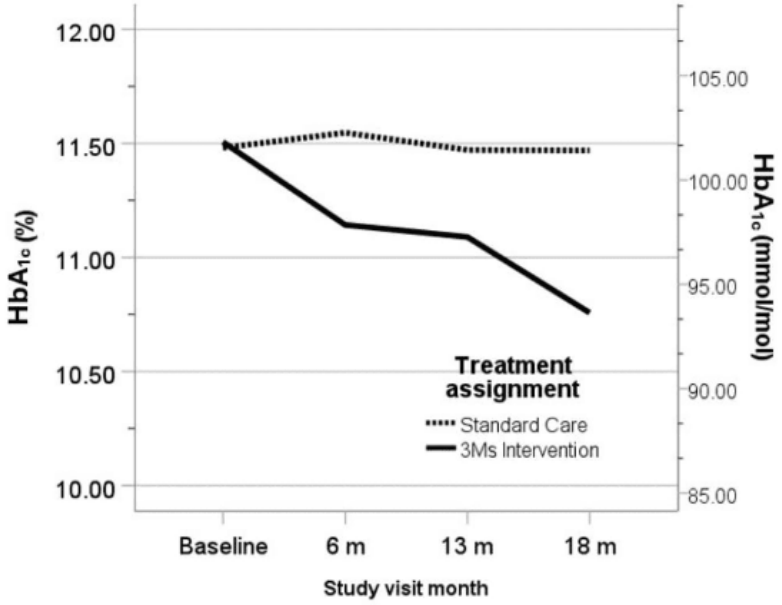
Results

Sample characteristics are presented in Table 1. The mean age was 13.4 (SD 1.7; range 10.1-15.9) years. The mean HbA_{1c} level expressed as a percentage was 11.5% (SD 2.7%; range 5.3%-18.2%) and that expressed as mmol/mol was 102.1 (SD 29.7; range 34.4-175.4) mmol/mol, suggesting that the sample's glycemic control was outside of the recommended range, consistent with known disparities in glycemic outcomes for Black youth [3,4]. The majority of adolescents (108/149, 72.5%) were managed with injected insulin, while 27.5% (41/149) used insulin pumps. The mean yearly family income was US $34,933 (SD US $27,076; range US $5000-US $105,000), and the median was US $25,000 (IQR US $15,000-US $55,000), corresponding to approximately 95% of the US 2020 poverty line for a family of 4.

The mean HbA_{1c} level expressed as a percentage was 11.5% (SD 2.7%; range 5.3%-17.8%), and that expressed in mmol/mol was 102.3 (SD 29.1; range 34.4-171.1) mmol/mol in The 3Ms condition, and 11.5% (SD 2.8%; range 6.7%-18.2%) and 102.0 (SD 30.5, range 49.7-175.4) mmol/mol in the control condition, respectively, with no significant difference between groups. A total of 24.8% (37/149) of the youth in the sample fell at or above the PROMIS-D cutoff score of 23, suggesting they had elevated depressive symptoms. The number of The 3Ms sessions received was evenly distributed across the sample, with 36% (27/75), 36% (27/75), and 28% (21/75) of caregivers in The 3Ms group receiving 1, 2, and 3 sessions, respectively.

Adolescents assigned to The 3Ms had lower HbA_{1c} levels at each of the postbaseline assessments relative to the control group, with a reduction in HbA_{1c} relative to the control condition of 0.56% (5.99 mmol/mol) at 6-month follow-up (P=.10), 0.42% (4.50 mmol/mol) at 13-month (P=.28) follow-up, and 0.68% at 18-month follow-up (P=.09; Figure 3).

Figure 3. Hemoglobin A_{1c} (HbA_{1c}) trajectories by intervention group from baseline to 18 months.



Planned group×time contrasts were not significant (Table 2 provides between-group differences). However, the change in HbA_{1c} within The 3Ms group was statistically significant and was also clinically significant (≥0.5%). Adolescents assigned to The 3Ms had a significant reduction in HbA_{1c} levels of 0.53% (5.70 mmol/mol) at 6-month follow-up (P=.02), and 0.83% (2.07 mmol/mol) at 18 months (P=.002; Table 2 provides changes from baseline). The change in HbA_{1c} levels from baseline within the control group was small at each time point (ie, less than 0.15%) and not significant.

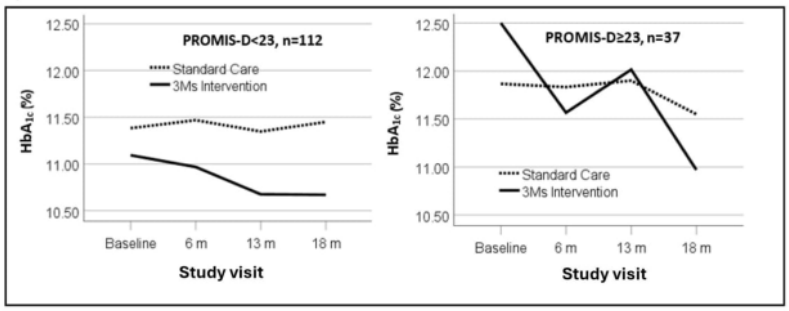
Table 2. Changes in hemoglobin A_{1c} (HbA_{1c}) levels at 6, 13, and 18 months after baseline. At baseline, N=149, with 74 in the control condition and 75 in the intervention group. Mean estimates and statistical tests used the linear mixed effect model with covariates held at their mean level with conventionally injected insulin=.07, insulin pump=.27, adolescent age=13.38 years, family income=US $35,731, and using all available data.

Study visit	Metric	Changes from baseline				Between-group differences[a]			Frequency, n
		Control, mean (SD)	*P* value	Intervention, mean (SD)	*P* value	Mean (95% CI)	*P* value	Cohen *d*	
At 6 months			.92		.02		.10	0.34	142
	%	0.03 (1.75)		–0.53 (1.50)		–0.56 (–1.23 to 0.11)			
	mmol/mol	0.29 (22.27)		–5.70 (19.89)		–5.99 (–13.56 to 1.58)			
At 13 months			.97		.11		.28	0.21	135
	%	0.01 (2.09)		–0.41 (1.89)		–0.42 (–1.18 to 0.34)			
	mmol/mol	0.06 (27.31)		–4.44 (24.52)		–4.50 (–12.94 to 2.38)			
At 18 months			.63		.002		.09	0.32	121
	%	–0.14 (2.12)		–0.83 (2.07)		–0.68 (–1.48 to 0.12)			
	mmol/mol	–2.24 (28.31)		–9.01 (23.37)		–6.77 (–15.91 to 2.38)			

[a]Tests of between-group differences used group×time planned contrasts at 6 months, 13 months, and 18 months. Statistical significance for the planned contrasts was defined as 2-sided *P*<.05.

Examination of tests of post hoc simple effects of PROMIS-D suggested a moderation effect, with the most prominent decreases in HbA_{1c} levels found in the high depressive symptom subgroup whose caregiver received The 3Ms (Figure 4). The effects were significant in the high depression subgroup at 6-month follow-up (decrease of 0.94%, CI –1.68 to –0.19; or 10.25 mmol/mol, CI –18.36 to –2.14; *P*=.01) and 18-month follow-up (decrease of 1.42%, CI –2.32 to –0.53; or 15.68 mmol/mol, CI –25.41 to –5.91; *P*=.002).

Figure 4. Hemoglobin A_{1c} (HbA_{1c}) trajectories by the Patient-Reported Outcome Measurement Information System Pediatric Short Form Depressive Symptoms (PROMIS-D): depressive symptoms low to moderate (<23) versus high (≥23). The high cut-point was 1 SD above the PROMIS-D scale mean at baseline. In the high depressive symptom subgroup, the drops in HbA_{1c} from baseline to 6 months and from baseline to 18 months were significant (*P*<.05).



Discussion

While a number of studies have tested the efficacy of eHealth interventions for adolescents with T1D [10], evidence that they improve glycemic control is limited. Those few previous studies testing the efficacy of eHealth interventions to improve the diabetes-related health of Black adolescents used small samples and pilot designs. Lack of attention to the needs of Black families and insufficient focus on the development and testing of relevant, culturally tailored interventions contribute to significant health disparities for this population [38]. In recent years, there has also been a growing interest in the use of technology-based behavioral interventions to promote health in communities of color, as they may circumvent some of the barriers faced by such communities in accessing such services [39].

The results of this study did not support a significant improvement in glycemic control for adolescents in The 3Ms group in comparison to controls overall. However, findings from this study showed a significant moderation effect of baseline depression. Adolescents with higher depressive symptoms were most likely to benefit from The 3Ms, as they had the greatest reductions in glycemic control. The mean reduction in HbA_{1c} levels was 1.4% at 18-month follow-up for this group, which is both statistically significant and clinically meaningful. One-fourth of the present sample of Black youth had elevated symptoms of depression, which is consistent with previous studies showing that youth with T1D are at risk for

depression, negative affect, and diabetes distress, as well as current guidelines suggesting that youth with T1D should be screened for depression [40]. Depression and negative affect have been linked to suboptimal glycemic control in previous studies [28]. Our results suggest that increasing parent oversight of daily diabetes care was the most effective for this subset of adolescents, where motivational or other factors associated with depressed mood may interfere with youth completing their routine care. Although not directly measured in the study, adolescents may also have perceived increased parental support, empathy, or warmth when parents engaged in daily oversight of their diabetes management, which could have been of increased benefit for those adolescents experiencing more depressive symptoms.

The use of a multicenter design and the recruitment of adolescents from 7 different clinics in 2 major US cities increase confidence in the generalizability of the findings to samples of urban, low-income, Black youth. However, the findings may not be applicable to rural adolescents or to Black youth of higher socioeconomic status. Study limitations also include the clinic-based intervention delivery approach and the use of a recruitment strategy where only families who obtained their diabetes care in a tertiary care setting were approached. Clinic-based delivery was chosen due to the well-established finding of limited engagement with eHealth interventions that rely on the individual's own motivation to use them [32]. However, future studies could evaluate the efficacy of The 3Ms if the intervention is provided to caregivers through a cellphone app or freely accessible internet site. Future studies could also investigate barriers and facilitators to broader dissemination of the intervention within pediatric diabetes clinic settings, including the potential value of the intervention for providing family-centered care [41] or culturally competent care for Black youth and their families [42].

In summary, this study demonstrates the potential of a brief, culturally tailored, family-based behavioral intervention delivered during diabetes clinic appointments to improve the health of Black adolescents with T1D, particularly those with depressive symptoms. More research is needed to develop effective interventions to improve health equity for this population.

Acknowledgments

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Conflicts of Interest

JLM's spouse is a majority owner of Element Bars, Inc, a snack bar company. The other authors have no conflicts of interest to disclose.

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Abbreviations

FDA: Food and Drug Administration
HbA_{1c}: hemoglobin A_{1c}
LME: linear mixed effects
PROMIS-D: Patient-Reported Outcome Measurement Information System Pediatric Short Form Depressive Symptoms
T1D: type 1 diabetes

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Original Paper

Implementation of Artificial Intelligence–Based Diabetic Retinopathy Screening in a Tertiary Care Hospital in Quebec: Prospective Validation Study

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Abstract

Background: Diabetic retinopathy (DR) affects about 25% of people with diabetes in Canada. Early detection of DR is essential for preventing vision loss.

Objective: We evaluated the real-world performance of an artificial intelligence (AI) system that analyzes fundus images for DR screening in a Quebec tertiary care center.

Methods: We prospectively recruited adult patients with diabetes at the Centre hospitalier de l'Université de Montréal (CHUM) in Montreal, Quebec, Canada. Patients underwent dual-pathway screening: first by the Computer Assisted Retinal Analysis (CARA) AI system (index test), then by standard ophthalmological examination (reference standard). We measured the AI system's sensitivity and specificity for detecting referable disease at the patient level, along with its performance for detecting any retinopathy and diabetic macular edema (DME) at the eye level, and potential cost savings.

Results: This study included 115 patients. CARA demonstrated a sensitivity of 87.5% (95% CI 71.9-95.0) and specificity of 66.2% (95% CI 54.3-76.3) for detecting referable disease at the patient level. For any retinopathy detection at the eye level, CARA showed 88.2% sensitivity (95% CI 76.6-94.5) and 71.4% specificity (95% CI 63.7-78.1). For DME detection, CARA had 100% sensitivity (95% CI 64.6-100) and 81.9% specificity (95% CI 75.6-86.8). Potential yearly savings from implementing CARA at the CHUM were estimated at CAD $245,635 (US $177,643.23, as of July 26, 2024) considering 5000 patients with diabetes.

Conclusions: Our study indicates that integrating a semiautomated AI system for DR screening demonstrates high sensitivity for detecting referable disease in a real-world setting. This system has the potential to improve screening efficiency and reduce costs at the CHUM, but more work is needed to validate it.

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KEYWORDS

artificial intelligence; diabetic retinopathy; screening; clinical validation; diabetic; diabetes; screening; tertiary care hospital; validation study; Quebec; Canada; vision; vision loss; ophthalmological; AI; detection; eye

Introduction

Diabetes mellitus is a prevalent metabolic disease affecting 5.7 million Canadians, or 14% of the population, in 2022. This number is expected to increase to 7.3 million by 2032 [1]. Diabetic retinopathy (DR) is a common complication of the disease, affecting up to 25% of patients in Canada [2]. DR is also the leading cause of vision loss in people of working age and is associated with increased mortality [3]. Detection of DR at an early stage, when it can be treated with the best prognosis, is crucial in preventing vision loss [4].

Diabetes Canada recommends annual to biennial DR screening by an ophthalmologist or an optometrist for all people with diabetes [3]. Despite this recommendation, up to a third of diabetic patients go unscreened in Ontario, for example [5]. Demographic and socioeconomic factors, such as low income and immigration, are the main risk factors for being unscreened [5]. Numerous Canadian provinces have implemented more inclusive DR screening programs through DR telescreening (DRTS) [6-10].

In Quebec, significant progress has been made in developing DRTS pathways for patients with diabetes in distant regions [11]. However, in large urban centers, only a minority of patients benefit from such access [6]. For most patients, screening is carried out in optometry clinics, resulting in out-of-pocket expenses, as these services are not covered by the provincial health insurance program [12]. Many patients are referred to consult with an ophthalmologist at a hospital. However, this care process is usually inefficient, with numerous obstacles to effective screening [6].

The recent demonstrations of artificial intelligence (AI)-based grading systems for DR have sparked interest into their integration in pre-established DRTS care pathways in Quebec [11,13]. These systems can integrate existing DRTS pathways in 2 ways: a semiautomated manner, where they replace the preliminary triage currently performed by level 1 trained graders [14]. Alternatively, they can operate in a fully autonomous way, which would not require any human oversight [15].

In this study, we share findings from incorporating a semiautomated AI model into the care strategy for diabetic patients at a major tertiary care center in Quebec. We report on the prospective clinical validation of this AI system, showcasing its real-world performance at both the patient and eye levels for detecting retinopathy and diabetic macular edema (DME). We also perform an economic analysis to estimate the potential cost savings achievable with the implementation of the AI system.

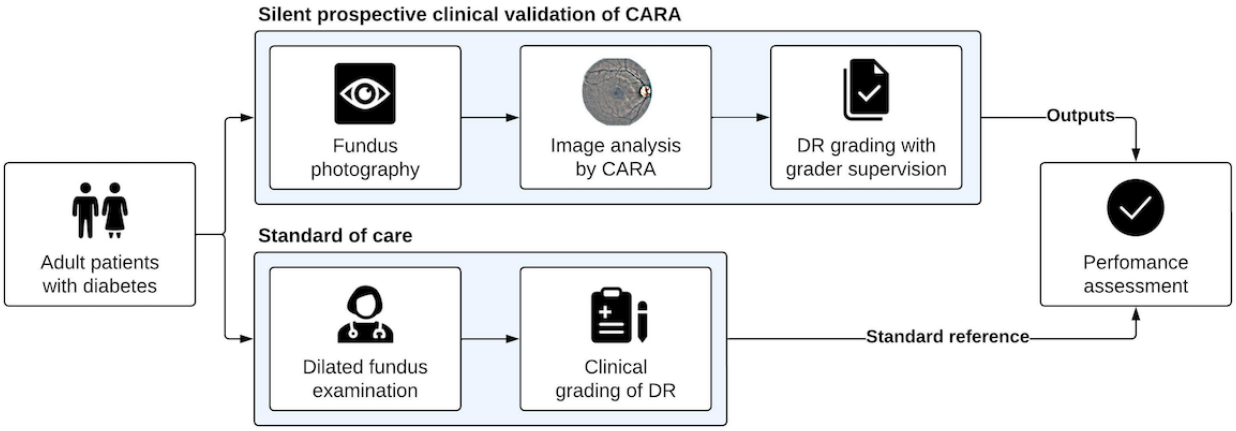
Methods

Study Design

The Centre hospitalier de l'Université de Montréal (CHUM) is a tertiary and quaternary care teaching hospital and one of the two major health care networks in Montreal, Quebec, Canada. It serves 500,000 patients annually. At the CHUM, patients with diabetes are managed by the endocrinology service in specialized clinics, with DR screening conducted either externally or within the ophthalmology department, depending on patient and physician choice.

To improve the patient experience and increase screening uptake, we implemented an AI-based DRTS pathway within the CHUM. To evaluate our approach, we designed a silent prospective clinical validation trial. All recruited patients were screened through 2 parallel pathways: screening by an AI-based system called Computer Assisted Retinal Analysis (CARA), followed by standard of care screening by a CHUM ophthalmologist who was masked to the output of CARA. The study pathway is described in Figure 1.

Figure 1. Overview of the silent prospective clinical validation study. Adult patients with diabetes were recruited from CHUM's endocrinology service. After consenting, fundus photography was obtained on the same day. The fundus images were then transferred through the cloud to the prospective validation pipeline. The images were automatically analyzed by the CARA algorithm. Before generating the report, a trained grader employed by the service provider would grade the CARA-processed images. Within a month, with the outputs of CARA masked, the patients were referred to receive standard of care screening with an ophthalmologist at the CHUM. To determine the discriminative performance of CARA, the outputs from the silent prospective validation were compared to the ophthalmologist exam (standard reference). CARA: Computer Assisted Retinal Analysis; CHUM: Centre hospitalier de l'Université de Montréal; DR: diabetic retinopathy.



Study Population

Patients who attended the diabetes clinic of the endocrinology service between September 2018 and January 2019 were recruited. All patients were new patients to the department of ophthalmology. Previous DR diagnosis, past retinal disease, or intraocular surgery was not exclusionary.

CARA: A Semiautomated AI Model for DR Detection

The CARA system, a semiautomated AI developed by Diagnos Inc. in Montreal, is a clinically inspired machine learning (ML) algorithm designed to detect retinopathy and maculopathy. As a traditional ML model, CARA required the handcrafting of feature extractors that transform pixel values of a retinal image into feature vectors for an ML classifier [16,17]. This is different from deep learning approaches which became prominent after the development of CARA [17,18]. CARA identifies specific lesions in retinal images, including dark lesions like microaneurysms and hemorrhages, as well as bright lesions such as hard exudates and cotton wool spots [19,20].

The algorithm uses a multistep process involving image enhancement, laterality determination, vascular network, optic nerve and fovea detection, and lesion identification. A final output is reached by a weighted combination of image quality, the highest probability of bright and dark lesions, and image conformity. This output is reviewed by a Diagnos Inc senior grader before being sent to the CHUM, marking the process as semiautomated. The senior grader, an ophthalmologist with 12 years of grading experience, was employed by Diagnos Inc. The CHUM was not informed of any formal auditing or quality assessment methods used by Diagnos Inc.

CARA received approval from the US Food and Drug Administration as a class II medical device in 2011 through the 510(k) pathway. It was intended as a software platform to visualize, store, and enhance color fundus images through computerized networks, but was not certified for diagnosing DR at that time. Prior to this current study, CARA had shown a 93% sensitivity and 71% specificity in retinopathy detection across an international data set of 509 eyes (personal communication with Diagnos Inc). Our study served as a first prospective clinical validation study for the CARA service.

Fundus Photography

On recruitment day, in the endocrinology clinic, 45-degree, nonstereoscopic color fovea-centered fundus photographs were obtained by a technician, without pupillary mydriasis, using the Centervue DRS camera (Hillrom, Chicago, United States). A single image was obtained per eye as CARA was designed to make classifications from single-field images. At the time of the study's design, there were no Canadian recommendations in that regard, but this approach seemed reasonable as single-field images were being used in the Scottish DR screening services, for example [21]. The acquired images were uploaded to the CARA platform for them to be processed by the ML algorithm. The generation of AI outputs was carried out asynchronously and the patient, the referring endocrinologist, and all eye care providers were masked to the output of the AI system.

Ophthalmologist Examination (Standard Reference)

Within a month of recruitment, patients were referred to undergo screening by an ophthalmologist using slit lamp examination, typically with a 78 or 90D lens. Fundus photography and optical coherence tomography were not routinely carried out. Each patient's grading was performed by a single attending ophthalmologist, with the study including a total of 28 ophthalmologists with diverse subspecialties and levels of experience (Multimedia Appendix 1). No specific grading training was administered; however, all participating ophthalmologists were board-certified by the Royal College of Physicians and Surgeons of Canada. They were expected to have the competence to diagnose and grade DR, as it is considered an objective (#3.1.2.4.2.2) of ophthalmology training

by the Royal College [22]. Using standardized case report forms, the ophthalmologists graded each eye using the Scottish Diabetic Retinopathy Grading Scheme [23,24]. Standardized imaging examples were available as needed. This represented the standard reference to which the AI model was compared to.

Disease Definition

In a DR screening program, individuals with no or mild DR undergo annual monitoring, while those with more than mild (mtmDR), and those with DME are referred for evaluation [25]. Accordingly, numerous pivotal trials of AI-based DR screening models have focused on their ability to detect mtmDR [13,15]. The intended use of CARA, however, was as a tool to detect any retinopathy (including mild disease) and DME. This included, according to the Scottish Diabetic Retinopathy Grading Scheme: R1, R2, R3, and R4 for retinopathy grading, and M1 and M2 for DME grading [23]. This is equivalent to level 1 triaging responsibility as defined by the CR2N Tele-Retina Steering Committee [14].

For each patient, we determined if they were referable by mapping the retinopathy and DME labels to “retinopathy or DME present” (referable) or “retinopathy and DME absent” (not referable), taking the worst of the 2 eyes to correspond to the outputs of the AI system at the patient level. Patients without referral outputs for both eyes were considered “inconclusive.”

Economic Analysis

We conducted an economic evaluation to estimate the costs of adopting the CARA system for screening 5000 annual patients with diabetes at the CHUM, analyzed from a health care system perspective. The direct costs of screening, and costs for inconclusive outputs and false positive referrals were considered in the analysis. All values are presented in Canadian dollars.

Outcomes and Statistical Analysis

The primary outcomes were the sensitivity and specificity of the AI system to detect referable disease at the patient level. The secondary outcomes were first, the sensitivity and specificity of the AI system for the detection of retinopathy and DME at the eye level, and second, the cost savings in Canadian dollars should the system be implemented.

Sensitivity, specificity, positive predictive value, and negative predictive value for each of retinopathy and DME detection were computed from the confusion matrices. We used the Wilson score interval method to calculate 95% CI. The study follows the Standards for Reporting of Diagnostic Accuracy (STARD) checklist [26].

Ethical Considerations

Patients were enrolled only if they understood the study and provided informed consent. This research complied with the Declaration of Helsinki. Departmental approval was obtained, and an ethical waiver was granted by the CHUM given the silent, noninterventional nature of the study. All data was deidentified.

Results

Patient Flow

Between September 2018 and January 2019, the endocrinology service referred 133 patients to the study, of which 115 (230 eyes) underwent fundus imaging and received CARA outputs. Multimedia Appendix 2 presents demographics of the 18 excluded patients, showing no significant differences from those included. Figures 2 and 3 illustrate recruitment at the patient and eye levels for retinopathy and DME, respectively.

Figure 2. STARD (Standards for Reporting of Diagnostic Accuracy) flowchart at the patient level. Referable disease was defined as "retinopathy or DME present" and not referable was defined as "retinopathy and DME absent", taking the worst of the two eyes to correspond to the outputs of the AI system at the patient level. CARA: Computer Assisted Retinal Analysis; DME: diabetic macular edema.

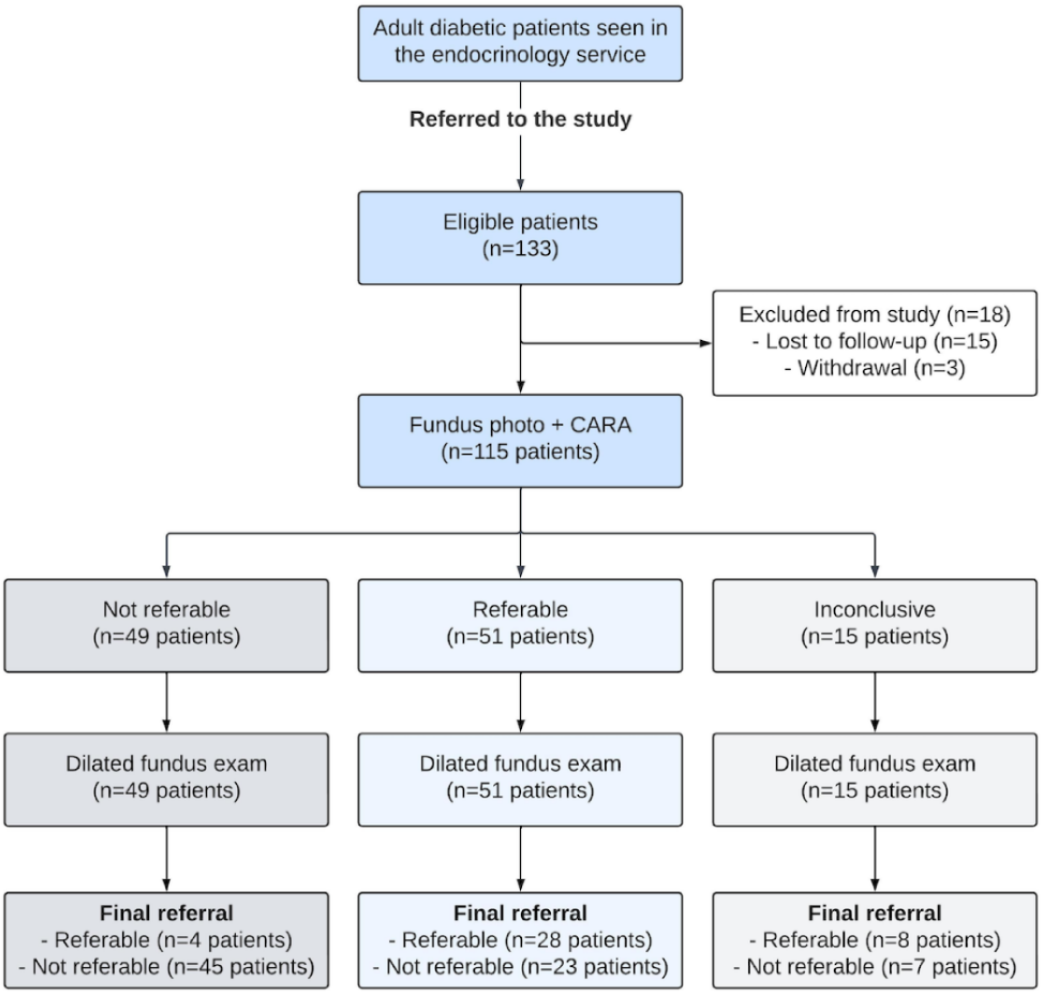
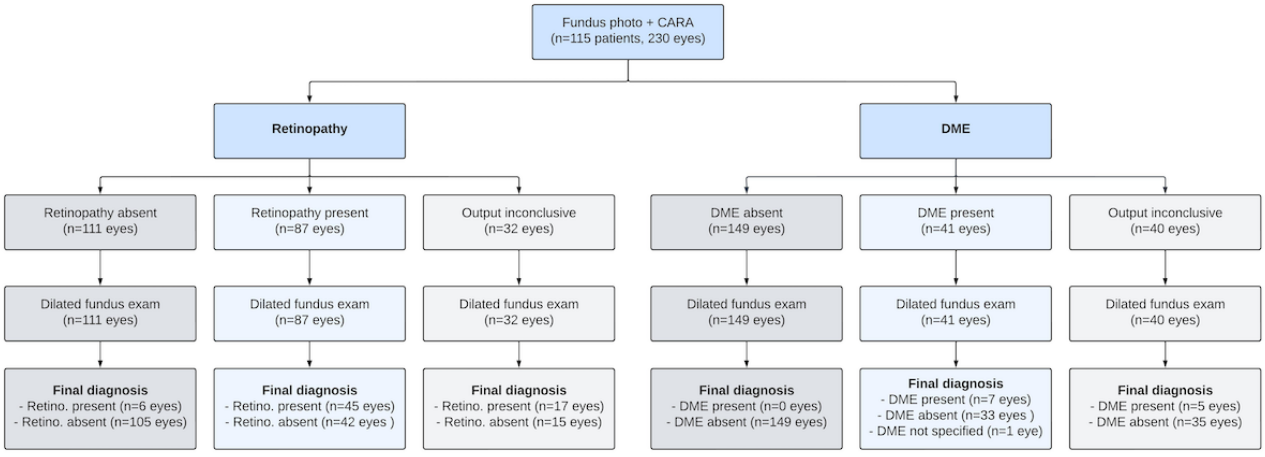


Figure 3. STARD (Standards for Reporting of Diagnostic Accuracy) flowchart at the eye level. Using the Scottish Diabetic Retinopathy Grading Scheme, retinopathy was defined as the presence of any retinopathy (corresponding to R1, R2, R3, and R4). DME was defined as the presence of M1 or M2. CARA: Computer Assisted Retinal Analysis; DME: diabetic macular edema.



Study Cohort

Patient demographics and characteristics are summarized in Table 1. The majority of patients were male (57.4%) with a mean age of 55.4 (SD 15.6) years. Most patients were White (60.9%). While the type of diabetes was the most often unspecified (43.5%), type 2 diabetes (36.5%) was more common than type 1 (20.0%).

Table 1. Patient demographics for the patients included in the study.

Demographic	Value (N=115)
Sex, n (%)	
Male	66 (57.4)
Female	49 (42.6)
Age (years)	
Mean (SD)	55.4 (15.6)
Range	20-90
Diabetes type, n (%)	
Type 1	23 (20)
Type 2	42 (36.5)
Unspecified[a]	50 (43.5)
Ethnicity, n (%)	
White	70 (60.9)
Middle-Eastern	17 (14.8)
Hispanic	13 (11.3)
Black	11 (9.6)
Unknown	4 (3.5)

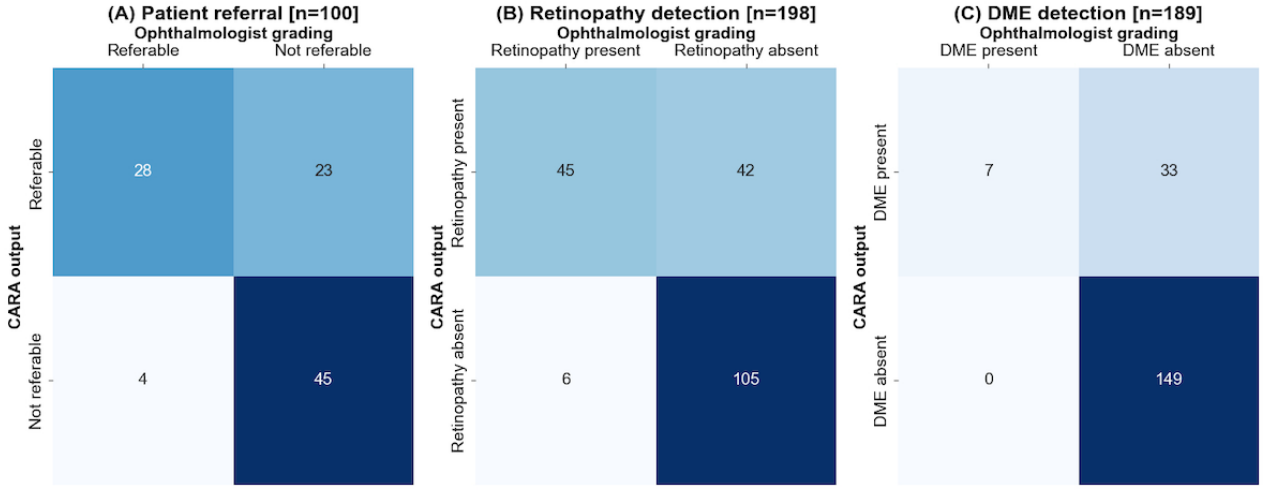
[a]Diabetes subtype not specified on the study referral form.

Performance for Detecting Referable Patients

The primary outcome was model performance at the patient level. For the 100 patients with analyzable data, the confusion matrix demonstrating the performance of CARA for referable patient detection is shown in Figure 4A. CARA had a sensitivity of 87.5% (95% CI 71.9-95.0) and a specificity of 66.2% (95% CI 54.3-76.3). There were 4 false negatives with mild background retinopathy (R1) not requiring treatment. No cases of vision-threatening retinopathy were missed.

Inconclusive outputs occurred in 13% (15/115) patients. Reasons varied, including imageability issues like small pupil (n=5), uncooperative patient (n=1), and media opacity (n=2), along with ungradable model outputs due to processing errors or unmet decision thresholds (n=7). Multimedia Appendix 3 describes the demographics of this patient cohort, noting older age in patients with inconclusive outputs (69.5 vs 53.3, $P<.001$). In this group, 8 patients (53.3%) had referable disease, including 3 cases of DME but no cases of severe nonproliferative or proliferative retinopathy.

Figure 4. Confusion matrices showing the discriminative performance of CARA (Computer Assisted Retinal Analysis) at the patient level (referral) and eye level (retinopathy and DME [diabetic macular edema] detection) for patients with analyzable outputs. At the patient level (n=115), 100 had analyzable outputs, and 15 were inconclusive. At the eye level, from 230 eyes, 32 and 40 eyes had inconclusive AI outputs for retinopathy and DME, respectively, and 1 eye lacked an ophthalmologist's grading (DME). This resulted in 198 and 189 eyes with analyzable outcomes for retinopathy and DME, respectively.



Performance for Detecting Disease at the Eye Level

The confusion matrix demonstrating the performance of CARA for retinopathy detection is shown in Figure 4B. CARA had a sensitivity of 88.2% (95% CI 76.6-94.5) and a specificity of 71.4% (95% CI 63.7-78.1). Among the 32 eyes with an inconclusive CARA output for retinopathy, 17 eyes had retinopathy (53.1%) and 15 did not (46.9%).

The confusion matrix demonstrating the performance of CARA for DME detection is shown in Figure 4C. CARA had a sensitivity of 100% (95% CI 64.6-100) and a specificity of 81.9% (95% CI 75.6-86.8). The remaining performance metrics are summarized in Table 2. Among the 40 eyes with an inconclusive CARA output for DME, 5 eyes had DME (12.5%) and 35 did not (87.5%).

Table 2. Summary of the discriminative performance of CARA[a].

Metric	Patient level	Eye level	
	Referable disease	Retinopathy	DME[b]
Sensitivity (95% CI)	87.5 (71.9-95.0)	88.2 (76.6-94.5)	100.0 (64.6-100)
Specificity (95% CI)	66.2 (54.3-76.3)	71.4 (63.7-78.1)	81.9 (75.6-86.8)
PPV[c] (95% CI)	54.9 (41.4-67.7)	51.7 (41.4-61.9)	17.5 (8.8-32.0)
NPV[d] (95% CI)	91.8 (80.8-96.8)	94.6 (88.7-97.5)	100.0 (97.5-100)

[a]CARA: Computer Assisted Retinal Analysis

[b]DME: Diabetic macular edema.

[c]PPV: Positive predictive value (precision).

[d]NPV: Negative predictive value.

Economic Analysis

A detailed description of the assumptions and calculations performed for the economic analysis is described in Multimedia Appendix 4**.** Implementing the AI system for screening could result in a yearly savings of CAD $245,635 (US $177,643.23, as of July 26, 2024) or CAD $49 (US $35.44) per patient, as shown in Table 3.

These estimates are based on 5000 patients followed annually at the diabetes clinic of the CHUM. The calculations are based on specific costs per patient, the prevalence of diabetic retinopathy among analyzable cases, the percentage of inconclusive outputs by the AI system, and the AI system's specificity. The final row highlights the total cost savings achievable when employing the AI system for screening, demonstrating a significant economic advantage over the current standard of care.

Table 3. Cost comparison between standard of care and AI[a] system screening for DR[b] screening.

Cost component (CAD $[c])	Standard of care	AI system
Direct screening cost	590,500	150,000
Cost for inconclusive outputs	N/A[d]	76,765
Cost for false positive referrals	N/A	118,100
Total cost	590,500	344,865
Cost savings	N/A	245,635
Average cost per patient	118	69
Average cost savings per patient	N/A	49

[a]AI: Artificial intelligence

[b]DR: Diabetic retinopathy

[c]As of July 26, 2024, CAD $1=US $0.7232)

[d]N/A: not applicable.

Discussion

Principal Findings

AI-based telescreening is a promising approach that has the potential to improve community-based screening of DR [27,28]. When effective, AI-based DRTS systems can help reduce unnecessary examinations of patients without DR, allowing resource allocation to those who need more active management [28]. In this work, we describe the outcomes of real-world implementation of an AI-based DRTS for the screening of DR in a tertiary care hospital in Montreal.

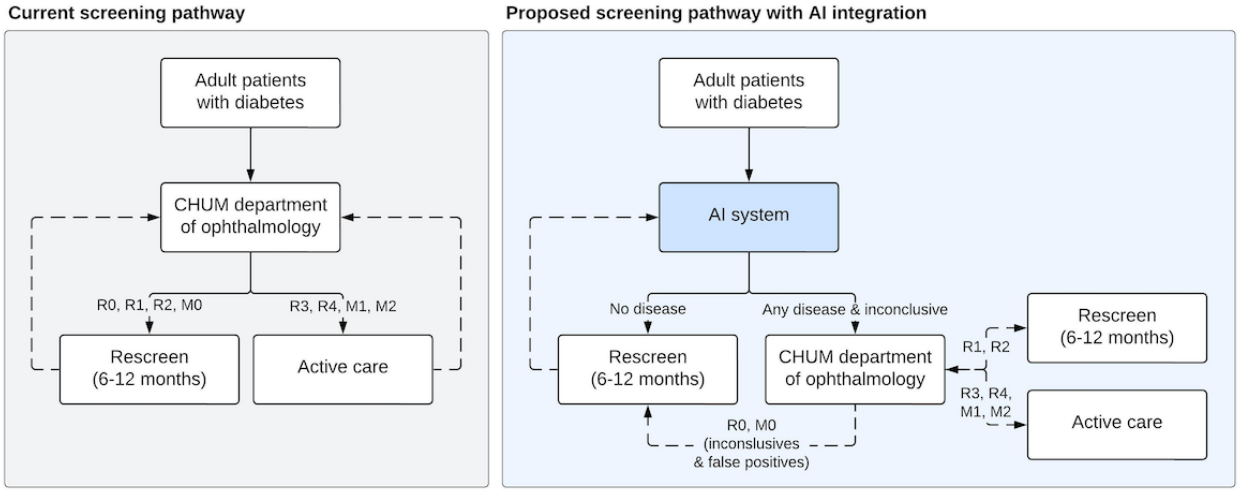
We carried out a silent prospective clinical validation study to assess the performance of the CARA system prior to its implementation in our local population [29]. Our cohort featured

an equitable sex distribution and a strong representation of several visible minority groups in Montreal (Black, Middle-Eastern, and Hispanic), which makes our findings generalizable to the local population [30]. The retention rate in this study was notably high, with 86.5% completing the study. While this hints at positive patient acceptance, further studies will be needed for a conclusive understanding of patient acceptability of this technology. The literature suggests a general preference among patients for automated DR screening [31,32], especially when clinicians are involved in supervising the AI system's decisions [33].

CARA identified patients for referral with 87.5% sensitivity and 66.2% specificity. It detected retinopathy with 88.2% sensitivity and 71.4% specificity, and DME with 100% sensitivity and 81.9% specificity. These results meet the 85% sensitivity benchmark obtained by several similar AI systems designed for DR screening [34]. In the real-world setting, a recent meta-analysis showed a pooled sensitivity of 91% (95% CI 87-94) and specificity of 92% (95% CI 88-94) for detecting any retinopathy at the eye level [35]. For vision-threatening DR, which includes DME, sensitivity was 99% (95% CI 95-100) and specificity 92% (95% CI 74-98) [35]. CARA's performance in detecting retinopathy and DME is on par with other systems in sensitivity but not in specificity, suggesting it effectively identifies disease needing referral but may result in higher false positive rates than desired. The performance gap between CARA and the current state of the art may be partly due to the inherent limitations of traditional feature-based models like CARA [36,37]. In contrast, novel neural network–based models have seen significant improvements in recent years, driven by enhanced architectures and the availability of extensive training data sets [38].

Despite the limited specificity, CARA could significantly reduce the workload of the ophthalmology department at the CHUM by filtering out patients without DR (Figure 5). While false positives can create patient stress and costs [39], since ophthalmologists evaluate these cases, they are unlikely to lead to unnecessary treatments. A similar approach has been successful in the Scottish DRTS program, where all images undergo a first pass through an “autograder” algorithm [40]. With similar specificity to CARA, the Scottish system’s automated grading has been shown to be safe [41], and has reduced the burden of manual grading by up to one-third [42]. The current CARA service, in its semiautomated setup, however, still requires grader oversight. Despite that, we expect it could also reduce the burden of manual grading.

Figure 5. Proposed clinical pathway for the artificial intelligence (AI) system implementation. In the current screening pathway, all patients are evaluated by the department of ophthalmology. With AI system integration as a level 1 triage agent, disease-free patients would be filtered out, reducing unnecessary referrals. Only those with referable disease or an inconclusive AI output would be directed to ophthalmology. False positives would re-enter the AI screening pathway, while patients with any disease receive follow-up care in ophthalmology. CHUM: Centre hospitalier de l’Université de Montréal.



Implementing CARA in our screening pathway could yield an estimated first-year saving of approximately CAD $245,635 (US $177,643.23) for 5000 patients (CAD $49 [US $35.44] per patient), considering direct screening costs and those related to false positive and inconclusive outputs. Of note, the potential costs associated with false negatives (missed cases) were not considered in the analysis due to the lack of such data in our context. The impact of the CARA system on quality-adjusted life years also was not assessed. In the future, we will focus on modeling the screening pathway with decision trees to calculate the incremental cost-effectiveness of our approach, also accounting for false negative cases.

Our study has several limitations and design flaws that have become identifiable in hindsight. Firstly, the provision of the CARA AI system as a service provided to the CHUM introduced several constraints to our study. We lacked control over the model both before and during its implementation. The final outputs were sent to us post grader assessment, without insights into model failures and ungradable images. The semiautomated nature of the pipeline meant that the performance metrics could have been influenced by grader performance, which we are now unable to measure retrospectively. Secondly, we employed dilated fundus examinations as the reference standard instead of using image-assisted evaluations with fundus photographs and optical coherence tomographic scans. This screening method, common in Quebec, might not capture the full human

diagnostic accuracy achievable through a multimodal approach. Due to these limitations, our findings should not be used as a basis to support the approval of CARA as a software medical device. Instead, this study should be viewed as a preliminary trial that helped develop pathways for future, more robust studies involving AI in the DR screening process at CHUM.

Building on those learnings, we have designed a new clinical trial to evaluate the real-world performance of a fully automated deep learning system called NeoRetina (Diagnos Inc) [43]. This new model uses neural networks, which represent the current state of the art in AI. To have a more robust standard reference, in addition to the routine ophthalmological evaluation of DR and DME, masked grading of the same retinal photographs used by NeoRetina will be performed. These images will be assessed for quality and then graded by at least 2 fellowship-trained retina specialists, with a predefined arbitration process. The new trial will leverage the screening pathways developed in this study and will aim to recruit 630 patients by December 2026.

Conclusions

In conclusion, we report findings from the first real-word implementation study of an AI-based DRTS system in the province of Quebec and possibly in Canada [35]. Large-scale implementation of CARA at CHUM would be expected to result in cost savings and reduced waiting times. However, we are currently investigating more advanced models that we aim to validate more robustly. Once deployed, any model will require routine audits to ensure model performance is maintained, especially with changes in population demographics and disease patterns over time [44,45]. Similarly, ensuring strict information governance policies will be crucial for protecting patient data and responsibly leveraging the benefits of AI systems.

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Authors' Contributions

IH, MCT, AB, and AP conceptualized the project. MLDJ provided logistical support. KH, MAR, and DG provided critical expertise on study design. MCT collected the data. IH, MCT, and FA analyzed the results. FA wrote the manuscript, designed the figures, and performed the statistical analyses. CB performed the economic analysis. AYO validated the results. MHD, PAK, and AP provided supervision. All authors reviewed and edited the manuscript. All authors reviewed and approved the final manuscript.

Conflicts of Interest

FA is supported by a Moorfields Eye Charity Springboard Award and a postdoctoral bursary from the Fonds de recherche du Québec - Santé (FRQS). PAK has acted as a consultant for Google, DeepMind, Roche, Novartis, Apellis, and Bitfount, and is an equity owner in Big Picture Medical. He has received speaker fees from Heidelberg Engineering, Topcon, Allergan, and Bayer. He is supported by a Moorfields Eye Charity Career Development Award (R190028A) and a UK Research & Innovation Future Leaders Fellowship (MR/T019050/1). These potential conflicts of interest are unrelated to the present work. Other authors have no conflicts to declare.

Multimedia Appendix 1
Subspecialties, years of experience of the grading ophthalmologists, and numbers of images graded.
[PDF File (Adobe PDF File), 17 KB - diabetes_v9i1e59867_app1.pdf]

Multimedia Appendix 2
Patient demographics of the 18 patients who were excluded from the study. After recruitment, 15 patients were lost to follow-up and 3 patients withdrew. There were no statistically significant differences in the patient demographics. *The comparison between the study cohort (n=115) and excluded group (n=18) was performed using Mann-Whitney U test for all continuous variables. For categorical variables, we used the Chi-squared test. **Diabetes subtype not specified on the study referral form.
[PDF File (Adobe PDF File), 20 KB - diabetes_v9i1e59867_app2.pdf]

Multimedia Appendix 3
Patient demographics of the 15 patients with inconclusive Computer Assisted Retinal Analysis (CARA) outputs. The cohort of patients with inconclusive CARA outputs was significantly older than the one with analysable outputs (P< 0.001). *The comparison between the cohort with analysable outputs (n=100) and the group with inconclusive outputs (n=15) was performed using

Mann-Whitney U test for all continuous variables. For categorical variables, we used the chi-squared test. **Diabetes subtype not specified on the study referral form.
[PDF File (Adobe PDF File), 19 KB - diabetes_v9i1e59867_app3.pdf]

Multimedia Appendix 4
Cost parameters, assumptions and calculations for the economic analysis. AI: artificial intelligence; FPR: false positive rate: pt: patient.
[PDF File (Adobe PDF File), 22 KB - diabetes_v9i1e59867_app4.pdf]

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Abbreviations

AI: artificial intelligence
CARA: Computer Assisted Retinal Analysis
CHUM: Centre hospitalier de l'Université de Montréal
DME: diabetic macular edema
DR: diabetic retinopathy
DRTS: DR telescreening
ML: machine learning
STARD: Standards for Reporting of Diagnostic Accuracy

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Lightening the Load: Generative AI to Mitigate the Burden of the New Era of Obesity Medical Therapy

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Abstract

Highly effective antiobesity and diabetes medications such as glucagon-like peptide 1 (GLP-1) agonists and glucose-dependent insulinotropic polypeptide/GLP-1 (dual) receptor agonists (RAs) have ushered in a new era of treatment of these highly prevalent, morbid conditions that have increased across the globe. However, the rapidly escalating use of GLP-1/dual RA medications is poised to overwhelm an already overburdened health care provider workforce and health care delivery system, stifling its potentially dramatic benefits. Relying on existing systems and resources to address the oncoming rise in GLP-1/dual RA use will be insufficient. Generative artificial intelligence (GenAI) has the potential to offset the clinical and administrative demands associated with the management of patients on these medication types. Early adoption of GenAI to facilitate the management of these GLP-1/dual RAs has the potential to improve health outcomes while decreasing its concomitant workload. Research and development efforts are urgently needed to develop GenAI obesity medication management tools, as well as to ensure their accessibility and use by encouraging their integration into health care delivery systems.

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KEYWORDS

obesity; artificial intelligence; AI; clinical management; GLP-1; glucagon-like peptide 1; medical therapy; antiobesity; diabetes; medication; agonists; glucose-dependent insulinotropic polypeptide; treatment; clinician; health care delivery system; incretin mimetic

Introduction

Highly effective antiobesity and diabetes medications such as glucagon-like peptide 1 (GLP-1) agonists have ushered in a new era of treatment of these highly prevalent, morbid conditions that have increased across the globe over the past few decades. It is estimated that by 2030 nearly 30 million people in the United States will be on GLP-1 or glucose-dependent insulinotropic polypeptide/GLP-1 (dual) receptor agonists (RAs; henceforth referred to as GLP-1/dual RA) medications. Currently, their use is throttled by limited availability and insurance coverage challenges. As these issues resolve, their widespread use will trigger an even larger bottleneck—the substantial clinical management burden driven by the frequent communication, titration, and administrative interactions required to successfully manage obesity and related conditions using these important new medications. Indeed, health care providers (HCPs) and their practices have already begun to experience the strain of managing the high demand for weight loss medications. Relying on existing systems and resources to address the oncoming rise in GLP-1/dual RA use will be insufficient. Generative artificial intelligence (GenAI) has the potential to offset the clinical and administrative demands associated with the management of patients on these medication types. Research and development efforts are urgently needed to develop GenAI GLP-1/dual RA medication management tools, as well as to ensure their accessibility and use by encouraging their integration into health care delivery systems.

The High Burden of Obesity Medications

When an HCP chooses to prescribe a GLP-1/dual RA to their patient, they are embarking on a months-long journey of clinical or administrative burden greater than most common chronic disease medications. A clinical team will be tasked with regularly balancing weight loss goals, hemoglobin A_{1c} targets,

and side effects; continuously evaluating whether to continue to titrate up (or down) the medication until a maintenance dose is achieved. Moreover, HCPs will likely be faced with navigating insurance preauthorizations and fielding patient calls and messages about side effects, while searching for alternative pharmacies or bridging medications to address medication shortages.

On a small scale, this may be manageable, but as the number of patients on GLP-1/dual RAs expands to accommodate the 42% of Americans with obesity [1], it is unsustainable. With clinical practices already overburdened by administrative workload and HCPs at high risk for burnout [2], it is unreasonable to assume that the additional labor demands to manage patients on GLP-1/dual RAs could be handled by the existing workforce or that a health care system could feasibly hire enough additional personnel to meet this demand. To address the potential wave of future patients on GLP-1/dual RAs, tools are needed to reduce communication and administrative burden, allowing HCPs to focus on more complex patient care.

GenAI Role in Medication Management

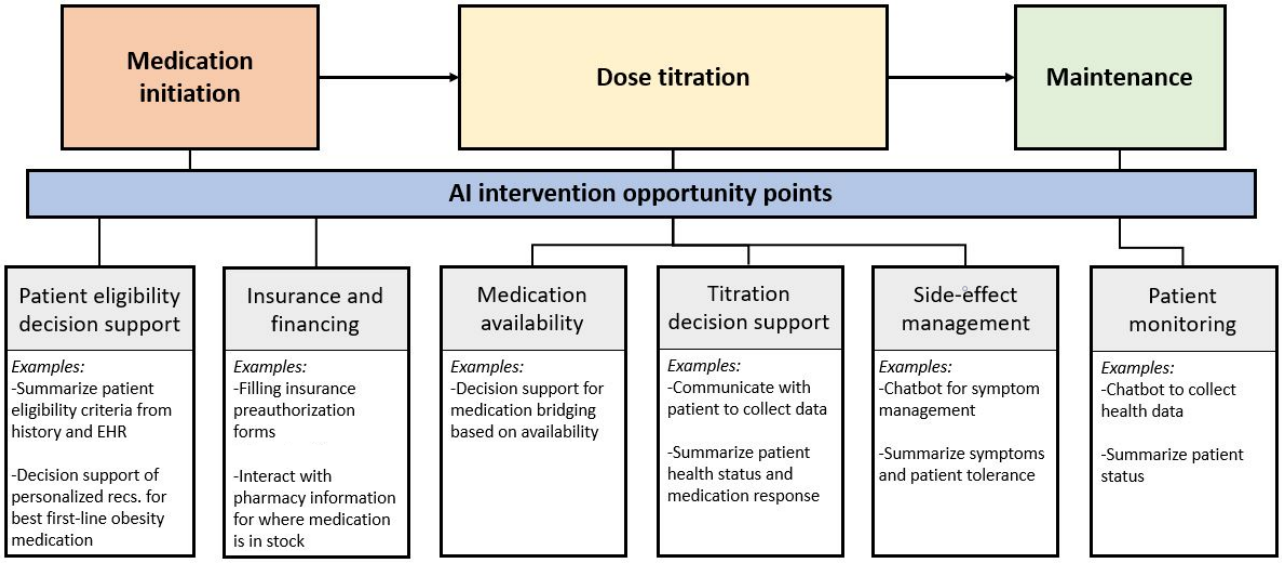
GenAI may represent an opportunity to automate many of the low-complexity, high-burden GLP-1/dual RA management tasks. As compared to previous iterations of artificial intelligence (AI), the technical functionality of GenAI allows for the creation of content, addressing numerous aspects of care management tasks that were previously impossible or overly burdensome to automate. Specifically, through the use of recurrent neural networks [3], generative adversarial networks [4], and large language models [5] with natural language processing [6] capabilities, GenAI has an inherent flexibility to combine heterogeneous sources of data to generate summaries, perform calculations, and create original content, including the production of potentially impactful metrics to improve clinical decision-making [7-10]. Furthermore, advancements in natural language understanding research have enabled the design of AI-driven chatbots—conversational agents that mimic human interaction through written, oral, and visual forms of communication with a user [11,12]. AI chatbots can learn from previous interactions, offering a more personalized, engaging, and on-demand user experience to support health behaviors [13,14]. The addition of GenAI functionality to AI-driven chatbots further improves the chatbot's ability to respond dynamically. In these ways, the capabilities of GenAI extend its potential functionality well beyond a single algorithm for medication titration.

Indeed, while still an emerging technology, GenAI has shown itself to be a potentially effective tool for patient medication and care management in the areas of diabetes insulin management, hypertension, and weight management. In the form of chatbots, AI has demonstrated its use to facilitate the collection of patient data, reduce HCP message burden [14], and deliver health coaching for adults with overweight and obesity [12], producing similar results to those expected from in-person lifestyle interventions [15]. AI chatbots have also demonstrated the potential integration of wearable device data and messaging platforms for the creation of personalized intervention messaging [16]. GenAI-generated responses to patient questions have even been shown to be perceived as higher quality, more empathetic, and have greater clinical decision support accuracy than physician responses [17,18]. GenAI is also powering new "ambient clinical documentation" tools that effectively transform patient-clinician conversations into medical documentation [19].

Through the synthesis of patient data, clinical guidelines, and information databases, GenAI can provide effective and accurate clinical decision support and patient intervention, and even pharmacist-validated medication management [20]. For example, a voice-based conversational GenAI application effectively provided an autonomous real-time remote patient intervention for basal insulin management among patients with type 2 diabetes by incorporating HCP-selected titration algorithms and emergency protocols (parameters) for hypoglycemia and hyperglycemia based on daily patient reports of insulin dose and blood sugar value. This intervention led to significantly improved insulin management as compared to standard care [21]. Similarly, GenAI has revealed promise as a potential solution to the high burden incurred in remote patient monitoring for hypertension. By creating a GenAI-powered messaging platform for patient interactions, and integrating GenAI-created smart summaries into the electronic health record (EHR), these tools assisted in the management of the large volume of incoming data and have the potential to enhance both patient and HCP-facing tasks associated with digital health care for hypertension management [22]. These examples highlight how GenAI tools may be capable of supporting more efficient GLP-1/dual RA dose titration and increasing patient engagement without significantly increasing HCP workload.

Similar to these example cases, the management of GLP-1/dual RA medications requires patient engagement, as well as the collation of information from patients themselves, medical records, and clinical guidelines. Furthermore, GLP-1/dual RA management can be subjective with nuance in the interpretation of patient symptom tolerability and thus requires greater use of clinical judgment as opposed to hard and fast rules or cutoffs. GenAI has the potential to address multiple aspects of GLP-1/dual RA management, including streamlining patient-HCP communication, giving HCPs recommendations on optimal dose titration, and providing prescribing guidance based on nonclinical factors such as insurance coverage and medication availability (Figure 1). Through its inherent flexibility to incorporate multiple data sources, GenAI can interpret patient natural language responses regarding side effects and weight-loss goals, as well as incorporate information living in the EHR and other databases such as patient characteristics including weight changes, medical history, current medication dose, blood sugar levels, and insurance status [7]. This enables GenAI to provide a broad range of GLP-1/dual RA management services from personalized guidance for patients on the management of side effects to clinical advisement to optimize dose titrations.

Figure 1. GLP-1/dual RA medication management workflow and example opportunities for GenAI intervention. AI: artificial intelligence; EHR: electronic health record; GenAI: generative artificial intelligence; GLP-1: glucagon-like peptide 1; RA: receptor agonist.



Health Care System Integration of GenAI Interventions

Scaling the effective management of GLP-1/dual RAs, however, cannot be achieved through stand-alone development of GenAI tools, bots, and algorithms—they must be deeply integrated into the health care delivery system. This requires careful EHR and clinical workflow integration; a “last-mile” problem that most health care startups and innovators avoid until the end of their product development journey. While this may be consistent with their business plan, it has repeatedly led to low penetration of these potentially valuable digital tools. GenAI-assisted GLP-1/dual RA management will need early and deep clinical and EHR integration to disrupt this pattern.

To achieve clinical integration, however, there will be several privacy, cost, implementation, and ethical challenges that must be considered [23]. First, as with other forms of digitization of health care, the use of AI may introduce additional data privacy concerns regarding data storage, sharing, and use in model training [24]. Consequently, accommodations will need to be made to house and maintain any patient data, and the AI models being used, on internal firewall-protected servers, as opposed to externally hosted AI platforms [17].

The cost of integrating GenAI into clinical practice is also not insubstantial. In addition to costs associated with setting up and maintaining additional secure servers to house data, there are costs associated with each GenAI interaction. Depending on the task demanded, a sequence of several back-end prompts is likely required to achieve the desired outcome, with each prompt costing a multitude of “tokens” (ie, the basic units of text or code GenAI uses to process and generate language) and the use of each token coming at a monetary cost [25]. Moreover, each use of GenAI comes with an additional inference cost due to energy consumption, which can overtake the energy costs of training a GenAI model with high volumes of use [26].

To promote the successful implementation of GenAI products into clinical practice, usability, workflow integration, and user trust must be considered. Although presumptions have been made that the user-friendly, adaptable, and rapidly iterative aspects of GenAI will improve efficiency, productivity, and quality in ways not achieved with previous technologies [27], the deployment of GenAI interventions must be cognizant of clinical workflows, current technology integrations, and be designed with the user needs in mind [28]. Furthermore, the use of AI technologies in clinical care is not universally trusted by HCPs and patients [29,30], suggesting that substantial training and trust-building efforts will be required to improve acceptability and gain universal adoption.

Furthermore, there remain numerous ethical concerns associated with relying on GenAI in clinical care, including the potential exacerbation of disparities in health equity. Some ethical issues are associated with the technological aspects of GenAI functionality including the potential impact of algorithmic and language bias built into the training data used to create GenAI models, and how the reliability of models, including their potential for AI hallucinations, may impact clinical safety [31,32]. To address these types of concerns, health care institutions are likely to need a governance committee to oversee GenAI implementation, detail policies around data protection and data management practices, and thoroughly test GenAI models prior to allowing them for clinical use [33].

Digital health equity is another ethical consideration that will need to be addressed early and often in the development and deployment of GenAI-enabled clinical care, such as GLP-1/dual RA management tools. Due to structural inequities of access to insurance coverage, digital tools, and digital literacy, as well as health care system resources for GenAI adoptions, the potential benefits of GenAI GLP-1/dual RA management tools may be inequitably distributed.

Bias within GenAI training datasets has the potential to reinforce existing inequities [17]. Conscious efforts are likely to be needed to evaluate and tailor model training data for the populations of interest and through comparing and validating different samples of training data for representativeness [34]. The

development and use of frameworks to evaluate the impact of GenAI use on health disparities and guide model modifications, as explored in other areas such as clinical predictive modeling [35], may be useful for guiding the equitable use of GenAI in clinical care [36].

Correspondingly, the development of GenAI obesity medication management and other GenAI-driven clinical tools should engage equitable digital design philosophies such as liberatory design [37]. Practical outcomes of this may include integrating GenAI into current system technologies that are widely available, such as SMS text messaging or existing EHR platforms, thus allowing for greater accessibility to these tools. Furthermore, to serve as health equity promotion interventions themselves, GenAI tools could be designed to detect and address known structural inequities, thereby proactively mitigating potential conscious or unconscious biases from the HCP.

Conclusions

The rapidly escalating use of GLP-1/dual RA medications is poised to overwhelm an already overburdened HCP workforce and health care delivery system, stifling its potentially dramatic benefits. Early adoption of GenAI to facilitate the management of these GLP-1/dual RAs has the potential to improve health outcomes while decreasing its concomitant workload. Investment in GenAI's potential to support GLP-1/dual RA management is greatly needed. This effort should be guided by inclusive design principles and deep integration into clinical workflows to achieve scalable impact on clinical outcomes.

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Generative artificial intelligence (AI) was not used in the writing of this study.

Authors' Contributions

ERS contributed to conceptualization, methodology, writing the first draft, and revisions. AES contributed to conceptualization, methodology, writing the first draft, and revisions. HL contributed to conceptualization and revisions. DMM contributed to conceptualization, methodology, writing the paper draft, and revisions.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
EHR: electronic health record
GenAI: generative artificial intelligence
GLP-1: glucagon-like peptide 1
HCP: health care provider
RA: receptor agonist

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Original Paper

A Machine Learning Model for Risk Stratification of Postdiagnosis Diabetic Ketoacidosis Hospitalization in Pediatric Type 1 Diabetes: Retrospective Study

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Abstract

Background: Diabetic ketoacidosis (DKA) is the leading cause of morbidity and mortality in pediatric type 1 diabetes (T1D), occurring in approximately 20% of patients, with an economic cost of $5.1 billion/year in the United States. Despite multiple risk factors for postdiagnosis DKA, there is still a need for explainable, clinic-ready models that accurately predict DKA hospitalization in established patients with pediatric T1D.

Objective: We aimed to develop an interpretable machine learning model to predict the risk of postdiagnosis DKA hospitalization in children with T1D using routinely collected time-series of electronic health record (EHR) data.

Methods: We conducted a retrospective case-control study using EHR data from 1787 patients from among 3794 patients with T1D treated at a large tertiary care US pediatric health system from January 2010 to June 2018. We trained a state-of-the-art; explainable, gradient-boosted ensemble (XGBoost) of decision trees with 44 regularly collected EHR features to predict postdiagnosis DKA. We measured the model's predictive performance using the area under the receiver operating characteristic curve–weighted F_1-score, weighted precision, and recall, in a 5-fold cross-validation setting. We analyzed Shapley values to interpret the learned model and gain insight into its predictions.

Results: Our model distinguished the cohort that develops DKA postdiagnosis from the one that does not (P<.001). It predicted postdiagnosis DKA risk with an area under the receiver operating characteristic curve of 0.80 (SD 0.04), a weighted F_1-score of 0.78 (SD 0.04), and a weighted precision and recall of 0.83 (SD 0.03) and 0.76 (SD 0.05) respectively, using a relatively short history of data from routine clinic follow-ups post diagnosis. On analyzing Shapley values of the model output, we identified key risk factors predicting postdiagnosis DKA both at the cohort and individual levels. We observed sharp changes in postdiagnosis DKA risk with respect to 2 key features (diabetes age and glycated hemoglobin at 12 months), yielding time intervals and glycated hemoglobin cutoffs for potential intervention. By clustering model-generated Shapley values, we automatically stratified the cohort into 3 groups with 5%, 20%, and 48% risk of postdiagnosis DKA.

Conclusions: We have built an explainable, predictive, machine learning model with potential for integration into clinical workflow. The model risk-stratifies patients with pediatric T1D and identifies patients with the highest postdiagnosis DKA risk using limited follow-up data starting from the time of diagnosis. The model identifies key time points and risk factors to direct clinical interventions at both the individual and cohort levels. Further research with data from multiple hospital systems can help us assess how well our model generalizes to other populations. The clinical importance of our work is that the model can predict

patients most at risk for postdiagnosis DKA and identify preventive interventions based on mitigation of individualized risk factors.

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KEYWORDS

pediatric type 1 diabetes; postdiagnosis diabetic ketoacidosis; risk prediction and stratification; XGBoost; Shapley values; ketoacidosis; risks; predict; prediction; predictive; gradient-boosted ensemble model; diabetes; pediatrics; children; machine learning

Introduction

Background

Diabetic ketoacidosis (DKA) is the leading cause of morbidity and mortality among patients with pediatric type 1 diabetes (T1D), accounting for nearly 50% of all deaths in this population [1,2]. DKA occurs in 20% of patients with T1D, with an average cost of US $26,566 per DKA admission and a total economic cost of US $5.1 billion/year in the United States [3-7]. Hospitalizations for DKA in the United States have increased by 6.3% each year from 2009 to 2014 despite many attempts at prevention [8]. The incidence of DKA hospitalizations postdiagnosis has been estimated to be about 8 to 16 per 100 person-years in the pediatric population, with variations in both patient populations and in hospital or care systems [9]. DKA has a significant impact on growth and development in children, potentially leading to neurocognitive impairment, cerebral edema, coma, or even death [1,2,10].

Most prior studies pertaining to DKA hospitalization risk in pediatric patients are associational in nature, focusing on assessing DKA prevalence, predicting the risk of DKA at onset, and relating DKA at onset to its impact on glycemic control. These studies [11-18], conducted with a limited number of electronic health record (EHR)–derived features, using classical statistical methods, have identified the most common factors associated with DKA in patients with pediatric T1D. They include (1) insulin omission, especially in the context of chronic hyperglycemia (high glycated hemoglobin [HbA_{1c}]) [5], (2) females of age greater than 10 years, (3) racial minority youths (Hispanic and African American) [19-21], (4) nonprivate health insurance (a proxy for socioeconomic disadvantage) [22,23], (5) underlying mental health comorbidities, and (6) prior-DKA [19,23-25].

Despite knowledge of DKA risk factors, there are few predictive tools ready for clinical integration that can accurately stratify DKA risk for established patients. This is partly because the relationship between known risk factors and postdiagnosis DKA is complex [4,20,25] and highly nonlinear, whereas tools for elucidating them have been generally limited to simple statistical models, such as logistic regression. Over the last 2 decades, nonlinear predictive techniques ranging from deep neural networks [26] to ensemble methods such as bagging and boosting [27], have been devised in the field of supervised machine learning. These methods derive their power from the ability to infer complex prediction functions directly from raw data. They have allowed for great progress in some diagnostic areas: diabetic retinopathy [28], machine translation of clinical notes [29], object recognition in radiologic or pathologic images [30], as well as in DKA prediction in both patients with pediatric and adult T1D [31,32], but pose challenges in terms of interpretability.

Objective

We develop an explainable, machine-learning model to predict pediatric patients with T1D who are at risk of DKA hospitalization postdiagnosis using a time-series of routinely collected, EHR data. We evaluate the predictive performance of our gradient-boosted decision tree model (XGBoost) on one of the largest cohorts of pediatric patients with T1D. Further, we use Shapely value analysis of our model outputs to (1) derive key predictive factors for postdiagnosis DKA, both at the cohort and at the individual levels, (2) reveal the progression of postdiagnosis DKA risk over time, and (3) automatically perform cohort-level risk stratification by agglomerative clustering of Shapley values.

Methods

Study Design

This study accessed deidentified EHR data from 6288 pediatric patients with diabetes, 3794 of them with a confirmed T1D diagnosis, between January 1, 2010, and June 30, 2018, treated at Texas Children's Hospital (TCH). TCH is one of the largest tertiary-care pediatric health systems in the United States, and likely has some of the largest sets of pediatric patients with diabetes.

To limit unintended biases and erroneous predictions caused by missing data, we defined stringent inclusion criteria to select the training cohort for model building. We selected patients who were (1) initially diagnosed at, and subsequently followed up within the TCH system with an onset date on or after January 1, 2010, (2) whose age at diagnosis was between 0 and 21 years, (3) who had at least 1 positive antibody titer (glutamic acid decarboxylase 65-kilodalton isoform [GAD65], islet cell autoantigen 512 [ICA512], and insulin AB) at diagnosis, and (4) with a clinical diagnosis of T1D by an endocrinologist. These criteria excluded 1723 patients from the first criterion, 45 from the second, and 239 from the third; with a remainder of 1787 patients included in the final analysis. Of these 1787 patients, 324 experienced at least 1 postdiagnosis DKA hospitalization. The small number of overall and positive cases is a consequence of T1D itself being a rare pediatric disease and postdiagnosis DKA being a rare complication of this disease.

Feature Generation and Selection

Feature Construction

For each patient in the cohort, we extracted more than 100 features available in the EHR, from the time of diagnosis to 3-month clinic follow-ups for up to 2 years after onset. The data included demographic information, clinical data, laboratory values, treatment modality (insulin delivery), hospitalization records, and ambulatory care components. Demographic features included age at diagnosis (onset age), sex, race, ethnicity, and socioeconomic status proxies such as type of insurance, and zip code of residence. Clinical features included vital signs, BMI, and laboratory values including titers at the time of diagnosis. We included both raw diabetes titer values, as well as discretized Boolean (0 or 1) titer values (1 if GAD65 [33] titer >5 IU/mL, 1 if ICA512 [33] titer >5.4 IU/mL, 1 if insulin AB [33] titer >0.4 U/mL). We also included HbA_{1c} values at diagnosis and at 3-month clinic follow-ups for up to 24 months. Hospitalization features included length of stay, laboratory-test time-series during the stay, as well as therapeutic interventions. Ambulatory care features included the use of auxiliary services (educators, nutrition services, psychology, and social workers), as well as no-shows and cancellations. We also included diabetes age (years after T1D onset), whether there was DKA at onset, and C-peptide value at the time of diagnosis since they were clinically relevant features.

Feature Selection

We omitted features that were missing values for more than 50% of the cohort. We dropped ambulatory care component features and most laboratory test features (except for HbA_{1c}) on this basis. We also omitted features highly correlated with HbA_{1c} values (such as the BMI time series) because they did not add to the predictive power of the model. In addition, we dropped all features perfectly correlated with the outcome variable—these included all hospitalization-derived features including laboratory tests conducted during DKA hospitalization and therapeutic interventions during hospitalization. This left us with 44 features described in detail later. We did not use additional feature selection methods, relying instead on XGBoost to select relevant features in the construction of the final decision ensemble.

Missing Value Imputation

We used a simple piecewise linear interpolation technique to fill in missing values in HbA_{1c} records. HbA_{1c} imputation was done only between 2 known values—for example, if the 3-month and 9-month HbA_{1c} values for a patient were known, then the 6-month value was imputed as the average. We did not perform any other imputation. The XGBoost learning algorithm handles missing values by default, obviating the need for more imputation.

Final Features

The 44 features finally used for each patient in our cohort included 15 demographic features: sex (male or female), insurance (private or Medicaid or self-pay), race (White, African American, Asian, and Other), ethnicity (Hispanic, non-Hispanic, and Other), first 3 digits of zip code, 7 diabetes titers (raw values and discretized values for GAD65, ICA512, insulin AB, and the total number of positive antibody titers), 17 HbA_{1c} features including 9 values of HbA_{1c} (at diagnosis, and at 3-month follow-ups from 3 to 24 months), as well as 8 delta measures (differences between HbA_{1c} measurements at successive follow-ups), and 5 other features: diabetes age (years since T1D diagnosis), onset age, DKA at onset (yes or no), C-peptide titer at diagnosis, and discretized C-peptide (>1 U/mL).

Outcome Definition

We used hospitalization with DKA after diagnosis of T1D to define the outcome variable. We split the cohort into 2 classes: those who experienced at least 1 DKA episode after diagnosis (324/1787, 18%) and those who did not.

Model Selection and Training Protocol

We trained a multivariate gradient boosting decision tree ensemble on the data, using the Python XGBoost open-source library [34]. As illustrated in Figure S1 in Multimedia Appendix 1, we used a 5-fold stratified cross-validation approach. We divided the data set into 5 equal-sized folds, with the ratio of patients with postdiagnosis DKA and non-DKA being equal in all groups. We used 4 of the folds for training a gradient-boosted ensemble and used the held-out fold for testing the ensemble. We repeated the process 5 times, each time with a different held-out fold, yielding 5 sets of performance measures. We used 4 standard metrics to quantify the performance of the postdiagnosis DKA classifier: area under the receiver operating characteristic curve (AUC), weighted F_1-score, weighted precision, and weighted recall. We reported the mean and SD of these 4 scores across the 5 folds, to characterize the predictive performance of the ensemble model.

Key hyper-parameters for XGBoost (number of trees and tree depth) were selected using the standard hyperparameter tuning process described in section 5.3 of *Deep Learning* by Goodfellow et al [35]. We held out 10% of the training data in each cross-validation fold as a validation set—this data does not participate in model construction.

One of the challenges in model training is handling class imbalance (324 positive examples in a set of 1787 patients, in our case). This is an inherent consequence of postdiagnosis DKA being relatively uncommon. XGBoost handles imbalanced data sets by using the parameter scale_pos_weight, to reflect the degree of imbalance. This parameter weights the components of the cross-entropy loss function used by the training algorithm, assigning a higher weight to the minority class examples, in effect, simulating the process of up-sampling the minority class [36].

Explaining Classifier Performance: Bee-Swarm and Main-Effects Plots

We used the Shapley value [37] framework to assign predictive importance to each feature. The Shapley value, or SHAP (Shapley additive explanations) value, of a feature for a patient, is a quantification of the contribution made by that feature to the DKA or no-DKA prediction made for that patient. The unit of measurement for SHAP values is the change in logarithmic odds of postdiagnosis DKA with and without the feature.

Positive SHAP values mean a positive impact on prediction, that is, they lead the model to predict postdiagnosis DKA. Negative SHAP values mean a negative impact on prediction, that is, they lead the model to predict no DKA after diagnosis. Unlike regular feature importance plots, SHAP values show the directionality of the impact of the feature value on the outcome. We use plots of averaged SHAP values over the whole cohort for each feature, called a bee-swarm plot, to rank key factors that determine the risk of postdiagnosis DKA at the level of the entire cohort.

Main-effects plots show variation in the log-odds of postdiagnosis DKA as functions of a single predictor, all else being equal. A sharp change in log-odds in the main-effects plot of a feature reveals important thresholds at which postdiagnosis DKA risk increases or decreases. For example, these plots help answer questions such as: does the risk of postdiagnosis DKA increase linearly with diabetes age, or is there an age interval where the risk rises significantly? For an individual patient, SHAP values allow for the selection of features relevant to the prediction outcome and explain the outcome as an additive combination of SHAP values. We produce main-effects plots for key cohort-level risk factors identified in the bee-swarm plot.

Cohort Risk Stratification by Clustering Shapley Values

Cohort risk stratification is a byproduct of the Shapley value analysis. We clustered the Shapley value matrix constructed from the output of the XGBoost model using a hierarchical agglomerative clustering algorithm, based on Ward linkage [38]. The algorithm groups patients according to similarities in their Shapley value vectors, producing a dendrogram. Any horizontal cut of the dendrogram induces a clustering of the original data. We select a cut level to maximize the dissimilarity between clusters.

Personalized Risk Assessment

In addition to cohort-level predictions, the model is equally useful for generating interpretable predictions for individual patients. The model produces an additive risk score, which is the sum of the Shapley values for each predictive feature for that patient. When the sum is positive, it indicates higher than baseline risk for that patient; if it is negative, then the patient is at lower risk relative to the whole cohort.

Ethical Considerations

Data were gathered under institutional review board (number H-42624), which was approved by the institutional review board of Baylor College of Medicine. The institutional review board covers secondary analysis utilizing this data without additional consent. Data were deidentified prior to analysis.

Results

Descriptive Analysis of Data

We summarize the value distributions of key predictors in Table 1. Surprisingly, DKA at the onset which has been shown to be associated historically with worsening glycemic control over time [13], does not have a strong correlation with postdiagnosis DKA. The median diabetes age at the first DKA after diagnosis is 2.43 (IQR 1.26-4.09) years. It validates the selection of time-series of HbA_{1c} measurements from baseline to the first 24 months after diagnosis, as the basis for postdiagnosis DKA prediction.

Table 1. Value distributions of key demographics and laboratory test values for the entire cohort of 1787 patients with type 1 diabetes treated at Texas Children's Hospital between January 1, 2010, and June 30, 2018.

Feature	Variables
Sex (female), n (%)	891 (49.86)
Race, n (%)	
African American	299 (16.73)
Asian	65 (3.64)
White	1364 (76.33)
Other	59 (3.30)
Ethnicity, n (%)	
Non-Hispanic	1301 (72.80)
Hispanic	442 (24.73)
Other	44 (2.46)
Insurance, n (%)	
Private	1146 (64.13)
Medicaid	641 (35.87)
Antibody titer, median (IQR)	
Glutamic acid decarboxylase 65-kilodalton isoform	13.0 (3.85-30.00)
Islet cell autoantigen 512	6.80 (1.2-20.8)
Insulin antibody	0.4 (0.4-3.50)
HbA_{1c}[a], median (IQR)	
HbA_{1c} baseline at diagnosis (n=1787)	11.1 (9.5-12.90)
HbA_{1c} at 3 months (n=1768)	7.51 (6.76-8.48)
HbA_{1c} at 6 months (n=1712)	7.34 (6.52-8.37)
HbA_{1c} at 9 months (n=1651)	7.71 (6.87-8.7)
HbA_{1c} at 12 months (n=1553)	7.85 (7.08-8.84)
HbA_{1c} at 15 months (n=1471)	7.95 (7.20-8.91)
HbA_{1c} at 18 months (n=1401)	8.07 (7.30-9.07)
HbA_{1c} at 21 months (n=1320)	8.13 (7.31-9.10)
HbA_{1c} at 24 months (n=1239)	8.15 (7.33-9.20)
C-peptide, median (IQR)	0.43 (0.26-0.725)
Duration of T1D[b] (in years; diabetes age), median (IQR)	4.10 (1.80-6.47)
Age at T1D diagnosis (in years; onset age), median (IQR)	10.40 (6.73-13.43)
DKA[c] at onset, n (%)	623 (34.86)
Diabetes age at first DKA postdiagnosis (years postdiagnosis), median (IQR)	2.43 (1.26-4.09)
Patients with at least 1 postdiagnosis DKA, n (%)	324 (18.13)

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

[b]T1D: type 1 diabetes.

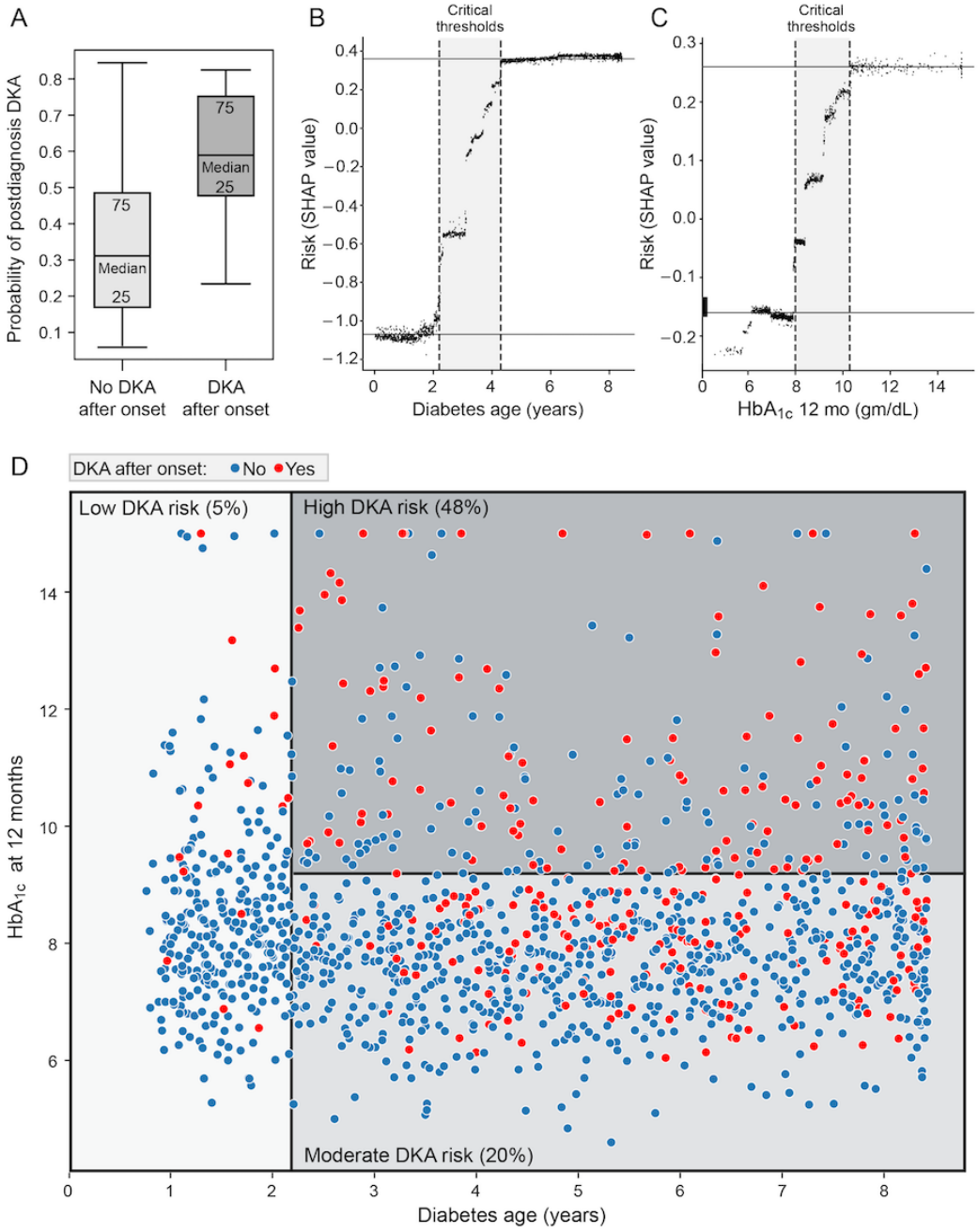
[c]DKA: diabetic ketoacidosis.

Model Evaluation by Cross-Validation With AUC, Precision, and Recall

The box plot in Figure 1A shows the clear separation in probability between the no DKA and DKA postdiagnosis cohort (P value <.001). The model is able to distinguish between the postdiagnosis DKA cohort and the non-DKA cohort at a statistically significant level. The cross-validated model with all 9 HbA_{1c} measurements from baseline to 24 months has an

AUC of 0.80 (SD 0.04) and a weighted F_1-score of 0.78 (SD 0.04). The weighted precision and recall of the model are 0.83 (SD 0.02) and 0.76 (SD 0.07) respectively. Cross-validation allows robust estimation of the predictive performance of the model on new patients. Table S1 in Multimedia Appendix 1 shows the incremental effect of the addition of HbA_{1c} values from 3 to 24 months on these performance measures. Model performance stops improving after the addition of HbA_{1c} at 18 months after onset.

Figure 1. (A) Probability of postdiagnosis DKA at the cohort level, (B,C) risk by individual key features of diabetes age and HbA_{1c} at 12 months, and (D) risk stratification into group. The cohort that will develop DKA can be distinguished from the one that will not, with a (A) *P* value <.001. The main-effects plots show critical thresholds where risk sharply rises (gray regions), (B) for diabetes age between 2.2 and 4.3 years, and (C) for HbA_{1c} at 12 months between 8 and 10.3. (D) The scatterplot uses a diabetes age cutoff of 2.2 years and HbA_{1c} at 12 months of 9.2 to stratify the population into 3 risk groups for postdiagnosis DKA. A total of 30% of the population has 5% or low risk for DKA, shown in light gray; 50% of the population is at 20% or moderate risk (in medium gray), and 20% is at 48% or high risk of postdiagnosis DKA. DKA: diabetic ketoacidosis; HbA_{1c}: glycated hemoglobin.



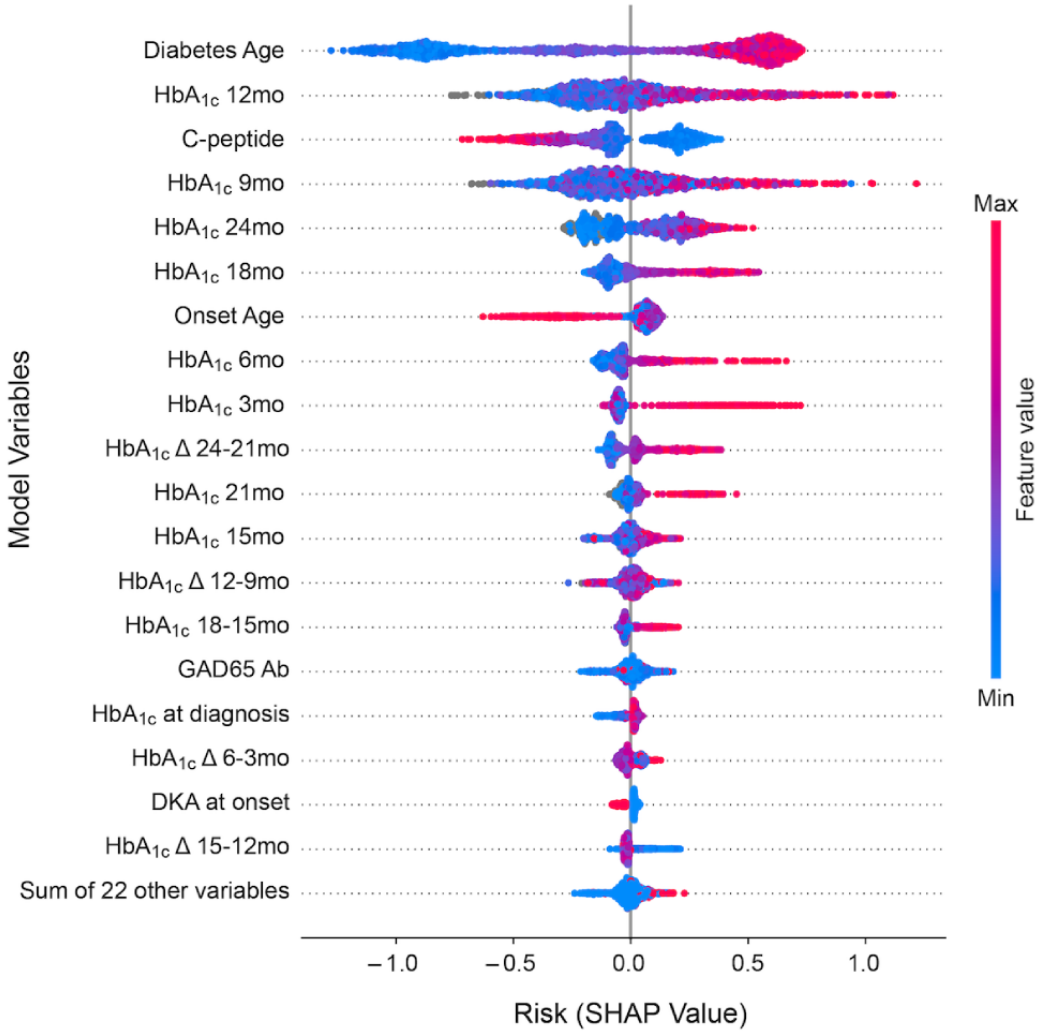
Key Predictors of Postdiagnosis DKA

Figure 2 shows a bee-swarm plot summarizing the entire distribution of SHAP values for each predictor. The x-axis of the plot shows the impact on model output (log-odds of postdiagnosis DKA risk) of each of the predictors sorted along the y-axis by decreasing importance. The most important feature that predicts postdiagnosis DKA is diabetes age (top row). Every point in the top row denotes a patient's diabetes age and the impact of the value of diabetes age on their log-odds of

postdiagnosis DKA risk. Patients with low diabetes age (newly diagnosed, and colored blue) have negative SHAP values and thus lower postdiagnosis DKA risk, while patients with higher diabetes age (colored red) have positive SHAP values and higher postdiagnosis DKA risk. As diabetes age increases, the log-odds of DKA risk goes from –1.25 to +0.7. While the plot shows the overall trend of increasing diabetes age contributing to increased risk of postdiagnosis DKA it does not elucidate the exact nature of that trend. HbA_{1c} value at 12 months is the second most important feature, and the plot shows a trend of increasing postdiagnosis DKA risk with an increase in HbA_{1c} values. For the third most important feature, C-peptide at diagnosis, the plot shows that higher values at diagnosis are associated with lower postdiagnosis DKA risk. Higher HbA_{1c} levels at 9, 18, and 24 months are all associated with higher postdiagnosis risk. Higher onset age, ranked seventh in the ordering, is associated with lower postdiagnosis DKA risk. Not only has the model identified and ranked key predictors, but it also provides a quantitative measure of the impact of each of these features on the probability of postdiagnosis DKA risk.

Figures 1B and 1C show the main effects of 2 of the top predictors in the model: diabetes age and HbA_{1c} at 12 months. The log-odds of postdiagnosis DKA risk do not vary linearly with diabetes age. Rather, there is a threshold effect, with a rapid increase in log-odds of risk from –0.95 to +0.35 units between diabetes ages of 2.2 and 4.3 years. HbA_{1c} levels at 12 months reveal a similar threshold effect: levels below 8 are at relatively low risk of postdiagnosis DKA, with the risk rising steeply from –0.15 to +0.26 units for patients with HbA_{1c} levels between 8 and 10.3. Beyond the value of 10.3, the risk contribution of the 12-month-HbA_{1c} level plateaus at a log-odds of 0.26. Taken together, as shown in the shaded regions of the plots, the model predicts that at the cohort level, diabetes age between 2.2 and 4.3 years, and HbA_{1c} levels at 12 months between 8 and 10.3 offer the best intervention points to influence postdiagnosis DKA risk.

Figure 2. Model features displayed in order of decreasing importance for postdiagnosis DKA risk prediction. Each feature in this bee-swarm plot is shown with its full range of values—from a minimum in blue, to a maximum in red; see the color scale on right for values in between. The x-axis defines the log-odds of postdiagnosis DKA risk (SHAP value). Each colored dot in a horizontal line represents the value of the corresponding feature for a patient in the training cohort. The most important predictors are diabetes age, HbA_{1c} at 12 months, and C-peptide titer at diagnosis. DKA: diabetic ketoacidosis; GAD65: glutamic acid decarboxylase 65-kilodalton isoform; HbA_{1c}: glycated hemoglobin; SHAP: Shapley additive explanations.



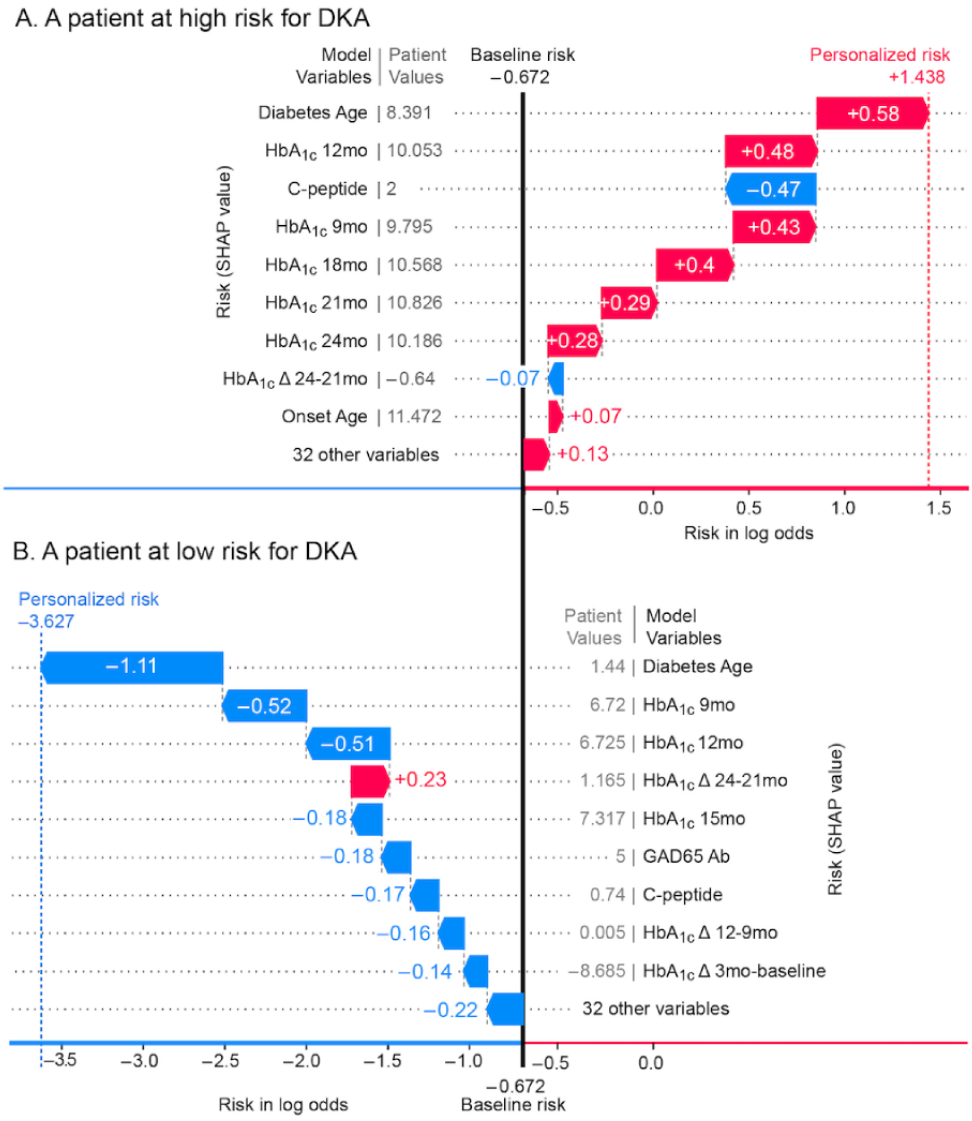
Cohort Risk Stratification by Clustering Shapley Values

The agglomerative clustering analysis reveals 3 well-separated groups characterized by postdiagnosis DKA rates of 5%, 20%, and 48% respectively. Note that the clustering algorithm does not have access to the features or the labels (DKA or non-DKA) for each patient, but only the Shapley value of each feature for that patient. By using a decision tree algorithm to predict cluster membership, we identified the primary criteria to be a diabetes age cutoff of 2.2 years and an HbA_{1c} at a 12-month cutoff of 9.2. Figure 1D visually displays these clusters across the dimensions of diabetes age and HbA_{1c} at 12 months. Cluster 1, which is the low-risk group (5% probability of postdiagnosis DKA) consists of patients whose diabetes age is less than 2.2 years. Cluster 2, the medium risk group (20% probability of postdiagnosis DKA) is composed of patients with diabetes age of 2.2 years and older and HbA_{1c} at 12 months <9.2. Cluster 3, the high-risk group (48% probability of postdiagnosis DKA) consists of patients with diabetes age of 2.2 years and older and HbA_{1c} at 12 months>9.2. Patients at low risk constitute 30% of the population, those at medium risk constitute 50% of the population, and the high-risk group constitutes 20% of the population.

Personalized Risk Assessment

Figure 3 shows the individualized risk predictions for a patient at high risk for postdiagnosis DKA (Figure 3A) and low risk for postdiagnosis DKA (Figure 3B). For the patient in Figure 3A, the model shows the features contributing to high risk: worsening HbA_{1c} values from 9 to 21 months post diagnosis (9.8 → 10.1 → 10.6 →10.8), and high diabetes age of 8.39 years. For the patient in Figure 3B, the model identifies a low diabetes age of 1.44 years as the primary reason for low DKA risk. HbA_{1c} levels for this patient start at 6.7 at 9 months postdiagnosis and remain at 6.72 at the 12-month mark.

Figure 3. Risk models for 2 individual patients (A) at high risk and (B) at low risk of postdiagnosis DKA shown as waterfall plots. The baseline risk of –0.672 marked with a black vertical line represents the overall risk of postdiagnosis DKA at the cohort level. Factors in red are associated with higher DKA risk, and those in blue are associated with lower risk. The personalized risk score represents an individual's unique risk profile. DKA: diabetic ketoacidosis; GAD65: glutamic acid decarboxylase 65-kilodalton isoform; HbA_{1c}: glycated hemoglobin.



Discussion

Principal Findings

Approximately 18% of patients with T1D experience DKA after onset and yet there are few tools available to assist clinicians in assessing postdiagnosis DKA risk, either at the cohort level or at an individual level [39]. Our gradient-boosted ensemble of decision trees trained on a diverse cohort of 1787 patients with T1D has demonstrated the ability to predict DKA after onset with high accuracy, revealing insights into the features most predictive of high risk, and offering explainable risk scores at the level of an individual patient.

With an AUC of 0.80 (SD 0.04), a weighted F_1-score of 0.78 (SD 0.04), and weighted precision and recall of 0.83 (SD 0.03) and 0.76 (SD 0.05) respectively, the model delivers performance similar to Food and Drug Administration–approved predictive computational tools for detecting cervical and breast cancer [40,41]. Using Shapley value analysis, the model identified diabetes age and HbA_{1c} at 12 months as the top 2 drivers of postdiagnosis DKA (Figure 1). Even more interesting, is the data-driven discovery of a "critical period" between 2.2 and 4.3 years of disease and an HbA_{1c} at 12 months between 8 and 10.3 that poses the greatest risk for postdiagnosis DKA, as revealed by the main-effects Shapley value plots. During this period, a sharp nonlinear rise in DKA risk (Figures 1B and 1C) suggests that the optimal window for preventive intervention may exist years prior to the adverse event. By clustering Shapley values using a hierarchical agglomerative clustering technique, we can cleanly stratify the population into 3 major risk classes: 30% in the low-risk group (5% risk of postdiagnosis DKA), 50% in the medium-risk group (20% risk of postdiagnosis DKA) and 20% in the high-risk group (48% risk of postdiagnosis DKA). Consistent with the high AUC scores, the model displayed clear separation between patients with T1D with no DKA postdiagnosis, and those with DKA postdiagnosis ($P<.001$; Figure 1A), holding promise for accurate identification of at-risk patients, with personalized risk scores highlighting individual patient-level factors that drive postdiagnosis DKA risk (Figure 3).

Our model, made interpretable by Shapley value analysis, provides insights into the key determiners of risk for postdiagnosis DKA, and elucidates the nonlinear relationships between key predictors and postdiagnosis DKA risk. Using the Shapley value framework, the model assesses risks at both the cohort and at the individual level, guiding the choice of therapeutic interventions.

Comparison With Prior Work

Data-driven approaches to building predictive risk models are becoming important in clinical applications as prescriptive analytics and targeted personalized therapy become more readily available [28,42]. Recent models [22,23] for predicting patients at high risk for DKA have used logistic regression analyses to identify the top 3 features indicative of postdiagnosis DKA in pediatric T1D: most recent HbA_{1c}, type of health insurance, and prior occurrence of DKA in the past 2 years. These models were qualitatively evaluated in a retrospective setting.

Our unique contribution is the design of an explainable predictive model for postdiagnosis DKA using one of the largest pediatric T1D cohorts studied in the literature. Our model's predictive performance surpasses the state of the art on this problem (Williams et al [31]) on a similar patient cohort. It does so using variables collected on a patient with pediatric T1D during diagnosis, and routine clinic follow-ups for up to 24 months, and not measurements gathered from DKA hospitalization visits (which are fully correlated with our outcome variable). In addition, through our choice of model and statistical analysis using the Shapley value framework, we identify key risk factors predictive of postdiagnosis DKA at the population level and the individual level. We are able to reveal sharp changes in postdiagnosis DKA risk over time, identifying intervals for possible intervention. Finally, we perform risk stratification by automatically deriving risk clusters from Shapley values.

The ensemble model developed here has robust quantitative performance measures. It captures the heterogeneity inherent in the T1D population by building a set of weighted models, rather than a single linear model. Further, it can be operationalized as a predictive tool within existing EHR frameworks, allowing for better clinical management of pediatric T1D with enhanced resource allocation where specialized diabetes care is scarce [43,44].

Our model is derived from data spanning a decade in a large and diverse cohort of patients with pediatric T1D at a major tertiary-care children's hospital. Data readily available in the EHR was included in the data input to the model. The model lets the data drive the selection of key predictors, thus eliminating human bias. The gradient-boosted ensemble method is key to predictive performance since (1) the relationships between predictors and the outcome variable are highly nonlinear (Figures 1B and 1C), precluding the use of simpler models such as logistic regression, and (2) there is significant variation among patients in the cohort, precluding the use of a one-size-fits-all model [32,33,45]. To our knowledge, this is the first deployment of such a model to predict DKA occurrence in a pediatric context. However, successful deployment of the model in a decision support context requires careful integration into clinical workflow.

Limitations and Strengths

This study is a single-center, retrospective study with data limited to what was currently available in the EHR. We acknowledge that the EHR does not capture every patient characteristic that impacts clinical outcomes. Including data collected outside of the traditional health care environment, that is, remote patient monitoring data, and social determinants of health, can improve the predictive performance of our model.

We further acknowledge that DKA occurrences postdiagnosis are not always deterministically predictable, particularly in cases involving infection, illness, and instances of inadequate parental supervision.

In our study, the postdiagnosis DKA outcome in a patient with T1D is determined by hospitalization for DKA; this is a commonly used criterion in prior work on pediatric T1D [31].

However, it is possible that patients with mild cases of postdiagnosis DKA who did not require hospitalization, or were treated at a different facility are not accounted for in our outcome definition.

Conclusions

We have built an explainable, predictive, machine learning model with potential for integration into clinical workflow. The model risk-stratifies patients with pediatric T1D and identifies patients at the highest postdiagnosis DKA risk using limited follow-up data starting from the time of diagnosis. The model identifies key time points and risk factors to direct clinical interventions at both the individual and cohort levels. The clinical import of our work is that the model can predict patients most at risk for postdiagnosis DKA and identify preventive interventions based on mitigation of individualized risk factors.

Future work includes further developing the model with data from multiple hospital systems, testing its generalizability across cohorts from other institutions, and prospectively studying whether it can assist clinicians target interventions to improve outcomes.

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Authors' Contributions

DS, RS, and IS participated in the conceptual design of the study, analysis, and interpretation of the data. DS and IS drafted the manuscript, and all authors reviewed and edited the manuscript and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary figures and tables.
[DOCX File , 162 KB - diabetes_v9i1e53338_app1.docx]

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Abbreviations

AUC: area under the receiver- operating characteristic curve
DKA: diabetic ketoacidosis
EHR: electronic health record
GAD65: glutamic acid decarboxylase 65-kilodalton isoform
HbA_{1c}: glycated hemoglobin
ICA512: islet cell autoantigen 512
SHAP: Shapley additive explanations
T1D: type 1 diabetes
TCH: Texas Children’s Hospital

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Original Paper

Effectiveness of a Continuous Remote Temperature Monitoring Program to Reduce Foot Ulcers and Amputations: Multicenter Postmarket Registry Study

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Abstract

Background: Neuropathic foot ulcers are the leading cause of nontraumatic foot amputations, particularly among patients with diabetes. Traditional methods of monitoring and managing these patients are periodic in-person clinic visits, which are passive and may be insufficient for preventing neuropathic foot ulcers and amputations. Continuous remote temperature monitoring has the potential to capture the critical period before the foot ulcers develop and to improve outcomes by providing real-time data and early interventions. For the first time, the effectiveness of such a strategy to prevent neuropathic foot ulcers and related complications among high-risk patients in a real-world commercial setting is reported.

Objective: This study aims to evaluate the effectiveness of a real-world continuous remote temperature monitoring program in preventing neuropathic foot ulcers and amputations in patients with diabetes.

Methods: In this retrospective analysis of a real-world continuous remote temperature monitoring program, 115 high-risk patients identified by clinical providers from 15 geographically diverse private podiatry offices were analyzed. Patients received continuous remote monitoring socks as part of the program. The enrollment was based on medical necessity as decided by their managing physician. We evaluated data from up to 2 years before enrollment and up to 3 years during the program. The primary outcome was the rate of wound development. Secondary outcomes included amputation rate, the severity of the foot ulcers, and the number of visits to an outpatient podiatry clinic after enrolling in the program.

Results: We observed significantly lower rates of foot ulceration (relative risk reduction [RRR] 0.68; 95% CI 0.52-0.79; number needed to treat [NNT] 5.0; $P<.001$), less moderate to severe ulcers (RRR 0.86; 95% CI 0.70-0.93; NNT 16.2; $P<.001$), less amputations (RRR 0.83; 95% CI 0.39-0.95; NNT 41.7; $P=.006$), and less hospitalizations (RRR 0.63; 95% CI 0.33-0.80; NNT 5.7; $P<.002$). We found a decrease in outpatient podiatry office visits during the program (RRR 0.31; 95% CI 0.24-0.37; NNT 0.46; $P<.001$).

Conclusions: Our findings suggested that a real-world continuous remote temperature monitoring program was an effective strategy to prevent foot ulcer development and nontraumatic foot amputation among high-risk patients.

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KEYWORDS

neuropathy; neuropathic foot ulcer; diabetes; diabetic foot ulcer; amputation; remote patient monitoring; temperature monitoring; prevention; socks

Introduction

Overview

Neuropathic foot ulcers are a common complication of peripheral neuropathy. Among different etiologies leading to peripheral neuropathy, foot ulcers related to diabetic peripheral neuropathy (ie, diabetic foot ulcers [DFUs]) are the most prevalent, expensive, and deadly complications in health care [1]. Up to a third of the cost of diabetes is estimated to be related to foot care [2]. It has been reported that 10% of ulcers become infected and that 20% of infected ulcers result in an amputation [3]. While it has been reported that patients fear amputation more than death, lower extremity amputations have a close to 80% mortality rate [4,5]. DFUs also place a substantial personal burden on people and their families. Nearly half of patients report depression when they have a foot ulcer [6]. Having a foot ulcer can also cascade into other health problems when people lose their mobility, which in turn has a negative effect on the rest of their health, for example, the cardiovascular system.

Fortunately, DFUs and amputations can be prevented. Since 2007, a series of large-scale randomized control trials have shown the efficacy of temperature monitoring [7-10]. By tracking inflammation, a precursor to foot ulcers, patients and providers have an opportunity to intervene early, for example, by offloading and reducing activity. The goal is to alert people who have lost their protective sensation as early as possible of potential skin breakdown and the development of a foot ulcer. As a result of these studies, temperature monitoring is recommended in multiple clinical guidelines.

Since early 2020, a variety of remote patient monitoring (RPM) technologies have seen a rapid rise in adoption, mostly in the fields of primary care, cardiology, and pulmonology [11]. New remote temperature monitoring technologies for lower extremity care have become commercially available as well. The specific technology reported on in this study is a continuous temperature monitoring sock combined with a nursing team that monitors the data generated by the device, under the supervision of a podiatrist. Previous studies have reported on the utilization of the device and the use of the device in monitoring inflammation [12,13]. The hypothesis is that patients enrolled in the remote temperature monitoring program, designed to detect early signs of inflammation and injury, will have a statistically significant reduction in the incidence of neuropathic foot ulcers, hospitalizations, amputations, and other related complications compared with their pre-enrollment status.

Objectives

With those new trends in mind, we wanted to study the clinical outcomes of real-world patients through a retrospective analysis before and during their use of a commercially available continuous remote temperature monitoring program.

Methods

Study Design

This study was from the real-world postmarket registry of an RPM program used in a commercial setting by 15 geographically diverse private podiatry practices across the state of California. This real-world study used a before-and-after study design. The design was chosen to reflect the effect of remote temperature monitoring in a real-world setting, as each patient serves as their own control group. This is an especially effective design for RPM programs and devices because device data and monitoring results are collected and transmitted in real time.

Recruitment

The study was conducted with real-world patient data from patients who were enrolled by their provider in a remote temperature monitoring program. Given this was a real-world study, the only inclusion criterion was enrollment in the continuous remote temperature monitoring program. While the enrollment into the program was determined solely by the providers based on the patient's medical necessity, clinical considerations included history of neuropathic foot ulcers with or without underlying peripheral arterial disease. The etiology of peripheral neuropathy includes, but is not limited to, idiopathic neuropathy, alcohol-induced neuropathy, and chemotherapy-induced neuropathy. Data of individual study participants from 2 years before enrollment were compared with data of up to 3 years during the program.

Patients from clinics that began participating in the registry study after initiating their remote monitoring program were approached if they were active within the last 12 months. We chose this cutoff because reaching out to those who left the program longer ago could be perceived as intrusive or irrelevant to their current health management.

Because this is a real-world study of an ongoing program that is offered by providers as part of their actual daily practice as opposed to a clinical trial, we did not disenroll patients. Follow-up stopped when patients no longer participated in the program; if they changed providers, changed locations, or lost or changed health insurance; could not afford copays and other out-of-pocket expenses; or stopped participating in the program for other reasons. Data from patients before they were lost to follow-up were included in the analysis of the program. The monitoring program is reimbursed by insurance and patients were responsible for any out-of-pocket expenses not covered by their insurance. Patient medical history, particularly the wound and amputation history prior to the enrollment, was reviewed based on chart review.

A total of 122 patients from 15 clinical sites that were enrolled in the remote monitoring program gave informed consent, out of which 7 patients with incomplete historical medical records were excluded from the analysis population (Figure 1). Therefore, a total of 115 patients were included in this analysis.

The average follow-up of this group was 14.5 (median 15.1) months, and the range was between 2 and 36 (SD 7.6) months. The reasons for early terminations are summarized in Table 1.

Figure 1. Flow diagram showing participant enrollment and dispositions.

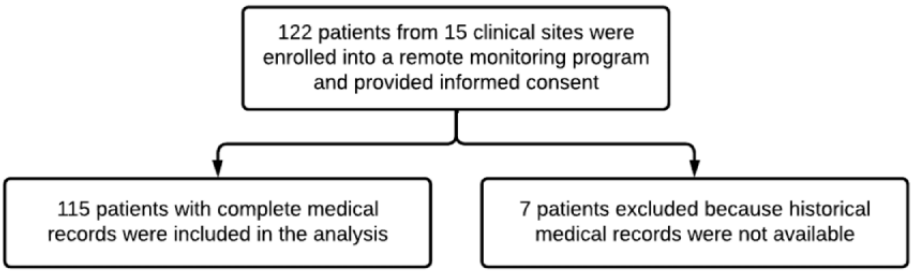

Table 1. Participant disposition.

Disposition	Participants (n=115), n (%)
Ongoing	62 (54)
Dropoff	53 (46)
Lost to follow-up (unresponsive)	22 (19.1)
Other health condition	14 (12.2)
Product (comfort, allergy, and technical)	7 (6.1)
Insurance related	4 (3.5)
Lost to follow-up (patient canceled)	3 (2.6)
Changed provider	2 (1.7)
Deceased	1 (0.9)

Prevention Program

As part of the continuous temperature monitoring prevention program, patients were given continuous remote temperature monitoring socks (Figure 2; Siren Socks; Siren Care, Inc). The socks have temperature sensors embedded that collect temperature from the plantar aspect of the feet. The socks are machine washable, turn on and off automatically, and do not need to be charged. The socks are shipped directly to the patient's home and there is no setup required. All a patient needs to do is plug in a wireless cellular data hub and put on the socks. A smartphone is not required, and the data are sent wirelessly through the data hub to the cloud.

Figure 2. Remote temperature monitoring sock (Siren Socks, courtesy of Siren Care, Inc).

An algorithm compares the temperature difference between the 2 feet and flags the system when a greater than 2.2 °C temperature difference is found. A 1-foot algorithm is applied for people with only 1 foot or with other amputations or deformities.

The continuous temperature monitoring prevention program also consists of a team of remote nurses who monitor the temperature data and contact a patient when a temperature difference between the feet is found. The nurses will ask the patient to reduce activity, check their feet, report symptoms, send photos, and continue wearing the socks. If the problem persists, the nurse escalates it to the patient's managing physician—in this particular study, the podiatrist—who will decide the next steps and whether the patient needs to be seen in person at the clinic for further diagnosis and treatment as part of standard diabetic foot care.

Measurement and Statistical Analysis

Detailed chart review and claims analysis were done and documentation, descriptions, and *International Classification of Diseases* codes in the patient's medical chart were used to identify foot ulcers and related complications. Analysis and summary of ulcers were done by independent physicians not related to the device manufacturer.

Based on the documentation and descriptions in the medical chart, ulcers were classified for severity according to the University of Texas classification system [14].

Repeated-measures Poisson regression with an offset of the months observed in each period was used to compare the following rates before and during the program: presence of foot ulcers, ulcer severity, hospitalizations, outpatient podiatry office visits, and any lower extremity amputations. All 115 patients in the analysis population contributed before and after data for analysis; the Poisson regression model adjusts for the variable lengths of observation in the before and follow-up periods. Our choice of outcome measures aligns with those commonly reported in the literature on diabetic foot care, as well as reported in similar studies, and were determined based on their clinical relevance in the context of temperature monitoring [3,7-10,15]. The statistical analysis was performed by an independent third party not affiliated with the device manufacturer.

Ethical Considerations

Patients from clinics participating in the registry were provided with detailed information about the study upon enrollment in the remote monitoring program and they were given the opportunity to provide informed consent for the inclusion of their data in the study. The study was reviewed and approved by WCG Clinical ethical board (WCG-IRB 1284366). All data were anonymized and deidentified.

Results

User Statistics

Around 91.3% (105/115) of patients had a documented diagnosis of diabetes (Table 2). Because this is a postmarket registry of a real-world private practice setting and medical necessity and enrollment were decided by the patient's managing physician, we also observed other risk factors and forms of neuropathy, such as idiopathic neuropathy, alcohol-induced neuropathy, and chemotherapy-induced neuropathy.

Table 2. Patient demographics at time of enrollment (n=115).

Variables	Patient, n (%)
Age (years), mean (SD)	71.3 (9.6)
Sex (female)	44 (38.3)
Diabetes	105 (91.3)
Diabetes type I	7 (6.1)
Diabetes type II	98 (85.2)
Race and ethnicity	
African American	28 (24.3)
Asian	3 (2.6)
Hispanic or Latino	9 (7.8)
White	73 (63.5)
Other	1 (0.9)
Not documented	1 (0.9)
Comorbidities	
Neuropathy	114 (99.1)
Peripheral arterial disease	58 (50.4)
Smoking	28 (24.3)
Hypertension	74 (64.3)
Kidney disease	17 (14.8)
Foot deformity	
Charcot	14 (12.2)
Hallux malleus	32 (17.8)
Hallux valgus	11 (9.6)
Other	24 (20.9)
History of ulcers	60 (52.2)
History of amputation	23 (20)

In our cohort, 63.5% (73/115) identified as White (58% nationally per the 2020 Census [16]), 24.3% (28/115) as African American (12% nationally), 7.8% (9/115) as Hispanic (19% nationally), 2.6% (3/115) Asian as (6% nationally), and 0.9% (1/115) were categorized as Other (6% nationally). The demographics of the at-risk population reflect the insured population in a private practice setting [16].

Around 52.2% (60/115) of patients had a previous history of ulcers, which reflects the clinical practice setting where not every patient at high risk of ulcerations has necessarily had a foot ulcer before. There are other risk factors, such as neuropathy, peripheral arterial disease, or deformities. A similar cohort was enrolled in one of the largest studies on temperature monitoring to date [8].

Outcomes

Table 3 shows the unadjusted rates of health care use before and during the prevention program. The hospitalization rate was 63% (unadjusted rates before is 14, which is 63% lower than 39, the result during the prevention program) lower, amputations were 82% (unadjusted rates before is 3, which is 82% lower than 17, the result during the prevention program) lower, and the number of ulcers was 65% (unadjusted rates before is 33, which is 65% lower than 94, the result during the prevention program) lower.

The severity of the ulcers also decreased. Around 29% (29/99) of ulcers became infected, in line with the average of 20% [3]. During the program, 6% (2/35) of ulcers became infected.

Table 3. Unadjusted results before and during enrollment in program.

Outcome	Unadjusted results	
	Before	During
Total follow-up years	138.9	133.9
Average follow-up months per patient, mean (SD)	14.5 (9.5)	14 (7.6)
Average follow-up months per patient, median (range)	15.2 (2-32)	15.1 (2-36)
Hospitalizations, n		
Total	39	14
Per patient-year	0.28	0.10
Outpatient office visits, n		
Total	1144	825
Per patient-year	8.2	6.2
Amputations, n		
Total	17	3
Per patient-year	0.12	0.02
Foot ulcers, n		
Total	94	33
Per patient-year	0.72	0.25
Per patient	0.86	0.30
Wound severity (before: n=99; during: n=35), n (%)		
1A	49 (50)	26 (74)
1B	15 (15)	1 (3)
1C	7 (7)	0 (0
1D	1 (1	0 (0)
2A	13 (13)	2 (6)
2B	2 (2)	1 (3)
2C	0 (0)	0 (0)
2D	1 (1)	0 (0)
3A	1 (1)	4 (11)
3B	8 (8)	0 (0)
3C	0 (0)	0 (0)
3D	2 (2)	1 (3)
Moderate and severe ulcers, n		
Total	50	9
Per patient-year	0.36	0.07
Per patient	0.43	0.08

Table 4 shows the main outcomes and metrics of health care utilization adjusted for trends. We observed a significantly lower rate of foot ulceration (relative risk reduction [RRR] 0.68; 95% CI 0.52-0.79; number needed to treat [NNT] 5.0; *P*<.001), less moderate to severe ulcers (RRR 0.86; 95% CI 0.70-0.93; NNT 15.3; *P*<.001), and less amputations (RRR 0.83; 95% CI 0.39-0.95; NNT 41.7; *P*<.006). We also found a decrease in hospitalizations (RRR 0.63; 95% CI 0.33-0.80; NNT 5.7; *P*<.002), and a decrease in outpatient podiatry office visits during the program (RRR 0.31; 95% CI 0.24-0.37; NNT 0.46; *P*<.001).

Table 4. Adjusted incidence and resource use rates before and during enrollment.

Outcome	Number needed to treat	Absolute risk reduction	Relative risk reduction (95% CI)	*P* value
All foot ulcers	5.0	0.200	0.683 (0.52-0.79)	<.001
Moderate to severe ulcers	16.2	0.062	0.856 (0.70-0.93)	<.001
Outpatient podiatry visits	0.45	2.23	0.308 (0.24-0,37)	<.001
Hospitalizations	5.7	0.180	0.628 (0.33-0.80)	<.002
Amputations	41.7	0.024	0.828 (0.39-0.95)	<.006

The RRR was greater for all ulcers, hospitalization, and amputations than those observed in a previous observational study, but the absolute risk reductions were lower in this study due to lower baseline rates [15].

Discussion

Principal Findings

Overall, during the observation period, patients who were enrolled in the continuous temperature monitoring program at the contracted clinical sites had substantially less severe foot ulcers, fewer overall occurrences of amputations, decreased outpatient visits to their podiatrists due to early capture of potential foot wounds, and decreased rate of hospitalization. These encouraging findings suggested that the temperature monitoring socks and the prevention program were effective in preventing neuropathic foot ulcer development and recurrence as well as nontraumatic foot amputations.

Efficacy of Continuous Remote Temperature Monitoring in the Real World

Nontraumatic amputation prevention has been a challenging task as providers often cannot capture the critical period before an ulcer has developed. The development of a neuropathic foot ulcer creates an opportunity for infection and subsequent amputations. Remote monitoring technology in foot ulcer prevention aims to help patients and providers capture signs of ulcer development. The success that was observed in this real-world study could be due to the early detection of the temperature monitoring socks followed by the foot ulcer prevention program. Our cohort exhibited a similar rate of foot ulcer prevention (absolute risk reduction 0.2, RRR 0.683, 95% CI 0.52-0.79) compared with a recent systematic review and meta-analysis focusing on temperature monitoring via thermometry (RRR 0.53, 95% CI 0.29-0.96) [17]. The program is substantially effective in preventing neuropathic foot ulcers (NNT 5.0; *P*<.001) and hospitalizations (NNT 5.7; *P*<.001), but it may be relatively less effective in preventing all types of lower extremity amputations (ie, minor and major; NNT 41.7; *P*<.006). Additionally, previously reported data suggested a relatively high rate of adherence to the program as 85% of the active patients had an average greater than 5 days per week during the program [12]. This finding may be due to different factors, including attentive nursing staff that monitored temperature changes and alerts and the ease of use of continuous temperature monitoring socks which automatically transmitted the data. From this real-world observation, the use of socks may increase compliance as opposed to other forms of remote monitoring.

Real-World Clinical Practice and Controlled Clinical Trials

Prior studies that investigated the effectiveness of temperature monitoring were conducted in a controlled environment. Specific follow-up protocol, including outreach from clinical staff, was part of the study design. This study followed patients in real-time and real-world settings. As prior trials have established the effectiveness of temperature monitoring in the prevention of foot ulcers and amputations, our observation further validated the benefits of temperature monitoring even where patients were not specifically enrolled in a trial. This finding may be due to the enrollment of the foot ulcer prevention program in addition to the continuous temperature monitoring socks. By actively checking in with patients whose continuous temperature monitoring socks sent alerts to trained nursing staff, capturing the critical period of foot ulcer development was made possible. This study demonstrated the importance of the monitoring process as well as the continuous temperature monitoring socks.

Real-World Clinical Scenarios and Realistic Patient Demographics

Given the presented results were based on real-world observation as opposed to a blinded randomized controlled trial, the results reflected the true use, real-world clinical scenarios, and realistic patient demographics. [18] A blinded randomized controlled trial also may not be the most ideal study design for this study as the temperature monitoring socks along with the foot ulcer prevention program would not be possible to blind either study participants or clinical providers. The observed cohort may also closely reflect podiatric practices where many high-risk patients without or with a history of foot ulcers would receive the care. This may explain a lower rate of prior foot ulcers among the cohort when compared with other controlled trials. To our knowledge, this study was the first real-world observation that investigated the effectiveness of remote temperature monitoring socks before and after their use.

Limitations

There are a few limitations to this study. While our real-world results reflect the population demographic and clinical scenario, the observed decreased rate of recurrence and rate of amputation after patients enrolled in the continuous remote monitoring prevention program may be explained by the care from the temperature monitoring socks, the nursing team, and the involvement of the provider. Additionally, the patient population is dictated by the contracted clinical practices and patient enrollment is at the providers' discretion. The provider's decision to enroll patients may be limited by insurance coverage which potentially biases the results toward those with insurance

coverage and adequate access to care. Nonetheless, such a real-world setting allows us to observe the real effect of the continuous remote temperature monitoring socks and the implanted care process. Another limitation is the challenge of adjusting for the disease process and other potential confounders due to the before-and-after study design. We also observed a possibly confounding factor as providers enrolled patients with other risk factors and forms of neuropathy, such as idiopathic, alcohol-induced, and chemotherapy-induced neuropathy. Given the continuous remote temperature monitoring socks are visible to patients, blinding and randomization, although effective to mitigate bias, may not be suitable in this case. Furthermore, patients opted to enroll in an insurance-covered service to prevent foot ulcers. It will be unethical to randomize patients especially when clinical providers recommend patients to enroll and subscribe for the continuous remote monitoring prevention program. Potentially, a head-to-head study in the future comparing the patients who opt out of the prevention program to those who are in the program may delineate the impacts of the program. We analyzed 115 patients from 15 sites in a single state in the United States. Although this study can benefit from a larger sample size to improve generalizability, the sample size is in line with similar studies [7-9,15]. A follow-up study with patients from multiple states is in progress to capture a larger population with more diverse demographics, health systems, geography, and cultural factors. The protocol did not allow access to medical records for the period after a patient was no longer enrolled in the monitoring program. As a result, this study provides valuable insights into the outcomes of patients during the remote monitoring program, it does not capture the outcomes after the program for those patients who discontinued the program but remained under clinical care from their provider. We will consider this for future studies or analyses.

Conclusions

We observed substantially less ulcers, less moderate to severe ulcers, and less amputations during the foot ulcer prevention program using continuous temperature monitoring socks and a decrease in outpatient podiatry visits. Our findings suggested that a real-world continuous remote temperature monitoring program was an effective strategy to prevent neuropathic foot ulcer development and subsequent amputation among high-risk patients with diabetes. Future studies may further investigate the potential cost savings in such a strategy.

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Conflicts of Interest

RM, HJS, and JF are employees of Siren Care Inc. AMR is a clinical advisor to and shareholder of Siren Care Inc. All other authors report no real or potential conflicts of interest.

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Abbreviations

DFU: diabetic foot ulcer
NNT: number needed to treat
RPM: remote patient monitoring
RRR: relative risk reduction

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