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Original Papers

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

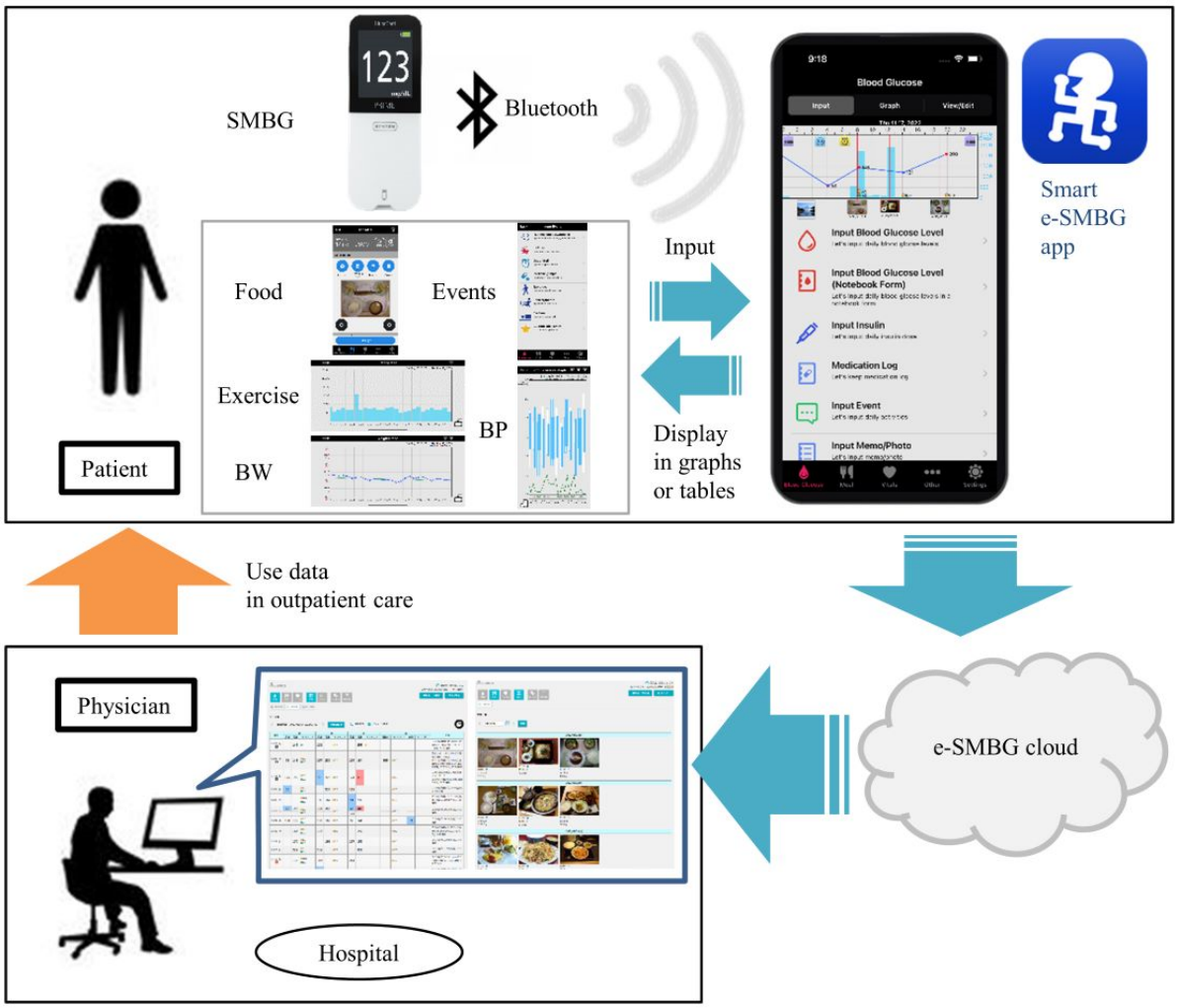
The study protocol was approved by the ethics committee of Nagoya University Graduate School of Medicine (2019-0142) and performed in accordance with the ethical principles of the Declaration of Helsinki. All enrolled patients provided written consent to participate after they were informed of the study 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.

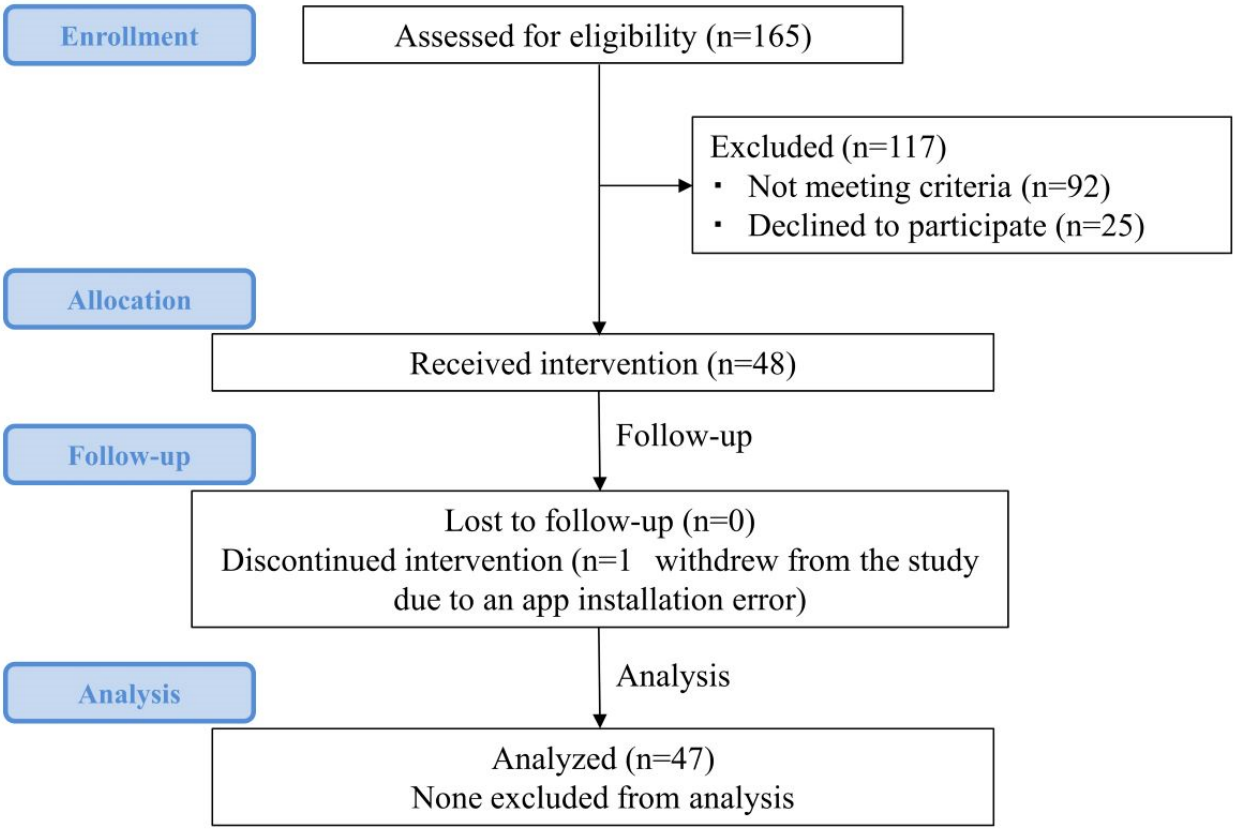


Table 1 shows the baseline characteristics of the patients. Overall, 34 patients were male and 14 were female, with a mean age of 59.8 (SD 11.9) years and a mean BMI of 25.2 (SD 4.8) kg/m^2. The mean HbA_{1c} was 7.7% (SD 0.6%), and the mean duration of diabetes was 18.2 (SD 10.8) years. Regarding the 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.

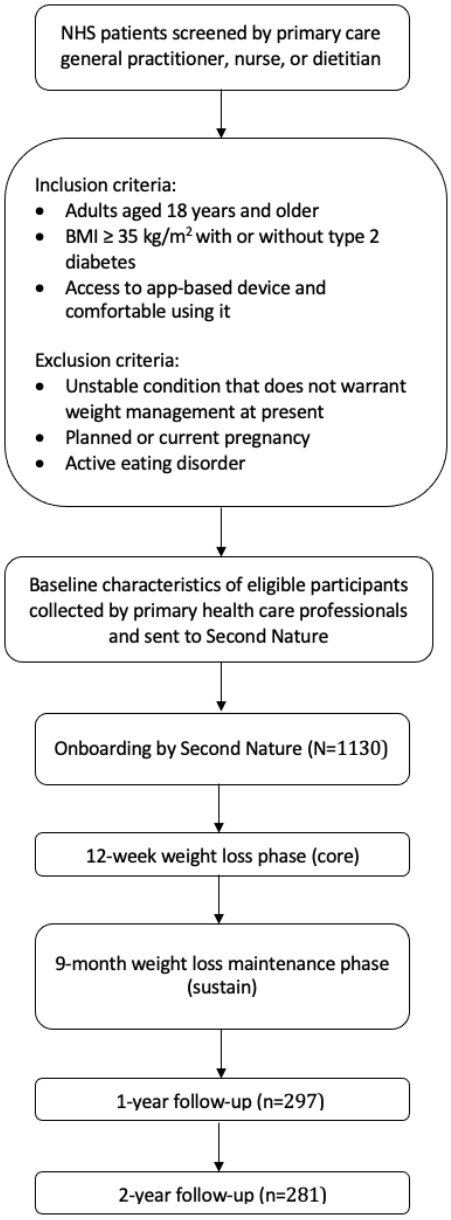
Participants

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.

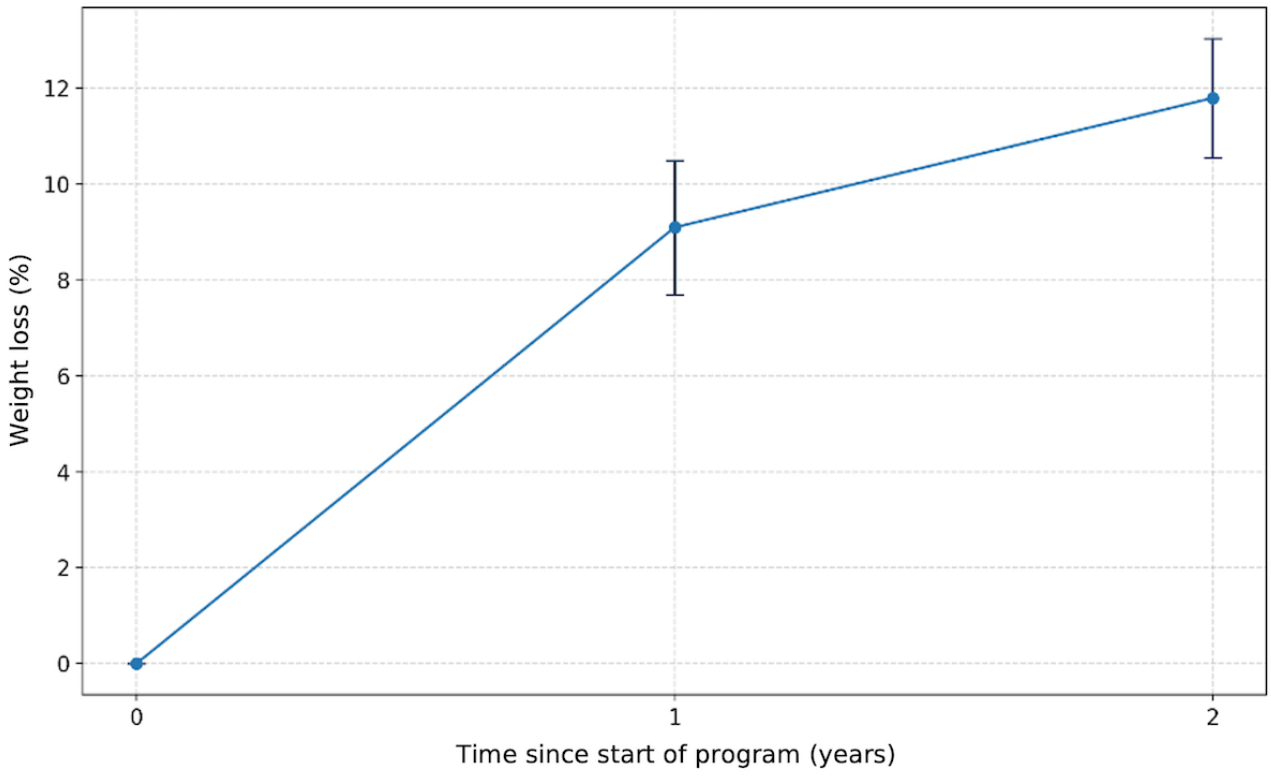
	At 1-year follow-up	At 2-year follow-up
All with weight recorded, n (%)	297 (26.2)	281 (24.9)
Weight loss (kg), mean (SD)	10.7 (12.3)[a]	13.8 (14.2)[a]
Weight loss from baseline (%), mean (SD)	9.1 (9.6)[a]	11.8 (10.9)[a]
≥5% Weight loss from baseline, n (%)	191 (17)	204 (18.1)
≥10% Weight loss from baseline, 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.

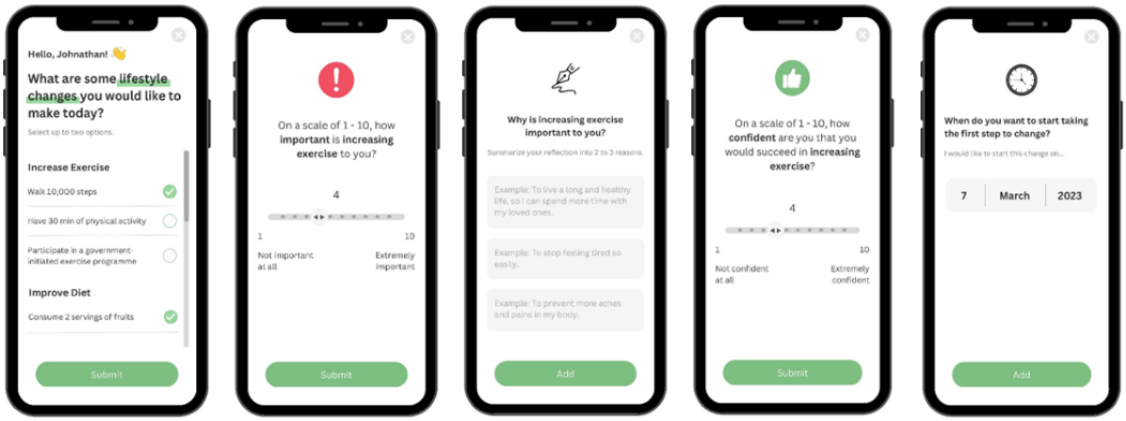
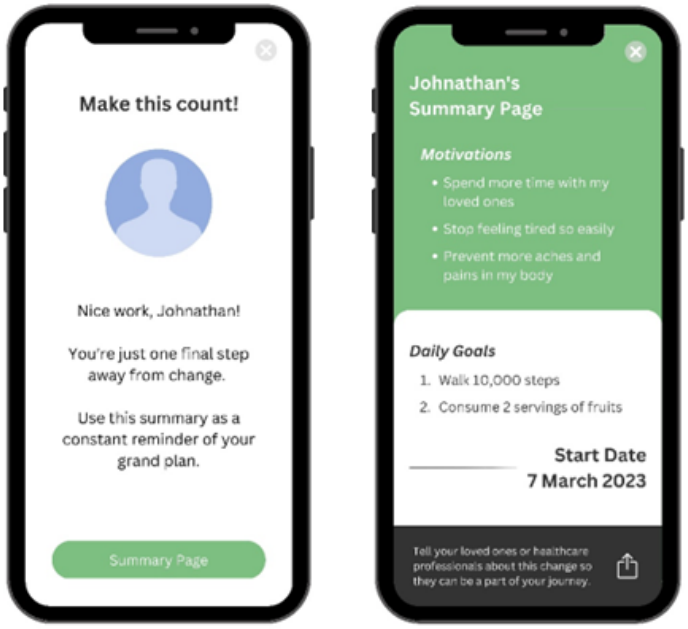


Figure 2. Summary of motivations and goals. The summary page serves to reinforce the patient's autonomy and intrinsic motivation. It can be shared with a human health coach remotely to improve a sense of relatedness.



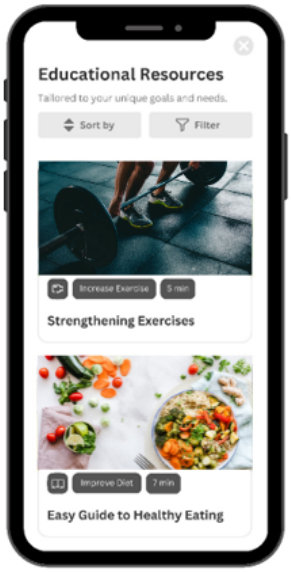
The goal setting will help me achieve what I want to achieve, by giving me better vision and future target, so once I have achieved that target, I can move on to the next target. As I move on, I achieve certain milestones, then from there, it sort of motivates me to continue. [Participant #16, male]

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.



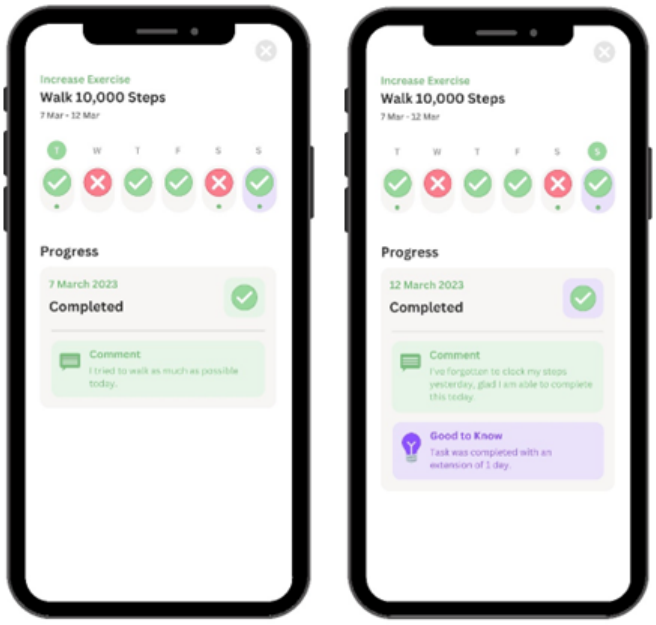
I would like to see more live ones. I don't like to read a lot of words or look at cartoons. Sometimes, those things are really misleading, and you don't understand what they are talking about, like some exercises I saw in graphic forms. [Participant #04, female]

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.



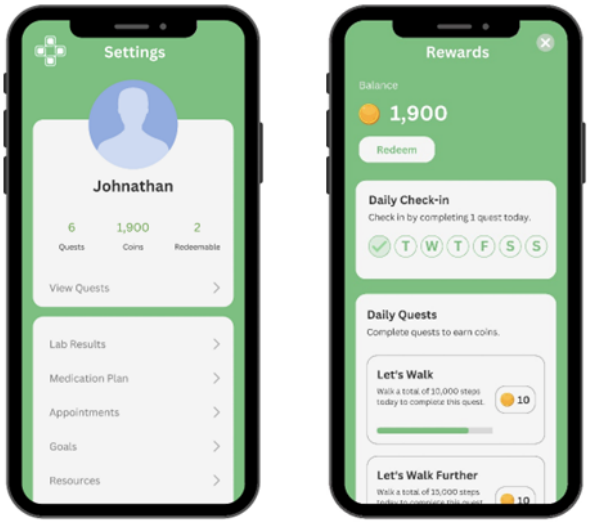
Reminders will help pay attention to your diabetes management, because you might forget and go back to old ways of eating sweet things. But if someone tells me that you must cut your sugar intake, then maybe it will remind me that I shouldn't be taking so much sugar. It's like having someone to remind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

Acknowledgments

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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

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.

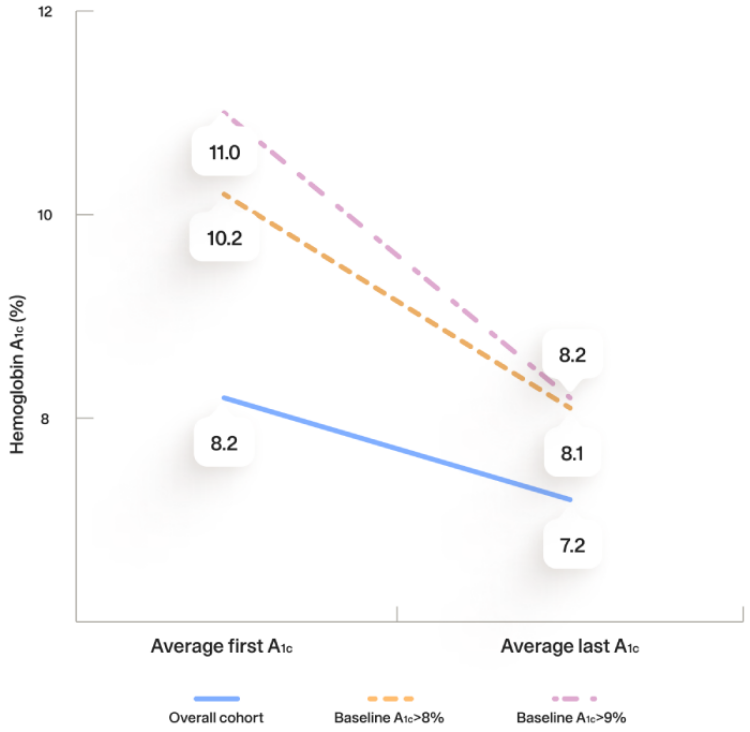
[b]HbA_{1c}: hemoglobin A_{1c}.

[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.

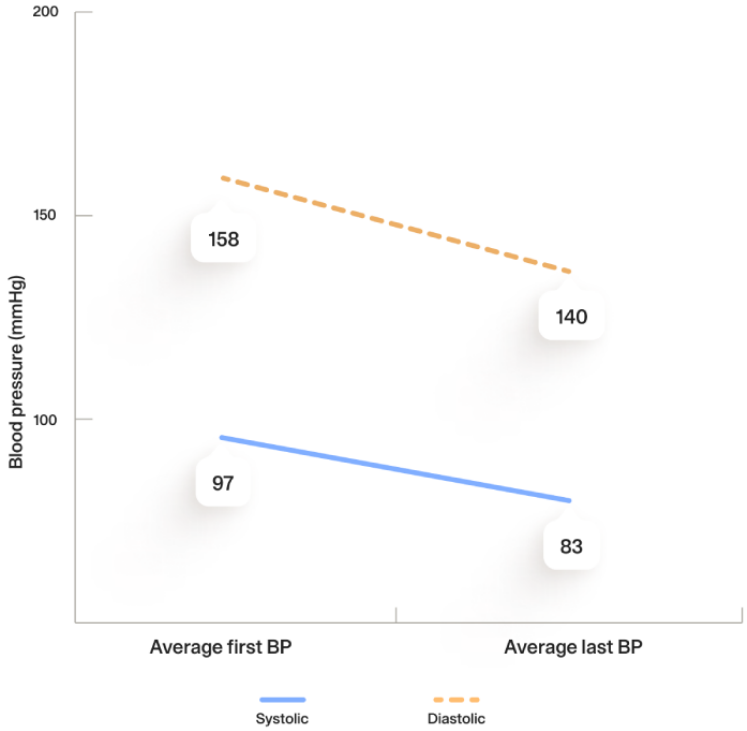


The results were consistent among members identifying as a race or ethnicity other than White. The average HbA_{1c} among participants who identified as a race or ethnicity other than White decreased from 8.6% to 7.4% (n=39; –1.2; *P*=.001). Further examination of subgroups confirms HbA_{1c} lowering 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

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

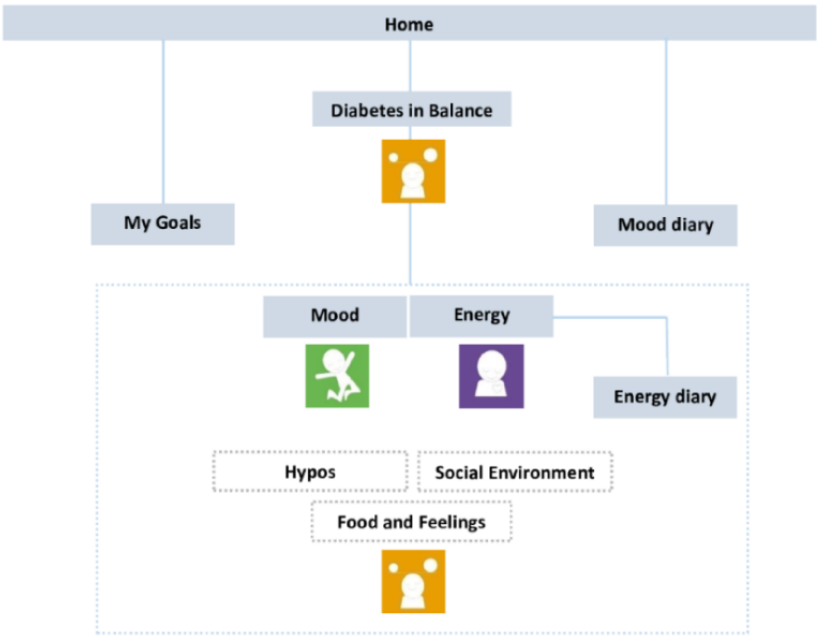
MyDiaMate

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

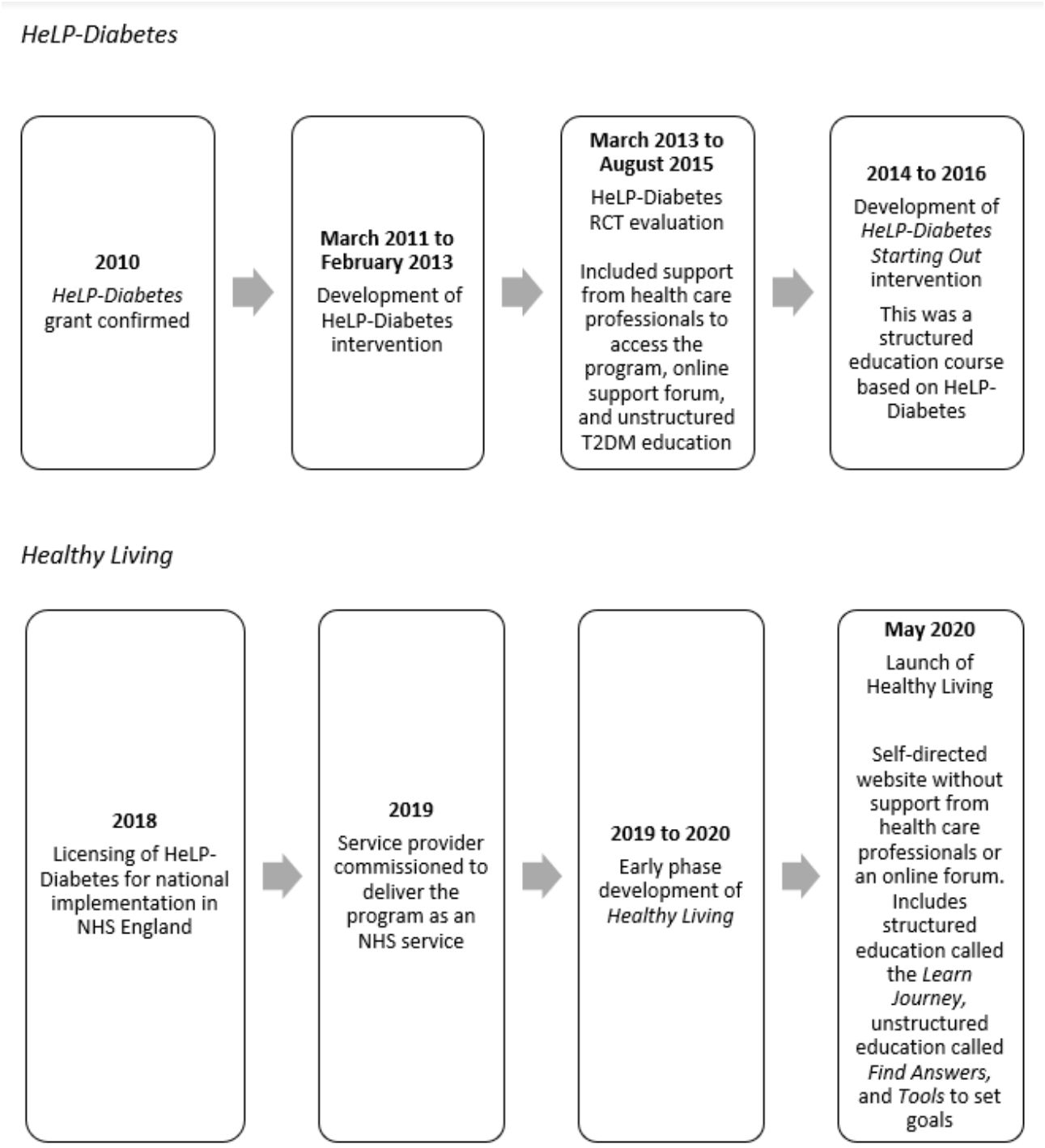
Background

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

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

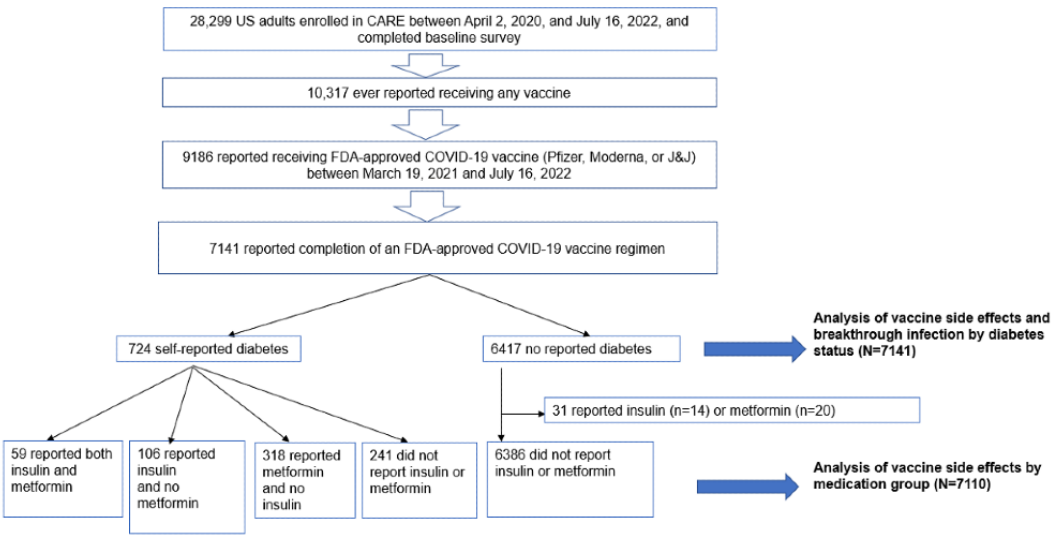
This study was reviewed and approved by an external institutional review board (Advarra; Pro00043030) and registered with ClinicalTrials.gov (NCT04368065) in the spirit of full disclosure, although this was not a clinical trial. This study fully complies with the Declaration of Helsinki.

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.

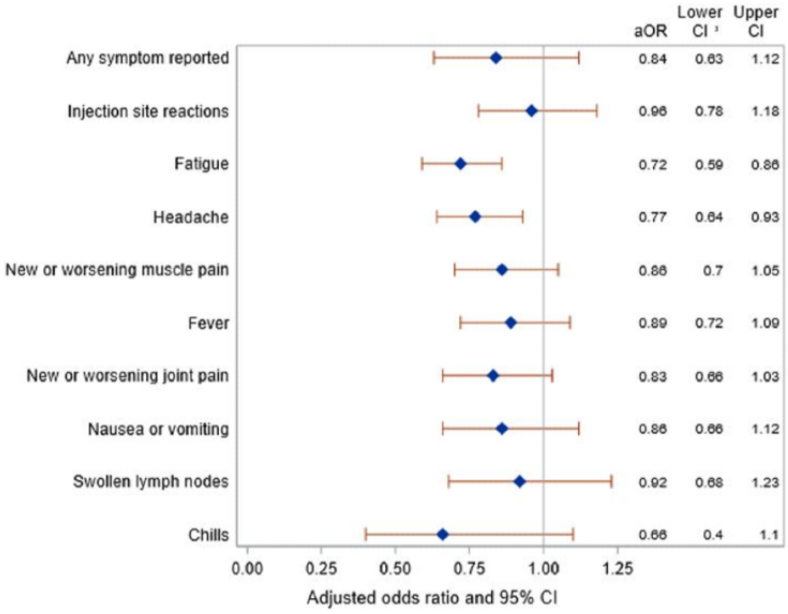


Figure 3. COVID-19 vaccine side effects comparing self-reported diabetes medication use among diabetes to those without diabetes (n=7110). Note that 31 people were excluded here who did not report having diabetes but who did report using insulin or metformin for treatment of another medication condition.

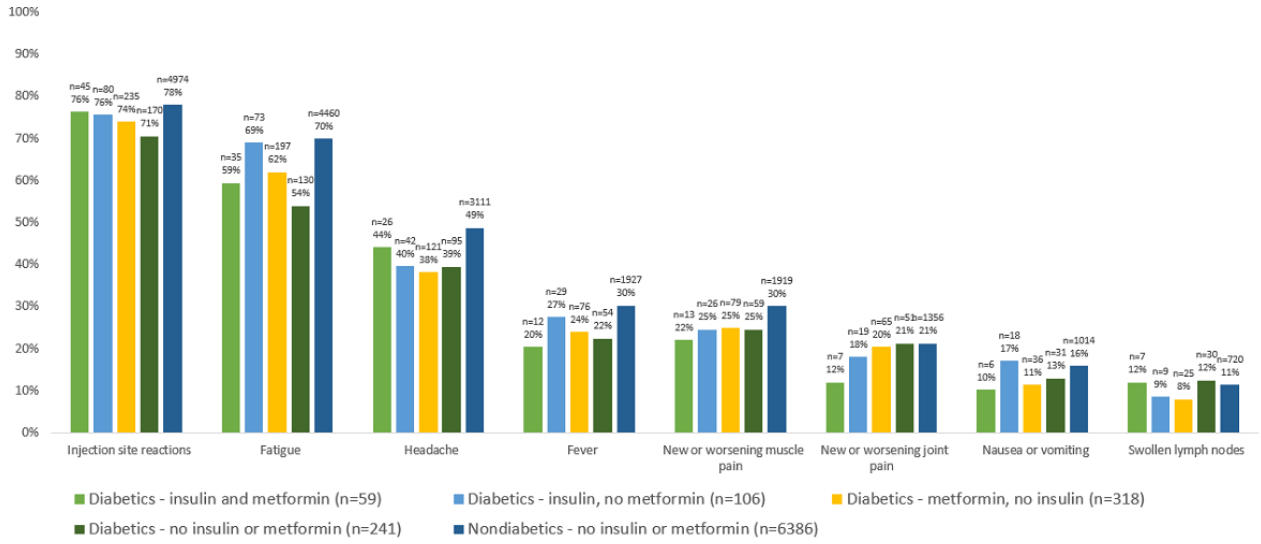
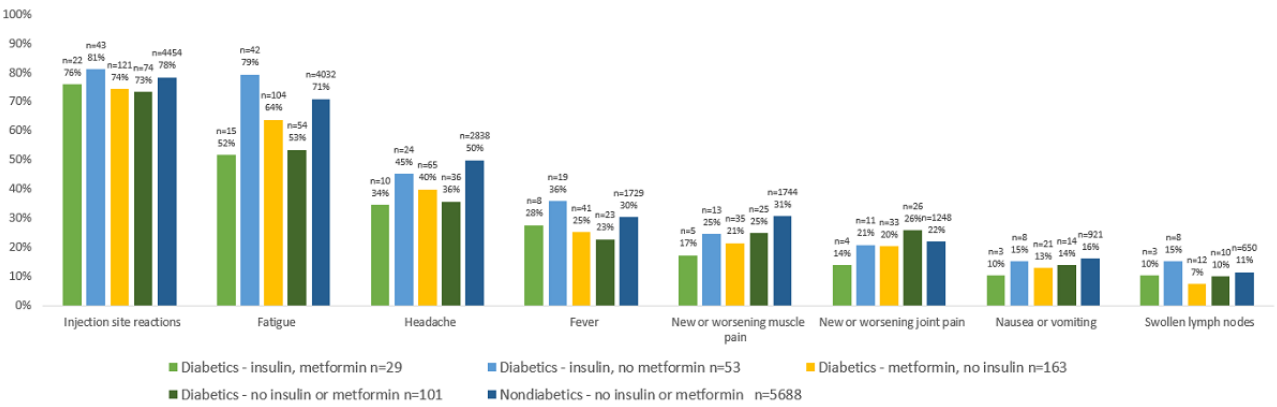


Figure 4. COVID-19 vaccine side effects by diabetes and diabetes medications confirmed through linked pharmacy claims (n=5034).



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.

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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

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

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 $n \in 1, \ldots, N$ 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, $|a^t|_1 \leq B \; \forall t \in 1, \ldots, H$.

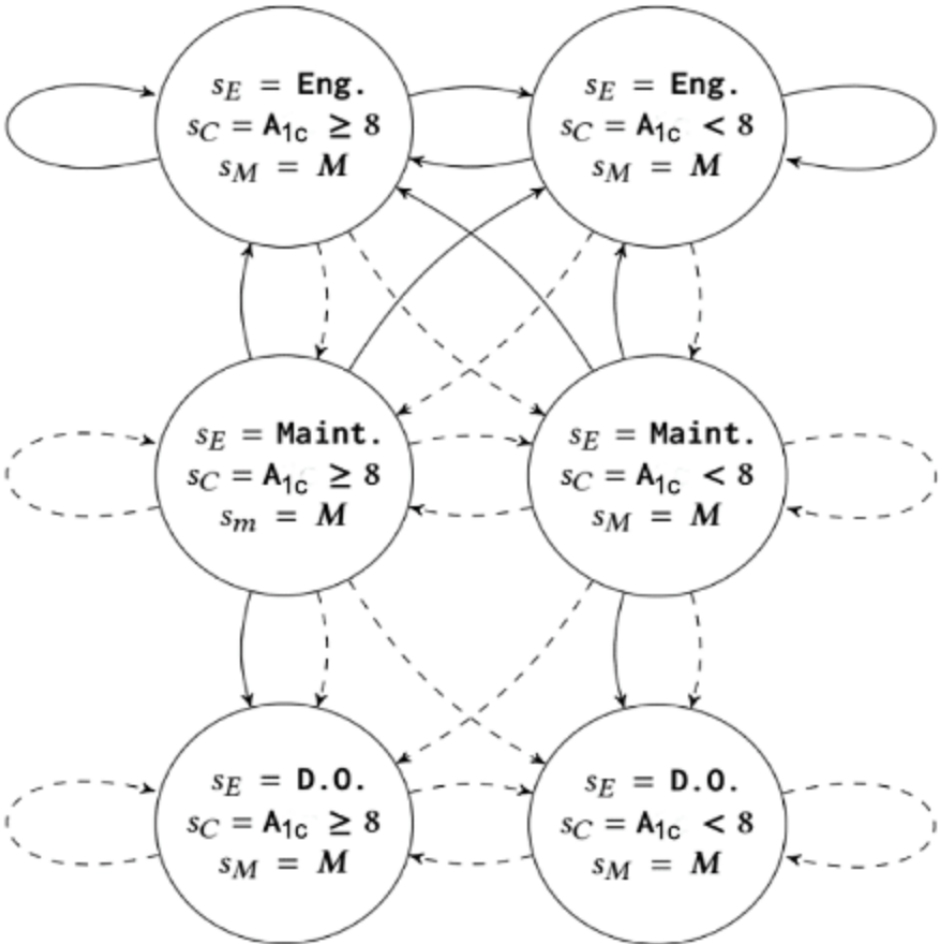
To capture the joint dynamics of engagement and health in digital health programs, we included a dimension for each factor in our state space. For the T2D domain, we also include a dimension for memory, since intervention effects have a delayed impact on clinical outcomes. We represent this 3D state 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.

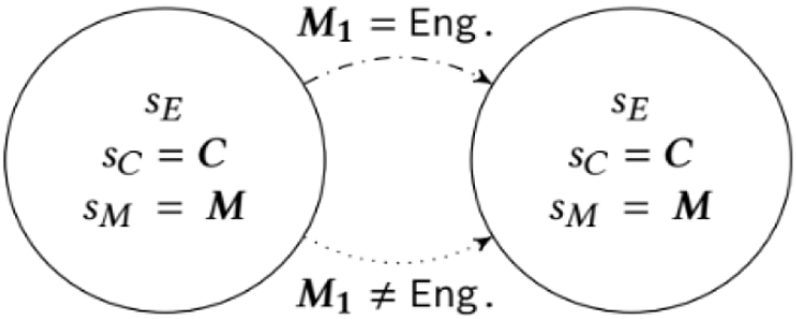


Table 1. The table shows the evolution of clinical state P (s′C = HbA_{1c} < 8|r, c) where r represents the memory state s_{M1} and c represents the current clinical state sC.

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
  $L(\boldsymbol{s}_g, b_g) = \text{INNEROPT}(g, b_g, \boldsymbol{s}_g, h) / |M^{-1}(g)|$
for $b \in [1, ..., B]$ **do**
  $g^\star = \text{ARGMIN}(L(\boldsymbol{s}_g, b_g))$
  $b_{g^\star} \mathrel{+}= 1$
  $L(\boldsymbol{s}_{g^\star}, b_{g^\star}) = \text{INNEROPT}(g^\star, b_{g^\star}, \boldsymbol{s}_{g^\star}, h) / |M^{-1}(g)|$
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
  UPSAMPLE(g, θ) // Resample arms, until g has size θ
  $L_0(\boldsymbol{s}_g, b_g) = \text{INNEROPT}(g, b_g, \boldsymbol{s}_g, h)$
  $L_1(\boldsymbol{s}_g, b_g) = \text{INNEROPT}(g, b_g + 1, \boldsymbol{s}_g, h)$
  $L_\Delta(\boldsymbol{s}_g, b_g) = \log(L_1(\boldsymbol{s}_g, b_g)) - \log(L_0(\boldsymbol{s}_g, b_g))$
for $b \in [1, ..., B]$ **do**
  $g^\star = \text{ARGMAX}(L_\Delta(\boldsymbol{s}_g, b_g))$
  $b_{g^\star} \mathrel{+}= 1$
  $L_0(\boldsymbol{s}_{g^\star}, b_{g^\star}) = L_1(\boldsymbol{s}_{g^\star}, b_{g^\star})$
  $L_1(\boldsymbol{s}_{g^\star}, b_{g^\star}) = \text{INNEROPT}(g^\star, b_{g^\star} + 1, \boldsymbol{s}_{g^\star}, h)$
  $L_\Delta(\boldsymbol{s}_{g^\star}, b_{g^\star}) = \log(L_1(\boldsymbol{s}_{g^\star}, b_{g^\star})) - \log(L_0(\boldsymbol{s}_{g^\star}, b_{g^\star}))$
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

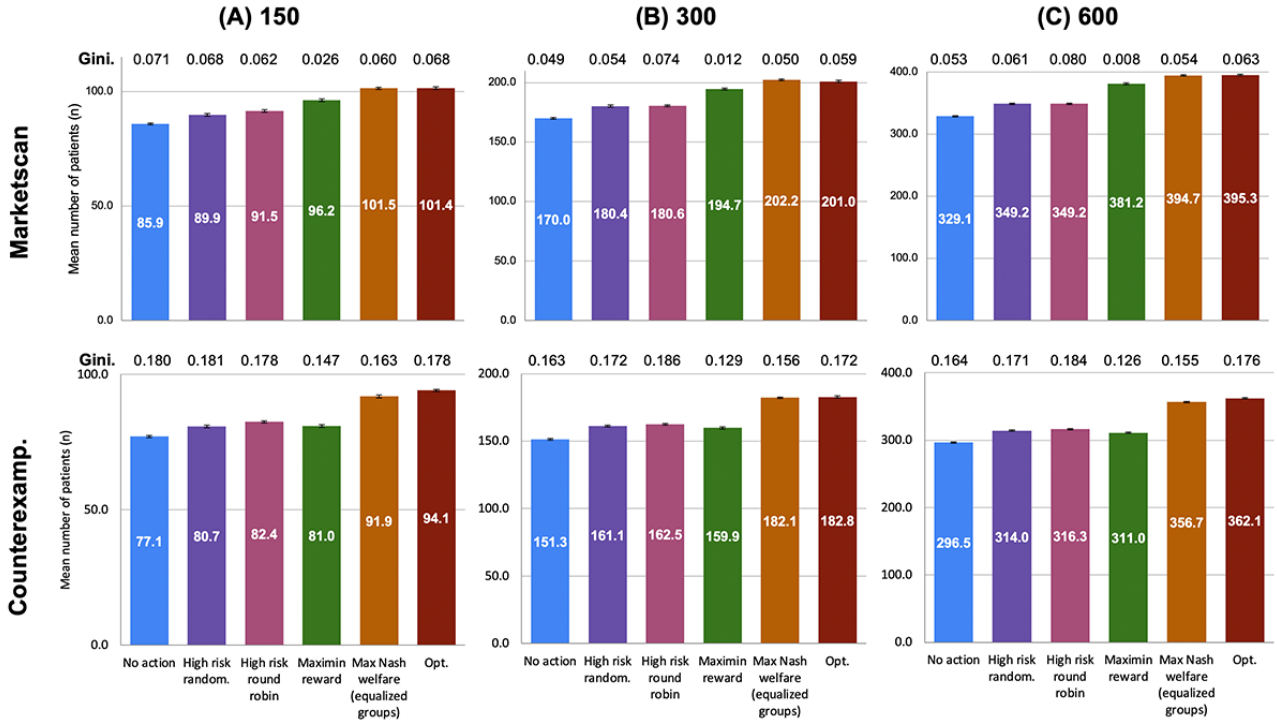
We evaluated our modeling and algorithmic contributions in simulation environments with data derived from publicly available sources on diabetes progression and health program engagement.

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

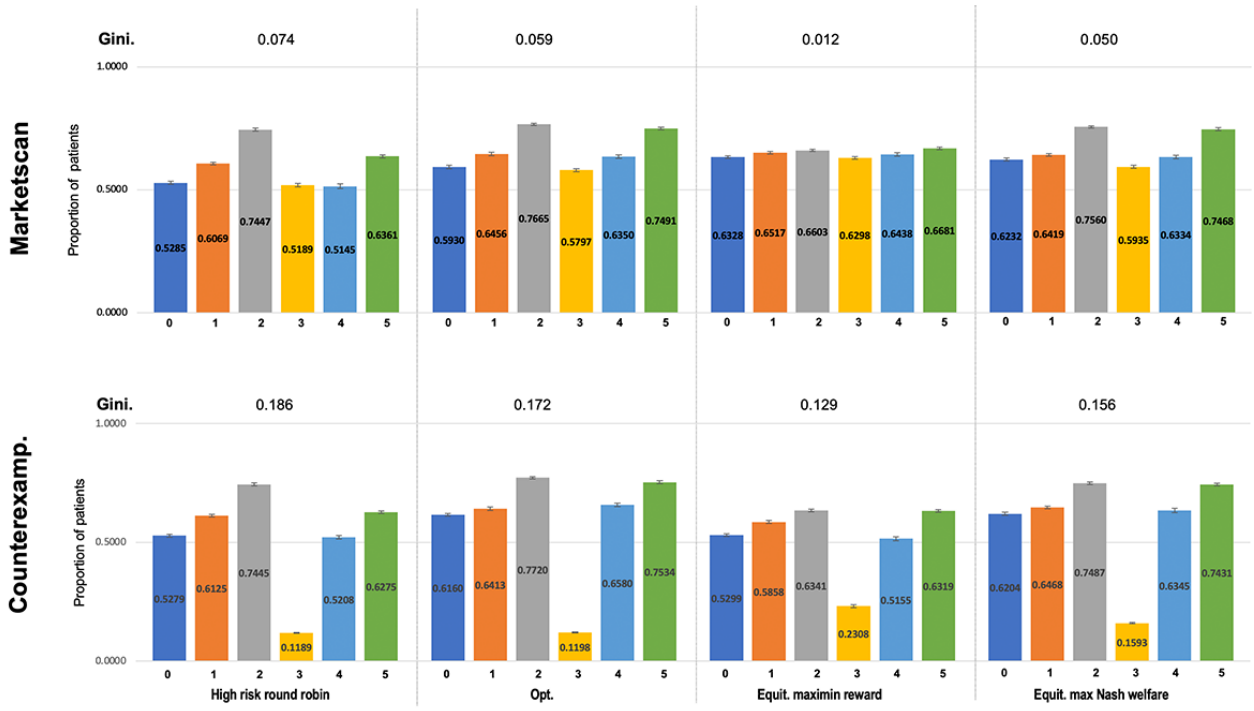
After 12 months, the Opt, MMR, and MNW-EG policies produced better individual clinical outcomes (measured by number of patients reaching healthy HbA_{1c} levels) and engagement than the baselines (Figure 4). The baselines increased the number of users with healthy HbA_{1c} after 12 months by roughly 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.

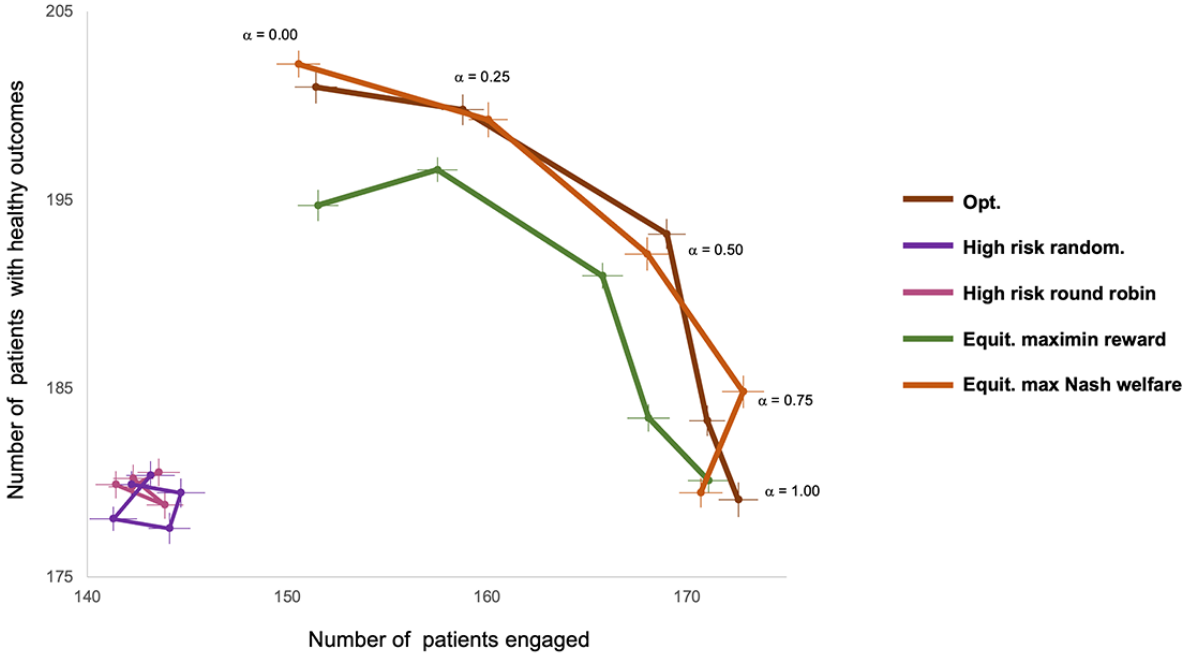
Figure 5. Individual clinical outcomes (proportion of patients reaching healthy HbA_{1c} level) across demographic subgroups. Bars show average proportions by group (0-5) and policy. Gini coefficient is displayed atop each policy. N = 300, B = 30. Top: MarketScan. Bottom: MMR-Counterexample. Counterexamp: 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.

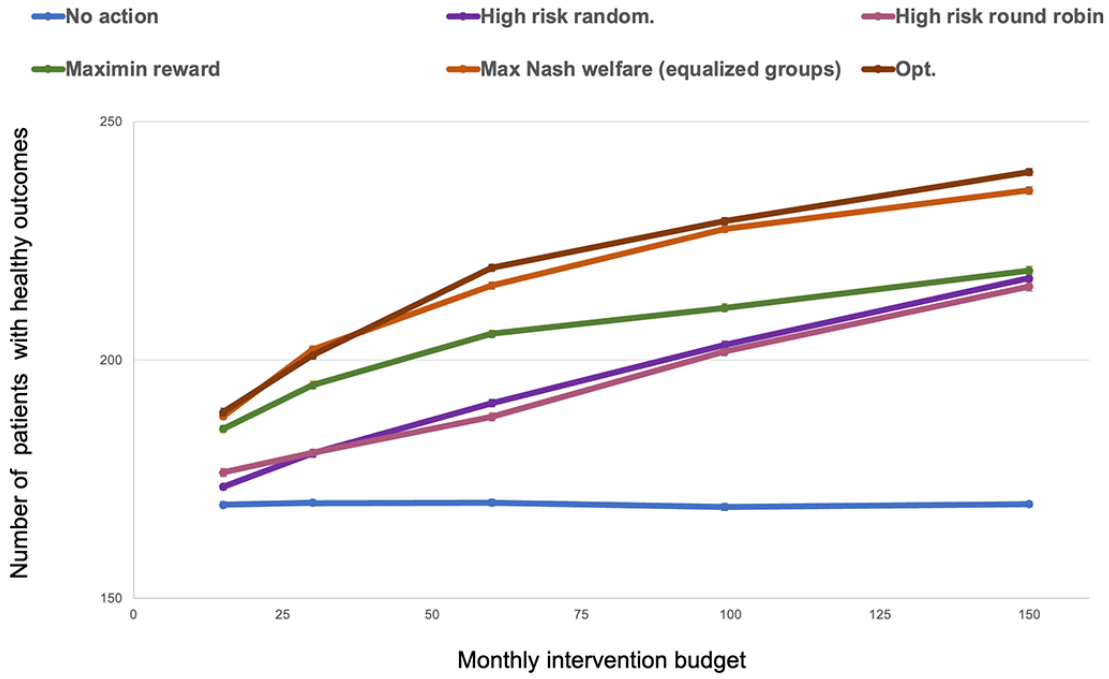
Figure 6. Pareto curve for each policy as α varies from 0 to 1, with number of engaged patients after 12 months (ie, in E or M states) on the x-axis and number of patients with healthy clinical outcomes (HbA_{1c} < 8) on the y-axis. The results are shown for the MarketScan data set with N = 300 and B = 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.

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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

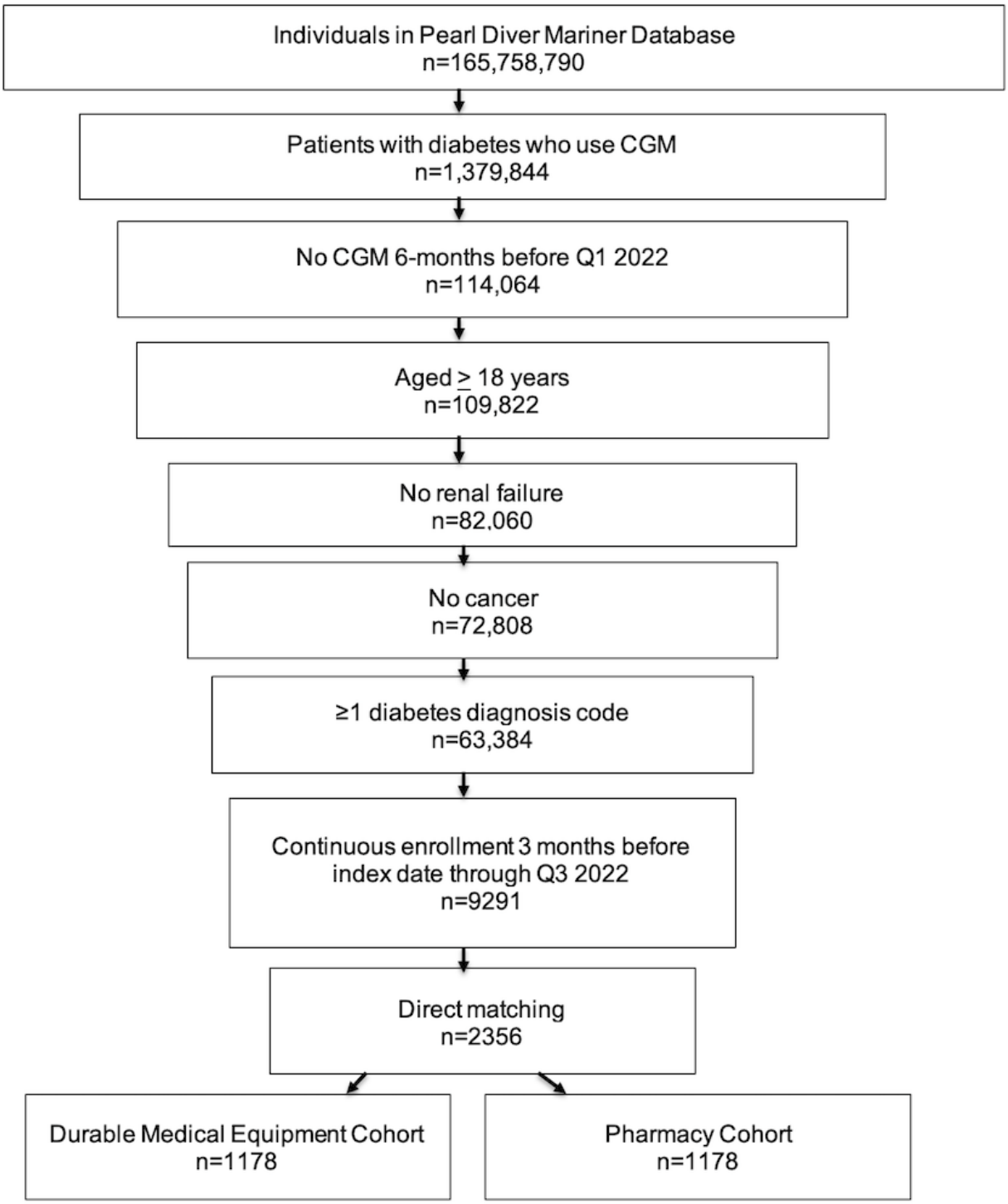
Data were de-identified and comply with the patient requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996; therefore, no review by an institutional review board was required per Title 45 of CFR, Part 46.101(b)(4) [14]. The authors obtained permission to use the data 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

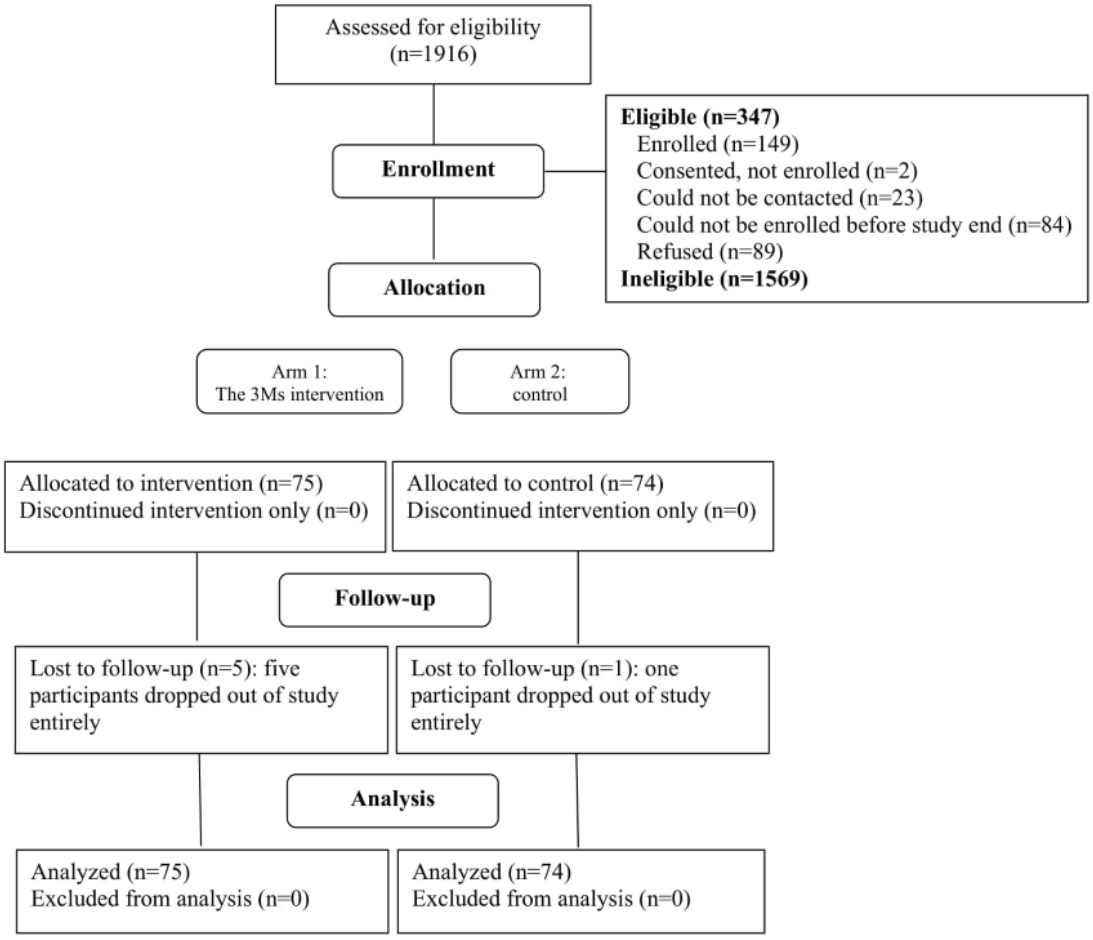
Adolescent participants and their primary caregivers were recruited from 3 pediatric diabetes clinics located in the greater metropolitan Detroit area and 4 in the Chicago area. The study took place from 2017 to 2021. Eligible adolescents had to be aged between 10 years, 0 months, and 14 years, 11 months, 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

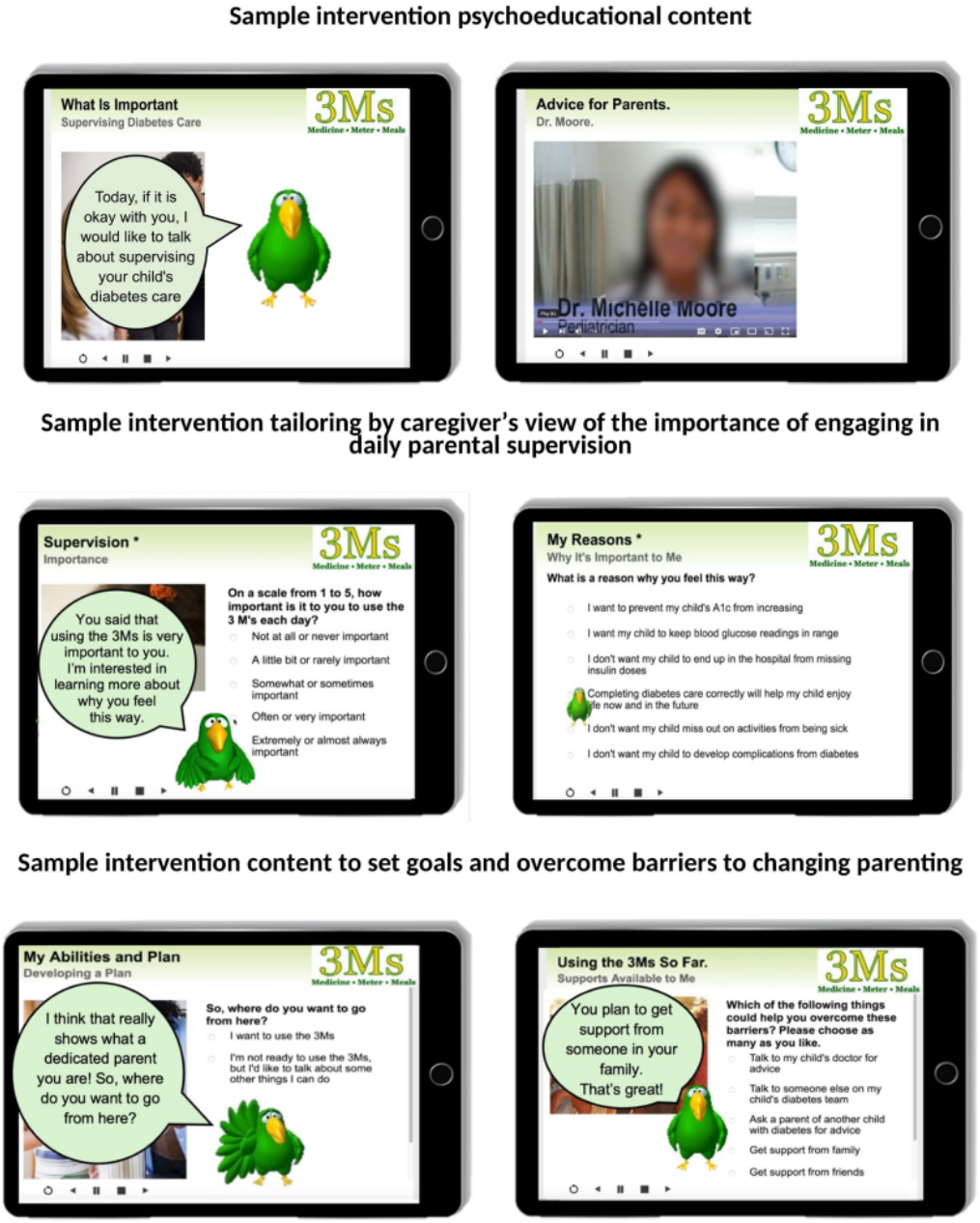
follow-up data collections completed after this date, participants either had HbA_{1c} test kits dropped at their home or were mailed the test kit to complete and return. In both cases, study staff watched the adolescents complete the test during a videoconference call to ensure reliable collection of 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.

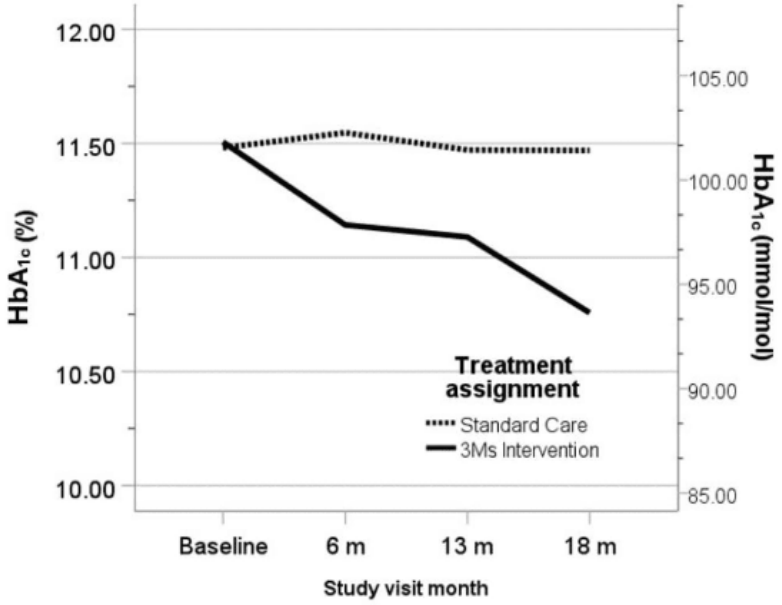
Results

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.

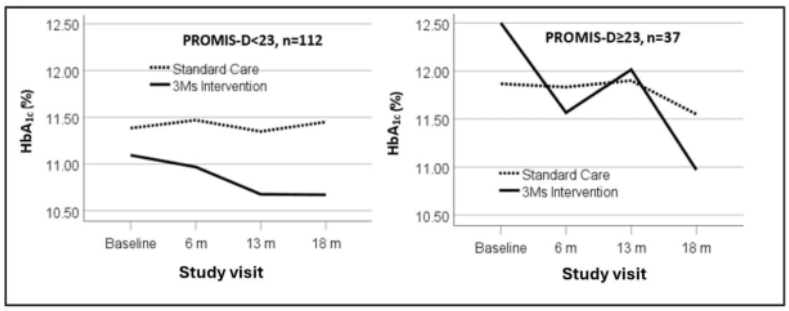
Table 2. Changes in hemoglobin A_{1c} (HbA_{1c}) levels at 6, 13, and 18 months after baseline. At baseline, N=149, with 74 in the control condition and 75 in the intervention group. Mean estimates and statistical tests used the linear mixed effect model with covariates held at their mean level with 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.

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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

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.

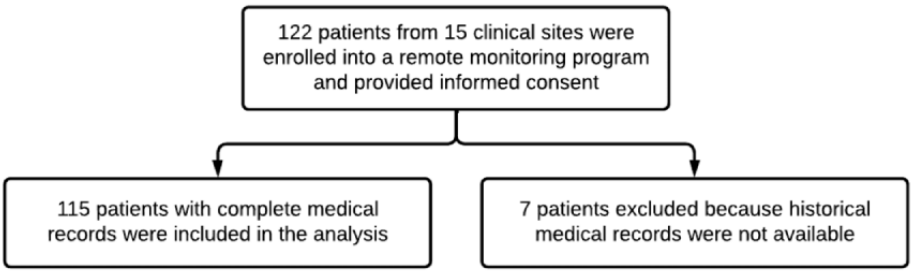

Table 1. Participant disposition.

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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