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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 (HbA₁c) levels.

Results: Although HbA₁c 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 HbA₁c 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://jRCTs042190057

https://diabetes.jmir.org/2024/1/e48019
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-arm 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 (HbA1c) 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 HbA1c 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 HbA1c 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/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/m². The mean HbA₁c 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).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>59.8 (11.9)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>34 (71)</td>
</tr>
<tr>
<td>Female</td>
<td>14 (29)</td>
</tr>
<tr>
<td>BMI (kg/m²), mean (SD)</td>
<td>25.2 (4.8)</td>
</tr>
<tr>
<td>HbA₁c a, mean (SD)</td>
<td>7.7 (0.6)</td>
</tr>
<tr>
<td>Duration of diabetes (years), mean (SD)</td>
<td>18.2 (10.8)</td>
</tr>
<tr>
<td>Type of diabetes, n (%)</td>
<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Type 2</td>
<td>40 (83)</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Steroid</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Type of disease, n (%)</td>
<td></td>
</tr>
<tr>
<td>Retinopathy</td>
<td>22 (46)</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>26 (54)</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>19 (40)</td>
</tr>
<tr>
<td>Cardiovascular disease</td>
<td>6 (13)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Insulin treatment, n (%)</td>
<td></td>
</tr>
<tr>
<td>Use of insulin</td>
<td>31 (65)</td>
</tr>
<tr>
<td>Use of GLP-1RA b</td>
<td>7 (15)</td>
</tr>
<tr>
<td>Use of both insulin and GLP-1RA</td>
<td>10 (21)</td>
</tr>
<tr>
<td>Insulin dose (n=41; units per day), mean (SD)</td>
<td>32.8 (22.4)</td>
</tr>
<tr>
<td>Total (n=47)</td>
<td></td>
</tr>
<tr>
<td>MDI d</td>
<td>2.3 (0.9)</td>
</tr>
<tr>
<td>Others (n=12)</td>
<td>2.4 (0.9)</td>
</tr>
</tbody>
</table>

aHbA₁c: glycated hemoglobin.
bGLP1RA: glucagon-like peptide 1 receptor agonist.
cSMBG: self-monitoring of blood glucose.
dMDI: multiple daily injection.

Table 2 shows the changes in glycemic outcomes and questionnaire scores in patients. Compared to the baseline values, HbA₁c 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 HbA₁c 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).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Change at 12 weeks (95% CI)</th>
<th>P value</th>
<th>Change at 24 weeks (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (a) (%)</td>
<td>−0.13 (−0.31 to 0.05)</td>
<td>.15</td>
<td>−0.06 (−0.24 to 0.13)</td>
<td>.53</td>
</tr>
<tr>
<td>Insulin dose (units per day)</td>
<td>−1.02 (−2.53 to 0.49)</td>
<td>.18</td>
<td>−1.34 (−2.85 to 0.17)</td>
<td>.08</td>
</tr>
<tr>
<td>Glycemic outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD of glucose (mg/dL)</td>
<td>3.46 (−1.80 to 8.71)</td>
<td>.19</td>
<td>0.37 (−4.93 to 5.67)</td>
<td>.89</td>
</tr>
<tr>
<td>MAGE (b) (mg/dL)</td>
<td>5.37 (−7.17 to 17.92)</td>
<td>.39</td>
<td>−3.04 (−15.69 to 9.62)</td>
<td>.63</td>
</tr>
<tr>
<td>LBGI (c)</td>
<td>0.73 (−0.48 to 1.94)</td>
<td>.23</td>
<td>0.41 (−0.81 to 1.64)</td>
<td>.50</td>
</tr>
<tr>
<td>Frequency of daily SMBG (d)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (n=46)</td>
<td>0.66 (0.25 to 1.07)</td>
<td>.002 e</td>
<td>0.43 (0.02 to 0.84)</td>
<td>.04</td>
</tr>
<tr>
<td>MDI (e) (n=35)</td>
<td>0.76 (0.29 to 1.23)</td>
<td>.002</td>
<td>0.50 (0.03 to 0.97)</td>
<td>.04</td>
</tr>
<tr>
<td>Others (n=11)</td>
<td>0.33 (−0.63 to 1.29)</td>
<td>.46</td>
<td>0.20 (−0.76 to 1.16)</td>
<td>.65</td>
</tr>
<tr>
<td>DTSQ (f) score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>1.74 (0.10 to 3.39)</td>
<td>.04</td>
<td>2.23 (0.59 to 3.87)</td>
<td>.01</td>
</tr>
<tr>
<td>Q1: Current treatment</td>
<td>0.06 (−0.21 to 0.34)</td>
<td>.65</td>
<td>0.21 (−0.07 to 0.49)</td>
<td>.13</td>
</tr>
<tr>
<td>Q2: Frequency of hyperglycemia</td>
<td>−0.13 (−0.65 to 0.39)</td>
<td>.62</td>
<td>−0.06 (−0.58 to 0.46)</td>
<td>.81</td>
</tr>
<tr>
<td>Q3: Frequency of hypoglycemia</td>
<td>−0.13 (−0.62 to 0.36)</td>
<td>.60</td>
<td>−0.17 (−0.66 to 0.32)</td>
<td>.49</td>
</tr>
<tr>
<td>Q4: Convenience</td>
<td>0.60 (0.10 to 1.09)</td>
<td>.02</td>
<td>0.74 (0.25 to 1.24)</td>
<td>.004</td>
</tr>
<tr>
<td>Q5: Flexibility</td>
<td>0.49 (0.09 to 0.89)</td>
<td>.02</td>
<td>0.70 (0.30 to 1.10)</td>
<td>.001</td>
</tr>
<tr>
<td>Q6: Understanding</td>
<td>0.32 (−0.01 to 0.65)</td>
<td>.06</td>
<td>0.32 (−0.01 to 0.65)</td>
<td>.06</td>
</tr>
<tr>
<td>Q7: Recommend</td>
<td>0.11 (−0.38 to 0.60)</td>
<td>.66</td>
<td>0.13 (−0.36 to 0.62)</td>
<td>.60</td>
</tr>
<tr>
<td>Q8: Continue</td>
<td>0.17 (−0.10 to 0.44)</td>
<td>.22</td>
<td>0.13 (−0.15 to 0.40)</td>
<td>.35</td>
</tr>
</tbody>
</table>

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. HbA1c 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 HbA1c 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.

---

(a) HbA1c: 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.

https://diabetes.jmir.org/2024/1/e48019
Table 3. Changes in glycemic outcomes and questionnaire scores in patients whose antidiabetic medication had not been adjusted during the study (n=21).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Change at 12 weeks (95% CI)</th>
<th>(P) value</th>
<th>Change at 24 weeks (95% CI)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA(_1c) (a) (%)</td>
<td>-0.26 (–0.47 to –0.05)</td>
<td>.02 (b)</td>
<td>–0.07 (–0.28 to 0.14)</td>
<td>.49</td>
</tr>
<tr>
<td>Glycemic outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD of glucose (mg/dL)</td>
<td>0.54 (–7.44 to 8.52)</td>
<td>.89</td>
<td>0.64 (–7.34 to 8.61)</td>
<td>.87</td>
</tr>
<tr>
<td>MAGE(c) (mg/dL)</td>
<td>4.33 (–12.43 to 21.08)</td>
<td>.60</td>
<td>–0.31 (–17.06 to 16.45)</td>
<td>.97</td>
</tr>
<tr>
<td>LBGI(d)</td>
<td>0.49 (–0.47 to 1.46)</td>
<td>.30</td>
<td>–0.25 (–1.21 to 0.72)</td>
<td>.60</td>
</tr>
<tr>
<td>Frequency of daily SMBG(e)</td>
<td>0.31 (–0.34 to 0.97)</td>
<td>.33</td>
<td>0.25 (–0.41 to 0.91)</td>
<td>.44</td>
</tr>
<tr>
<td>DTSQ(f) score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>2.33 (0.06 to 4.61)</td>
<td>.04</td>
<td>3.19 (0.91 to 5.47)</td>
<td>.01</td>
</tr>
<tr>
<td>Q1: Current treatment</td>
<td>0.14 (–0.26 to 0.55)</td>
<td>.47</td>
<td>0.48 (0.07 to 0.88)</td>
<td>.02</td>
</tr>
<tr>
<td>Q2: Frequency of hyperglycemia</td>
<td>0.43 (–0.20 to 1.08)</td>
<td>.19</td>
<td>0.67 (0.02 to 1.32)</td>
<td>.04</td>
</tr>
<tr>
<td>Q3: Frequency of hypoglycemia</td>
<td>–0.38 (–1.06 to 0.29)</td>
<td>.25</td>
<td>–0.52 (–1.20 to 0.15)</td>
<td>.12</td>
</tr>
<tr>
<td>Q4: Convenience</td>
<td>0.52 (–0.13 to 1.18)</td>
<td>.11</td>
<td>0.71 (0.06 to 1.37)</td>
<td>.04</td>
</tr>
<tr>
<td>Q5: Flexibility</td>
<td>0.33 (–0.15 to 0.82)</td>
<td>.17</td>
<td>0.67 (0.18 to 1.15)</td>
<td>.01</td>
</tr>
<tr>
<td>Q6: Understanding</td>
<td>0.24 (–0.21 to 0.69)</td>
<td>.28</td>
<td>0.19 (–0.26 to 0.64)</td>
<td>.39</td>
</tr>
<tr>
<td>Q7: Recommend</td>
<td>0.71 (–0.16 to 1.59)</td>
<td>.10</td>
<td>0.76 (–0.11 to 1.64)</td>
<td>.09</td>
</tr>
<tr>
<td>Q8: Continue</td>
<td>0.38 (–0.01 to 0.77)</td>
<td>.06</td>
<td>0.38 (–0.01 to 0.77)</td>
<td>.06</td>
</tr>
</tbody>
</table>

\(a\)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.

<table>
<thead>
<tr>
<th>Question and response</th>
<th>Patients, n (%)</th>
<th>Physicians, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Was the use of this e-SMBG app useful for motivating you to improve your lifestyle? (patients: n=47; physicians: n=47)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>8 (17)</td>
<td>15 (32)</td>
</tr>
<tr>
<td>Useful</td>
<td>31 (66)</td>
<td>21 (45)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>6 (13)</td>
<td>10 (21)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>2 (4)</td>
<td>1 (2)</td>
</tr>
<tr>
<td><strong>Was the use of this e-SMBG app useful for adjusting the insulin dose? (patients: n=46; physicians: n=46)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>8 (17)</td>
<td>18 (39)</td>
</tr>
<tr>
<td>Useful</td>
<td>25 (54)</td>
<td>17 (37)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>8 (17)</td>
<td>11 (24)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>5 (11)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Was the use of this e-SMBG app useful for diabetes treatment? (patients: n=47; physicians: n=47)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>7 (15)</td>
<td>17 (36)</td>
</tr>
<tr>
<td>Useful</td>
<td>32 (68)</td>
<td>26 (55)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>6 (13)</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>2 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Do you want to continue to use this e-SMBG app for diabetes treatment? (patients: n=46; physicians: n=47)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>44 (96)</td>
<td>45 (96)</td>
</tr>
<tr>
<td>No</td>
<td>2 (4)</td>
<td>2 (4)</td>
</tr>
<tr>
<td><strong>Did you find the following app items useful?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood glucose logbook (patients: n=47; physicians: n=47)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>21 (45)</td>
<td>19 (40)</td>
</tr>
<tr>
<td>Useful</td>
<td>23 (49)</td>
<td>25 (53)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>0 (0)</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>3 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Blood glucose variability graph (patients: n=47; physicians: n=47)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>18 (38)</td>
<td>20 (43)</td>
</tr>
<tr>
<td>Useful</td>
<td>24 (51)</td>
<td>24 (51)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>4 (9)</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>1 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Weekly summary (patients: n=46; physicians: n=45)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>7 (15)</td>
<td>16 (36)</td>
</tr>
<tr>
<td>Useful</td>
<td>18 (39)</td>
<td>18 (40)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>14 (30)</td>
<td>10 (22)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>7 (15)</td>
<td>1 (2)</td>
</tr>
<tr>
<td><strong>Event record (patients: n=42; physicians: n=46)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>5 (12)</td>
<td>14 (30)</td>
</tr>
<tr>
<td>Useful</td>
<td>7 (17)</td>
<td>11 (24)</td>
</tr>
<tr>
<td>Not very useful</td>
<td>20 (48)</td>
<td>15 (33)</td>
</tr>
<tr>
<td>Not useful at all</td>
<td>10 (24)</td>
<td>6 (13)</td>
</tr>
<tr>
<td><strong>Dietary record (patients: n=43; physicians: n=45)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very useful</td>
<td>4 (9)</td>
<td>16 (36)</td>
</tr>
<tr>
<td>Useful</td>
<td>9 (21)</td>
<td>10 (22)</td>
</tr>
</tbody>
</table>
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 HbA1c 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 HbA1c 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 HbA1c 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 HbA1c 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 HbA1c 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

We are grateful to all staff responsible for data collection. This study was funded by ARKRAY Inc, Kyoto, Japan.

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.

References


15. Alanzi T, Alanazi NR, Istepanian R, Philip N. Evaluation of the effectiveness of mobile diabetes management system with social networking and cognitive behavioural therapy (CBT) for T2D. Mhealth 2018;4:35 [FREE full text] [doi: 10.21037/mhealth.2018.06.05] [Medline: 30221168]


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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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/m², 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/m² 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] DWTI 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 $\geq 35$ 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).
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.

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

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

$^a$IMD: index of multiple deprivation.

---
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.

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

aP < .001.
bThe 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.

<table>
<thead>
<tr>
<th>Baseline characteristic</th>
<th>Weight loss from baseline to 1 year(^a) ( \beta ) (95% CI)</th>
<th>Weight loss from baseline to 2 years(^a) ( \beta ) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity (reference=Black, Asian, mixed, or other ethnicities)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>.77 (–3.8 to 5.3)</td>
<td>.74 (–4.4 to 5.7)</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>–3.79 (–17.9 to 10.3)</td>
<td>–12.78 (–39.5 to 14.0)</td>
</tr>
<tr>
<td>IMD(^b) tertile (reference=1-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-6</td>
<td>–1.58 (–4.8 to 1.67)</td>
<td>.40 (–3.4 to 4.2)</td>
</tr>
<tr>
<td>7-10</td>
<td>–1.60 (–4.9 to 1.7)</td>
<td>1.46 (–2.5 to 5.4)</td>
</tr>
<tr>
<td>Type 2 diabetes (reference=no)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.05 (–2.4 to 4.5)</td>
<td>.24 (–3.8 to 4.3)</td>
</tr>
</tbody>
</table>

\(^a\)All models were adjusted for baseline weight. Separate analyses were run for each baseline characteristic.

\(^b\)IMD: index of multiple deprivation.

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 kg (SD 12.3 kg) at 1 year and 13.8 kg (SD 14.2 kg) at 2 years. When analyzed using BOCF, we found a statistically significant weight loss of 3.4 kg (SD 9.2 kg) at 1 year and 7.3% (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 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 A1c, 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/m², 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 SWMS 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.

**References**


34. Preventing excess weight gain. NICE guideline [NG7]. National Institute for Health and Care Excellence. 2015. URL: https://www.nice.org.uk/guidance/ng7 [accessed 2023-12-19]


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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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.

(JMIR Diabetes 2024;9:e48310) doi:10.2196/48310
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 A1c 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).

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

*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 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.

https://diabetes.jmir.org/2024/1/e48310
(7.0) among the participants in this study, it is possible that the voluntary nature of participation might have introduced a selection bias, with patients who were motivated to change behaviors being more prone to participate. Although we sought to recruit a balanced sample, there was limited representation of female and Indian or Malay participants in our multiethnic population. In addition, previous studies have shown that MI may increase the self-efficacy of participants [45-47]. However, we did not assess the self-efficacy of participants in this qualitative interview as there is no conclusive evidence regarding the sustained effect of MI delivery on self-efficacy. Lastly, because we used a mock-up wireframe of MI features, participant feedback may have been limited to the features presented during the interviews.

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

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Conflicts of Interest
None declared.

References


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 A₁c (HbA₁c) 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 HbA₁c decreased by –1.0 (from 8.2% to 7.2%; P<.001) over 12 months of program participation. In those with a baseline HbA₁c >8%, the average HbA₁c decreased by –2.1 (from 10.2% to 8.1%; P<.001), and in those with a baseline HbA₁c >9%, the average HbA₁c decreased by –2.8 (from 11% to 8.2%; P<.001). Among participants who identified as a race or ethnicity other than White, the HbA₁c decreased by –1.2 (from 8.6% to 7.4%, P=.001). Further examination of subgroups confirmed HbA₁c 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 HbA₁c 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 A1c (HbA1c) 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 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 HbA1c laboratory test results ≥6.5% or determined based on HbA1c 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 (Ascensia, 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 HbA1c, a comprehensive metabolic panel, a lipid panel, and a urine microalbumin to creatinine ratio test [21]. In brief, the protocol recommends an HbA1c 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, HbA1c, 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, amiodipine, 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 HbA1c results were compared among all included members, as well as in the subgroups with a baseline HbA1c >8% (poor control group) and a baseline HbA1c >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.

https://diabetes.jmir.org/2024/1/e53835

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(page number not for citation purposes)
Table 1. Baseline and follow up characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall population (N=95)</th>
<th>Self-identify as White (n=52)</th>
<th>Self-identify as race or ethnicity other than White (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), n (%)</td>
<td>48 (9)</td>
<td>49 (9)</td>
<td>46.5 (10)</td>
</tr>
<tr>
<td>Sex assigned at birth, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>32 (34)</td>
<td>14 (27)</td>
<td>18 (46)</td>
</tr>
<tr>
<td>Male</td>
<td>61 (64)</td>
<td>37 (71)</td>
<td>21 (54)</td>
</tr>
<tr>
<td>Declined</td>
<td>2 (2)</td>
<td>1 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Race or ethnicity, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>10 (11)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>1 (1)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Black or African American</td>
<td>13 (14)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Latinx</td>
<td>15 (16)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>White</td>
<td>52 (55)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Other or unknown</td>
<td>4 (4)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Average number of days with the program, mean (SD)</td>
<td>488.5 (75.0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Average baseline HbA1c(^b), mean (SD)</td>
<td>8.2 (2.2)</td>
<td>7.8 (2.2)</td>
<td>8.6 (2.1)</td>
</tr>
<tr>
<td>Average last HbA1c, mean (SD)</td>
<td>7.2 (1.9)</td>
<td>7.1 (2.0)</td>
<td>7.4 (1.9)</td>
</tr>
<tr>
<td>Average baseline BP(^c) (mm Hg), mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>158.7 (16.9)</td>
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<td>N/A</td>
</tr>
<tr>
<td>Diastolic</td>
<td>97.5 (4.5)</td>
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<td>N/A</td>
</tr>
<tr>
<td>Average last BP (mm Hg), mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>141.0 (26.2)</td>
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<td>N/A</td>
</tr>
<tr>
<td>Diastolic</td>
<td>83.3 (12.6)</td>
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<td>N/A</td>
</tr>
<tr>
<td>Number of participants who were prescribed each medication by 9amHealth, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amlodipine</td>
<td>9 (10)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>17 (18)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Glimepiride</td>
<td>4 (4)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Glipizide</td>
<td>8 (8)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>7 (7)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>10 (11)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Losartan</td>
<td>9 (10)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Omega-3-acid ethyl esters</td>
<td>3 (3)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Metformin</td>
<td>32 (34)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pioglitazone</td>
<td>19 (20)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>3 (3)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Simvastatin</td>
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<td>N/A</td>
</tr>
<tr>
<td>Dulaglutide</td>
<td>1 (1)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(^a\)N/A: not applicable.

\(^b\)HbA1c: hemoglobin A1c.

\(^c\)BP: blood pressure.
HbA1c Results

Figure 1 demonstrates the change in HbA1c in all participants and in the baseline HbA1c >8% and >9% cohorts. Among all 95 participants, the average HbA1c 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 HbA1c >8%, the average HbA1c decreased from 10.2% to 8.1% (n=46; –2.1; \( P < .001 \)). Among those with a baseline HbA1c >9%, the average HbA1c decreased from 11% to 8.2% (n=32; –2.8; \( P < .001 \)).

Figure 1. Change in hemoglobin A1c (HbA1c) over the study period.

The results were consistent among members identifying as a race or ethnicity other than White. The average HbA1c 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 HbA1c lowering within each race or ethnicity group, however, in small numbers. Among Asian participants, the average HbA1c decreased from 8.8% to 6.9% (n=10; –1.9; \( P = .004 \)); among Black or African American participants, the average HbA1c 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 HbA1c 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.
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 HbA1c 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 (HbA1c ≤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 HbA1c 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 HbA1c 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 HbA1c 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 HbA1c and BP and to engage successfully in digital health solutions. This may have positively impacted the outcomes, suggesting greater HbA1c 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 HbA1c 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 HbA1c (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.

Acknowledgments

We are grateful to Bernhard Schandl, PhD, for his assistance in data collection and formatting and to Darren Domingo for his preparation of tables and figures.

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.

References


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(page number not for citation purposes)


Abbreviations

BP: blood pressure
CLIA: Clinical Laboratory Improvement Amendments of 1988
GLP1: glucagon-like peptide 1
HbA1c: hemoglobin A1c
SGLT2: sodium-glucose transport protein 2
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%), or both (n=59, 8.1%).

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>
<thead>
<tr>
<th></th>
<th>All participants (N=7141)</th>
<th>People with diabetes (n=724)</th>
<th>No reported diabetes (n=6417)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of follow-up from completion of COVID-19 vaccine regimen (ie, last dose in regimen), n</td>
<td>724</td>
<td>6417</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>182.1 (144.4)</td>
<td>175.0 (143.9)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>170.0 (38.0-319.5)</td>
<td>145 (37.0-314.0)</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0-598.0</td>
<td>0-747.0</td>
<td></td>
</tr>
<tr>
<td>Age (years), n</td>
<td>724</td>
<td>6417</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>57.8 (12.04)</td>
<td>47.5 (15.57)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>60 (51.0-66.0)</td>
<td>46 (34.0-61.0)</td>
<td></td>
</tr>
<tr>
<td>Age group (years), n</td>
<td>724</td>
<td>6417</td>
<td></td>
</tr>
<tr>
<td>18-29, n (%)</td>
<td>14 (1.9)</td>
<td>767 (12.0)</td>
<td></td>
</tr>
<tr>
<td>30-39, n (%)</td>
<td>46 (6.4)</td>
<td>1704 (26.6)</td>
<td></td>
</tr>
<tr>
<td>40-49, n (%)</td>
<td>106 (14.6)</td>
<td>1013 (15.8)</td>
<td></td>
</tr>
<tr>
<td>50-59, n (%)</td>
<td>193 (26.7)</td>
<td>1104 (17.2)</td>
<td></td>
</tr>
<tr>
<td>&gt;60, n (%)</td>
<td>365 (50.4)</td>
<td>1829 (28.5)</td>
<td></td>
</tr>
<tr>
<td>Gender, n</td>
<td>724</td>
<td>6417</td>
<td></td>
</tr>
<tr>
<td>Self-described as female, n (%)</td>
<td>552 (76.2)</td>
<td>5375 (83.8)</td>
<td></td>
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<tr>
<td>Race, n</td>
<td>724</td>
<td>6409</td>
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</tr>
<tr>
<td>Black, n (%)</td>
<td>19 (2.6)</td>
<td>100 (1.6)</td>
<td></td>
</tr>
<tr>
<td>White, n (%)</td>
<td>651 (89.9)</td>
<td>5793 (90.4)</td>
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</tr>
<tr>
<td>Other, n (%)</td>
<td>54 (7.5)</td>
<td>516 (8.1)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity, n</td>
<td>720</td>
<td>6402</td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino, n (%)</td>
<td>39 (5.4)</td>
<td>369 (5.8)</td>
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</tr>
<tr>
<td>BMI, n</td>
<td>714</td>
<td>6286</td>
<td></td>
</tr>
<tr>
<td>Underweight or normal weight (15.0≤BMI&lt;25.0), n (%)</td>
<td>66 (9.2)</td>
<td>1802 (28.7)</td>
<td></td>
</tr>
<tr>
<td>Overweight (25.0≤BMI&lt;30.0), n (%)</td>
<td>150 (21.0)</td>
<td>1825 (29.0)</td>
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<tr>
<td>Obese (30.0≤BMI≤40.0), n (%)</td>
<td>323 (45.2)</td>
<td>2026 (32.2)</td>
<td></td>
</tr>
<tr>
<td>Severe obesity (BMI&gt;40.0), n (%)</td>
<td>175 (24.5)</td>
<td>633 (10.1)</td>
<td></td>
</tr>
<tr>
<td>Education, n</td>
<td>720</td>
<td>6406</td>
<td></td>
</tr>
<tr>
<td>High school or less, n (%)</td>
<td>89 (12.4)</td>
<td>525 (8.2)</td>
<td></td>
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<tr>
<td>Some college, n (%)</td>
<td>273 (37.9)</td>
<td>1845 (28.8)</td>
<td></td>
</tr>
<tr>
<td>4 year college degree, n (%)</td>
<td>140 (19.4)</td>
<td>1731 (27.0)</td>
<td></td>
</tr>
<tr>
<td>&gt;4 year college degree, n (%)</td>
<td>218 (30.3)</td>
<td>2305 (36.0)</td>
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<td>Smoker, n</td>
<td>671</td>
<td>6181</td>
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<tr>
<td>Yes, n (%)</td>
<td>73 (10.9)</td>
<td>571 (9.2)</td>
<td></td>
</tr>
<tr>
<td>Vaccinated for influenza, n</td>
<td>721</td>
<td>6358</td>
<td></td>
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<tr>
<td>Yes, n (%)</td>
<td>568 (78.8)</td>
<td>4659 (73.3)</td>
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<tr>
<td>Other medical conditions, n</td>
<td>724</td>
<td>6410</td>
<td></td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>409 (56.5)</td>
<td>1286 (20.1)</td>
<td></td>
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<tr>
<td>Depression, n (%)</td>
<td>294 (40.6)</td>
<td>2007 (31.3)</td>
<td></td>
</tr>
<tr>
<td>Insomnia or trouble sleeping, n (%)</td>
<td>275 (38.0)</td>
<td>1889 (29.5)</td>
<td></td>
</tr>
<tr>
<td>Anxiety, n (%)</td>
<td>272 (37.6)</td>
<td>2515 (39.2)</td>
<td></td>
</tr>
</tbody>
</table>
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 6 months 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 how they felt after vaccination for COVID-19. 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.

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.
Third, generalizability and missing data are concerns for every observational study. Despite participation from all 50 states, adults who join CARE are not representative of the US population in general or all people with diabetes. The CARE participants are more highly educated than the general population as is common in online research [12,14]. Most described themselves as Caucasian females, aged 30-50 years, and the responses of these unpaid volunteers reflect the experience of people who had both the time and interest to respond to internet advertisements on social media. That said, comparisons within this study population are unlikely to be subject to selection biases that would cause differential reporting between participants reporting or not reporting diabetes. Furthermore, there was no effort to specifically recruit people with diabetes, nor any advance notice of the intent to study vaccine side effects specifically or to compare side effects according to the medication use. However, people who had severe reactions from COVID-19 vaccination may not have participated in this study or may not have provided follow-up due to hospitalization or death.

Finally, most of these data were collected when the predominant COVID-19 variants were the Delta and the original Omicron (BA.1 and BA.2.12.1) variants. The rates of breakthrough infections may differ for other variants [18].

Conclusions
Overall, these results should provide assurance that simply having diabetes does not increase the risk of vaccine side effects compared with those not reporting diabetes. In fact, the risk of developing vaccine side effects in participants reporting diabetes appears lower than in those not reporting diabetes, without any increased risk of breakthrough infections after vaccination.

Acknowledgments
We would like to acknowledge Steven Toovey for his thoughtful medical guidance, Savitha Pallipuram for leading the tech team, and Tom Kown for his program management contributions. This work was supported largely by IQVIA and had support from the US Food and Drug Administration in the development of questionnaires and for work unrelated to the topic of this study. IQVIA was fully responsible for the design, data collection, analysis, and interpretation of the data.

Data Availability
Deidentified data sets generated during this study are available from the corresponding author upon reasonable request.

Authors' Contributions
NAD conceptualized the work, drafted the work, and revised it critically for important intellectual content. KBK and YX performed the data analysis, interpreted the results, reviewed the work, and supported revising the work. MWR, CDM, and NAD contributed to crafting the study design as well as leading project design, implementation, and data collection, and reviewed the work. All authors approved the work to be published. NAD is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest
None declared.

References


Abbreviations

**aOR**: adjusted odds ratio

**CARE**: COVID-19 Active Research Experience
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 ECLIPSE (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 ECLIPSE (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 ECLIPSE 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]. ECLIPSE 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 ECLIPSE 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 A1c (HbA1c) 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).
were adjusted for patient sociodemographic (age, gender, race or ethnicity, marital status, educational attainment, and limited English proficiency status) and clinical (HbA1c, 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)\textsuperscript{a}.

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Total (N=7659), n (%)</th>
<th>Never proxy (n=3877), n (%)</th>
<th>Any proxy (n=3782), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>50-59</td>
<td>3483 (45.5)</td>
<td>1933 (49.9)</td>
<td>1550 (41)</td>
<td></td>
</tr>
<tr>
<td>60-69</td>
<td>2877 (37.6)</td>
<td>1473 (38)</td>
<td>1404 (37.1)</td>
<td></td>
</tr>
<tr>
<td>70-79</td>
<td>1299 (16.9)</td>
<td>471 (12.1)</td>
<td>828 (21.9)</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>3548 (46.3)</td>
<td>1752 (45.2)</td>
<td>1796 (47.5)</td>
<td>.04</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Black</td>
<td>1089 (14.6)</td>
<td>587 (15.6)</td>
<td>502 (13.6)</td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>747 (10)</td>
<td>375 (10)</td>
<td>372 (10.1)</td>
<td></td>
</tr>
<tr>
<td>Filipino</td>
<td>905 (12.2)</td>
<td>506 (13.4)</td>
<td>399 (10.8)</td>
<td></td>
</tr>
<tr>
<td>Latino\textsuperscript{b}</td>
<td>999 (13.4)</td>
<td>468 (12.4)</td>
<td>531 (14.4)</td>
<td></td>
</tr>
<tr>
<td>Other Asian</td>
<td>663 (8.9)</td>
<td>368 (9.8)</td>
<td>295 (8)</td>
<td></td>
</tr>
<tr>
<td>Other or mixed</td>
<td>817 (11)</td>
<td>388 (10.3)</td>
<td>429 (11.7)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>2225 (29.9)</td>
<td>1073 (28.5)</td>
<td>1152 (31.3)</td>
<td></td>
</tr>
<tr>
<td>Married or living a partner</td>
<td>5573 (75.0)</td>
<td>2838 (75.5)</td>
<td>2735 (74.4)</td>
<td>.28</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Less than high school degree</td>
<td>861 (11.4)</td>
<td>343 (9)</td>
<td>518 (13.9)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>1911 (25.3)</td>
<td>888 (23.3)</td>
<td>1023 (27.5)</td>
<td></td>
</tr>
<tr>
<td>Some college or more</td>
<td>4768 (63.2)</td>
<td>2587 (67.8)</td>
<td>2181 (58.6)</td>
<td></td>
</tr>
<tr>
<td>LEP\textsuperscript{c,d}</td>
<td>499 (6.5)</td>
<td>194 (5)</td>
<td>305 (8.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>HbA$_{1c}$\textsuperscript{e} $\geq$8%\textsuperscript{f}</td>
<td>1705 (22.3)</td>
<td>871 (22.5)</td>
<td>834 (22.1)</td>
<td>.66</td>
</tr>
<tr>
<td>Charlson comorbidity\textsuperscript{g}</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>1</td>
<td>4075 (53.2)</td>
<td>2225 (57.4)</td>
<td>1850 (48.9)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2152 (28.1)</td>
<td>1011 (26.1)</td>
<td>1141 (30.2)</td>
<td></td>
</tr>
<tr>
<td>3+</td>
<td>1432 (18.7)</td>
<td>641 (16.5)</td>
<td>791 (20.9)</td>
<td></td>
</tr>
<tr>
<td>$\geq$3 outpatient visits\textsuperscript{g}</td>
<td>6467 (84.4)</td>
<td>3192 (82.3)</td>
<td>3275 (86.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>$\geq$1 emergency department visit\textsuperscript{g}</td>
<td>1471 (19.2)</td>
<td>682 (17.6)</td>
<td>789 (20.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>$\geq$1 hospital admission\textsuperscript{g}</td>
<td>701 (9.2)</td>
<td>315 (8.1)</td>
<td>386 (10.2)</td>
<td>.002</td>
</tr>
</tbody>
</table>

\textsuperscript{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%).

\textsuperscript{b}Includes Latino/a/x/Hispanic individuals.

\textsuperscript{c}LEP: limited English proficiency.

\textsuperscript{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”).

\textsuperscript{e}HbA$_{1c}$: hemoglobin A$_{1c}$.

\textsuperscript{f}Measured closest to study onset.

\textsuperscript{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=471; $P<.001$).
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 2015a.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Unadjusted hazard ratio (95% CI)</th>
<th>P value</th>
<th>Adjustedb hazard ratio (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never proxy</td>
<td>11.0 (10.7-11.3)</td>
<td>Reference</td>
<td>10.9 (10.7-11.2)</td>
<td>Reference</td>
</tr>
<tr>
<td>Any proxy</td>
<td>21.3 (20.8-21.8)</td>
<td>&lt;.001</td>
<td>20.7 (20.2-21.2)</td>
<td>&lt;.001</td>
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<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>17.0 (16.5-17.5)</td>
<td>Reference</td>
<td>15.9 (15.5-16.3)</td>
<td>Reference</td>
</tr>
<tr>
<td>60-69</td>
<td>15.9 (15.4-16.4)</td>
<td>&lt;.001</td>
<td>14.8 (14.4-15.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>70-79</td>
<td>16.9 (16.0-17.7)</td>
<td>.78</td>
<td>15.7 (15.0-16.5)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>16.6 (16.1-17.1)</td>
<td>Reference</td>
<td>15.5 (15.2-15.9)</td>
<td>Reference</td>
</tr>
<tr>
<td>Women</td>
<td>16.5 (16.1-17.0)</td>
<td>.87</td>
<td>15.3 (15.0-15.7)</td>
<td>.85</td>
</tr>
<tr>
<td>Race or ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>16.7 (15.8-17.5)</td>
<td>.02</td>
<td>15.6 (14.8-16.4)</td>
<td>.002</td>
</tr>
<tr>
<td>Chinese</td>
<td>15.4 (14.5-16.4)</td>
<td>&lt;.001</td>
<td>14.5 (13.7-15.3)</td>
<td>.01</td>
</tr>
<tr>
<td>Filipino</td>
<td>14.9 (14.0-15.7)</td>
<td>&lt;.001</td>
<td>14.0 (13.3-14.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Latino</td>
<td>16.1 (15.2-17.0)</td>
<td>.001</td>
<td>14.9 (14.2-15.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other Asian</td>
<td>15.8 (14.9-16.8)</td>
<td>&lt;.001</td>
<td>14.8 (14.0-15.5)</td>
<td>.009</td>
</tr>
<tr>
<td>Other or mixed</td>
<td>16.4 (15.4-17.3)</td>
<td>.005</td>
<td>15.2 (14.4-15.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>White</td>
<td>18.0 (17.4-18.7)</td>
<td>Reference</td>
<td>16.8 (16.3-17.3)</td>
<td>Reference</td>
</tr>
<tr>
<td>Marital status</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or living with partner</td>
<td>16.4 (16.0-16.8)</td>
<td>Reference</td>
<td>15.2 (14.9-15.5)</td>
<td>Reference</td>
</tr>
<tr>
<td>Never married or widowed or divorced</td>
<td>17.2 (16.6-17.9)</td>
<td>.03</td>
<td>16.3 (15.7-16.9)</td>
<td>.02</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>15.9 (15.0-16.8)</td>
<td>Reference</td>
<td>15.1 (14.3-16.0)</td>
<td>Reference</td>
</tr>
<tr>
<td>High school</td>
<td>16.4 (15.8-17.1)</td>
<td>.34</td>
<td>15.4 (14.9-15.9)</td>
<td>.91</td>
</tr>
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<td>Some college or more</td>
<td>16.7 (16.3-17.1)</td>
<td>.11</td>
<td>15.5 (15.2-15.8)</td>
<td>.02</td>
</tr>
<tr>
<td>English proficiency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English proficient</td>
<td>16.7 (16.4-17.1)</td>
<td>Reference</td>
<td>15.6 (15.3-15.9)</td>
<td>Reference</td>
</tr>
<tr>
<td>LEPc,d</td>
<td>13.3 (12.3-14.4)</td>
<td>&lt;.001</td>
<td>12.7 (11.8-13.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>HbA1ce,f</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;8%</td>
<td>16.3 (16.0-16.7)</td>
<td>Reference</td>
<td>15.3 (15.0-15.6)</td>
<td>Reference</td>
</tr>
<tr>
<td>≥8%</td>
<td>17.4 (16.7-18.1)</td>
<td>.008</td>
<td>16.1 (15.6-16.7)</td>
<td>.02</td>
</tr>
<tr>
<td>Charlson comorbiditiesf</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>15.3 (14.9-15.7)</td>
<td>Reference</td>
<td>14.3 (14.0-14.7)</td>
<td>Reference</td>
</tr>
<tr>
<td>2</td>
<td>17.2 (16.5-17.8)</td>
<td>&lt;.001</td>
<td>16.1 (15.6-16.6)</td>
<td>.003</td>
</tr>
<tr>
<td>3+</td>
<td>19.4 (18.5-20.2)</td>
<td>&lt;.001</td>
<td>18.1 (17.4-18.8)</td>
<td>&lt;.001</td>
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<tr>
<td>Number of outpatient visitsg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;3</td>
<td>13.8 (13.1-14.5)</td>
<td>Reference</td>
<td>13.0 (12.4-13.5)</td>
<td>Reference</td>
</tr>
<tr>
<td>≥3</td>
<td>17.1 (16.7-17.4)</td>
<td>&lt;.001</td>
<td>15.9 (15.6-16.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Number of emergency department visitsg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>16.1 (15.8-16.5)</td>
<td>Reference</td>
<td>15.0 (14.8-15.3)</td>
<td>Reference</td>
</tr>
<tr>
<td>Any</td>
<td>18.5 (17.7-19.3)</td>
<td>&lt;.001</td>
<td>17.3 (16.7-18.0)</td>
<td>.02</td>
</tr>
</tbody>
</table>

https://diabetes.jmir.org/2024/1/e49491


**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 HbA1c 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

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**Table 2**

<table>
<thead>
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<th>Characteristics</th>
<th>Unadjusted hazard ratio (95% CI)</th>
<th>Unadjusted hazard ratio (95% CI)</th>
<th>Adjusted(^b) hazard ratio (95% CI)</th>
<th>Adjusted(^b) hazard ratio (95% CI)</th>
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<td>15.3 (15.0-15.5)</td>
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<tr>
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<td>&lt;.001</td>
<td>17.4 (16.4-18.3)</td>
<td>.83</td>
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<td></td>
</tr>
</tbody>
</table>

\(a\) 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 A1c, 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”).

\(e\) HbA1c: hemoglobin A1c.

\(f\) Measured closest to study onset.

\(g\) Usage in the 12 months before this study’s entry.
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.

Acknowledgments
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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, JK, CK, JYL, JLT, and DS. Preparation of this paper was by WS, AJK, CRL, MER, JK, CK, JYL, JLT, 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.

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).

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2. The ONC patient engagement playbook. The Office of the National Coordinator for Health Information Technology (ONC). URL: https://www.healthit.gov/playbook [accessed 2023-12-22]


Abbreviations

DISTANCE: Diabetes Study of Northern California
ECLIPSE: Employing Computational Linguistics to Improve Patient-Provider Secure Emails
HbA1c: hemoglobin A1c
HR: hazard ratio
SM: secure messaging

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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 \( \sim 50\% \) [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 A1c (HbA1c) 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 HbA1c). 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 (ERMB), 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 $A_n = \{ \text{User self-care, Intervention} \}$ (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 $s'_n$, 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, $|a'_t| \leq B \ \forall t \in 1, \ldots, H$.

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 $(s_E, s_C, \text{and } s_M)$, 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: $\{ \text{Engaged, Maintenance, and Dropout} \}$. 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 HbA1c value (via 2 states: $\{ \text{HbA1c < } 8, \text{HbA1c } \geq 8 \}$). This threshold was chosen to model the clinical outcome target for app users in publicly available data, that is, reducing their HbA1c 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 HbA1c 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 $a = \text{intervention}$ and dotted arrows represent transitions when $a = \text{user self-care}$. 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, $p_{\text{EngMtoEng}}$, $p_{\text{EngEtoEng}}$, $p_{\text{MtoDrop}}$, and $p_{\text{MtoDrop}}$, 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, $p_{\text{EngE}, A_{1c} \geq 8}$, $p_{\text{EngE}, A_{1c} < 8}$, $p_{\text{MtoDrop}, A_{1c} \geq 8}$, and $p_{\text{MtoDrop}, A_{1c} < 8}$, 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, $s_C$, 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 $s_M$ and $c$ represents the current clinical state $s_C$.

| Evolution of clinical state $P(s'_C = HbA_1c < 8 | r, c)$ | $s'_C = HbA_1c \geq 8$ | $s'_C = HbA_1c < 8$ |
|------------------------------------------------------|--------------------------|--------------------------|
| $s_M = \text{Eng}^a$ | $p^E_{A1c<8}$ | $p^E_{A1c<8}$ |
| $s_M \neq \text{Eng}$ | $p^E_{A1c<8}$ | $p^E_{A1c<8}$ |

$^a$Eng: Engaged.

**Memory Dynamics**

The memory dimension is a sliding window to record the engagement state of the previous 3 months:

$$P(s'M0 = s_E, s'M1 = sM0 | s_E, sM0) = 1$$

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 HbA1c in a given time period. We assume that users in the Engaged state have fully observable $s_C$, for example, they will measure their HbA1c upon request from the program, patients in the Maintenance state have a partially observable HbA1c, for example, they will measure their HbA1c in a given round with probability $q^{\text{Obs}}_{\text{Maint}}$, and users in the Dropout state have an unobservable HbA1c. 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:

$$\text{The reward for a patient's full state is then computed as } R(s_E, s_C, s_M) = \alpha r_E(s_E) + (1 - \alpha) r_C(s_C).$$

Thus the parameter $\alpha$ 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 ERMB. Here, we give a brief overview of the ERMB framework and the equitable objectives considered for our simulation analysis. For full technical background on restless bandits and full derivations of ERMBs 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 $V^g_0(s^0_g, b_g)$, where:

$\text{\textbf{Figure 2. Construction of the delayed intervention effect on clinical state, } s_C, \text{ via zoomed in view of Figure 1. Each transition (arrow) in Figure 1 encodes 2 transitions with different probabilities (the dashed and dotted arrows in this figure), each of which depend on the engagement state of the user 3 months ago, that is, the last entry of the memory state, } M. \text{ Specifically, the probability of transitioning to a better clinical state will be larger if the user was in the engaged state 3 months ago. Eng: engaged.}}$

$\text{\textbf{Table 1. The table shows the evolution of clinical state } P(s'_C = HbA_1c < 8 | r, c) \text{ where } r \text{ represents the memory state, } s_M, \text{ and } c \text{ represents the current clinical state, } s_C.}}$

$\text{\textbf{Figure 2. Construction of the delayed intervention effect on clinical state, } s_C, \text{ via zoomed in view of Figure 1. Each transition (arrow) in Figure 1 encodes 2 transitions with different probabilities (the dashed and dotted arrows in this figure), each of which depend on the engagement state of the user 3 months ago, that is, the last entry of the memory state } M. \text{ Specifically, the probability of transitioning to a better clinical state will be larger if the user was in the engaged state 3 months ago. Eng: engaged.}}$

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$\text{\textbf{Table 1. The table shows the evolution of clinical state } P(s'_C = HbA_1c < 8 | r, c) \text{ where } r \text{ represents the memory state, } s_M, \text{ and } c \text{ represents the current clinical state, } s_C.}$
and \( V^H(g) = 0 \). 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 \( L^t(g,s^t, b^t) \), rather than \( V^t(g,s^t, b^t) \).

**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.

\[
\text{Maximin Reward (MMR)}
\]

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 \( L.g \), 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 \( L.g \), 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 \( L.g(s^t, b^t) \) output by algorithms 1 or 2 (for complete algorithm derivation, with additional proofs and technical detail, see Killian et al [21]).
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 HbA1c. 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 HbA1c to derive statistics per group on monthly HbA1c change (full details in Multimedia Appendix 1). These provide values of $p_{\text{E}}^{\geq}$ and $p_{\text{E}}^{<}$ 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 HbA1c 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 $P_{\text{U}}^{\text{Mod}}$ in our model, with about 4% variation between groups.

---

**Algorithm 1:** ERMAB water filling: maximin reward

**Data:** $G, B, s, h$

$b = 0$ // $|G|$-length vector, of budgets

for $g \in G$ do // Initialize

$L(s_g, b_g) = \text{INNEROPT}(g, b_g, s_g, h)$

/ $|M^{-1}(g)|$

for $b \in [1, ..., B]$ do

$g^* = \text{ARGMIN}(L(s_g, b_g))$

$b_{g^*} += 1$

$L(s_{g^*}, b_{g^*}) = \text{INNEROPT}(g^*, b_{g^*}, s_{g^*}, h)$

/ $|M^{-1}(g)|$

return $L, b$

---

**Algorithm 2:** ERMAB greedy: max Nash welfare

**Data:** $G, B, s, h$

$b = 0$ // $|G|$-length vector, of budgets

\(\theta = \max_{g} \{|M^{-1}(g)|\}$

for $g \in G$ do // Initialize

\(\text{UPSAMPLE}(g, \theta) \quad \text{// Resample arms, until g has size } \theta\)

$L_0(s_g, b_g) = \text{INNEROPT}(g, b_g, s_g, h)$

$L_1(s_g, b_g) = \text{INNEROPT}(g, b_g + 1, s_g, h)$

$L_\Delta(s_g, b_g) = \log(L_1(s_g, b_g)) - \log(L_0(s_g, b_g))$

for $b \in [1, ..., B]$ do

$g^* = \text{ARGMAX}(L_\Delta(s_g, b_g))$

$b_{g^*} += 1$

$L_0(s_{g^*}, b_{g^*}) = L_1(s_{g^*}, b_{g^*})$

$L_1(s_{g^*}, b_{g^*}) = \text{INNEROPT}(g^*, b_{g^*} + 1, s_{g^*}, h)$

$L_\Delta(s_{g^*}, b_{g^*}) = \log(L_1(s_{g^*}, b_{g^*})) - \log(L_0(s_{g^*}, b_{g^*}))$

\(\text{RESCALE}(b, G, \theta) \quad \text{// Rescale budgets proportional to original group size}\)

return $L, \theta$
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 $p^E_{A1c \geq 8}$ and $p^E_{A1c < 8}$, 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 $p^I_{End}$ and $p^I_{Mod}$, we assign values of 99% and 3%, respectively, encoding an assumption that patients are more likely to stay in the program if intervened on if already engaged. For $p^I_{End}$, 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$_{1c}$ ≥ 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 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 $s_{C} = \text{HbA}_{1c} \geq 8$ (termed high-risk random allocation), and a round robin approach which prioritized acting on patients with both $s_{C} = \text{HbA}_{1c} \geq 8$ 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.
MMR and MNW-EG achieved their lift in the proportion of patients with healthy HbA1c 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 (i.e., \( \alpha = 1.0 \)), 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 HbA1c 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 HbA1c targets. We hypothesize that this is due to the “sticky” nature of healthy HbA1c in the MarketScan data set, that is, patients with HbA1c < 8 have a <1% chance of flipping back to HbA1c > 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 $\alpha$ and B.
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 HbA1c < 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 $\alpha$-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.
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 HbA1c 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 HbA1c 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.

References


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Abbreviations

ERMAB: equitable restless multiarmed bandit
HbA1c: hemoglobin A1c
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
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<.001). 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.

**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.

<table>
<thead>
<tr>
<th>Disposition</th>
<th>Participants (n=115), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>62 (54)</td>
</tr>
<tr>
<td><strong>Dropoff</strong></td>
<td></td>
</tr>
<tr>
<td>Lost to follow-up (unresponsive)</td>
<td>22 (19.1)</td>
</tr>
<tr>
<td>Other health condition</td>
<td>14 (12.2)</td>
</tr>
<tr>
<td>Product (comfort, allergy, and technical)</td>
<td>7 (6.1)</td>
</tr>
<tr>
<td>Insurance related</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>Lost to follow-up (patient canceled)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>Changed provider</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>Deceased</td>
<td>1 (0.9)</td>
</tr>
</tbody>
</table>

**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).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Patient, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>71.3 (9.6)</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>44 (38.3)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>105 (91.3)</td>
</tr>
<tr>
<td>Diabetes type I</td>
<td>7 (6.1)</td>
</tr>
<tr>
<td>Diabetes type II</td>
<td>98 (85.2)</td>
</tr>
<tr>
<td>Race and ethnicity</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>28 (24.3)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>9 (7.8)</td>
</tr>
<tr>
<td>White</td>
<td>73 (63.5)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Not documented</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Neuropathy</td>
<td>114 (99.1)</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>58 (50.4)</td>
</tr>
<tr>
<td>Smoking</td>
<td>28 (24.3)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>74 (64.3)</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>17 (14.8)</td>
</tr>
<tr>
<td>Foot deformity</td>
<td></td>
</tr>
<tr>
<td>Charcot</td>
<td>14 (12.2)</td>
</tr>
<tr>
<td>Hallux malleus</td>
<td>32 (17.8)</td>
</tr>
<tr>
<td>Hallux valgus</td>
<td>11 (9.6)</td>
</tr>
<tr>
<td>Other</td>
<td>24 (20.9)</td>
</tr>
<tr>
<td>History of ulcers</td>
<td>60 (52.2)</td>
</tr>
<tr>
<td>History of amputation</td>
<td>23 (20)</td>
</tr>
</tbody>
</table>

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) as Asian (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.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unadjusted results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
</tr>
<tr>
<td>Total follow-up years</td>
<td>138.9</td>
</tr>
<tr>
<td>Average follow-up months per patient, mean (SD)</td>
<td>14.5 (9.5)</td>
</tr>
<tr>
<td>Average follow-up months per patient, median (range)</td>
<td>15.2 (2-32)</td>
</tr>
<tr>
<td><strong>Hospitalizations, n</strong></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
</tr>
<tr>
<td>Per patient-year</td>
<td>0.28</td>
</tr>
<tr>
<td><strong>Outpatient office visits, n</strong></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1144</td>
</tr>
<tr>
<td>Per patient-year</td>
<td>8.2</td>
</tr>
<tr>
<td><strong>Amputations, n</strong></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
</tr>
<tr>
<td>Per patient-year</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Foot ulcers, n</strong></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>94</td>
</tr>
<tr>
<td>Per patient-year</td>
<td>0.72</td>
</tr>
<tr>
<td>Per patient</td>
<td>0.86</td>
</tr>
<tr>
<td><strong>Wound severity (before: n=99; during: n=35), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>1A</td>
<td>49 (50)</td>
</tr>
<tr>
<td>1B</td>
<td>15 (15)</td>
</tr>
<tr>
<td>1C</td>
<td>7 (7)</td>
</tr>
<tr>
<td>1D</td>
<td>1 (1)</td>
</tr>
<tr>
<td>2A</td>
<td>13 (13)</td>
</tr>
<tr>
<td>2B</td>
<td>2 (2)</td>
</tr>
<tr>
<td>2C</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2D</td>
<td>1 (1)</td>
</tr>
<tr>
<td>3A</td>
<td>1 (1)</td>
</tr>
<tr>
<td>3B</td>
<td>8 (8)</td>
</tr>
<tr>
<td>3C</td>
<td>0 (0)</td>
</tr>
<tr>
<td>3D</td>
<td>2 (2)</td>
</tr>
<tr>
<td><strong>Moderate and severe ulcers, n</strong></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
</tr>
<tr>
<td>Per patient-year</td>
<td>0.36</td>
</tr>
<tr>
<td>Per patient</td>
<td>0.43</td>
</tr>
</tbody>
</table>

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).
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

Table 4. Adjusted incidence and resource use rates before and during enrollment.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number needed to treat</th>
<th>Absolute risk reduction</th>
<th>Relative risk reduction (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All foot ulcers</td>
<td>5.0</td>
<td>0.200</td>
<td>0.683 (0.52-0.79)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Moderate to severe ulcers</td>
<td>16.2</td>
<td>0.062</td>
<td>0.856 (0.70-0.93)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Outpatient podiatry visits</td>
<td>0.45</td>
<td>2.23</td>
<td>0.308 (0.24-0.37)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>5.7</td>
<td>0.180</td>
<td>0.628 (0.33-0.80)</td>
<td>&lt;.002</td>
</tr>
<tr>
<td>Amputations</td>
<td>41.7</td>
<td>0.024</td>
<td>0.828 (0.39-0.95)</td>
<td>&lt;.006</td>
</tr>
</tbody>
</table>

P value

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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.

Acknowledgments
The authors would like to acknowledge the nurses of the remote monitoring program for their care toward their patients, with special thanks to Denise Garris, Elizabeth Dubberly, and Salina Morris for assisting with data acquisition and tabulation. This study is based on real-world data, and as such, no external funding was provided. Siren Care Inc provided the funding to support the data analysis by an independent third party. We acknowledge the contributions of Chia-Ding Shih DPM, MPH, MA, Gavin Ripp DPM, BS Kirthana Srikanth, BS Caileigh Smith, BA Henk Jan Scholten LLM, BSc Ran Ma, Jie Fu ME, Alexander M Reyzelman DPM.

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