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Original Paper

# Implementation Plan for a High-Frequency, Low-Touch Care Model at Specialized Type 1 Diabetes Clinics: Model Development

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## Abstract

**Background:** Individuals with type 1 diabetes (T1D) are more likely to achieve optimal glycemic management when they have frequent visits with their health care team. There is a potential benefit of frequent, telemedicine interventions as an effective strategy to lower hemoglobin A1c (HbA1c).

**Objective:** The objective of this study was to understand the provider- and system-level factors affecting the successful implementation of a virtual care intervention in type 1 diabetes (T1D) clinics.

**Methods:** Semistructured interviews were conducted with managers and certified diabetes educators (CDEs) at diabetes clinics across Southern Ontario before the COVID-19 pandemic. Deductive analysis was carried out using the Theoretical Domains Framework, followed by mapping to behavior change techniques to inform potential implementation strategies for high-frequency virtual care for T1D.

**Results:** There was considerable intention to deliver high-frequency virtual care to patients with T1D. Participants believed that this model of care could lead to improved patient outcomes and engagement but would likely increase the workload of CDEs. Some felt there were insufficient resources at their site to enable them to participate in the program. Member checking conducted during the pandemic revealed that clinics and staff had already developed strategies to overcome resource barriers to the adoption of virtual care during the pandemic.

**Conclusions:** Existing enablers for high-frequency virtual care for T1D can be leveraged, and barriers can be overcome with targeted clinical incentives and support.

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**KEYWORDS**

type 1 diabetes; virtual care; high-frequency care; implementation science; diabetes; support; incentives; clinics; intervention; behavior change; education; glycemic control; self-management

## Introduction

Individuals with type 1 diabetes (T1D) are more likely to achieve optimal glycemic management when they have frequent

visits with their health care team [1]. Further, prior clinical trials suggest a potential benefit of frequent telemedicine interventions as an effective strategy to lower hemoglobin A1c (HbA1c) among individuals with T1D [2,3]. However, it is not just the frequency of visits that has a significant effect on clinical and

quality of life outcomes but also the type of interaction. There is a growing body of research on the effect of synchronous—or real-time—interactions (ie, in-person, phone calls, or video visits) compared to asynchronous interactions (ie, email or text). For example, Verhoeven et al [4] showed that synchronous telemedicine interactions lowered costs for both patients and the health care system by reducing unscheduled visits compared to usual in-person care. A model of care that includes frequent synchronous interactions between individuals with T1D and their health care teams is particularly beneficial to patients who are not meeting glycemic targets and need to make changes to their diabetes self-management [5]. Unfortunately, this was difficult to deliver in the context of pre-COVID-19 care, which typically involved time-consuming in-person visits during working hours. The necessary move to virtual care during the COVID-19 pandemic provided a window of opportunity to address this gap in T1D management through virtual models of care.

The TIME (Type 1 Diabetes Virtual Self-Management Education and Support) trial aims to test the effectiveness of a model of high-frequency, low-touch (ie, virtual, remote) care with real-time visits for individuals with T1D who are not meeting glycemic targets (HbA1c >8%). If the TIME trial is to be successful during the COVID-19 pandemic and beyond, it must be implemented using evidence-based processes [6]. Evidence-based implementation approaches help bridge the gap between the care that practitioners know is effective and that which is delivered [7] by understanding and targeting the contextual factors of the health care setting [6,8]. These complex contextual factors include organizational support [9], willingness of staff to participate in the intervention [10], and current health care delivery systems [11]. Implementation strategies must be developed to effectively target all these contextual factors. Additionally, most published multifaceted implementation strategies do not provide an explanation for why certain components were chosen [12], making it difficult to assess whether interventions sufficiently address known barriers.

Therefore, in this study, we sought to clarify the complex provider and system factors that need to be considered when implementing a high-frequency virtual care model in T1D diabetes clinics prior to and during the COVID-19 pandemic. Additionally, we sought to comprehensively describe how we developed an implementation plan suited to address the identified factors.

## Methods

### Study Design

This was a theory-informed, qualitative study seeking to understand the determinants of engagement with high-frequency virtual care in general and the TIME trial components and to map those determinants to feasible implementation strategies.

### Ethics Approval

Ethics approval for this study was granted by the Women's College Hospital (2018-0108-E) and the Ottawa Health Science Network Research Ethics Board (20190527-01H).

### Context

Clinical practice guidelines suggest that people with T1D have visits with their diabetes team every 3 months unless their glycemic management is already optimized [13]. More frequent visits with certified diabetes educators (CDEs) and other care providers are often needed to help patients recognize glucose patterns, adjust their insulin doses, and offer education and technical support on the use of insulin pumps and continuous or flash glucose monitoring. In Ontario, people with T1D may be eligible to receive government funding for insulin pumps and related supplies through Ontario Health's Assistive Devices Program (ADP). Individuals registered in this program are required to receive frequent care from a certified pump team. Within this model of care, patients may need to wait 3 to 6 months for appointments with their diabetes team to troubleshoot issues with diabetes self-management. Prior to the COVID-19 pandemic, most visits were conducted in person, requiring individuals with T1D to take time off work or school to visit their team members. This model of care may not be well suited to patients who need additional support or timely enough to enable them to make real-time changes to their diabetes self-management.

The traditional T1D care model, which featured mainly in-person care, was applicable up until the pandemic [14]. In March 2020, diabetes clinics in Ontario, Canada, were mandated to adopt a virtual care model rapidly and with minimal preparation due to COVID-19 lockdown measures implemented. As of December 2021, most T1D care continues to be delivered virtually. However, despite virtualization, indicators suggest that care is still provided with longer, infrequent appointments every 3 to 6 months. Although second vaccination rates have surpassed 80%, and booster doses have surpassed 30% in Ontario [15], it is unlikely that T1D care will return to the prepandemic norm, especially with new variants arising. Instead, diabetes clinics will most likely adopt a "new normal" model of care that will include virtual options when in-person visits are not feasible or needed, as there will be lingering concerns regarding social distancing for some time, and many clinics have already invested in virtual care technologies. Virtualization of diabetes care offers an opportunity to consider shorter, more frequent contacts through more feasible virtual modalities.

The TIME trial seeks to improve this T1D care model and focus on more patient-centered care, which will allow patients to become an important part of the care team and decision-making process. The TIME trial is comprised of 3 components aimed at supporting self-management changes and goal advancement: (1) virtual care software that enables video (or audio and instant messaging) visits between patients and their health care providers; (2) automatic appointment reminders and goal setting prompts; and (3) a centralized virtual library that houses curated and vetted education and self-management resources for individuals living with T1D.

If our high-frequency virtual model is to be successful, we must target key workflow processes and behaviors among diabetes clinic staff. First, many traditionally in-person visits will need to be changed to virtual. This includes understanding and targeting workflow processes related to the uptake of new

telecommunication technology. Second, we must understand the behavior changes in CDEs, clinic leaders and managers, and clinic support staff needed to accommodate a high-frequency care model. Within this model, patients will meet with their CDEs for shorter but more frequent touch points. This will change the nature of the interaction and affect workflow processes. Additionally, we will need to evaluate current resource allocation and the potential impact of our high-frequency, low-touch model on clinic resources. Therefore, in this study, we sought to understand workflow processes, resource allocation, and other factors in implementing a high-frequency, low-touch care model in diabetes clinics.

### Participants and Recruitment

We aimed to recruit between 30 and 40 nurses or dietician CDEs and managers in diabetes education programs at specialized T1D clinics in Southern Ontario. Sites were purposefully selected for variation in factors thought to potentially affect implementation of the intervention, including the total number of patients, number of patients under age 25, number of health professionals, number of patients with most recent HbA1c above 8%, and rurality. For each site, a recruitment email was sent to the lead physician or clinic manager inviting them to participate in a 30- to 45-minute telephone interview. We also sent invitation emails to CDEs and managers identified by the investigators' personal networks. We then recruited additional key informants at each site using snowball sampling. In particular, we sought a team member of the chosen T1D clinic who provided clinical care or support and/or had knowledge regarding the organization of the clinic processes, including technological processes (eg, electronic medical records).

### Data Collection

First, an electronic survey was sent to the clinic manager at each clinic to obtain descriptive information about the clinic, including the number and type of health care professionals, types of communication with patients, wait times, and history with implementations of new programming. Author SdS then conducted semistructured 1-on-1 telephone interviews that were 30 to 45 minutes in duration during working hours. Interviews were recorded, deidentified, and transcribed. Oral informed consent was obtained before beginning the interviews. Field notes were made after each interview.

Interviews followed a semistructured guide (developed by authors NI, JP, SdS, GB, and LLL) that aimed to (1) explore current processes and procedures for management of T1D patients under routine and semiurgent scenarios and (2) examine the determinants of uptake and implementation of our high-frequency, low-touch model of care using the Theoretical Domains Framework (TDF). The TDF is an integrated framework synthesized from 128 theoretical constructs from 33 theories judged most relevant to implementation questions. Domains of the TDF include items such as knowledge, goals, optimizing, and belief about capabilities [16].

### Analysis

Research team members with a range of disciplinary backgrounds in endocrinology (GB), psychology (JP), family medicine (NI), and public health (SdS) reviewed the electronic

survey data and transcriptions in depth to understand the current processes in the clinic and, importantly, the changes required for the intervention to be implemented as intended. The transcripts were examined to explore how the changes required might vary across clinics [17].

Transcriptions of the interviews were then coded using the TDF domains by 2 independent researchers (authors SdS and IP) using a word processor. Coding was mainly deductive, involving content analysis [18] and assigning utterances to the relevant TDF domains. Open coding was used when important issues were identified that did not seem to fit any existing domain. A codebook was maintained and updated regularly to ensure intercoder reliability.

When all transcripts were coded, authors NI, JP, SdS, and GB identified the most important determinants (domains) to be addressed in the implementation and training plan by (1) frequency (ie, which domains, and for which key targeted behavior, most commonly arise as issues to be addressed in the transcripts); (2) conflict (ie, presence of disagreement across participants on certain domains representing a potential need for tailored strategies); (3) strongly held and strongly emphasized beliefs amongst participants about the targeted behavior; and (4) most important determinants to be addressed (ie, determinants that have the highest likelihood of impeding or facilitating implementation) [19]. Additionally, themes within each domain were inductively coded into higher-level barriers and enablers. Then, we mapped out how each domain interacted with other domains. This allowed us to generate a list of theoretical domains most likely to influence the targeted behaviors for the successful implementation of the TIME trial.

Finally, authors NI, JP, and SdS used the Behavior Change Techniques Taxonomy Version 1 (BCTTv1), developed through an international consensus process, to identify actions that would enable the interventions to become more easily adopted into routine care [20,21]. This taxonomy provides clarity surrounding the specific, active ingredients needed to elicit behavior change and draws on applied research in behavioral medicine, as well as social and health psychology. BCTs likely to influence key TDF domains have been previously mapped [21]. Team members (authors NI and JP) with training and experience identified the most promising BCTs thought to be feasible to utilize in the implementation and training strategies for the intervention. We used these BCTs and the most relevant theoretical domains to create a comprehensive implementation and training plan, which could be tailored to each site if necessary.

Analysis and data collection occurred concurrently, and recruitment ceased once thematic saturation was reached. Our threshold for thematic saturation was 2-fold. First, our initial analysis sample (minimum sample size) included at least 1 CDE and 1 manager from each site. Following that, our stopping criterion was a 0% new information threshold in the key theoretical domains [22,23].

### Member-Checking Calls

Author SdS conducted member-checking calls with participants to ensure that our interpretation of the barriers and enablers



from the original interviews accurately reflected the context of their specific clinics [24]. Since the member-checking calls were conducted during the COVID-19 pandemic, we also took the opportunity to inquire about whether our interview results held true during the context of completely virtual care and understand processes that clinics initiated to accommodate virtual care.

Member-checking calls were recorded, deidentified, and transcribed. Field notes were made during the member-checking call. Two independent researchers (authors SdS and IP) coded the transcripts using a word processor. We used deductive analysis, assigning quotes to the barriers and enablers from the original interviews. We also used open coding for issues other than the barriers and enablers identified in the interviews. A

member-checking codebook was maintained and updated regularly to ensure intercoder reliability.

## Results

### Participants and Sites

Between February 1 and May 16, 2019, we interviewed 35 participants across 12 diabetes clinics in Southern Ontario. Of the 35 interviews completed, 20 (57%) participants were CDEs, 13 (37%) were managers, 1 (3%) was an administrative coordinator, and 1 (3%) was a social worker. Two sites declined participation, and 3 sites did not respond to the invitation email. **Table 1** contains the demographic information and process in each participating clinic.

**Table 1.** Descriptive information about Ontario Health's Assistive Devices Program (ADP) pump sites.

Clinic	Providers per site or network <sup>a</sup> , n	EMR <sup>b</sup>	Minutes per day calling or emailing patients <sup>c</sup>	Methods used for virtual communication (other than in-person visits)	
				Prepandemic	Postpandemic
1	23	Yes	20-40	Telephone, email	N/A <sup>d</sup>
2	81	Yes	>60	Telephone, email	Telephone, email, Zoom
3	25	Yes	>60	Telephone, email, OTN <sup>e</sup>	Telephone, email, Zoom
4	16	No	>60	Telephone, email, OTN	Telephone, email
5	22	Yes	40-60	Telephone, email	Telephone, email, Zoom
6	28	Yes	>60	Telephone, email	Telephone, email, WebEx
7	15	No	20-40	Telephone, email, OTN	Telephone, email
8	8	Yes	N/A	Telephone, email, SMS	Telephone, email, Zoom
9	19	Yes	20-40	Telephone, email	Telephone, email, OTN, MS <sup>f</sup> teams
10	15	Yes	40-60	Telephone, email, OTN, SMS	Telephone, email, OTN, Zoom
11	15	Yes	N/A	N/A	Telephone, email, Zoom
12	N/A	No	N/A	N/A	N/A

<sup>a</sup>All health care providers for type 1 diabetes (T1D) care (endocrinologists, nurses, dieticians, etc); based on full-time equivalent, rounded-up.

<sup>b</sup>EMR: electronic medical record.

<sup>c</sup>Prepandemic.

<sup>d</sup>N/A: not applicable.

<sup>e</sup>OTN: Ontario Telemedicine Network.

<sup>f</sup>MS: Microsoft.

### Key Barriers and Enablers to High-Frequency, Low-Touch Care

We separated our findings into the 2 components of the TIME trial (ie, high frequency and low touch).

Within the component of low-touch (virtual) care, we found 2 main barriers. First, there was the belief that low-touch care would lead to an increased workload. This included double administrative work and increased time and work spent on troubleshooting technical glitches. As 1 participant stated, "It takes up a very [large] amount of our health care practitioners' time to troubleshoot the technology" [participant #19].

Second, managers reported that there was a lack of financial resources to obtain virtual care technology and a lack of private clinic space and offices to offer virtual care.

Alternatively, participants noted that there was an interest and intention to use virtual care. However, this interest and intention varied depending on the CDE, manager, and institution. For example, as 1 CDE noted, their "organization as a whole wants [low-touch care], and [I] know that part of their strategic direction for the next five years is to increase virtual visits, so this aligns with that" [#15]. On the other hand, some managers wanted to observe the success of the program before agreeing to participate: "If the feedback is positive, then yes, absolutely" [#22]. Finally, the CDEs and managers who believed that low-touch care would improve patient outcomes and had

existing skills and comfort with virtual care (ie, phone, email, video visits) had more of an intention to participate in the TIME trial.

We also found barriers and enablers relating to high-frequency care. First, the belief that high-frequency care would increase the workload of charting and documentation was a barrier to the uptake of the TIME trial. Second, clinic staff reported that there was a lack of resources such as staff, capacity, and time to successfully implement high-frequency care. For example, 1 manager stated that she was “very hesitant about [participating in the TIME trial], just because the volumes that we deal with and the admin support that we have, we just can’t handle that” [#6].

However, clinic staff who believed that high-frequency care would lead to better patient outcomes and increased patient engagement were more likely to participate in the TIME trial. As 1 CDE stated, high-frequency care would be “wonderful” for patients:

*More frequent low-touch follow-up is probably going to be a wonderful thing for them, a way to check in or get questions clarified. Now, I’m trying this out. Now, the rubber meets the road. Here’s a little hiccup. Being able to troubleshoot that. [#27]*

To further enable the successful implementation of the TIME trial as a whole, engagement of CDEs throughout the TIME trial was deemed necessary:

*Most of the staff here are very open to trying different things if the patients want it. Again, it has to be something that the patients are willing to do. [#5]*

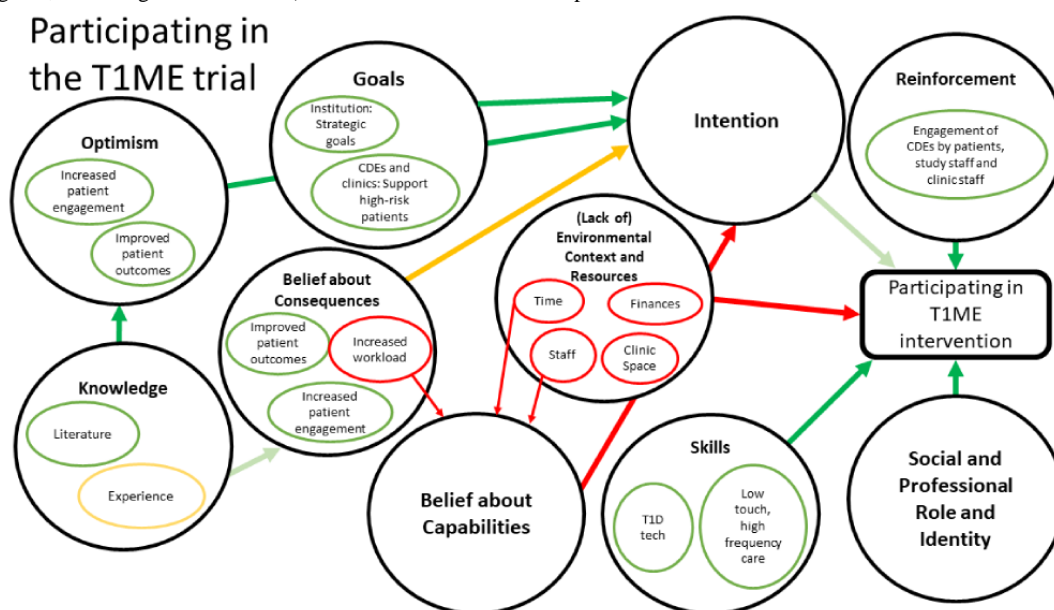
Positive patient feedback, adoption of the program by a local champion and other clinic staff, and continuing support from the TIME trial team were suggested as methods to encourage CDE participation and offer ongoing engagement in the program.

### Theoretical Domains

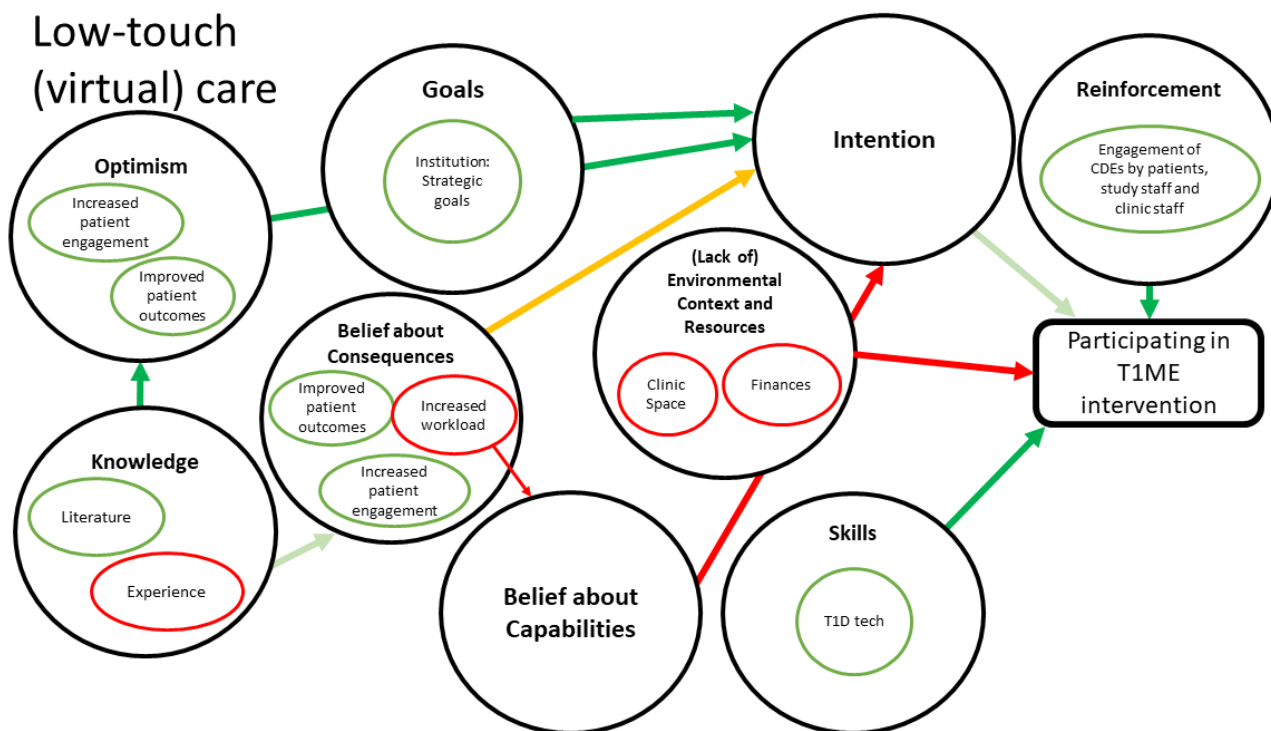
We identified that themes coded within some theoretical domains related to those in the same domain and other domains. For example, there were 3 themes within the “beliefs about consequences” domain: (1) improved patient engagement, (2) improved patient outcomes, and (3) increased workload. If participants believed that the TIME trial would increase their workload, they reported less intention to participate. On the other hand, if participants believed that the TIME trial would improve patient outcomes and engagement, they were more likely to participate in the program. Therefore, multiple different beliefs about consequences likely affected the relative intention to participate.

Figure 1 maps how constructs within domains may relate to other domains and ultimately affect clinic staff participation in the TIME trial. Figure 2 exhibits the map for low-touch care, which contains the theoretical domains of knowledge, optimism, belief about consequences, goals, skills, reinforcement, and intention. In addition to the aforementioned domains, the high-frequency component (Figure 3) was informed by the domain of social and professional roles and identity.

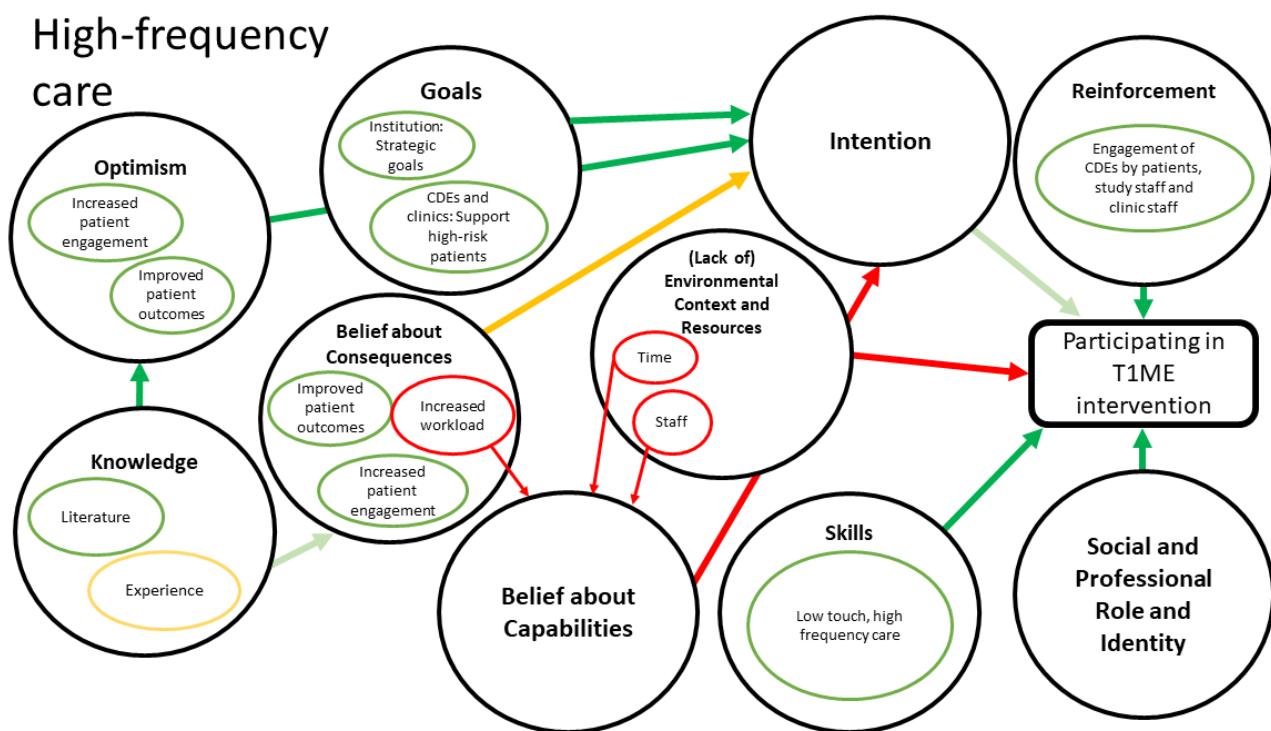
**Figure 1.** Map of interactions between theoretical domains. Large black circles show Theoretical Domains Framework (TDF) domains important to our project. Smaller circles within the large circles identify concepts that were identified during our analysis. Green arrows and circles indicate facilitators (the darker the green, the stronger the facilitator). Yellow arrows and circles depict a mixed effect. Red arrows and circles show the barriers.



**Figure 2.** Map of interactions between theoretical domains for low-touch (virtual) care. Large black circles show Theoretical Domains Framework (TDF) domains important to our project. Smaller circles within the large circles identify concepts that were identified during our analysis. Green arrows and circles indicate facilitators (the darker the green, the stronger the facilitator). Yellow arrows and circles depict a mixed effect. Red arrows and circles show the barriers.



**Figure 3.** Map of interactions between theoretical domains for high-frequency care. Large black circles show Theoretical Domains Framework (TDF) domains important to our project. Smaller circles within the large circles identify concepts that were identified during our analysis. Green arrows and circles indicate facilitators (the darker the green, the stronger the facilitator). Yellow arrows and circles depict a mixed effect. Red arrows and circles show the barriers.



**Member-Checking Calls**

Between June 23 and September 10, 2020, we completed member-checking calls with 20 of our 35 participants at 8 out

of 12 sites. We spoke to 13 CDEs, 6 managers, and 1 administrative coordinator. Some of the staff we originally interviewed were redeployed to COVID-19 testing centers at



their respective institutions and were therefore unable to complete the member-checking call.

In general, participants agreed with the barriers and enablers we previously identified in this paper. Additionally, a few opportunities arose during the COVID-19 pandemic. First, even though participants agreed with the barriers, 1 CDE noted that barriers never impeded offering care to patients who needed it:

*I would say that staffing has always been an issue to some extent...but I don't know that it necessarily affected our ability to see those patients who really needed to be seen. [#16]*

Additionally, some clinics invested in technology, such as laptops for staff to offer virtual care to patients. Moreover, during the forced switch to virtual care, those who wanted evidence of success in high-frequency, low-touch care before agreeing to participate in the TIME trial received it:

*I worried that accountability wouldn't be there as much, but I think that's proven me wrong very much. Since COVID-19, I think people are more engaged even by phone. [#19]*

The pandemic provided an opportunity to explore both barriers and enablers of the current implementation of (low-touch) virtual care and distinguish them from those of high-frequency care. Like clinic staff, patients also had to get accustomed to virtual care visits. This included learning how to log on to and participate in virtual visits and read, interpret, upload, and share blood sugar data from pumps and continuous glucose monitors. Moreover, patients had to change their mindset and understand

that the phone call was an actual visit. One CDE noted that her appointments were longer because patients were not as prepared for the virtual visit as they would be for an in-person appointment:

*We tell [patients] that we're going to be calling them for care. Next thing you know, "Well, wait a minute, my meter is up in my bedroom. Oh, wait a minute, my pills are in the kitchen." [#20]*

However, most CDEs noted that as the pandemic progressed, patients acclimated to virtual care and began to enjoy it, which was a significant source of engagement for the CDEs:

*Some people are saying, "So, do I have to come in the next time?" That's kind of been the message. And almost everyone's like, "I'm really fine if it's this virtual again." Very rarely do I get the question of, "When can I come in person?" [#33]*

### Implementation Plan

We identified the antecedent and key domains in our map (Figures 1-3) and linked them to the behavior change techniques shown to influence those specific domains. Additionally, during our member-checking process, we learned that clinic staff created a number of workarounds to offer a similar level of care virtually. We integrated these lessons into specific components of our implementation plan, such as the TIME manual of operations. Thus, we created a comprehensive implementation and training plan targeting the key domains and lessons learned during the pandemic (Table 2).

**Table 2.** Implementation and training plan.

Component and its theoretical domains	Behavior change techniques	Actions
<b>Manual of operations</b>		
<ul style="list-style-type: none"> <li>Knowledge</li> <li>Belief about consequences</li> <li>Intention</li> </ul>	<ul style="list-style-type: none"> <li>Information about health consequences</li> </ul>	<ul style="list-style-type: none"> <li>Create 1-page summary of relevant literature supporting high-frequency, low-touch care</li> </ul>
<ul style="list-style-type: none"> <li>Knowledge</li> <li>Skills</li> <li>Belief about capabilities</li> </ul>	<ul style="list-style-type: none"> <li>Problem solving</li> <li>Instruction on how to perform behavior</li> </ul>	<ul style="list-style-type: none"> <li>Plan how to resolve IT issues</li> </ul>
<ul style="list-style-type: none"> <li>Belief about capabilities</li> </ul>	<ul style="list-style-type: none"> <li>Problem solving</li> </ul>	<ul style="list-style-type: none"> <li>Plan how to schedule and block off time for virtual visits</li> <li>FAQs<sup>a</sup> (eg, what to do if patient misses virtual visit)</li> </ul>
<ul style="list-style-type: none"> <li>Knowledge</li> <li>Skills</li> <li>Belief about capabilities</li> </ul>	<ul style="list-style-type: none"> <li>Instruction on how to perform behavior</li> </ul>	<ul style="list-style-type: none"> <li>Frequency and duration of virtual visits</li> </ul>
<b>Training session</b>		
<ul style="list-style-type: none"> <li>Belief about capabilities</li> </ul>	<ul style="list-style-type: none"> <li>Demonstration of behavior</li> </ul>	<ul style="list-style-type: none"> <li>Create modeling session</li> </ul>
<ul style="list-style-type: none"> <li>Belief about capabilities</li> <li>Skills</li> </ul>	<ul style="list-style-type: none"> <li>Demonstration of behavior</li> <li>Problem solving</li> <li>Rehearsal/practice</li> </ul>	<ul style="list-style-type: none"> <li>Create practice session processes (including with glitchy technology and common patient issues)</li> </ul>
<ul style="list-style-type: none"> <li>Belief about capabilities</li> </ul>	<ul style="list-style-type: none"> <li>Problem solving</li> </ul>	<ul style="list-style-type: none"> <li>FAQs (eg, what to do if patient misses virtual visit)</li> </ul>
<b>Monthly newsletters</b>		
<ul style="list-style-type: none"> <li>Reinforcement</li> <li>Social influences</li> </ul>	<ul style="list-style-type: none"> <li>Social reward</li> </ul>	<ul style="list-style-type: none"> <li>Highlight a CDE<sup>b</sup> or site every month when they do something good in the trial</li> </ul>
<ul style="list-style-type: none"> <li>Memory</li> <li>Attention and decision processes</li> <li>Environmental context and resources</li> </ul>	<ul style="list-style-type: none"> <li>Prompts/cues</li> </ul>	<ul style="list-style-type: none"> <li>Write feature piece on topic on virtual library</li> </ul>
<ul style="list-style-type: none"> <li>Knowledge</li> <li>Belief about consequences</li> <li>Intention</li> </ul>	<ul style="list-style-type: none"> <li>Information on health consequences and social and environmental consequences (depending on what the patient story is about)</li> </ul>	<ul style="list-style-type: none"> <li>Write piece on patient stories</li> </ul>
<b>Monthly meetings</b>		
<ul style="list-style-type: none"> <li>Reinforcement</li> <li>Social influences</li> </ul>	<ul style="list-style-type: none"> <li>Social reward</li> </ul>	<ul style="list-style-type: none"> <li>Compile success statistics</li> </ul>
<ul style="list-style-type: none"> <li>Environmental context and resources</li> <li>Social influences</li> </ul>	<ul style="list-style-type: none"> <li>Practical and social support</li> <li>Problem solving</li> </ul>	<ul style="list-style-type: none"> <li>Create process for problem solving as a team</li> </ul>
<ul style="list-style-type: none"> <li>Emotion</li> </ul>	<ul style="list-style-type: none"> <li>Reduce negative emotions</li> </ul>	<ul style="list-style-type: none"> <li>Create process for study team to gauge frustrations and come up with solutions</li> </ul>
<ul style="list-style-type: none"> <li>Goal</li> </ul>	<ul style="list-style-type: none"> <li>Discrepancy between current behavior and goal</li> </ul>	<ul style="list-style-type: none"> <li>Create audit and feedback processes</li> </ul>
<b>Data collection to share with CDEs and managers</b>		
<ul style="list-style-type: none"> <li>Belief in capabilities</li> <li>Belief in consequences</li> </ul>	<ul style="list-style-type: none"> <li>Information about social and environmental consequences</li> <li>Pros/cons comparative</li> </ul>	<ul style="list-style-type: none"> <li>Collect data on CDE workload</li> </ul>

Component and its theoretical domains	Behavior change techniques	Actions
<ul style="list-style-type: none"> <li>• Belief in capabilities</li> <li>• Belief in consequences</li> </ul>	<ul style="list-style-type: none"> <li>• Salience of consequences</li> <li>• Information about social and environmental consequences</li> <li>• Pros/cons comparative</li> </ul>	<ul style="list-style-type: none"> <li>• Collect data on patient use</li> </ul>

<sup>a</sup>FAQ: frequently asked question.

<sup>b</sup>CDE: certified diabetes educator.

## Discussion

### Principal Findings

It is estimated that only 20% of health research funding makes a public health impact [25]. This can be explained in part by the evidence-to-practice gap, which refers to the disconnect between the care that practitioners know is effective and that which is actually delivered [7]. To overcome this gap, implementation science approaches have been developed to understand the contextual factors of the setting in which the health care intervention is being implemented [6,8]. In this study, we took an implementation science approach to design and implement a virtual, high-frequency model of care intervention for type 1 diabetes clinics in Ontario, Canada, based on site-specific characteristics, semistructured interviews with clinic staff, and behavior change and implementation literature. Our interviews were completed before the COVID-19 pandemic; therefore, we completed a member-checking exercise during the pandemic to assess if our interview findings were still relevant within the context of predominantly virtual care.

Prior to the pandemic, health care providers in the T1D clinics we interviewed reported 2 main barriers in both the high frequency and low touch components. First, they shared the belief that this model of care would lead to an increased workload. Second, they felt that clinics did not have the necessary resources to implement the program successfully. However, during the pandemic when all clinics were utilizing virtual care, these clinics quickly developed strategies to overcome those barriers. Although the workload increased due to some clinic staff being redeployed to COVID-19 testing centers, those we spoke to felt that patients who needed care still received it. Additionally, some institutions invested in virtual care technology during this time, decreasing the barrier that was voiced prior to the pandemic regarding the lack of financial resources to obtain technology. These findings are encouraging, and they suggest that existing barriers to participating in virtual health care interventions can be overcome with the right support, such as technical training and resource allocation by the organization. However, these needs are not specific to diabetes clinics. Mohammed et al [26] showed that technical training and in-house organizational and administrative assistance were also important to primary care physicians and nurses in Ontario when using virtual care during the COVID-19 pandemic.

Our study also revealed important enablers to participating in a high-frequency, virtual health care intervention. During interviews that were conducted prior to the pandemic, participants noted an interest and intention among staff to deliver

high-frequency, low-touch care and that continued engagement of staff would encourage the long-term success of studies such as the TIME trial. Patient feedback was reported as being a great source of engagement for staff, and belief that the intervention would result in better patient outcomes was associated with an increased intention to participate in the trial. Similar to observations reported from health care providers across Canada during the pandemic, the CDEs we interviewed learned that patients were just as engaged in their care virtually as they were during the prepandemic period when most visits were conducted in person, and many patients wanted to continue virtual care as their primary means of follow up [27].

Lessons learned during the COVID-19 pandemic helped us update our implementation and training plan. Staff overcame some virtual care barriers (Figure 2) during the pandemic, and we used these lessons to make our implementation plan more robust. For example, we learned about common IT issues and how staff solved them, as well as about common patient issues and questions. We used these findings to update our manual of operations and training sessions. Moreover, we were able to collect examples of positive experiences between health care providers and patients using virtual care. These experiences will be used to increase the uptake of the TIME trial by staff. Finally, now that clinic staff have become comfortable with virtual care, our team has focused more attention on tailoring our implementation plan to target factors surrounding a high-frequency care model. This includes dedicating more time to the modeling and practice portions of training sessions that offer guidance to CDEs on how to offer patient-centered care in shorter but more frequent touch points than are currently used.

### Strengths and Limitations

This study has a few notable strengths. First, we used a theory-based approach to create our interview guide. The TDF has mainly been used for implementation in health care contexts when understanding the behaviors of clinicians [19]. Therefore, we were able to ascertain significant implementation factors in this context. While other implementation theories have also been used to successfully implement complex interventions in health care, they come with limiting factors. For example, the Normalization Process Theory, which is centered around behavior rather than belief or intentions [28], has been criticized for focusing on the actions of health care providers rather than the experiences of the patients for whom the intervention is supposed to benefit [29]. Unlike our findings using TDF, Ross et al [10] found that the Normalization Process Theory did not account for the importance that diabetes health care providers placed on patient feedback; therefore, they were not able to include this factor in their implementation strategy. The TDF,

however, does not come without critiques. For example, a strictly deductive analysis using the TDF will not allow non-TDF elements to be identified [30]. We overcame this limitation by using open coding when important issues were identified that did not clearly fit within an existing TDF domain. We also developed themes inductively within domains. Additionally, we will evaluate our implementation strategy, which will allow us to further refine our research plan to include any missing factors. Finally, our data collection prior to and during the pandemic facilitated the creation of a more robust implementation plan that can be applied to a variety of contexts. The feedback we obtained provides insights into what diabetes care will look like in the post-COVID-19 context so that we can adjust our research plan to meet these needs.

There are also a few limitations in our study to note. While we were able to interview diabetes staff in diverse clinics, all but 1 of our clinics were in urban settings. Therefore, the experiences of staff in these clinics may not reflect those of clinic staff in nonurban settings. Additionally, we were not able to reach staff from 3 clinics during the member-checking exercise, so we may have missed some important COVID-19-related barriers. Moreover, many members of our team are endocrinologists or research staff in diabetes clinics. Our prior experience and working relationships with some

participants could be a potential bias in how we carried out the interviews and in our interpretation of the findings. Finally, end-user implementation factors were not assessed in this project. However, the TIME trial team has conducted a separate project to understand the needs of people living with T1D regarding high-frequency, virtual care. Together, the results of both projects will give us a robust and comprehensive plan to implement the TIME trial.

## Conclusion

For a complex health intervention to be successful, an implementation science approach is needed to understand contextual factors and identify levers that can support behavior change. Using site-specific characteristics, semistructured interviews with clinic staff, and behavior change and implementation literature, we developed a robust implementation and training plan to successfully implement a high-frequency, low-touch care model in diabetes clinics in Southern Ontario. Data were collected before and during the COVID-19 pandemic to enhance the effectiveness of our implementation strategy. An evaluation of our implementation plan in diabetes clinics in Toronto will allow us to create an improved iteration before applying it to other clinics in Ontario in the post-COVID-19 context.

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## Authors' Contributions

SdS, JP, GB, LLL, BAP, RS, GL, and NI were integral in planning the study. SdS, JP, GB, LLL, and NI created the interview guide. SdS conducted the original and member-checking interviews. SdS and IP conducted qualitative coding for the original and member-checking interviews. SdS, JP, GB, and NI conducted the secondary qualitative analysis and created the implementation plan. SdS and NI drafted the manuscript. SdS, JP, GB, LLL, IP, BAP, RS, GL, and NI edited and approved the final version of the manuscript. GB, LLL, BAP, RS, and NI obtained the funding for this study.

## Conflicts of Interest

BAP has received speaker honoraria from Abbott, Medtronic, Insulet, and Novo Nordisk; served as an advisor to Insulet, Boehringer Ingelheim, Novo Nordisk, and Abbott; and has received research support to his research institute from Boehringer Ingelheim, Novo Nordisk, and the Bank of Montreal (BMO). NI has received speaker honoraria from Janssen; provided evaluation consulting from Merck, IQVIA, Centre for Effective Practice, and Diabetes Canada; and serves on the advisory board for Novo-Nordisk. LLL has received an honorarium for a presentation by the Alberta Diabetes Institute. RS has received speaking fees from Dexcom.

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## Abbreviations

**ADP:** Assistive Devices Program

**BCT:** behavior change technique

**BCTTv1:** Behavior Change Techniques Taxonomy Version 1

**CDE:** certified diabetes educator

**EMR:** electronic medical record

**HbA1c:** hemoglobin A1c

**T1D:** type 1 diabetes

**TIME:** Type 1 Diabetes Virtual Self-Management Education and Support

**TDF:** Theoretical Domains Framework

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Original Paper

# Exploring the Experiences and Perspectives of Insulin Therapy in Type 2 Diabetes via Web-Based UK Diabetes Health Forums: Qualitative Thematic Analysis of Threads

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## Abstract

**Background:** Despite the advent of type 2 diabetes (T2D) remission strategies and novel therapeutic agents, many individuals with T2D will require insulin treatment to achieve target glycemia, with the aim of preventing or delaying diabetes complications. However, insulin refusal and cessation of treatment in this group are common, and their needs are underreported and relatively unexplored.

**Objective:** This study aimed to explore the experiences and perspectives of individuals with T2D for whom insulin therapy is indicated as expressed on web-based health forums, in order to inform the development of evidence-based structured educational and support strategies and improve health care provider awareness.

**Methods:** Retrospective archived forum threads from the 2 largest, freely and publicly accessible diabetes health forums in the United Kingdom were screened over a 12-month period (August 2019-2020). The Diabetes UK and Diabetes.co.uk forums were searched for relevant threads. A total of 3 independent researchers analyzed the forum threads and posts via thematic analysis. Pertinent themes were identified and illustrated by paraphrasing members' quotes to ensure anonymity. A total of 299 posts from 29 threads from Diabetes UK and 295 posts from 28 threads Diabetes.co.uk were analyzed over the study period. In all, 57 threads met the inclusion criteria and were included in the final analysis.

**Results:** Four overarching themes were generated to illustrate the unmet needs that prompted members to seek information, advice, and support regarding insulin therapy outside of their usual care provision via the forums: empowerment through sharing self-management strategies, seeking and providing extended lifestyle advice, relationships with health care professionals, and a source of psychological peer support.

**Conclusions:** This is the first study to collect data from web-based health forums to characterize the experiences and perspectives of people with T2D for whom insulin therapy is indicated. The observed naturalistic conversations have generated useful insights; our findings suggest that there are significant unmet self-management and psychological needs within this group that are not being met elsewhere, prompting the seeking of information and support on the web. These include practical aspects such as insulin injection technique, storage and dose titration, driving and travel considerations, the emerging use of technology, and a strong interest in the effects of extended lifestyle (diet and activity) approaches to support insulin therapy. In addition, problematic relationships with health care professionals appear to be a barrier to effective insulin therapy for some. In contrast, seeking and offering mutually beneficial, practical, and psychological support from peers was viewed as enabling. The study results will help to directly inform insulin-focused self-management and support strategies to enable individuals in this group to achieve their best outcomes.

**KEYWORDS**

type 2 diabetes; adults; qualitative; insulin; internet; web-based

## Introduction

### Background

Type 2 diabetes (T2D) is a significant public health challenge worldwide. In the United Kingdom, the prevalence rate of 3.9 million diagnosed individuals, plus an additional 1 million undiagnosed and unaware, is predicted to rise to 5.3 million by 2025, potentially affecting over 11% of the population [1]. The treatment of largely preventable long-term complications of T2D, including cardiovascular disease, nephropathy, retinopathy, and neuropathy, already uses 11% of the National Health Service (NHS) budget. This figure is set to rise, mirroring prevalence rates as well as the cost of increasingly expensive diabetes therapeutic agents. In addition, T2D can place a huge burden on affected individuals, their families, and society; for example, loss of income, use of social security benefits, and early retirement [2].

Effective treatment of T2D can help prevent or delay the onset of complications [3]. However, to achieve target glycemia and glycated hemoglobin (HbA1c), individuals are often required to adopt extensive self-management behaviors, such as attention to diet, activity, and adherence to multiple therapeutic agents, which may include insulin therapy. Recent developments such as diet based “remission,” and the advent of pharmacological agents such as glucagon-like peptide-1 and sodium-glucose co-transporter-2 classes have highlighted the potential to prevent or delay the requirement for insulin for some individuals [4,5]. However, for many, T2D will remain a lifelong and progressive condition, advancing from the insulin-resistant state to pancreatic beta-cell exhaustion and insulin insufficiency [6]. Mirroring these prevalence rates, the estimated number of people with T2D who were insulin-treated increased from 136,800 (95% CI 120,700-155,200) in 1991 to 421,300 (95% CI 399,800-444,100) in 2010 in the United Kingdom [7].

### Lifestyle and Therapy Challenges With Insulin in T2D

The multifaceted challenges of insulin therapy for people with T2D are complex. Current worldwide literature suggests that 25% to 47% of individuals with T2D refuse or are unwilling to start insulin [8-11]. Negative health beliefs (cognitions) are common, including fear of injections, uncertainty around efficacy, fears around hypoglycemia, potential weight gain and misconceptions that starting insulin represents a poorer prognosis, or “the end of the road” in their treatment and condition [12,13]. In total, 20% of individuals who start insulin disrupt their treatment (omitting doses) [13], and 20% to 40% cease treatment altogether [14-17]. One in 5 who do persist are affected by “diabetes distress,” an emotional state characterized by feelings of frustration, defeat or being overwhelmed [18]. In addition, health care professionals (HCPs) may perpetuate these cognitions by demonstrating “clinical inertia,” an aversion or delay in recommending insulin therapy. Collectively, these

phenomena have been termed “psychological insulin resistance” [9,11].

### Diabetes Self-Management Education and Support in Insulin Therapy

Diabetes Self-Management Education and Support (DSMES) is a strategy that can be used to empower and support insulin-treated individuals with T2D. Most UK-based programs are developed and led by diabetes specialist nurses and diabetes dietitians. However, they vary in structure and curriculum, and their efficacy is limited, fractured, and rarely evidence based. A meta-analysis of insulin DSMES interventions for adults with T2D from our research group suggested a small significant reduction in HbA1c levels (N=10, standardized mean difference 0.22, 95% CI 0.34-0.10,  $P<.001$ ). The methodological quality was moderate to poor for most studies, and the theory and evidence bases for the interventions were not well described [19]. Therefore, there is a need for effective evidence-based DSMES for insulin-treated people with T2D.

### Using the Internet for Research

A total of 92% of adults in the United Kingdom were recent internet users in 2020 [20] and 70% of people using the internet have searched for health information on the web [21]. Web-based forums are increasingly accessed by the web-based “diabetes community” to seek information, support, and discuss their concerns [22]. By joining a diabetes health forum, members seek to improve their ability to understand the condition, treatment, and improve their self-management skills, while being presented with opportunities for peer support, reassurance, and friendship [23]. Previous studies on health forums have suggested benefits from these web-based interactions, resulting in better knowledge about their condition and improved “health activation” in members [24]. To date, the web-based diabetes community in the United Kingdom has been dominated by individuals with type 1 diabetes (T1D), or parents of children with T1D. It could be argued that this group may have specific demographics that are more likely to seek health advice and support on the web, being generally younger and more activated to achieve health goals, particularly around insulin therapy. This is reflected in the number of replies from people with T1D to the posts we examined. However, the number of people with T2D who currently access the forums is significant and increasing, reflecting the growing prevalence rates, diagnosis of T2D at a younger age and increased need for insulin treatment in this group. This study is the first to explore the needs of individuals with T2D who are recommended or prescribed insulin therapy, via a thematic analysis of diabetes health forums. The threads and posts that chart personal experiences within these forums contain a wealth of information and an opportunity for researchers to examine real-world experiences [25].

## Methods

### Overview

Accessing health forums for research allows for the examination of rich data and the subjective experiences of “members” (individuals who join the forum and may post or reply on the web). Analyzing interactions between peers in this way has the potential to provide a perspective and understanding that is difficult to achieve in offline contexts and may have an advantage over other qualitative methodologies; for example, a reduction in social desirability bias [26]. This unique approach may uncover additional data that traditional qualitative methodologies may not, providing a valuable contribution to the existing body of knowledge.

### Patient and Public Involvement

A recent qualitative study published by the study team used semistructured interviews with participants who had attended a traditional, non-evidence-based insulin initiation group. Positive experiences were associated with sharing experiences with peers, reassurance, and the skill of the facilitator in addressing both practical and psychological concerns [27]. However, a subsequent patient and public involvement group with 8 insulin-treated participants with T2D suggested that there were many additional unmet needs that the study had not identified. In addition, the patient and public involvement group consensus was that they (people with T2D receiving insulin therapy) felt neglected or “the poor cousins” in terms of the current research focus on diabetes, which they felt revolved around diabetes remission or newer therapeutic agents. It became clear that an understanding of the perspectives and needs of a significant population of people with T2D who are recommended or prescribed insulin therapy or will be in the future remains significantly lacking.

### Ethics Approval

Minimal risk ethical approval for the study was granted from King’s College London University (ref: MRA-19/20-20587). Important ethical questions related to intrusiveness and perceptions of a forum as a public or private domain were considered. Data that are freely and publicly accessible, particularly if carried out “passively,” that is, the researchers do not involve themselves in the forums, have been documented as ethical. As such, no interaction with the forum was made, in keeping with observing social responsibility and the British Psychological Association code of Human Research Ethics guidelines [28]. As the data were collected from open-access websites that are in the public domain, consent was not sought. Although we have chosen to disclose the names of the forums, care has been taken to maintain the anonymity of member’s identity from the “threads” (a discussion, usually starting with

a question from a member) and “posts” (questions and replies within a thread).

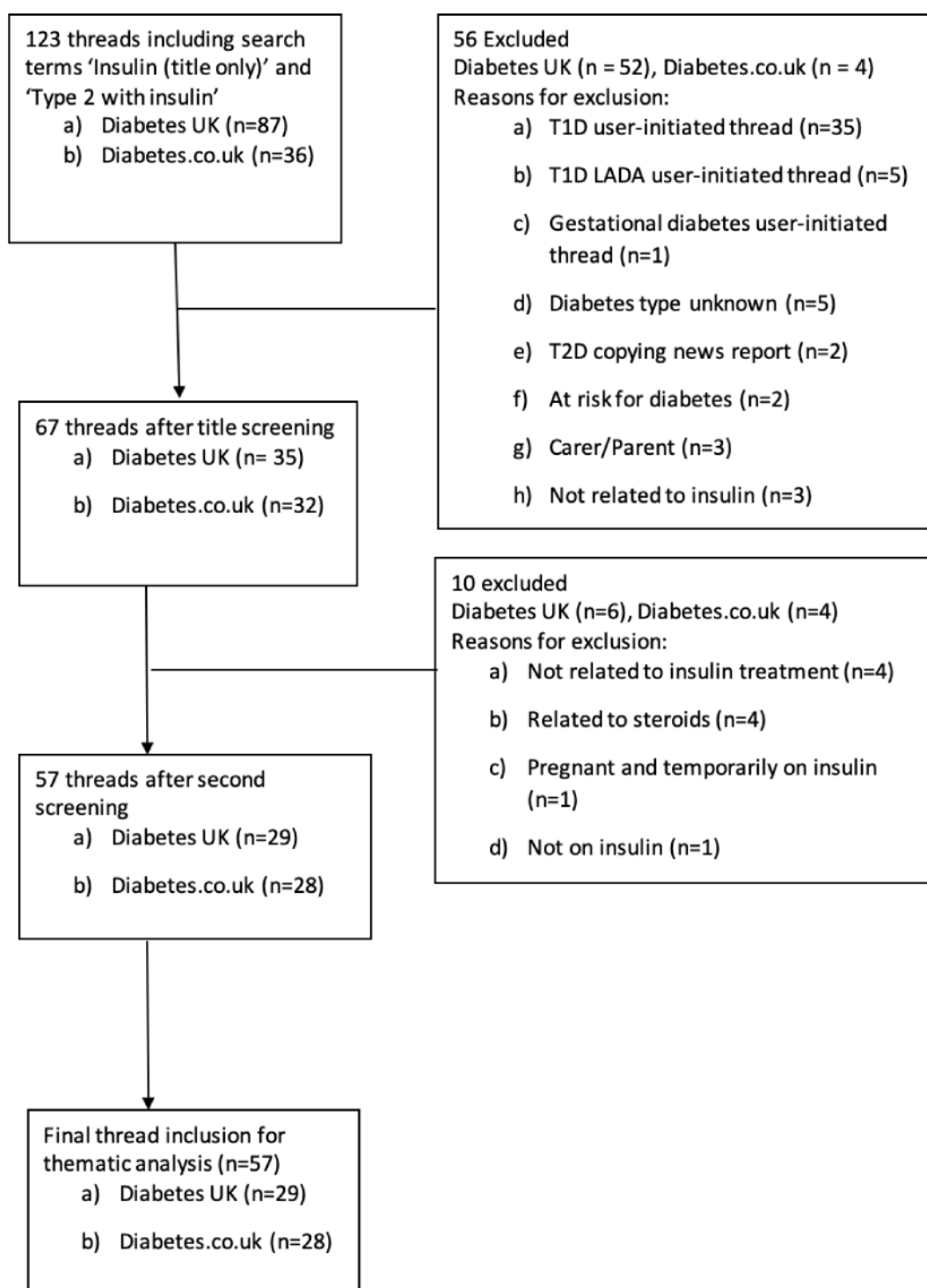
### Design

Two diabetes health forums were identified and selected via the 3 most popular UK internet search engines (Google, Bing, and Yahoo), accessed by 98.83% of users in 2019 to 2020 [29]. Diabetes.co.uk [30], a patient-focused, self-help website with nearly 343,000 members, is considered the most actively used social media forum for people with diabetes [31]. Diabetes UK, a charity, attracted over half a million visits to their forum in 2019 [32]. Both sites are nonsubscription, moderated (screened by the organization to ensure that only appropriate content is posted), and publicly accessible. There are other nonsubscription, web-based diabetes forums in the United Kingdom; however, these large forums were selected because of their reach, popularity, and dedicated message boards [33].

### Data Collection

Retrospective archived forum threads were screened between August 1, 2019, and August 1, 2020 (ie, a 12-month period). Within the Diabetes UK forum, the search term “insulin (title only)” was used. On Diabetes.co.uk [30], threads were screened within an existing “Type 2 with insulin” message board. In the first screening stage, 2 researchers (MAT and RU) independently reviewed the titles and thread descriptions to determine eligibility. These were compared among the researchers, and any uncertainty at this stage resulted in the titles being carried forward to the next screening phase. In the second screening stage, the posts and threads were reviewed. The initial post was screened to determine relevance, that is, it was posted by a person with T2D, and was regarding insulin therapy. All eligible threads were included and unrestricted by length. For both forums, members’ self-reported information linked to each post indicated which type of diabetes the member lived with; that is, T2D, T1D, other types of diabetes, or a caregiver of someone with diabetes. Owing to a large number of replies from people with self-reported T1D, these threads were included in the final analysis. Any disagreements over final inclusion were discussed with a third researcher (KWB), presented in Figure 1. The 57 final threads were extracted and imported into individual word documents to aid analysis. Additional information was extracted for each thread: title, date posted, general thread topic, number of replies, and frequency of replies by diabetes type. Demographics, such as age and sex, were not collected, as it was not possible to corroborate this information due to the forums’ use of anonymity and self-selected member usernames. It was not possible to determine if individual members posted factual information or multiple posts under alternative usernames; however, this was recognized as a possible methodological limitation.

**Figure 1.** Flow of forum thread selection. T1D=Type 1 Diabetes; T2D=Type 2 Diabetes; LADA=Latent autoimmune diabetes in adults.



## Data Analysis

All posts in relevant threads were analyzed. Identifying characteristics, such as usernames, were removed and replaced with a pseudonym to protect members' identities. Two researchers (MAT and RU) extracted the initial codes. NVivo 12 (QSR International) software was subsequently used to organize the data [34]. The data was analyzed using thematic analysis as described by Clarke and Braun [35]. Three

researchers (MAT, RU, and LR) read and reread the threads to ensure thorough comprehension. The initial codes were discussed and agreed upon. The codes were subsequently compared and grouped into 4 broad themes reflecting content and intent. To illustrate the themes, extracts from across the data sources with similar content were identified. Paraphrasing members' posts was used to ensure anonymity, which could have been compromised through the use of direct quotes. We considered the data extracts as observations of naturalistic



conversations and interpreted them accordingly. The quotes were presented as a representation of the initial posts and illustrative replies.

## Results

### Overview

We identified 299 posts from 29 threads from Diabetes UK and 295 posts from 28 threads from Diabetes.co.uk [30] during the

study period. A total of 57 threads met the inclusion criteria and were included in the thematic analysis after the second screening. More threads were identified via the Diabetes UK forum (n=87) than Diabetes.co.uk [30] (n=36).

In response to an initial post from a person with T2D, most replies in Diabetes UK threads were from people with T1D (155/299, 51.8%), and most replies from Diabetes.co.uk [30] threads were from people with T2D (189/295, 64.1%; Table 1).

**Table 1.** Number of replies and diabetes type of replies.

Forum member diabetes type	Diabetes UK replies (n=299), n (%)	Diabetes.co.uk [30] replies (n=295), n (%)
T2D <sup>a</sup>	111 (37.1)	189 (64.1)
T1D <sup>b</sup>	155 (51.8)	48 (16.3)
Carer or parent	9 (3)	1 (0.3)
Unknown	0 (0)	37 (12.5)

<sup>a</sup>T2D: type 2 diabetes.

<sup>b</sup>T1D: type 1 diabetes.

Following data familiarization, 91 codes were iteratively created and discussed by MAT and RU. Using the research team's diabetes nursing, clinical psychology, academic and qualitative research experience, the codes were collated collaboratively by MAT, RU, and LR. No significant discrepancies were established. After a final discussion with KWB, 4 main themes were agreed upon: empowerment through sharing self-management strategies, seeking and providing lifestyle advice, relationships with HCPs, and a source of emotional and peer support.

### Empowerment Through Sharing of Self-management Strategies

Several threads addressed relatively simple unmet practical needs, such as correct insulin storage and technique, indicating a lack of basic self-management skills or knowledge:

*Post: So much kit, where do I store it all?*

*Reply: All my daily supplies are in a pencil case, everything else I keep stored away and unopened insulin stays the fridge. [DC7]*

*Post: Is it OK to have bubbles in the pens (insulin devices)?*

*Reply: Tap the pen...keeping it vertical...dial up a couple of units and press the plunger, hey presto! [DUK05]*

While others expressed that they felt almost embarrassed at their lack of knowledge:

*Post: Just realised I didn't take my insulin—not sure what to do, take it now or wait until tomorrow? Silly I know but still getting used to it. [DC8]*

In addition, members sought advanced self-management skills such as insulin self-titration; that is, the confidence to increase and decrease insulin doses in response to personal glucose targets. However, most members were unwilling to advise on dose increases, fearful that this would constitute “prescribing,” revealing a limitation of the forum:

*Post: I've been on 10 units of insulin for a while now but my glucose levels are still high....should I increase the dose?*

*Reply: No one here on the forum can prescribe for you.*

This prompted an emotive response:

*Reply: I am obviously not asking for anyone to prescribe for me and I wouldn't even if they did! I just really need some help and was hoping someone might share their experiences with me. [DC8]*

Driving when insulin-treated comes with specific requirements, such as informing the driving licensing authority, monitoring glucose levels regularly while driving and keeping hypoglycemia treatment in the vehicle. Failure to do so can not only be dangerous in the event of hypoglycemia but can also lead to a driving suspension or a fine. However, some members were clearly not offered appropriate education and guidance and were shocked when they read other's posts:

*Reply: I didn't know I had to do all this! Neither my nurse nor my GP informed me when I switched to insulin nearly a year ago! [DUK30]*

Similarly, some members were unaware of key considerations when traveling, arguably vital information as insulin can be rendered unusable by becoming too hot or cold, leaving the person medically vulnerable, particularly when traveling overseas:

*Post: I am going away, how on earth and I supposed to keep this insulin cool for 2 weeks...what do I do when I go through security with all these needles and things?*

*Reply: We use the FRÍO bag [provides website details] if we are in a hot place and carry a medical letter to show at security, so we are not worried about traveling with insulin anymore. [DUK3]*

Some members, particularly those with T1D, were keen to recommend using continuous glucose monitoring technology, despite it being generally unavailable to people with T2D via the NHS:

*It's always easier if you have Flash monitor [continuous glucose monitor], less finger pricking and better picture. [DC27]*

### Seeking and Providing Lifestyle Advice

Successful diabetes self-management often requires individuals to adapt their lifestyle behaviors (diet and activity). This was brought into sharper focus when starting insulin treatment. There was a clear desire and need for extended advice regarding the perceived benefits of specific diets. A low carbohydrate diet was most likely to be discussed and recommended by members, despite not being recommended by most HCPs:

*Personally, I prefer to eat low carb...keeps the dose of insulin and risk of hypos [hypoglycemia] low, helps you lose weight and takes the pressure off your pancreas. [DUK10]*

In addition, carbohydrate counting was discussed and often extolled. Traditionally, a method used by people with T1D to calculate insulin doses in response to the carbohydrate content of food consumed, it is becoming more popular with people with T2D who are insulin-treated:

*Count them [carbohydrates] and adjust your insulin accordingly, try cutting down on the carbs, all of them turn to glucose once ingested. [DUK35]*

*I'm self taught...I can tell you, it made Christmas day far easier for me! [DUK35]*

The weight gain that can be induced by insulin is a known concern and a common psychological barrier to treatment for some individuals. Several suggestions to mitigate this problem were proposed by members:

*Post: Right, I really need to knock my eating back into shape again to get on top of this weight gain, what do you suggest?*

*Reply: The reason people put weight on when they start insulin is that they do not modify their diet...if you continue to eat lots...the weight will go on.*

Other members offered alternative strategies:

*Reply: One thing I have found helpful is intermittent fasting...it really works a treat.*

*Reply: I follow the MUFA diet—lots of dark chocolate, oils, olives, and nuts and seeds and avocados won't hurt!*

This led to gratitude, but some confusion:

*Original poster: Thank you for all your interesting answers. I feel more positive about it, but it's all quite confusing, I just don't want to have this pot belly anymore! [DC10]*

Advice to increase physical activity levels is a core lifestyle recommendation in traditional diabetes care. However, barriers including affordability, acceptability, and conflicting advice

regarding the need for and the type of physical activity in this group were illustrated in the threads:

*Can't afford a gym and would be too embarrassed to walk into one anyway! [DCUK10]*

*Exercise is good and can help with insulin resistance, it isn't necessarily needed for weight loss, it's a must! [DCUK10]*

*Exercise helps but the type of exercise is important [provides a list of weight bearing activity e.g., squats, lifting water bottles above head] [DCUK10]*

*For me, running disappointingly sends my BG upwards, but a good brisk walk or working in the garden will almost always bring it down [DUK1]*

### Relationships With HCPs

Forum members also shared experiences of their relationships with HCPs. Many referred to the positive, if limited, access to the support of general practice or diabetes specialist nurses, who were evidently their preferred diabetes caregivers:

*Post: Was doing fine on insulin for a couple of years and now its 69 (HbA1c) since my doctor changed the brand, should I just change back?*

*Reply: Best thing is to see your doctor, are you due to see him or her?*

*Reply: No, I but have been waiting to see my nurse for a while, I know if I explain it to her, she should be able to help me to make this work. [DCUK04]*

Furthermore, some members described negative experiences with HCPs. A paternalistic attitude appeared a common but unwelcome finding and was not appreciated, particularly when things were not going well:

*I did as I was told, I was being a "good girl", but my HbA1c was getting progressively worse [DCUK 31]*

*It makes sense not to overload with too much information...but my view is we should be given all the information we need to manage our condition...rather than taking a paternalistic attitude and treating us like children. [DUK35]*

Lack of perceived HCP knowledge or expertise was also expressed:

*Truth be told I never really understood diabetes before, but now I think I understand more [than their HCP] and it seems I haven't been given great advice. [DUK10]*

In addition, a lack of educational provision and support was highlighted, reflecting the known inconsistency in care provision and "clinical inertia" in the United Kingdom:

*Post: I have never been given any education or support, I diagnosed myself with diabetes after years of problems, no one even told me what kind of diabetes I had.*

*Reply: That is awful, please ask your GP for access to an education course... for type 2 [DUK09]*

The apparent lack of confidence in HCPs translated into some members querying their diagnosis altogether, for example, through further tests, such as c-peptide, a blood test which indicates how much endogenous insulin (made by the body) a person is still producing, but which is not a routine diagnostic test for T2D in the United Kingdom:

*So I had the test [c-peptide] privately, and it shows I do in fact have "robust levels of insulin" [ie, T2D].*  
[DUK09]

Finally, signposting to alternative and extended publicly available sources of information between members was used. For example, recommending links to YouTube videos, websites such as Bertie.org (carbohydrate counting), low carbohydrate diet pages, Diabetes.org, as well as an NHS helpline for insulin-treated adults with T2D. These strategies were perceived as more empowering and easily accessible than seeking help from existing health care provision.

### A Source of Psychological Peer Support

It was clear that many members felt unprepared to self-manage the practicalities of insulin treatment; however, unmet psychological factors were given equal weight.

Anxiety and emotional distress around insulin were common but countered by sharing reassuring and empowering messages from those who were already on established treatment:

*Post: So scared and anxious to start insulin*  
*Reply: I just dreaded the thought of insulin!...but don't be scared...because it can really change your life for the better...once I was done with the initial phase, my BG [blood glucose] levels returned to somewhat normal and I literally felt amazing.* [DUK15]  
*Reply: Please try not to panic. I've been on insulin for a couple of years and tbh I am glad I am on it. Yes it's a bit scary initially* [DUK20]

Other members were clearly fearful of injecting insulin and looking for reassurance and advice:

*Post: I am really worried about getting the technique right [injection].*  
*Reply: It won't kill you or anything serious if you forget [the full technique]' as long as the dose is right.* [DUK20]  
*Post: Where can I inject that won't hurt, I'm scared to do this.*  
*Reply: I find below the naval more comfortable and the outside of my thighs, just make sure to rotate [injection sites].* [DUK20]

In addition, sharing experiences of difficulties adjusting to insulin treatment elicited supportive responses:

*Post: I am finding it difficult to get used to [taking insulin]...did it take people long?*  
*Reply: I have been on it a few months and am still trying to figure it out...so yes it can take time to get right.*  
*Reply: Thanks, good to know I'm not alone.* [DUK10]

## Discussion

### Principal Findings

For people with T2D who for whom insulin therapy is recommended or prescribed, web-based forums provide an opportunity to seek and receive advice, participate in discussions, and gain psychological support. Our analysis revealed that some individuals were struggling with basic unmet self-management needs such as injection technique. In addition, some were interested in extended self-management skills such as dose titration. However, giving titration advice was seen as out of bounds by some members, comparing it to prescribing and is a clear limitation of the forums. It was not evident whether members had been offered a one-to-one or structured group DSMES when starting insulin or ongoing support. However, the apparent need to seek alternative sources of information via the forum and elsewhere suggests that this is lacking or inconsistent for many. This finding is consistent with previous research findings from our team [19,27].

A new finding was the strong desire of the members to acquire extended advice about diet in relation to insulin treatment. Threads focused on achieving stable blood glucose levels and mitigating weight gain. A popular recommendation was a low or lower carbohydrate diet and in some cases carbohydrate counting. This may be unsurprising, as many of the responses were from people with T1D, who may be better educated and knowledgeable about the effects of carbohydrates on blood glucose levels. However, intermittent fasting and other weight management strategies were also topics of conversation. Although alternative diet strategies are currently popular in the media and are likely to be tried by many individuals, they are not routinely recommended or discussed as options in traditional health care provision. This is despite the National Institute of Health and Care Excellence and the current United Kingdom "evidence-based diet guidelines for the prevention and management of diabetes" [36] recommending that a personalized approach to diet choices, with ongoing support, is best practice. Our findings highlight that, although an alternative dietary approach is appealing to individuals in this group, appropriate dietary advice to support it is not available to most who receive routine care.

There was debate within the forum regarding the benefits of physical activity; some members lending it minimal importance, with others promoting the benefits and extolling the advantages of different forms; for example, weight bearing and aerobic. The current NHS recommendations for activity in adults are not condition-specific [37]. In addition, research on the benefits of different forms of exercise is currently emerging, particularly regarding weight loss and glycemia in T2D [37-39]. It appears that in this arguably motivated group, as with diet, there is a lack of appropriate education, information, or support available for individuals to make informed choices.

Some members recommended continuous glucose monitoring or Flash technology to others, despite it not being widely available to this group via the NHS [40]. However, there is a growing trend for self-funding within the T2D community, particularly in individuals who are insulin-treated. However,

many HCPs responsible for diabetes care remain unfamiliar with emerging technology and are unable to advise on how to interpret it or use its full functionality. Issues around equity in health care provision regarding diabetes technology in the United Kingdom are not in the remit of this study, but are in need of further research in this group.

It was discouraging to discover continued reports of experiences of paternalistic attitudes from some HCPs, a phenomenon that has been documented for several decades [41]. Some members likened themselves to being made to feel like misbehaving children. This lack of trust and absence of a sense of equality in the HCP-patient relationship led some members to question their diabetes diagnosis altogether. Some sought private testing, which is not readily available via the NHS for people diagnosed with T2D; that is, c-peptide. It could be argued that this test is not necessary to make a clear diagnosis when an accurate history and full clinical picture is considered. However, the need for individuals to seek this reassurance outside of the NHS appears to reflect a lack of trust within it. This highlights the discrepancy that still appears to be present between best practice guidelines, such as the National Institute of Health and Care Excellence [42] and the American and European Diabetes Societies [43], all of whom advocate personalized care planning and support patient empowerment versus the realities of the clinical arena. This area warrants continuing close ethical scrutiny and the development of HCP educational strategies, incorporating awareness of the benefits of web-based forums for patients.

Underscoring the themes was the empowering nature of peer support. In addition to offering practical advice, usually based on members' personal experiences, empathy and encouragement to counter negative cognitions were openly offered and exchanged. NHS England concurs that people living with similar conditions may feel connected to one another, and gaining support from people with direct relevant experience can enable them to manage their condition better [44]. Indeed, peer support has been identified by our team as an important aspect of group insulin DSMES [27]. Our current findings add a depth of understanding of the specific unmet needs that peers can help meet in this group, which has not been documented before.

### Strengths and Limitations

A growing, inclusive social media culture has enabled more individuals from diverse backgrounds to feel comfortable

seeking and sharing advice and information on the web. By analyzing naturalistic interactions and conversations on the selected forums, additional insights into this field have been gained. There are potential limitations of this type of methodology, which we acknowledge. As highlighted previously, although 87% of adults use the internet and 72% of internet users have sought health information on the web, only 13% have posted on health-related forum [29]. Therefore, there is a risk that a few confident members, or "key players" posted on the forums, which may result in skewed data [45]. In addition, individuals who use forums may not be representative of the wider population. A lack of ability to count "views" (members reading a post or thread but not posting themselves) or the ability to collect detailed demographics are other limiting factors in this study.

### Implications

Internet-based research is an evolving field that serves to better understand the experiences and perspectives of individuals, which may not be included in traditional qualitative research methods, thus providing novel and rich data. The in-depth insights gathered from this study have provided a useful and valid contribution to the understanding of the experiences, perspectives, and unmet needs of individuals with T2D for whom insulin therapy is recommended, or prescribed.

### Conclusions

Our findings reveal that for people with T2D, health forums provide a rich source of self-management information while gaining psychological support, empathy, and encouragement from peers regarding insulin treatment. The forums also provide a safe space for individuals to express their frustration that these needs are not met through their usual health care provision, resulting in ambiguity over how to manage insulin effectively. This highlights a clear gap in the current health care provision in the United Kingdom for this group. The ultimate aim of our study was to enable individuals with T2D in this group to achieve their best outcomes. These new findings will directly contribute to the development of evidence-based insulin treatment, DSMES strategies, and raise awareness among HCPs and providers.

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### Conflicts of Interest

None declared.

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## Abbreviations

**DSMES:** diabetes self-management education and support  
**HbA1c:** glycated hemoglobin  
**HCP:** health care professional  
**NHS:** National Health Service  
**T2D:** type 2 diabetes

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Original Paper

# Clinical Utility of a Digital Therapeutic Intervention in Indian Patients With Type 2 Diabetes Mellitus: 12-Week Prospective Single-Arm Intervention Study

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## Abstract

**Background:** Patients with type 2 diabetes mellitus (T2DM) having elevated levels of blood glucose and glycated hemoglobin (HbA<sub>1c</sub>) are at higher risk of macro- and microvascular complications. Nonetheless, the goal of achieving glycemic control cannot be met with the use of pharmacotherapy alone. The recent emergence of digital therapeutic tools has shown the possibility of improving the modifiable risk factors and self-management of diabetes.

**Objective:** The aim of this study was to examine the clinical utility of a digital therapeutic intervention as an add-on therapy to achieve glycemic control in patients with T2DM.

**Methods:** This was a 12-week prospective, single-arm digital intervention study in patients with T2DM receiving regular antidiabetic treatment. The eligibility criteria included male and female patients with HbA<sub>1c</sub> ≥ 6.5%, functional English literacy, and a mobile phone capable of running the intervention app. Outcome measures of the study were mean changes in HbA<sub>1c</sub>, fasting blood glucose (FBG), postprandial blood glucose (PPBG), BMI, and Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) index at the end of 12 weeks.

**Results:** A total of 128 participants completed the study period of 12 weeks. There were 54.7% (70/128) men and 45.3% (58/128) women with a mean age of 48.48 years (SD 10.27). At the end of 12 weeks, the mean change in HbA<sub>1c</sub>, FBG, PPBG, and BMI for the overall study population was -0.84% ( $P < .001$ ), -8.39 mg/dl ( $P = .02$ ), -14.97 mg/dl ( $P < .001$ ), and -0.24 kg/m<sup>2</sup> ( $P = .06$ ), respectively. Among the participants showing improvement in the HbA<sub>1c</sub> value at the end of 12 weeks (responders), the mean change in HbA<sub>1c</sub>, FBG, PPBG, and BMI was -1.24% ( $P < .001$ ), -12.42 mg/dl ( $P = .003$ ), -21.45 mg/dl ( $P < .001$ ), and -0.34 kg/m<sup>2</sup> ( $P = .007$ ), respectively. There was an increase in HOMA-IR values for the overall study population (0.54,  $P = .29$ ). HbA<sub>1c</sub> response showed a significant association with a baseline HbA<sub>1c</sub> level ≥ 7.5%, no prior history of smoking, and no prior COVID-19 infection, as well as with higher levels of program engagement.

**Conclusions:** A digital therapeutic intervention when used alongside standard medications significantly reduces HbA<sub>1c</sub>, FBG, and PPBG levels in patients with T2DM.

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**KEYWORDS**

HbA<sub>1c</sub>; type 2 diabetes; digital therapeutics; fasting blood glucose; postprandial blood glucose; mHealth; digital health intervention; glycemic control; mobile health

## Introduction

### Background

Type 2 diabetes mellitus (T2DM) is a metabolic endocrine disorder that is characterized by continually elevated blood glucose levels. In India, it is estimated that there are approximately 74.2 million people with diabetes, accounting for 13.8% of the global prevalence [1]. It is projected that by 2045, India will have 124.9 million adults with diabetes, corresponding to 16% of the global burden of the disease [1]. Even more alarming, the age of onset of diabetes in the Indian population is younger and with a considerably lower BMI as compared with those of other racial-ethnic groups [2,3]. This is typically classified as the “Asian Indian or South Asian phenotype,” represented by higher levels of belly fat, less muscle mass, and increased insulin resistance, even at low BMI [4].

As a chronic progressive disease, the medical management of T2DM often necessitates the intensification of medications during the course of treatment. However, there is also compelling evidence to support the role of therapeutic lifestyle changes such as weight loss, dietary restrictions, exercise, adequate sleep, and health coaching in the effective management of diabetes without requiring intensification of the medications [5-10]. The participation of patients by way of self-monitoring of blood glucose (SMBG), strict compliance to dietary restrictions, and exercise routine, along with adequate sleep to abate stress is essential in avoiding disease progression and the long-term complications associated with T2DM [11].

In recent years, digital technologies have attracted increasing attention to enable lifestyle modification by patients and help them achieve the goal of self-management of diabetes to reduce the disease burden [11-15]. As a mostly remote intervention form, digital therapeutic interventions (DTIs) may not be as impactful as in-person counseling and follow-ups, but have the advantage of ease of communication, anytime-anywhere accessibility, and availability of information. A DTI overcomes the barrier of physical transportation, particularly in restricted conditions such as during the COVID-19 pandemic [12-15]. The machine learning capabilities through cloud computing and interactive interfaces of smartphones have made behavior modification possible based on personalized nudges, information sharing, and communication [12-14]. The ease of intervention along with autonomy and constant reminders can keep a patient motivated in achieving the desired therapeutic goals. Several studies have demonstrated the role of digital technology such as digital therapeutic platforms, telehomecare systems, digitally enhanced diabetes self-management, education and support programs, as well as smartphone-based integrated online real-time diabetes care systems in the effective management of T2DM, without requiring escalation of existing medication [12-17]. However, there is also substantial variation in the reported intervention approaches and observed changes in outcome parameters. In view of these variations of the impact

of DTIs, there is a requirement of measuring the effectiveness of a particular DTI approach before it can be scaled up for a larger target population.

### Objectives

The goal of our study was to assess the utility of a DTI in achieving glycemic control in Indian patients with T2DM. We hypothesized that lifestyle and behavior modification through the DTI would improve glycated hemoglobin (HbA<sub>1c</sub>) of the participants from the preintervention level. Additional parameters to assess the effectiveness of the intervention included changes in fasting blood glucose (FBG) and postprandial blood glucose (PPBG) levels, BMI, and the Homeostatic Model Assessment for Insulin Resistance (HOMA-IR) index. Moreover, we aimed to assess the potential relationships between user engagement and outcome results.

## Methods

### Study Design, Sample Size Calculation, and Eligibility Criteria

This was a 12-week, prospective, single-arm intervention study in Indian patients with T2DM receiving regular antidiabetic treatment from their physician. The sample size calculation was based on the study of Bollyky et al [18]. To detect a mean change in HbA<sub>1c</sub> levels of -0.4% with a sample SD of 1.5, using a 5% level of significance, 80% power, and correlation coefficient of 0.5 with a two-tailed *t* test of paired mean difference, a sample size of 113 was needed. Assuming a dropout rate of 20%, a sample size of 136 was chosen for this study. The sample size was calculated using SAS software version 9.4 (SAS Institute Inc).

The eligibility criteria included male and female patients with T2DM, aged 18-65 years, HbA<sub>1c</sub> ≥ 6.5%, functional English literacy for use of the mobile app, and a smartphone capable of running the intervention app. Participants were also required to be on a stable dose of antidiabetic medications at the time of entry in the study, with the expectation to remain on the same stable dose during the study period. Subjects were excluded if they were unable or unwilling to provide informed consent and comply with the protocol procedures; had a previous diagnosis of gestational diabetes, myocardial infarction, or stroke; were pregnant or lactating; and had restricted physical movements as per the clinical judgment of the treating physician. The study was conducted between October 2021 and March 2022 at three metropolitan outpatient clinics catering specifically to patients with diabetes.

### Ethics Considerations

The study was conducted according to the ethical principles stated in the latest version of the Helsinki Declaration and the applicable guidelines for good clinical practice. Ethics committee approval for this study was obtained from the Good Society for Ethical Research-Independent Ethics Committee

for Biomedical Research, Delhi (approval numbers: GSER/2021/BMR-AP/035, GSER/2021/BMR-AP/037, and GSER/2021/BMR-AP/039 dated October 8, 2021). The outpatient subjects who were willing to participate in the study were asked to sign a written informed consent form to assess their eligibility. Those unwilling to participate continued to receive the usual standard of care at the clinics.

## Study Intervention

### *Digital Therapeutic App*

The DTI model for this study was developed by Phable Care, India. The intervention approach connects patients with doctors through smartphone apps. The patient app can be connected with Bluetooth-enabled devices such as a glucometer or blood pressure monitor, as well as with other fitness applications such as Google Fit and Apple Health. Any vital measurement data from these devices are transmitted to the patient app. These data are shared with the connected physician for any real-time intervention necessary through the doctor app. Depending on the deviation of measured vitals from normal values, both the patients and doctors are informed via the study app. However, medication reminders for the patients are created from the doctor's prescription and any changes therein. Further, based on the user's disease profile and vitals-related data, personalized health education is provided. The health education-related content and communication are provided based on various behavior change theories (eg, the transtheoretical model of behavior change, nudge theory), which were integrated in the form of nudges, incentives, and reminders. The DTI model can be further intensified by a care team of nutritionists, physical trainers, and health coaches. For this study, we used the smartphone app plus care team approach.

### *Care Team Intervention*

Participants who met the eligibility criteria and provided informed consent were included in the study. The participants were asked to download the app from either the Google Play or Apple App store as per the compatibility of their mobile phones. Participants were also provided with the Roche Accu-Chek Instant Glucometer, test strips, and lancets for SMBG. Thereafter, they were trained on the use of the study app and glucometer. During the study period of 12 weeks, participants received notifications and reminders via the study app to complete various study-specific tasks, including SMBG at fasting and 2 hours postmeal at least once a week, as well as participating in digital consultations with a doctor (weeks 1, 5, 9), dietician (weeks 1, 3, 5, 7, 9, 11), and exercise coach (weeks 1, 5, 9) to receive personalized instructions for the management of their disease condition. Beyond this structured intervention, interested participants could speak with care team members via phone call anytime as per need. Participants used the app to register their daily health activities personalized by their care provider as well as for the logging of weekly SMBG readings. Furthermore, they received patient education material on a weekly basis to strengthen their knowledge and awareness about the self-management of diabetes. At the end of the study period, participants were required to undergo laboratory testing and

complete a study-specific questionnaire to evaluate the impact of the study intervention on the self-management of T2DM.

## Outcome Measures

The outcome measures of the study were mean changes in HbA<sub>1c</sub>, FBG, PPBG, BMI, and HOMA-IR index at the end of the 12-week intervention from the respective baseline values. The data pertaining to the above variables were collected from the laboratory reports and SMBG readings. The outcomes were measured based on a pre-post change in the values of these variables. Participants were classified as "responders" if they showed an improvement in the HbA<sub>1c</sub> value at the end of 12 weeks and as "nonresponders" if the HbA<sub>1c</sub> value had either remained unchanged or had increased at the end of 12 weeks.

Based on the level of participation, participants were also divided into three groups: low-engagement group (50%-60% engagement), medium-engagement group (61%-80% engagement), and high-engagement group (>80% engagement). Program engagement was assessed subjectively by the health coaches based on the participant's response to communication, dietary changes, physical activities, and SMBG. Participation was measured quantitatively in terms of the frequency of engagement components as reported by the participants themselves. A monthly report of progress and participation was shared with participants based on these data. The engagement score for final analysis was calculated from the arithmetic sum of individual scores and then converted into percentages. A questionnaire was further administered to the participants at the end of the intervention to assess the impact of the program on diabetes self-management. The responses were summarized in simple arithmetic measures.

## Statistical Analysis

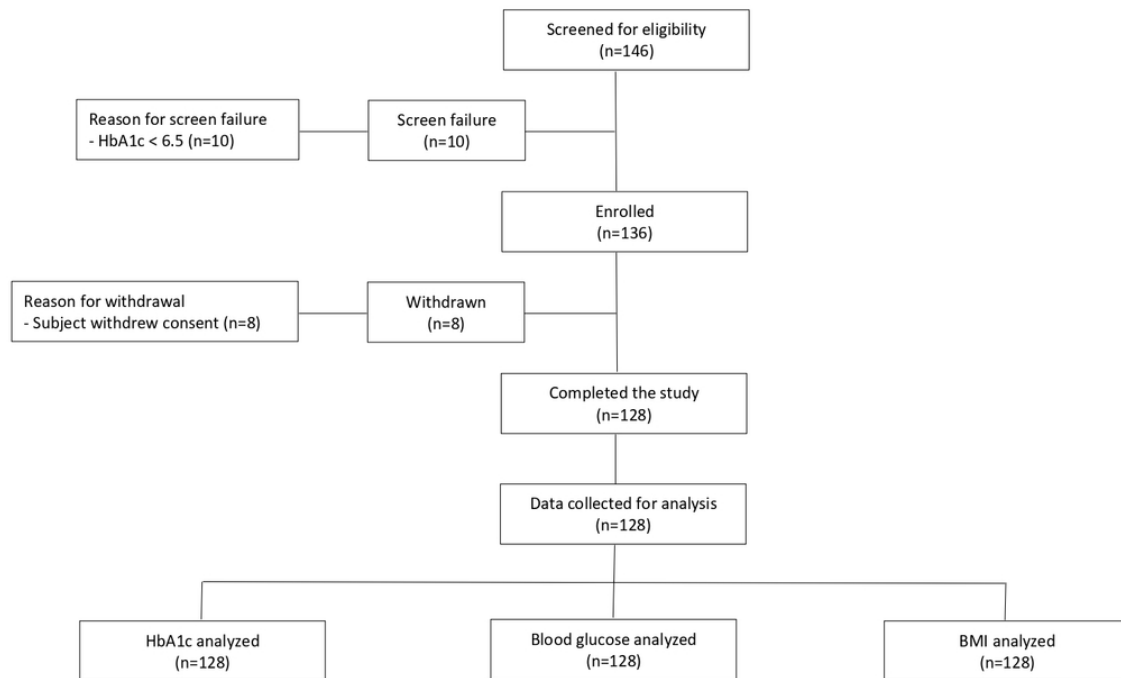
Continuous variables are summarized by the arithmetic mean (SD). A paired-sample *t*-test or repeated-measures ANOVA (as applicable) was used to compare the change in the mean values of parameters at the end of the study. Categorical variables are summarized using frequencies and percentages. Statistical analysis was performed using the Pearson  $\chi^2$  or Fisher exact test, as appropriate, to test the association between the variables. Two-sided  $P < .05$  was considered statistically significant. Simple logistic regression was performed to evaluate the association of each baseline characteristic with the achievement of HbA<sub>1c</sub> response. Statistical analysis was performed using SAS version 9.4 (SAS Institute Inc).

## Results

### Baseline Characteristics

A total of 146 subjects were screened for eligibility and 136 meeting the eligibility criteria were included in the study (Figure 1). Of these 136 subjects, 8 withdrew consent during the study period for personal reasons. Final results were analyzed for the remaining 128 subjects who completed the intervention period of 12 weeks (Figure 1). The final study population had a mean age of 48.48 years, with a slight majority of males. Baseline characteristics of the participants are presented in Table 1.



**Figure 1.** Participant recruitment and retention flowchart.

**Table 1.** Baseline characteristics of the study subjects (N=128).

Characteristics	Value
Age (years), mean (SD)	48.48 (10.27)
<b>Age group (years), n (%)</b>	
<30	3 (2.3)
30-50	62 (48.4)
>50	63 (49.2)
<b>Sex, n (%)</b>	
Male	70 (54.7)
Female	58 (45.3)
Weight (kg), mean (SD)	79.00 (16.12)
BMI (kg/m <sup>2</sup> ), mean (SD)	29.13 (4.86)
<b>Blood pressure (mmHg), mean (SD)</b>	
Systolic	125.07 (14.12)
Diastolic	79.02 (8.20)
Heart rate (beats/min), mean (SD)	88.38 (10.73)
<b>Comorbid conditions, n (%)</b>	
Hypertension	55 (42.9)
COVID-19	33 (25.8)
Thyroid disorder	10 (7.8)
Respiratory disease	1 (0.8)
Kidney disease	1 (0.8)
<b>Smoking history, n (%)</b>	
Yes	15 (11.7)
No	113 (88.3)
<b>Alcohol history, n (%)</b>	
Yes	31 (24.2)
No	97 (75.8)
<b>Dietary habit, n (%)</b>	
Vegetarian	83 (64.8)
Nonvegetarian	45 (35.2)
<b>Level of activity with respect to job/work, n (%)</b>	
Sedentary	57 (44.5)
Mildly active	53 (41.4)
Moderately active	17 (13.3)
Extremely active	1 (0.8)
<b>Stress level, n (%)</b>	
Low	39 (30.5)
Medium	54 (42.2)
High	35 (27.3)

The general characteristics of T2DM of the participants at the time of entry into the study are presented in [Table 2](#). Over 90% of the subjects had diabetes for  $\geq 1$  year. The mean baseline

HbA<sub>1c</sub> for participants was 8.32% and the mean baseline FBG was 139.16 mg/dl.

**Table 2.** Baseline type 2 diabetes mellitus (T2DM) characteristics of the study population (N=128).

Pattern of T2DM	Value
<b>Diabetes history, n (%)</b>	
<1 year	12 (9.4)
≥1 year	116 (90.6)
Family history of diabetes, n (%)	99 (77.3)
<b>Number of times diabetes medicine is missed in a month, n (%)</b>	
0	106 (82.8)
<4	15 (11.7)
≥4	7 (5.5)
<b>Number of hypoglycemic events in a month, n (%)</b>	
0	104 (81.3)
<2	13 (10.2)
≥2	11 (8.5)
<b>Frequency of blood sugar testing, n (%)</b>	
<2 times a week	87 (67.9)
≥2 times a week	41 (32.1)
HbA <sub>1c</sub> <sup>a</sup> (%), mean (SD)	8.32 (1.48)
FBG <sup>b</sup> (mg/dl), mean (SD)	139.16 (40.01)
PPBG <sup>c</sup> (mg/dl), mean (SD)	175.30 (43.39)
HOMA-IR <sup>d</sup> index, mean (SD)	5.39 (4.82)

<sup>a</sup>HbA<sub>1c</sub>: glycated hemoglobin.

<sup>b</sup>FBG: fasting blood glucose.

<sup>c</sup>PPBG: postprandial blood glucose.

<sup>d</sup>HOMA-IR: Homeostatic Model Assessment for Insulin Resistance.

## Outcome Measures

### Change in HbA<sub>1c</sub>

At the end of the intervention period, 76.6% (98/128) of the subjects showed a reduced HbA<sub>1c</sub> from the preintervention level (responders), whereas 23.4% (30/128) showed an HbA<sub>1c</sub> level that was either the same or increased from the preintervention level (nonresponders). The mean decrease in HbA<sub>1c</sub> for the complete study population was 0.84% (SD 1.36;  $P<.001$ ) from a baseline value of 8.32% (SD 1.48) to 7.48% (SD 1.18) at the end of 12 weeks. The responder subgroup showed a reduction of 1.24% (SD 1.30;  $P<.001$ ) in HbA<sub>1c</sub> from 8.51% (SD 1.55) at baseline to 7.27% (SD 1.11) postintervention. Among the 98 responders, 33 (34%) had an HbA<sub>1c</sub> reduction  $\leq 0.5\%$ , whereas 32 (33%), 11 (11%), and 22 (23%) showed a reduction of  $>0.5\%$  to  $\leq 1.0\%$ ,  $>1.0\%$  to  $\leq 1.5\%$ , and  $>1.5\%$ , respectively. Conversely, the nonresponders showed a significant increase in the mean HbA<sub>1c</sub> level by 0.46% (SD 0.44;  $P<.001$ ) from a mean baseline level of 7.70% (SD 1.05) to a postintervention level of 8.16% (SD 1.15).

### Changes in FBG, PPBG, BMI, and HOMA-IR

Among the other outcome parameters, the mean FBG reduced by 8.39 mg/dl (SD 40.65;  $P=.02$ ) from a baseline level of 139.16 mg/dl (SD 40.01), and the mean PPBG decreased by 14.97 mg/dl (SD 46.11;  $P<.001$ ) from a baseline level of 175.30 mg/dl (SD 43.39). The mean BMI decreased by 0.24 kg/m<sup>2</sup> (SD 1.40;  $P=.06$ ), whereas the HOMA-IR index of the participants increased by 0.54 (SD 5.49;  $P=.29$ ). Details are provided in Table A1 of [Multimedia Appendix 1](#).

### Impact of the Intervention on Self-Management of Diabetes

Among the 128 participants, 113 (88.3%) found a positive impact of the intervention program on their self-management of diabetes ( $P<.001$ ), whereas 95.3% (122/128) of the participants found a positive impact of the reminders and nudges in improving their overall adherence to the diabetes treatment ( $P<.001$ ).

### Level of Program Engagement

We performed the engagement analysis only for the responders whose HbA<sub>1c</sub> level was reduced at the end of the intervention (n=98). The summary of this analysis is shown in Table A2 of [Multimedia Appendix 1](#). There was a reduction in mean HbA<sub>1c</sub>

by 1.31% (SD 1.45;  $P=.006$ ) in the low-engagement group. In the medium-engagement group, there was a significant reduction in mean HbA<sub>1c</sub>, FBG, PPBG, and BMI by 1.16% (SD 1.22;  $P<.001$ ), 15.49 mg/dl (SD 39.71;  $P=.02$ ), 14.30 mg/dl (SD 32.20;  $P=.007$ ), and 0.39 kg/m<sup>2</sup> (SD 0.81;  $P=.003$ ), respectively. Further, in the high-engagement group, there was also a significant reduction in mean HbA<sub>1c</sub>, FBG, and PPBG levels by 1.30% (SD 1.32;  $P<.001$ ), 14.21 mg/dl (SD 43.69;  $P=.04$ ), and 31.12 mg/dl (SD 56.45;  $P=.001$ ), respectively.

#### ***Association of Individual Baseline Characteristics With HbA<sub>1c</sub> Response***

Logistic regression was performed to evaluate the association of baseline characteristics with achievement of HbA<sub>1c</sub> response

(Table 3). HbA<sub>1c</sub> response showed a significant association with a baseline HbA<sub>1c</sub> level of  $\geq 7.5\%$ , no prior history of smoking, no prior history of COVID-19 infection, as well as a medium and high level of program engagement.

Figure 2 presents the comparison of HbA<sub>1c</sub> levels among different subgroups. The change in blood sugar levels among different subgroups is presented in Figure 3. Four participants had very low HbA<sub>1c</sub>, PPBG, and FBG values at 12 weeks. However, none of them had reported any episode of hypoglycemia during interactions with the care providers, and thus we suspect these instances to represent asymptomatic hypoglycemia episodes.

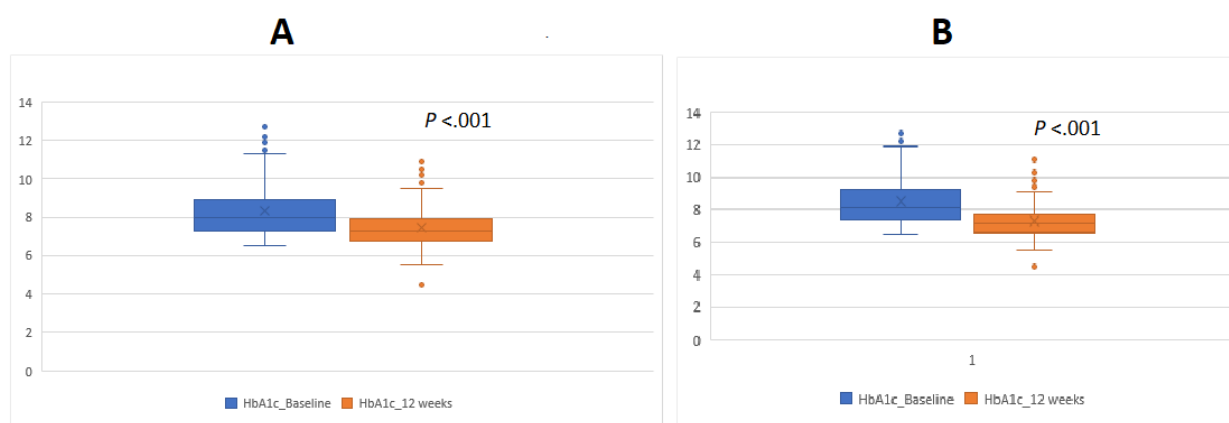


**Table 3.** Association of each baseline characteristic with achievement of glycated hemoglobin (HbA<sub>1c</sub>) response (N=128).

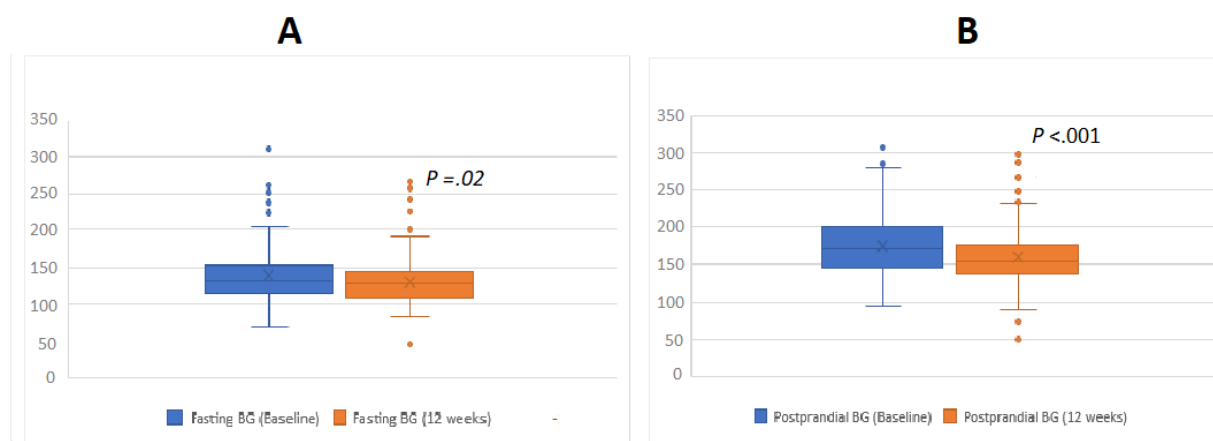
Variable	HbA <sub>1c</sub> response		$\chi^2$ (df=21)	P value
	Yes, n (%)	No, n (%)		
<b>Age (years)</b>			1.5	.22
≤50	50 (51.0)	15 (50.0)		
>50	48 (49.0)	15 (50.0)		
<b>Sex</b>			1.1	.28
Male	54 (55.1)	16 (53.3)		
Female	44 (44.9)	14 (46.7)		
<b>HbA<sub>1c</sub> level (%)</b>			9.3	.002
<7.5	25 (25.5)	16 (53.3)		
≥7.5	73 (74.5)	14 (46.7)		
<b>BMI ( kg/m<sup>2</sup> )</b>			0.3	.56
<25	20 (20.4)	7 (23.3)		
≥25	78 (79.6)	23 (76.7)		
<b>Smoking history</b>			4.8	.03
Yes	10 (10.2)	5 (16.7)		
No	88 (89.8)	25 (83.3)		
<b>Alcohol history</b>			1.3	.26
Yes	24 (24.5)	7 (23.3)		
No	74 (75.5)	23 (76.7)		
<b>Prior hypertension</b>			1.7	.19
Yes	39 (39.8)	16 (53.3)		
No	59 (60.2)	14 (46.7)		
<b>Prior COVID-19 infection</b>			11.7	<.001
Yes	20 (20.4)	13 (43.3)		
No	78 (79.6)	17 (56.7)		
<b>Dietary habits</b>			0.7	.41
Vegetarian	60 (61.2)	23 (76.7)		
Nonvegetarian	38 (38.8)	7 (23.3)		
<b>Family history of diabetes</b>			0.5	.49
Yes	76 (77.5)	23 (76.7)		
No	22 (22.5)	7 (23.3)		
<b>Diabetes history</b>			0.1	.83
<1 year	12 (12.2)	0 (0.0)		
≥1 year	86 (87.8)	30 (100.0)		
<b>Level of activity</b>			1.5	.83
Sedentary	45 (45.9)	12 (40.0)		
Mildly active	40 (40.8)	13 (43.3)		
Moderately active	12 (12.2)	5 (16.7)		
Extremely active	1 (1.0)	0 (0.0)		
<b>Stress level</b>			0.6	.74
Low	29 (29.6)	10 (33.3)		

Variable	HbA <sub>1c</sub> response		$\chi^2$ ( <i>df</i> =21)	<i>P</i> value
	Yes, n (%)	No, n (%)		
Medium	43 (43.9)	11 (36.7)	7.3	.03
High	26 (26.5)	9 (30.0)		
<b>Program engagement level</b>				
Low	14 (14.2)	11 (36.7)		
Medium	42 (42.9)	9 (30.0)		
High	42 (42.9)	10 (33.3)		

**Figure 2.** Comparison of HbA<sub>1c</sub> levels. (A) Mean change in HbA<sub>1c</sub> among all participants, (B) mean change in HbA<sub>1c</sub> among those who had improvements in HbA<sub>1c</sub> levels.



**Figure 3.** Change in blood sugar levels. Difference between (A) mean fasting blood glucose (BG) levels reported in the first week and final week of the intervention, and (B) mean postprandial BG levels reported in the first week and final week of the intervention.



## Discussion

### Principal Results and Comparison With Prior Work

This study has shown that patients with diabetes benefit from a component of lifestyle modification through digital means along with routine care with antidiabetic medication. Lifestyle modification through digital therapeutics resulted in a decrease in HbA<sub>1c</sub>, thereby bringing diabetes under control. In our study, a significant reduction in HbA<sub>1c</sub> of 0.84% (SD 1.36;  $P < .001$ ), in FBG of 8.39 mg/dl (SD 40.65;  $P = .02$ ), and in PPBG of 14.97

mg/dl (SD 46.11;  $P < .001$ ) were observed for the overall study population at the end of 12 weeks. These results are consistent with similar findings from multiple studies. A previous study from India that evaluated glycemic control in 102 patients with T2DM of South Asian origin using a digital therapeutic platform found a significant change ( $-0.49\%$ , 95% CI  $-0.73$  to  $0.25$ ;  $P < .001$ ) in the mean HbA<sub>1c</sub> level after 16 weeks of the intervention [12]. Berman et al [11] also showed a mean change in HbA<sub>1c</sub> of  $-0.8\%$  (SD 1.3;  $P < .001$ ) after a 12-week intervention. A meta-analysis of 18 randomized controlled trials showed a significant change in mean HbA<sub>1c</sub> levels ( $-0.54\%$ ,

95% CI  $-0.75$  to  $-0.34$ ;  $P < .05$ ) with a telecare intervention [14]. A retrospective study of a digital health intervention in adults with T2DM also demonstrated a significant reduction in HbA<sub>1c</sub> levels ( $-0.81\%$ ;  $P < .001$ ) after 3 months [16].

A new approach is useful if the majority of patients are benefitting from it and if the benefit is highly probable. In our study, 76.6% (98/128) of the subjects benefitting from the digital intervention by achieving a reduction in their HbA<sub>1c</sub> of 1.24% (SD 1.30;  $P < .001$ ) from preintervention levels. This study used an inclusion criterion of HbA<sub>1c</sub>  $\geq 6.5\%$  at baseline, thereby ensuring close to real-world representation of patients with diabetes in terms of HbA<sub>1c</sub> levels, in contrast to similar effectiveness studies that have considered higher levels of baseline HbA<sub>1c</sub> such as above 7.5% [15,19] or 8% [20] as one of the inclusion criteria. This may have reduced the effective postintervention mean change in HbA<sub>1c</sub> for the total sample population. Yet, similar to studies by Wilson-Anumudu et al [15] and Krishnakumar et al [12], we also found that individuals with higher levels of baseline HbA<sub>1c</sub> stand to benefit more from lifestyle intervention. This finding has significance by indicating that rather than escalating the medication dosage or type, such patients may be advised to undergo a lifestyle intervention to bring their HbA<sub>1c</sub> levels under control or at manageable levels, without any significant side effects.

Comparison with other DTIs is difficult as these approaches differ with regard to the use of tools, frequency of interventions, and stakeholders involved, among other factors [21]. Hence, measurement of the impact of each DTI approach separately might be warranted. The DTI approach used in this study included a significant human component by way of involvement of the primary care physician of the patients, apart from dietitians and health coaches. The presence of a patient's physician in the DTI care team may have created the psychological impact that the participant's health is being monitored by their physician.

As seen in Table 3, there was a significant reduction in the mean BMI ( $-0.34$  kg/m<sup>2</sup>;  $P = .007$ ) in the responders subgroup. However, this reduction was relatively minimal compared with the observed change in HbA<sub>1c</sub> levels ( $-1.24\%$ ;  $P < .001$ ). Further subanalysis suggested the possibility of the impact of ongoing antidiabetic medications causing weight gain, as the majority (107/128) of the participants were on sulfonylureas, thiazolidinediones, alpha-glucosidase inhibitors, and insulin. Future studies may be needed to understand the confounding

impacts of antidiabetic drugs causing weight gain and weight loss, and simultaneous lifestyle modification guided toward weight loss.

With regard to the program engagement level, we hypothesized that greater program engagement should result in greater improvement in postintervention blood glucose parameters. However, in this study, all three engagement groups showed statistically significant improvement in HbA<sub>1c</sub> postintervention. In fact, the subjects in the medium-engagement group exhibited the smallest change in HbA<sub>1c</sub> of  $-1.16\%$  (SD 1.22), as compared to the low- and high-engagement groups with an HbA<sub>1c</sub> reduction of  $-1.31\%$  (SD 1.45) and  $-1.30\%$  (SD 1.32), respectively. Although the linear reduction in HbA<sub>1c</sub> in the medium- and high-engagement groups is in line with our hypothesis, the higher reduction in the low-engagement group could be attributed to the effect of a smaller sample size. This needs to be evaluated in future studies, as there is a difference between the mere arithmetic sum of engagement parameters vis-a-vis the compliance provided by the patient to engagement by the care team.

### Strengths and Limitations

The main limitations of our study are the lack of a control group, a short duration of follow-up to evaluate certain parameters such as BMI and HOMA-IR, and lack of measures to evaluate the compliance with respect to the level of program engagement. The prospective design of the study under a controlled environment, statistically derived sample size, and low dropout rate can be considered as the main strengths of the study. Further, one of the inclusion criteria of our study was patients on a stable dose of antidiabetic medication at the time of entry to the study, and they were expected to remain on the same stable dose during the study period. This minimized the scope of any potential observation bias and the baseline values of each subject served as their own control, thereby attributing the difference observed at the end of study to the study intervention. Further studies in this area in the form of randomized controlled trials are warranted.

### Conclusion

The use of a DTI as an adjunct therapy to conventional medications significantly reduced HbA<sub>1c</sub>, FBG, and PPBG levels in patients with T2DM. This in turn may reduce the risk of cardiovascular complications as well as all-cause mortality associated with T2DM.

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### Authors' Contributions

All authors critically reviewed all manuscript drafts and provided comments. All authors gave their approval for the final version to be published. SP is the guarantor of this work and as such takes full responsibility for the integrity of the data and the accuracy of the data analysis.

## Conflicts of Interest

RC, SJ, and AG received research grants from Terrals Technologies Pvt Ltd. SP is an employee of Terrals Technologies Pvt Ltd. GB is an Advisor for Terrals Technologies Pvt Ltd.

## Multimedia Appendix 1

Summary of outcome measures for responders and nonresponders (Table A1), and according to level of engagement (Table A2).

[[DOCX File, 19 KB - diabetes\\_v7i4e41401\\_app1.docx](#)]

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## Abbreviations

**DTI:** digital therapeutic intervention

**FBG:** fasting blood glucose

**HbA<sub>1c</sub>:** glycated hemoglobin

**HOMA-IR:** Homeostatic Model Assessment for Insulin Resistance

**PPBG:** postprandial blood glucose

**SMBG:** self-monitoring of blood glucose

**T2DM:** type 2 diabetes mellitus

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Original Paper

# Improved Glycemia and Quality of Life Among Loop Users: Analysis of Real-world Data From a Single Center

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## Abstract

**Background:** Despite do-it-yourself automated insulin delivery being an unapproved method of insulin delivery, an increasing number of people with type 1 diabetes (T1D) worldwide are choosing to use Loop, a do-it-yourself automated insulin delivery system.

**Objective:** In this study, we aimed to assess glycemic outcomes, safety, and the perceived impact on quality of life (QOL) in a local Edmonton cohort of known Loop users.

**Methods:** An observational study of adults with T1D who used Loop was performed. An assessment of glycemic and safety outcomes, HbA<sub>1c</sub>, time in range, hospital admissions, and time below range compared users most recent 6 months of Loop use, with their prior regulatory approved insulin delivery method. QOL outcomes were assessed using Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations, diabetes impact, and device satisfaction measures (with maximum scores of 100, 10, and 10, respectively) and semistructured interviews.

**Results:** The 24 adults with T1D who took part in this study 16 (67%) were female, with a median age of 33 (IQR 28-45) years, median duration of diabetes of 22 (IQR 17-32) years, median pre-Loop HbA<sub>1c</sub> of 7.9% (IQR 7.6%-8.3%), and a median duration of Loop use of 18 (IQR 12-25) months. During Loop use, the participants had median (IQR) values of 7.1% (6.5%-7.5%), 54 mmol (48-58) for HbA<sub>1c</sub> and 76.5% (64.6%-81.9%) for time in range, which were a significant improvement from prior therapy ( $P=.001$  and  $P=.005$ ), with a nonsignificant reduction in time below range; 3.0 to 3.9 mmol/L ( $P=.17$ ) and <3 mmol/L ( $P=.53$ ). Overall, 2 episodes of diabetic ketoacidosis occurred in a total of 470 months of Loop use, and no severe hypoglycemia occurred. The positive impact of Loop use on QOL was explored in qualitative analysis and additionally demonstrated through a median Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations score of 86 (IQR 79-95), a median diabetes impact score of 2.8 (IQR 2.1-3.9), and a median device satisfaction score of 9 (IQR 8.2-9.4).

**Conclusions:** This local cohort of people with T1D demonstrated a beneficial effect of Loop use on both glycemic control and QOL, with no safety concerns being highlighted.

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**KEYWORDS**

type 1 diabetes; closed loop; automated insulin delivery; do-it-yourself

## Introduction

### Background

Do-it-yourself (DIY) automated insulin delivery (AID) systems are user-designed systems that combine 2 regulated devices, an insulin pump that delivers a continuous subcutaneous insulin infusion and a continuous glucose monitor (CGM) that is controlled by an algorithm. Through this predictive algorithm, coded by the user, these systems facilitate an automated adjustment in insulin delivery, tailored to an individual's requirements [1]. People with type 1 diabetes (T1D) are increasingly using these systems worldwide because the rapidly evolving software with extensive opportunities for customization helps individuals to achieve personalized glucose targets and reduce the burden of diabetes management [2].

DIY AID systems can be subclassified into system types (including AndroidAPS, FreeAPSX, and Loop) depending on the technology and the algorithms on which they run. These systems have not gained regulatory approval; users are effectively *hacking* licensed technology to run these algorithms and modulate their insulin delivery [3]. Recently, the first randomized controlled trial to highlight both the safety and the efficacy of AndroidAPS has been completed [4]. There are also multiple published studies, single-arm cohort studies, user self-reported pre-post data, and case series, reporting beneficial outcomes in glycemic control, quality of life (QOL), and reassuring safety data with DIY AID use. The studies have reported on individual system types or combinations of these [5-12].

Studies on DIY AID system use consistently report excellent glycemic outcomes, with very high time in range (TIR) and low time below range (TBR). These values far exceed those suggested as clinically recommended targets, achieved by only a minority of people with T1D [13]. Individuals choosing to use DIY AID are a select sample of people with T1D who are highly motivated to engage in self-care. Users are actively involved in optimizing glycemia with the aims of preventing diabetes-related morbidity, increasing life expectancy, and improving sleep quality [12].

Internet resources and social media platforms are currently the mainstay of guidance for DIY AID users [2]. These platforms have been used by enthusiasts in the field to collect outcome data [14]. The average ages of users receiving insulin delivery via a DIY system are reported to be 35.8 years (AndroidAPS), 33 years (OpenAPS), and 28.5 years (Loop), but the extensive benefits of these systems have been reported in studies of both adults and children, with 26% of users in a cross-sectional survey being aged <16 years [11]. Similar benefits have been observed across the 3 DIY AID system types, with the type of system studied usually being dependent on the geographical distribution of system users. Loop is the most commonly used DIY AID system in North America and AndroidAPS is the most commonly used DIY AID system in Europe [12]. To date, there have been no cohort studies performed in Canada to assess user outcomes for DIY AID users.

### Objectives

We sought to explore the experiences of adults using Loop at a single center in Canada. We aimed to assess quantitative outcomes in the form of glycemic, QOL, and safety data and also used a qualitative approach to gain a greater understanding of the lived experiences of Loop users.

### Methods

A cross-sectional study of current glycemia, experiences of Loop use, and QOL was performed in adults with T1D who were attending the Kaye Edmonton Clinic, which is part of the University of Alberta Hospital in Edmonton, Alberta, and were known to be currently using any form of DIY AID system.

### Ethics Approval

This study was approved by the University of Alberta Research Ethics Board (Study ID pro00111577).

### Participants

Prospective participants were identified and contacted by a member of their clinical team at the Kaye Edmonton Clinic. All participants were adults (aged  $\geq 18$  years) with T1D who were using a DIY AID system at the time of data collection. We arranged a semistructured interview with a member of the study team for participants after obtaining informed consent from them to take part in the study.

### Outcome Measures

Up to 6 months of most recent glucose data, while using Loop, were collected from the participants' CGM download data, to record mean TIR 3.9 to 10.0 mmol/L (70-180 mg/dL), TBR 3.0 to 3.9 mmol/L (54-70 mg/dL), TBR; <3.0 mmol/L (<54 mg/dL), and time above range: >10.0 mmol/L (180 mg/dL). Where available, the same data were collected retrospectively from the participants' glucose sensor data for the 6-month period before commencing Loop, while they were using their previous mode of insulin delivery. The participants' laboratory HbA<sub>1c</sub> readings (%) were collected from hospital records, including the most recent value with Loop use, in addition to the participant's last reading before commencing Loop. The hospital records of all participants were reviewed for hospital admissions, specifically assessing the occurrence of severe hypoglycemia (SH) and diabetic ketoacidosis (DKA) throughout the duration of the participants' Loop use. The University of Alberta Hospital uses an integrated medical record system, enabling data capture of admissions to any facility in the province.

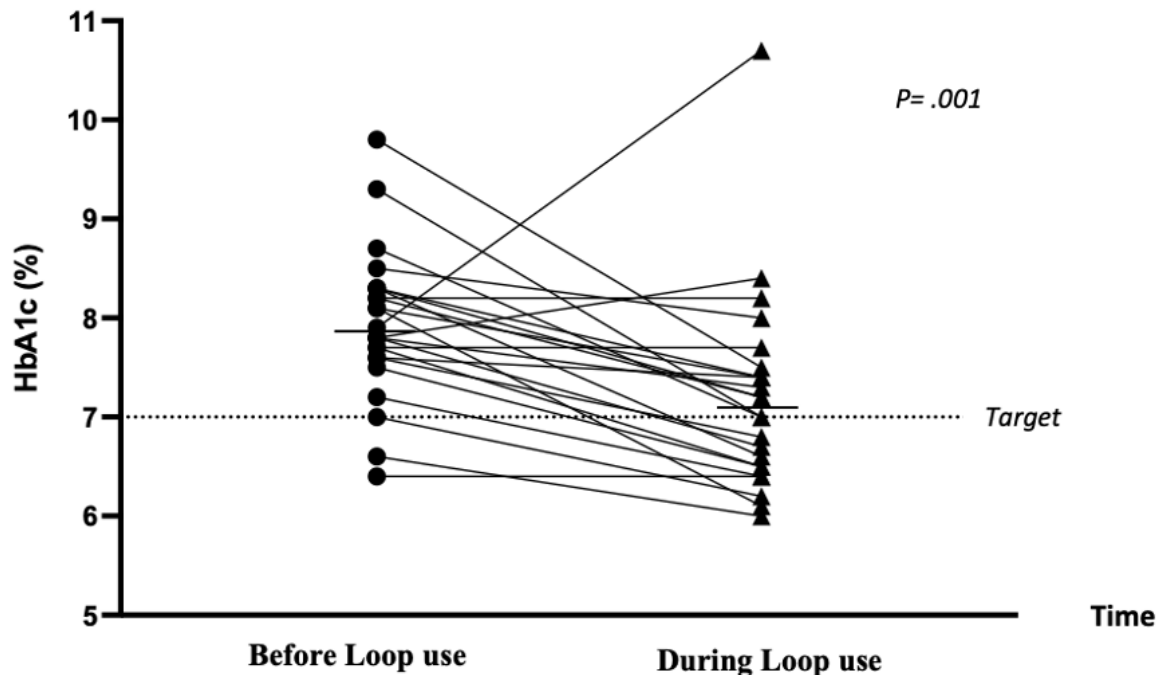
Semistructured interviews were arranged via telephone or through the use of the Zoom videoconferencing service (Zoom Video Communications, Inc) [15] between July and September 2021. A full interview transcript guide is available in Figure 1. Each interview was conducted by researchers AM and KC, with one asking questions while the other transcribed responses. During the interview process, demographic data were collected, including age, type of DIY AID system used, duration of DIY AID use, duration of diabetes, sex, ethnicity, occupation, and highest level of educational attainment. Participants were asked to report any episodes of SH that required the assistance of another person to treat and any occurrence of DKA during Loop

use. Qualitative questions were related to participants' reasons for commencing, challenges in its use, and support mechanisms with regard to using a DIY AID system as well as the benefits and barriers that they experienced with DIY AID use.

After the interviews, the participants electronically completed 2 validated questionnaires, Diabetes Impact and Device

Satisfaction (DIDS) [16,17] and Insulin Dosing Systems: Perceptions Ideas Reflections and Expectations (INSPIRE) [18], evaluating their perceived impact of using DIY AID on their QOL. Full copies of these questionnaires are available in the appendices.

**Figure 1.** HbA<sub>1c</sub> before Loop use and during 18 months of Loop use.



## Analysis

Descriptive statistical analysis and normality testing via the Shapiro-Wilk test were performed using GraphPad Prism (version 9.2.0 for macOS; GraphPad Software). A normal distribution was seen in both TIR and HbA<sub>1c</sub> data before but not after Loop use, with additional skewed distributions being seen in age and QOL outcome measures. Therefore, data are reported as median (IQR) in the analysis of this cohort with nonparametric tests being used and statistical significance being defined as  $P < .05$ . Paired groups were compared using the Wilcoxon signed-rank test and unpaired data were compared using the Mann-Whitney  $U$  test, in addition to the correlation of variables using the Spearman correlation coefficient.

Qualitative interview data were coded deductively by the research team using NVivo 12 (QSR International) [19], after the data-driven inductive generation of the code structure (Multimedia Appendix 1). This deductive code structure was developed inductively from our data in addition to the

consideration and inclusion of common themes identified in previous DIY AID user interview studies [20-22]. Overarching themes were constructed from the participants' viewpoints and reflexive thematic analysis was performed by AM [23].

## Results

### Overview

A total of 24 adults with T1D participated in this cross-sectional study, with a median age of 33 (IQR 27.5-44.8) years and median duration of diabetes of 21.5 (IQR 17.3-32.0) years. All 24 participants were using the Loop subtype of DIY AID as their method of insulin delivery for a median duration of 18 (IQR 12-25) months, with a total of 470 months or 39.2 years of Loop use in the cohort. The demographic characteristics of this cohort of Loop users are described in Table 1. Of the 24 participants, the majority (n=16, 67%) were female and (n=22, 92%) White and over one-third (n=9, 38%) were employed in health care professions.



**Table 1.** Characteristics of study participants (N=24).

Characteristics	Values
Age (years), median (IQR)	33 (27.5-44.8)
Duration of diabetes (years), median (IQR)	21.5 (17.3-32.0)
Duration of Loop use (months), median (IQR)	18.0 (12.0-25.0)
<b>Sex, n (%)</b>	
Male	8 (33)
Female	16 (67)
<b>Ethnicity, n (%)</b>	
White	22 (92)
South Asian	1 (4)
Mixed race	1 (4)
<b>Educational attainment, n (%)</b>	
Master's degree	4 (17)
University degree	12 (50)
Postsecondary certification or diploma	5 (21)
High school	3 (13)
<b>Occupation, n (%)</b>	
Health care professional	9 (38)
Public servant	5 (21)
Student	3 (13)
Teacher	2 (8)
Engineer	2 (8)
Electrician	1 (4)
Project manager	1 (4)
Retired	1 (4)
<b>Glucose sensor use before Loop, n (%)</b>	
Real-time CGM <sup>a</sup>	20 (83)
Intermittently scanned CGM	3 (13)
No sensor	1 (4)

<sup>a</sup>CGM: continuous glucose monitor.

## Glycemic Outcomes

HbA<sub>1c</sub> values were available both before and after commencing Loop use for all participants. CGM data were available for 6 months before commencing Loop use for 71% (17/24) of the study participants, with a mean of 5.8 (SD 0.66) months of CGM data with Loop use being reviewed per participant. No significant differences in age, duration of diabetes, duration of Loop use, baseline HbA<sub>1c</sub>, or QOL outcome measure scores were seen between those participants with and without pre-Loop CGM data. Before Loop, median HbA<sub>1c</sub> was 7.9% (IQR

7.6%-8.3%) or 63 (IQR 60-67) mmol/mol, and median TIR was 58% (IQR 52.3%-64.0%). A statistically significant improvement in these parameters was seen with Loop ( $P=.001$  and  $P=.005$ ). A median increase of 15% (IQR 6.3%-23.8%) in TIR was seen in 82% (20/24) of Loop users. Before Loop, 17% (4/24) of users achieved the clinical target of 70% TIR, in comparison with 67% (16/24) of users who achieved it with Loop use. HbA<sub>1c</sub> reduction was seen in 79% (19/24) of users with Loop; the median rate of improvement was 0.8% (IQR 0.28%-1.18%). In addition, a significant reduction in time above range was demonstrated with the introduction of Loop ( $P=.008$ ). Glycemic data are shown in Table 2 and Figures 1 and 2.

**Table 2.** Glycemic outcomes in users most recent 6 months of Loop use, in comparison with their prior insulin delivery method<sup>a</sup>.

Glycemic measure	Before Loop	After commencing Loop use	P value
Glycated hemoglobin (%), median (IQR)	8 (7.6-8.3)	7.1 (6.5-7.5)	.001
TIR <sup>b</sup> (3.9-10 mmol/L, 70-180 mg/dL; %), median (IQR)	58.0 (52.3-64.0)	76.5 (64.6-81.9)	.005
<b>TBR<sup>c</sup> (%), median (IQR)</b>			
3.0-3.9 mmol/L, 54-70 mg/dL	1.5 (1.0-2.8)	1.3 (0.6-2.4)	.16
<3.0 mmol/L, <54 mg/dL	0.5 (0.5-0.8)	0.5 (0.5-0.5)	.53
TAR <sup>d</sup> (>10 mmol/L >180 mg/dL; %), median (IQR)	40.0 (31.5-46.5)	21.8 (15.4-33.25)	.008
Target HbA <sub>1c</sub> (<7%), n (%)	2 (8.3)	10 (42)	— <sup>e</sup>
Target TIR (>70%), n (%)	3 (18)	16 (67)	—

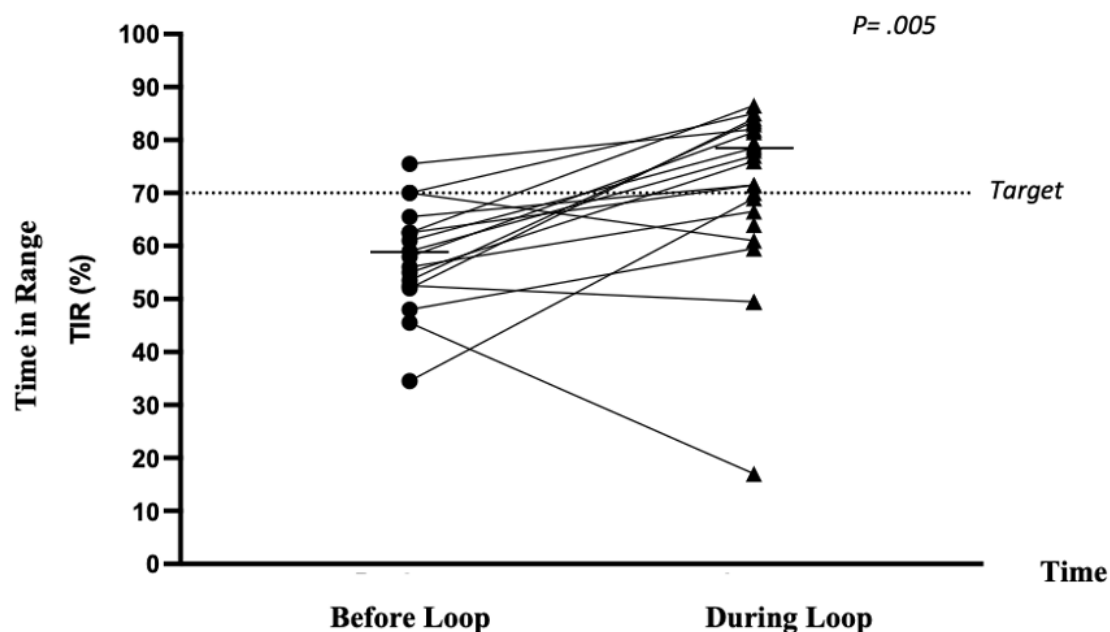
<sup>a</sup>Data are median (IQR) and n (%). The Wilcoxon signed-rank test has been used to compare glycemic outcomes before Loop use and during the most recent 6 months of Loop use.

<sup>b</sup>TIR: time in range.

<sup>c</sup>TBR: time below range.

<sup>d</sup>TAR: time above range.

<sup>e</sup>Not available.

**Figure 2.** Time in range before Loop use and during Loop use.

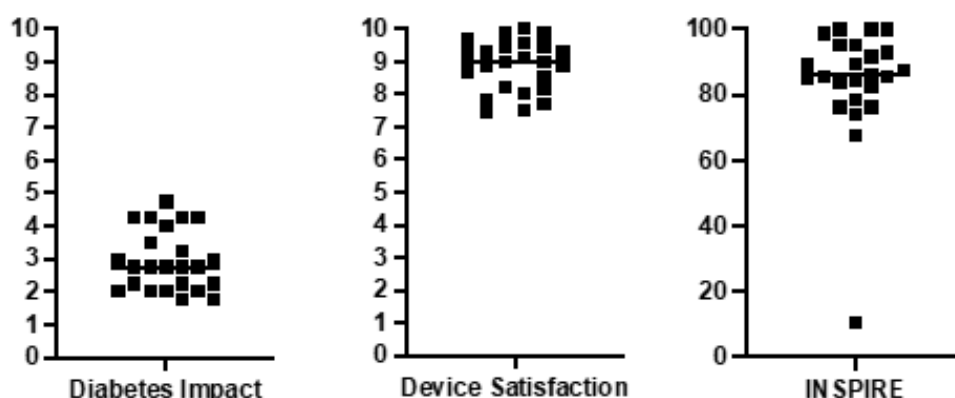
## Safety

Of the 24 participants, 2 (8%) experienced an episode of DKA, and no episodes of SH occurred in the cohort with Loop use. One episode of DKA was euglycemic and was associated with gastrointestinal infection and sodium-glucose cotransporter-2 inhibitor use; it required hospital admission, including intensive care unit stay for 4 days and was completely resolved. The other one was documented to be associated with a urinary tract infection; intensive care unit stay was not required and no insulin pump or Loop system failure was identified. These episodes of DKA occurred 15 and 11 months following starting Loop, respectively.

## QOL Measures

The QOL measures collected following participant interviews by using the DIDS and INSPIRE questionnaires are shown in Figure 3 and Table 3. The median diabetes impact score was 2.8 (IQR 2.1-4.8) out of a maximum of 10, with lower scores indicating better outcomes. The median device satisfaction score was 9.0 (IQR 8.2-9.4) out of 10, with higher scores indicating better outcomes. The median INSPIRE score was 86.0 (79.5-94.6), with 100 being the maximum and optimal score. An examination of these QOL scores and of glycemic variables showed no significant positive correlations with TIR ( $r=0.024$ ,  $r=0.007$ , and  $r=0.207$ ;  $P=.41$  or with HbA<sub>1c</sub> ( $r=-0.163$ ,  $r=-0.287$ , and  $r=-0.254$ ;  $P=.38$ ). A moderate correlation was seen between increased duration of Loop use and lower diabetes impact scores ( $r=-0.420$ ,  $P=.04$ ).

**Figure 3.** Quality of life outcome measures during Loop use. Scatter plots demonstrating diabetes impact out of 10 with lower scores being better, device satisfaction out of 10 with higher scores being better, and Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations scores out of 100 with higher scores being better. Median score line and individual values have been plotted. INSPIRE: Insulin Dosing Systems: Perceptions Ideas Reflections and Expectations.



**Table 3.** Quality of life outcomes with automated insulin delivery system use; comparison of outcomes of Loop use in this cohort with outcomes of Tandem Control-IQ use in 2 other cohorts [16,24].

Quality of life measure	Outcome with Loop use, median (IQR)	Tandem Control-IQ 1, median (IQR) <sup>a</sup>	Tandem Control-IQ 2, median (IQR) <sup>b</sup>
Diabetes impact score (maximum 10)	2.8 (2.1-4.8)	2.7 (1.8-3.7)	N/A <sup>c</sup>
Device Satisfaction score (maximum 10)	9.0 (8.2-9.4)	9.1 (8.4-9.8)	N/A
INSPIRE <sup>d</sup> score (maximum 100)	86.0 (79.5-94.6)	N/A	87 (77.6-96.5)

<sup>a</sup>Two months of Tandem Control-IQ use [16].

<sup>b</sup>Six months of Tandem Control-IQ use [24].

<sup>c</sup>N/A: not applicable.

<sup>d</sup>INSPIRE: Insulin Dosing Systems: Perceptions Ideas Reflections and Expectations.

## Qualitative Interview Outcomes

### Overview

The analysis of semistructured interview data highlighted frequent topics that participants had expressed as important in

their lived experiences of Loop use. Overarching themes were constructed from these viewpoints, comprising empowerment and control, the daily impact of living with diabetes with Loop use, quantification of risk, and society's understanding and awareness of Loop (Textbox 1).

**Textbox 1.** Thematic analysis outcomes with user experience examples.

### Theme and user experience

- Empowerment and control
  - “The control I get; recognizing that I will go low and it stops the insulin. Loop provides more flexibility and personalization, and it’s more in my control, that’s why I would stick with a DIY over a Commercial system.” [31 years, female; 21 years type 1 diabetes (DM); 12 months of Loop use]
  - “I feel a lot better all the time. My TIR is so much better. I have more freedom; I feel there is a little bit of that every time you get a device. Having Loop going on in the background to catch any mistakes is great. It makes me sleep better at night.” [24 years, female; 14.5 years DM; 5 months of Loop use]
  - “I just feel that my control in my worst weeks with Loop are like my glucose levels in the best weeks when I was self-managing. I feel like Loop is like having a holiday from diabetes.” [29 years, female; 27 years DM; 7 months of Loop use]
  - “Yes, just to note that the system has been so empowering. This disease can make you feel very powerless.” [49 years, female; 37 years DM; 7 months of Loop use]
- The daily impact of living with diabetes with Loop use
  - “It has taken the hourly weight of diabetes off. Loop is the best thing that has entered my life.” [33 years, female; 22 years DM; 18 months of Loop use]
  - “I have better control, reduced time worrying about diabetes but I would say I am spending more time managing my diabetes currently, as the system is relatively new to me.” [48 years, female; 35 years DM; 3 months of Loop use]
  - “Using Loop there are more things to have to worry about, more tech to charge and make sure you have all the pieces with you when you go places, just more stuff to remember.” [31 years, female; 21 years DM; 12 months of Loop use]
  - “Ordering the RileyLink took a while. Then, there was the time- building it, waiting. The financial aspect and finding the supplies. If you want to be on a Medtronic pump it is difficult to find one (522 or 722), or they are being sold for a very expensive price.” [27 years, female; 22 years DM; 40 months of Loop use]
- Quantification of risk
  - “Yes, but I think there are risks to everything. There are risks to crossing the street, but that doesn’t mean you would never cross the street does it. As long as you take the time to figure out and correct your ratios and put all the correct information into the system, you definitely get out what you put in. You just really need to know your diabetes.” [24 years, female; 17 years DM; 39 months of Loop use]
  - “Yes, it is safer than a regular pump- they remove the emotional element and decision-making and prevent snap decisions being made. The system is safe once the settings are correct, it is not safe with incorrect settings.” [51 years, male; 32 years DM; 17 months of Loop use]
  - “There is a risk of the software being incorrect as the builders don’t have the resources to test like big tech companies but at the same time anyone can review the algorithm so it is subject to a lot of scrutiny. I do worry what will happen if the developers move on to other projects.” [72 years, male; 19 years DM; 18 months of Loop use]
  - “Yes, it is safe. The only thing that I sometimes think about is the issue that the Dexcom can have and how Loop only acts according to the information it gets from Dexcom. I have no actual issues with Looping itself.” [24 years, female; 14.5 years DM; 5 months of Loop use]
- Society’s understanding and awareness of Loop
  - “I feel like it is just me and no one knows about it. Sometimes it can be a little bit lonely.” [22 years, female; 12 years DM; 12 months of Loop use]
  - “The Looped Facebook group was the biggest thing. Loop docs website was very easy to follow. Support from diabetes team, I felt pretty lucky because there are other physicians that don’t approve of loop or help you with it, I know.” [27 years, female; 22 years DM; 40 months of Loop use]
  - “I have had zero support since starting. I haven’t reached out to my DN and she may have been able to help, but pregnancy endos had no idea and were encouraging me to stop Looping even though I had found Loop very beneficial during pregnancy, especially in maintaining tight targets and avoiding severe hypoglycemia.” [29 years, female; 22 years DM; 25 months of Loop use]
  - “My family were not supportive at first, they were not sure until they saw the a1c and how it worked. My care team’s lack of support also scared them, but now my family is very supportive. Also, my partner is very supportive, he would stay up to ensure it was working properly.” [24 years, female; 12 years DM; 15 months of Loop use]

### ***Empowerment and Control***

The principle of autonomy, with individual choice in selecting an optimal management regimen for their condition that was best suited to and most beneficial for them, was a prominently featured theme in why participants had chosen Loop. The feeling

of dissatisfaction with a prior treatment option was described, with the need to make an individual choice to optimize their lifestyle:

*Honestly in my work I felt like I needed the added security, something better than my pump. I had heard*



*about Loop through social media and a diabetic influencer, I didn't even know if I could do it in Canada, but enquired through the internet and then worked through the shared information on set up. [24 years, female; 17 years DM; 39 months of Loop use]*

Control was a term that participants frequently mentioned, referring to both this treatment choice component and glucose targets. Most of them included improvements in TIR and HbA<sub>1c</sub> as motivating factors to commence and prominent benefits of Loop use. Increased lifestyle flexibility, particularly relating to diet and exercise patterns, was a commonly reported benefit:

*I have more time and don't have to worry as much about what I eat. I feel more flexible in eating schedules and working out. With Loop I can eat whenever I want and exercise when I want to, I can eat a surprise high carb meal for example. [24 years, female; 12 years DM; 15 months of Loop use]*

Another important benefit was the ability to sleep well overnight, being able to rely on Loop to ensure safety, particularly to avoid nocturnal hypoglycemia. Multiple participants reported struggling with nocturnal hypoglycemia before implementing Loop:

*A year prior to looping I was having a lot of night-time lows and not waking up (didn't feel them, didn't hear CGM alerts), and would get phone calls from my mom. [27 years, female; 22 years DM; 40 months of Loop use]*

It was apparent that Loop offered peace of mind to both users and their friends and family members by preventing nocturnal hypoglycemia. Individuals who had struggled with this issue previously described the importance of this new aspect of control that Loop had enabled:

*Having Loop going on in the background to catch any mistakes is great. It makes me sleep better at night. [24 years, female; 14.5 years DM; 5 months of Loop use]*

### **The Daily Impact of Living With Diabetes With Loop Use**

Participants discussed the psychological impact of living with diabetes both before and since using Loop, with notable improvements expressed in the time spent thinking about diabetes and diabetes-related distress:

*Especially for people diagnosed relatively late, whose whole lives have changed, especially with the mental health aspect that diabetes has put a veil over your life, Loop has really helped to stop diabetes being a nuisance and instead it is managed. [24 years, female; 17 years DM; 39 months of Loop use]*

Participants reported burnout as a result of day-to-day demands, and despite the beneficial impact of Loop on psychological well-being expressed by them, they noted that starting to use the system and the initial setup required a significant investment of time and energy:

*I felt burnout in managing my diabetes, spending all my time managing diabetes or filling out insurance forms for my diabetes, it was a real mental challenge to think about and set up a new system, a lot of mental energy. [29 years, female; 27 years DM; 7 months of Loop use]*

Significant financial investments, both initial and ongoing, were reported by Loop users. They required both the component technology (an insulin pump and a CGM) and appropriate devices on which to set up and use the app—an iPhone with iOS 12.4 or newer operating system and a Mac computer—as well as a communicating device (RileyLink, OrangeLink, or EmaLink) and an Apple developers' license [25]. Access to and cost of this hardware were the most commonly perceived barriers to Loop use in this cohort:

*I would recommend everyone to try it. It is quite a bit of work getting it setup and getting it ready but is pretty minimal effort for upkeep. The access to the devices is the one thing that makes it difficult (especially coverage for it). The peace of mind makes it worth it because it makes so much of a difference. [24 years, female; 14.5 years DM; 5 months of Loop use]*

Consequently, the use of a system such as Loop comprising multiple devices requires users to ensure that all necessary components are carried around with them and have sufficient battery charge. The devices must be in constant communication with each other to effectively use the app. Some participants reported these day-to-day aspects of Loop use to be challenging at times:

*Using Loop there are more things to have to worry about, more tech to charge and make sure you have all the pieces with you when you go places, just more stuff to remember. [31 years, female; 21 years DM; 12 months of Loop use]*

### **Quantification of Risk**

Because Loop is unregulated and therefore unsupported, there may be perceptions of risk. When asked about this, none of the participants considered that using Loop was any more of a risk than an alternate option in diabetes management. Indeed, most participants deemed it to be of much lower risk:

*Yes definitely, I am more concerned for the people who don't use Loop than those who do. It is safer to have a computer system shutting off your insulin and stopping you from going low. It is more trustworthy and makes more rational decisions compared to a person; it shuts off those irrational and emotive decisions so yes, I think it is safer. [30 years, male; 15 years DM; 44 months of Loop use]*

The importance of setting up the system correctly and “knowing your diabetes” in terms of having the correct insulin pump settings before commencing Loop was expressed by most participants:

*I think the only real risk is if there is a lack of understanding that is when problems will arise. I*

*think the system would be risky for newly diagnosed people because we don't leave the doctor's office after that first appointment knowing everything, we need to know how to make these systems work. It is a stepwise process but if the settings are set up correctly then I don't think there are any risks. [49 years, female; 37 years DM; 7 months of Loop use]*

The limitations of individual components (ie, insulin pump or CGM device), rather than the Loop system itself, were identified as a source of issues that arose during Loop use:

*Another challenge or a risk I find during the times when there is a sensor change and the Dexcom is in its warm up period, if the blood sugars haven't been linking for 2 hours and then it starts, Loop tends to over correct and risks dropping my blood sugars low (which has happened more often than not) it can be a bit better if I allow it to autocorrect. [33 years, female; 22 years DM; 18 months of Loop use]*

Many participants were using older and out-of-warranty pumps (because many newer in-warranty pumps were incompatible with the Loop app), which they identified as a potential risk in itself:

*I was worried about using the older pump but I have recently acquired both a backup pump and RileyLink so have more confidence in this. My pump looks really rough and I do worry occasionally about button errors especially in the heat. [29 years, female; 27 years DM; 7 months of Loop use]*

Participants reported dissatisfaction with the alternate diabetes management options that are currently available, including Commercial AID systems. A participant had used the Medtronic MiniMed 670G system but had struggled with the Enlite sensor, especially with its alarms. Another user was dissatisfied with Tandem Control-IQ as a result of the lack of customizable glucose targets, with the system providing fixed thresholds that some people felt were too high. Many expressed that they did not wish to consider any other options now that they had experienced Loop:

*I feel that Loop is the best option there is right now for people with type 1 diabetes, pump companies are not there yet. I like that people with type one diabetes have built these systems and the #wearenotwaiting movement; the principles and practice of these very gifted individuals who have helped so many people with this technology. I am very thankful to them and just wish more people could have access to it. [33 years, female; 18 years DM; 23 months of Loop use]*

### **Society's Understanding and Awareness of Loop**

Owing to the unregulated nature of Loop, some participants expressed concern in discussing the use of Loop with others, including with health care providers. All participants in this study were seen in the same diabetes clinic, although with multiple different care providers practicing within the clinic. Most participants expressed positive interactions in the health care setting, frequently describing "passive encouragement" to consider and use Loop. A participant explained that because of

the lack of support, with the discouragement of Loop by her previous health care team, she had moved to a new provider as she wished to continue using Loop. Another described being discouraged from continuing to use Loop while seeing a different endocrinologist during pregnancy, despite finding it very beneficial. All other participants felt they could discuss Loop with their clinical team without concern and that health care providers were largely keen to learn more about Loop:

*Yes, my healthcare team is very supportive. I have had no negative interactions; I was admitted to the medicine unit – they saw my chart and brought the team in and wanted me to talk about looping and everyone thought it was really cool. [27 years, female; 22 years DM; 40 months of Loop use]*

Most participants felt that their family and friends were supportive of Loop, although several noted that they had reservations at first, before seeing the benefits of the system for themselves:

*There was some hesitancy from my family at first because it's not government approved; you're tinkering with it yourself. I see DIY looping as the same as playing around with a pump for programming. Everyone is supportive now. I have friends with diabetes that I have started on loop. [24 years, male; 4.5 years DM; 25 months of Loop use]*

Many participants had recommended or assisted another person with diabetes in starting Loop, but they indicated that the system may not be beneficial for everyone and felt that prior diabetes education and an understanding of technology were crucial:

*Yes, I have helped lots of people with looping, but I would tailor that recommendation based on the individual. Only if they have a good understanding of diabetes management and can critically think through how the system is reacting and what is going on, and interpret the data. [33 years, female; 22 years DM; 18 months of Loop use]*

Social media, most frequently the Looped Facebook group [26], was a key support structure that all participants had used either currently or previously to set up and troubleshoot Loop. Some noted that through this group, they had been partnered with a current Loop user in a mentor role for further support with starting Loop:

*Yes, Looped Facebook group is amazing and so responsive. I also use Alberta diabetes group, Loop and learn and an OrangeLink group. I was set up with a mentor in the Looped group when starting Loop also. [48 years, female; 35 years DM; 3 months of Loop use]*

Users expressed frustration at the lack of industry support for Loop and the fact that it had required people with diabetes and their families to build this system. However, they also expressed concerns relating to future industry involvement with Loop and the potential changes in the system that this may involve:

*I do worry with the increasing success the system may be 'dumbed down' in the future and restricted flexibility especially if it is undergoing regulatory*

*approvals with bureaucracy and authorities changing the system. [44 years, female; 32 years DM; 20 months of Loop use]*

## Discussion

### Principal Findings

In this cohort of adults with T1D at a single center, we have highlighted improved glycemic outcomes with Loop use. With this glucose management system, 67% (16/24) of users achieved the clinically recognized TIR target of 70% [27]. In this first described Canadian cohort of Loop users, we have identified high QOL scores with Loop. The Loop users demonstrated superior glycemic outcomes relative to the general population of people with T1D, with 42% (10/24) of them achieving an HbA<sub>1c</sub> of <7%, in comparison with the reported average of 21% [13]. The users noted that the removal of an emotive decision-making component in diabetes management was an overwhelmingly favorable aspect of Loop and felt that it aided in the achievement of individualized glucose targets. The safety features of Loop were particularly felt to be important by our participants overnight, with associated improved sleep. Reduction in hypoglycemia (frequency and severity), improved overnight glycemic control, and improved sleep have been widely reported for all DIY AID system types [2,8,28].

We have demonstrated a strikingly similar TIR reported to that in a large prospective observational study of 558 residents of the United States, with a mean age of 23 (SD 13) years who had been new Loop users for 6 months [10]. In this large cohort, with a maximum of 7 days Loop experience at baseline, mean TIR at 6 months was 73% (SD 13%), compared with 71% (SD 16%) in the most recent 6 months of Loop use in our local cohort of 24 users. In comparison to the participants in this prospective study, our study participants were relatively experienced Loop users, with a median of 18 (IQR 12-25) months of Loop use. These results suggest that the benefits of Loop can occur early in its implementation and are somewhat durable, a desirable characteristic for a therapeutic intervention in a chronic condition such as T1D.

No adverse safety outcomes related to hypoglycemia because of Loop use were reported in our data; there was an improvement in TBR, with time <3.0 mmol/L and no admissions related to SH. However, 2 episodes of DKA occurred, both of which were associated with underlying infections. In people with T1D, the estimated incidence of DKA is reported to be 4.6 to 8.0 events per 1000 patient years [29]. Lum et al [10] reported no episodes of DKA with 6 months of Loop in 558 individuals (279 years); they reported 51 episodes of SH, with only one of these episodes being attributed to Loop use [10]. This larger prospective study used weekly electronic messages (with an 89% response rate) for data collection to maximize user recall but was dependent on self-reporting for these likely memorable and significant events for a person with diabetes [30]. Our data were reported based on retrospective recall from participants at the time of interview but were verified by reviews of their medical records. Only 1 of the 2 participants in our cohort self-reported the occurrence of an episode of DKA. All participants in our study reported that they perceived Loop to

be safe when the correct settings were in place. Interview responses relating to risk in this cohort were similar to those described by Schipp [20], highlighting a conscious weighing of risks against benefits for DIY AID users. With a detailed understanding of risk, including the use of unregulated and potentially out-of-warranty devices, using a DIY system was felt to be the best glucose management option available to them at this moment in time [19]. DIY AID systems were primarily designed for safety, initially targeting the avoidance of hypoglycemia. This concept of risk reduction through AID system use has been discussed by Lewis [24], highlighting the importance of taking the level of risk in AID use into context, with the risk faced by a person with diabetes who is manually dosing insulin representing the most appropriate comparator and not the risk faced by a person without diabetes. The use of AID systems removes a proportion of this total risk and provides an overall net risk reduction for people with T1D [24].

In terms of quantitative QOL outcomes, we found low diabetes impact and high device satisfaction and INSPIRE scores with Loop use for a median of 18 months in our cohort. The scores were very similar to DIDS outcomes of 2 months of Tandem Control-IQ use (Commercial AID) in 1435 people with T1D aged ≥14 years [15], with a median diabetes impact score of 2.7 (2.8 in this cohort) and median device satisfaction score of 9.1 (9.0 in this cohort). The INSPIRE outcomes of this study were also comparable with those reported with 6 months of Tandem Control-IQ use in another cohort of 112 users with a mean of 87 (IQR 77.6-96.5), in comparison with 86 in this cohort [26]. The median TIR achieved with Tandem Control-IQ was similar to that in our cohort, 79.2% (IQR 70.3%-86.2%) with a shorter duration of AID use, but closer to target glycemia at baseline; with a mean HbA<sub>1c</sub> of 6.9% (SD 0.9%) [15]. These studies of Commercial AID [17,31] were conducted with substantially greater supervision and support, as would be expected in a randomized controlled trial, in comparison with the real-world experiences collected from our Loop users.

We did not see a strong correlation between device perception and satisfaction outcome measures (DIDS and INSPIRE) or glycemic outcomes in this cohort. This may be a result of the small sample size with a narrow spectrum in these outcomes, but our qualitative data highlight a strong benefit of Loop use on QOL. After improved glycemic outcomes, enhanced QOL was the most frequently reported benefit of Loop use in our cohort. This concept comprises a reduction in the psychological impact of living with diabetes including time spent thinking about diabetes, diabetes-related distress, and burnout, in addition to greater flexibility in day-to-day life, notably related to diet and activity. The reduced mental burden of diabetes and less reliance on the accuracy of carbohydrate counting are consistently reported positive outcomes with DIY AID system use [2].

Another common theme identified was the financial resources required for Loop use, which restricted the availability of this beneficial system. We did not collect data relating to income or index of deprivation, but our participants' educational attainment and occupations indicated higher-than-average socioeconomic status [32]. Access and coverage of insulin



pumps across Canada remains unequal, with varying provincial health care funding models in place; insulin pump therapy is more commonly used in areas with reimbursement programs in place [33].

All except 1 Loop user in this cohort used both an insulin pump and a CGM device at the time of deciding to commence Loop. Having access to, but frequently experiencing dissatisfaction with these devices was a contributing factor to the process of behavior change in these users. For effective behavior change to occur, such as the initiation and continuation of Loop, there are key components for the user and their environment according to the capability, opportunity, motivation, behavior model of behavior change. These include capability (both physical and psychological), physical (including financial and material) and social opportunity (considering social and cultural norms) as well as motivation for change [34]. The components of this model are apparent in the lived experiences that we have described. Loop users highlighted the importance of this physical opportunity, with availability and access to technological devices being a potential limiting factor in the initiation of Loop. Most participants found their health care providers to be relatively supportive toward commencing Loop, despite the system being unregulated. This “social opportunity” enabled reassurance for users, this being an acceptable behavior change. This positive interaction is by no means guaranteed, with varied experiences reported with DIY AID use in health care settings [35].

This study had some strengths and weaknesses. The cohort were recruited from a single center with an integrated medical record that would capture admissions to any facility in the province. Objective collection of these data was performed by the health care team, rather than through self-reporting by users themselves, which has been a weakness in most previous reports of DIY AID systems that describe glycemic outcomes [2,8,11,12,28,36-38]. This study did not include a comparator control group. We collected qualitative data in addition to quantitative data, with Loop users being able to compare their own lived experiences, both with and without Loop use. The

sample size for the collection of quantitative outcome data was small, limited by the number of Loop users locally. Selection bias, as a result of the inclusion of individuals who chose to use Loop, must be considered in the generalizability of our findings to the wider population of people with T1D. We have only included current Loop users and therefore, have not been able to explore the reasons behind why users may decide to stop using this form of glucose management system. The fear of disapproval of Loop use from a diabetes care provider as well as barriers to acquiring the component devices have been reported as reasons for Loop discontinuation [22], although we cannot estimate whether these are significant factors in our cohort of individuals who had shared their DIY AID use with their health care providers.

## Conclusions

DIY AID use in this local cohort of individuals who have chosen to start and continue to use Loop has been associated with notable improvements in glycemic outcomes and excellent QOL. Through a combination of quantitative data collection and qualitative interview analysis, we have gained a greater understanding of the lived experiences of the Loop users in this cohort, including the common challenges and extensive benefits. What is most striking is the ability for motivated individuals to further increase their success in achieving glycemic targets while simultaneously experiencing reduced burden and distress from diabetes. Although most DIY users who have been studied to date have been those who were already successful in achieving glycemic targets, future studies should focus on the potential benefits of DIY AID for people who have found it difficult to achieve glycemic targets because of this goal being excessively burdensome or beyond their capacity, as a result of limited financial, social, or educational resources. It is hoped that the experience of Loop users described in this cohort, in combination with further broader user experience, may aid many other future users to access and experience the benefits of Loop use.

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## Conflicts of Interest

KF is a full-time employee of Beta Bionics, and all the research associated with this study was completed in a personal capacity on her own time. The opinions or views expressed in this presentation or publication are her own. They do not purport to reflect the opinions or views of Beta Bionics, its employees, agents, investors or board members. PAS has received grants from Novo Nordisk and is a board chair for Diabetes Canada and coinvestigator for Diabetes Action Canada. AL has received grants from the Juvenile Diabetes Research Foundation and Diabetes UK.

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## Multimedia Appendix 1

Interview transcript, coding structure, and validated quality of life surveys (Diabetes Impact and Device Satisfaction and Insulin Dosing Systems: Perceptions Ideas Reflections and Expectations).

[[DOCX File, 32 KB - diabetes\\_v7i4e40326\\_app1.docx](#) ]

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## Abbreviations

**AID:** automated insulin delivery

**CGM:** continuous glucose monitor

**DIDS:** Diabetes Impact and Device Satisfaction

**DIY:** do-it-yourself

**DKA:** diabetic ketoacidosis

**INSPIRE:** Insulin Dosing Systems: Perceptions Ideas Reflections and Expectations

**QOL:** quality of life

**SH:** severe hypoglycemia

**T1D:** type 1 diabetes

**TBR:** time below range

**TIR:** time in range

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Original Paper

# Effects of a Digital Patient Empowerment and Communication Tool on Metabolic Control in People With Type 2 Diabetes: The DeMpower Multicenter Ambispective Study

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## Abstract

**Background:** Diabetes is a major health care problem, reaching epidemic numbers worldwide. Reducing hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels to recommended targets is associated with a marked decrease in the risk of type 2 diabetes mellitus (T2DM)–related complications. The implementation of new technologies, particularly telemedicine, may be helpful to facilitate self-care and empower people with T2DM, leading to improved metabolic control of the disease.

**Objective:** This study aimed to analyze the effect of a home digital patient empowerment and communication tool (DeMpower App) on metabolic control in people with inadequately controlled T2DM.

**Methods:** The DeMpower study was multicenter with a retrospective (observational: 52 weeks of follow-up) and prospective (interventional: 52 weeks of follow-up) design that included people with T2DM, aged ≥18 and ≤80 years, with HbA<sub>1c</sub> levels ≥7.5% to ≤9.5%, receiving treatment with noninsulin antihyperglycemic agents, and able to use a smartphone app. Individuals were randomly assigned (2:1) to the DeMpower app–empowered group or control group. We describe the effect of empowerment on the proportion of patients achieving the study glycemic target, defined as HbA<sub>1c</sub> ≤7.5% with a ≥0.5% reduction in HbA<sub>1c</sub> at week 24.

**Results:** Due to the COVID-19 pandemic, the study was stopped prematurely, and 50 patients (33 in the DeMpower app–empowered group and 17 in the control group) were analyzed. There was a trend toward a higher proportion of patients achieving the study glycemic target (46% vs 18%; *P*=.07) in the DeMpower app group that was statistically significant when the target was HbA<sub>1c</sub> ≤7.5% (64% vs 24%; *P*=.02) or HbA<sub>1c</sub> ≤8% (85% vs 53%; *P*=.02). The mean HbA<sub>1c</sub> was significantly reduced

at week 24 ( $-0.81$ , SD  $0.89$  vs  $-0.15$ , SD  $1.03$ ;  $P=.03$ ); trends for improvement in other cardiovascular risk factors, medication adherence, and satisfaction were observed.

**Conclusions:** The results suggest that patient empowerment through home digital tools has a potential effect on metabolic control, which might be even more relevant during the COVID-19 pandemic and in a digital health scenario.

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## KEYWORDS

empowerment; home digital tool; telemedicine; type 2 diabetes; diabetic; home based; home care; self-management; digital tool; metabolic; HbA<sub>1c</sub>; glycated hemoglobin; glycemic control; adherence; satisfaction; observational study; health app

## Introduction

Diabetes is a major health care problem, reaching epidemic numbers worldwide [1,2]. Globally, approximately 537 million people had type 2 diabetes mellitus (T2DM) in 2021, but it is expected that these numbers will increase up to nearly 783 million people by 2045 due to aging populations and the negative impact of some lifestyles, such as obesity and sedentarism [1-3]. This translates into a huge socioeconomic impact in addition to the health care burden [4]. In Spain, the prevalence of T2DM is estimated to be approximately 14% [5], and the direct health costs of diabetes account for approximately 8% of total public health expenditures [6].

Reducing hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels to recommended targets is associated with a marked decrease in the risk of T2DM-related complications [7]. Although adopting a healthy lifestyle (diet and physical activity) is necessary in T2DM to improve metabolic control, most people with T2DM will need at least 1 antidiabetic agent to control blood glucose levels. The pharmacological options to treat hyperglycemia in T2DM have improved substantially over the past 20 years with the development of new therapeutic agents that not only safely reduce HbA<sub>1c</sub> levels but also have cardiovascular and renal benefits; unfortunately, many people with T2DM do not achieve recommended HbA<sub>1c</sub> targets ( $<7\%$ ) [8,9]. In Spain, the proportion of people with T2DM with good glycemic control has not improved markedly over the last decade, remaining at around 50%-60%, suggesting that additional approaches are warranted [10-12]. Moreover, the lockdown during the COVID-19 pandemic has led to a worsening of follow-up and metabolic control in people with T2DM globally and in Spain [13-16].

Although many causes have emerged to explain this poor metabolic control in people with T2DM, poor adherence to treatment and clinical inertia play a key role [17-19]. Therefore, proper management of T2DM is challenging and deserves constant attention and comprehensive patient-centered clinical assistance. Consequently, it is necessary to transform health care systems to provide integrated and patient-centered chronic care models [20].

In this context, the implementation of new technologies, particularly telemedicine, may be helpful to facilitate patient self-care and empowerment [21,22]. In fact, effective diabetes self-management is a key goal, but it should be measured and monitored as part of routine care and technology may help patients and guide clinical decisions [22]. Different studies have

shown that the use of telemedicine is associated with improvements in patients' outcomes such as adherence, pathology control, and engagement [21,23-27]. However, in Spain, there are few studies evaluating eHealth solutions for people with T2DM, mostly developed in small local settings [28-33].

Taking into account the high prevalence and burden of T2DM in Spain and the current high number of people with inadequate metabolic control, developing innovative solutions to improve this situation is necessary. This improvement should be made through patient empowerment by increasing self-management and communication between patients and health care professionals, allowing more effective T2DM control.

The aim of this study was to analyze the effect of a home digital patient empowerment and communication tool (DeMpower App) on metabolic control in people with T2DM and inadequate HbA<sub>1c</sub> levels compared to a control group, both treated according to usual clinical practice.

## Methods

### Overview

The DeMpower study was a multicenter and an ambispective study including adults with T2DM having inadequate glycemic control, treated according to clinical practice across Spain. The study population included people with T2DM aged  $\geq 18$  and  $\leq 80$  years from Spanish health care sites with HbA<sub>1c</sub> levels  $\geq 7.5\%$  and  $\leq 9.5\%$ , who were receiving treatment with noninsulin antihyperglycemic agents and who were able to use a smartphone-based home digital tool. The main exclusion criteria were the use of insulin treatments, pregnancy, any scheduled surgery, terminal or severe diseases, or any medical or psychological condition that, in the investigator's opinion, might have compromised the ability of the patient to provide informed consent. Patients were recruited consecutively as they visited the doctor's office, reducing the possibility of selection bias and strengthening the generalizability of the results.

The enrollment period was approximately 12 months and patients were followed up for 52 weeks. The primary end point was assessed at week 24 of follow-up. Retrospective data were collected during the 52 weeks prior to the baseline visit, and the HbA<sub>1c</sub> determination closest to the 24 weeks before baseline and the antidiabetic treatment prescribed at that time were recorded. After the enrollment period, patients were randomly assigned (2:1) to two comparative groups: group 1 (DeMpower app-empowered group), where patients were clinically managed

according to usual clinical practice and used the DeMpower app during the prospective study follow-up, and group 2 (control group), where patients were clinically managed according to usual clinical practice without the DeMpower app. After the primary assessment at week 24, patients in group 1 were randomized again (1:1) to assess the durability of the effect at week 52: group 1a (DeMpower app–empowered group, long-term use), where patients kept using the DeMpower app, and group 1b (DeMpower app–empowered group, short-term use), where patients stopped using the DeMpower app. Both groups continued being clinically managed according to usual clinical practice (Figure S1 in [Multimedia Appendix 1](#)). The follow-up of group 2 continued without changes.

In group 1, patients received the following commercially available devices to use in combination with and connected to the DeMpower app: scale, glucometer, blood pressure monitor, and activity wristband. Patients were also trained to use the devices according to routine clinical practice, as agreed with their health care professionals (ie, taking periodic measurements of their glucose and blood pressure levels as well as their weight and degree of physical activity). Data from these devices (body weight, glucose levels, blood pressure, and number of steps taken daily) were received wirelessly by the DeMpower app for each patient and sent to the corresponding health care team to review the patient's activity and measurements, answer patient questions, and contact the patient, when needed (Figure S2 in [Multimedia Appendix 1](#)). However, this channel of direct communication did not substitute clinical practice, and if health care was required due to an emergency, patients followed the usual procedure of going to the emergency department of primary care centers or hospitals.

Patients in both groups received the same routine care and did not undergo any interventions, whether diagnostic or monitoring, other than those planned according to routine clinical practice. Clinical data and antidiabetic treatment details were collected from the clinical history of patients and from information provided by the patient during the study visit and entered into the electronic case report form. Laboratory parameters, including HbA<sub>1c</sub>, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol, were taken from blood samples of all patients collected at baseline and thereafter, following local clinical practice until study completion or early study discontinuation.

The main evaluations compared groups 1 and 2 at week 24. The primary outcome of the study was to evaluate whether empowerment would reduce the proportion of patients persisting without metabolic control at week 24. The primary study glycemic target was an HbA<sub>1c</sub> level  $\leq 7.5\%$  with a reduction in HbA<sub>1c</sub> of  $\geq 0.5\%$  at week 24. Other secondary predefined study glycemic targets were HbA<sub>1c</sub>  $\leq 8\%$ , HbA<sub>1c</sub>  $\leq 7\%$ , and individualized HbA<sub>1c</sub> targets for each patient at week 24, as established by the investigators. The absolute HbA<sub>1c</sub> change at week 24 versus baseline was also a predefined secondary end point. In addition, mean changes in the body weight, BMI, blood pressure, LDL and HDL cholesterol levels, physical activity (measured as metabolic equivalent of task in min/week), and patient adherence to treatment were measured. Patient

satisfaction with the DeMpower app and experience with health care received were also assessed. Finally, the mean number of symptomatic and asymptomatic hypoglycemic events ( $\leq 70$  mg/dL) registered at emergency departments from baseline to week 24 between groups 1 and 2 was determined.

Questionnaires were used to evaluate study outcomes related to the degree of physical activity (International Physical Activity Questionnaire [IPAQ]), patient adherence to treatment (Medication Adherence Report Scale [MARS-5]), satisfaction with the DeMpower app (Diabetes Treatment Satisfaction Questionnaire status [DTSQs] version), and experience with health care received (Instrumento de Evaluación de la eXperiencia del PAciente Crónico [IEXPAC]) [19,34-37]. In this study, the short-form IPAQ was used, consisting of 4 generic domains with 7 questions in total for use in either interviews or self-administered methods [34]. The MARS-5 is a 5-item scale that includes questions about the way patients take their medicines and whether they forget to take them. Patients report agreement with statements about medicines using a 5-point Likert scale (from “always” [scored as 1] to “never” [scored as 5]). The maximum total score for all questions answered as “never” is 25 [35]. The DTSQs is an 8-item questionnaire, with 6 questions assessing treatment satisfaction and the other 2 assessing the perceived frequency of hyperglycemia and hypoglycemia. Each item is scored from 6 (ie, very satisfied) to 0 (ie, very dissatisfied), with the treatment satisfaction scale ranging from 36 (ie, very satisfied) to 0 (ie, very dissatisfied) and the perceived frequency of hyperglycemia and hypoglycemia scores ranging from 6 (ie, most of the time) to 0 (ie, none of the time) [36]. The IEXPAC is a 12-item scale that includes 11 questions plus 1 more conditional question about the experience of patients with chronic conditions regarding the health care and social attention that they have received. Items are answered as never (0 points), seldom (2.5 points), sometimes (5 points), most times (7.5 points), and always (10 points). The overall score of the 11 questions is calculated as their average score and ranges from 0 to 10. The additional question (item 12) is reported separately and ranges from 0 to 10 [19,37].

Assuming a bilateral contrast, an alpha risk of .05, a power of 80%, a proportion of response of 50% for each group and a patient loss of  $\leq 13\%$ , 100 patients were needed in group 1 (DeMpower app–empowered patients) and 50 patients in group 2 (control group) to detect a difference equal to or higher than 25% between both groups with regard to the primary study objective. For the descriptive analysis, quantitative variables were described with measures of centralization and dispersion (mean and SD), whereas qualitative variables were described by their absolute (N) and relative (%) frequencies. To compare 2 means between groups, parametric (Student *t* test) and nonparametric (Mann-Whitney *U* test) tests were used, as required. Categorical variables were compared with the chi-square or the Fisher exact test, when appropriate. Hypothesis tests were 2-tailed in all cases, with a significance level of .05. The evolution of HbA<sub>1c</sub> throughout treatment was evaluated using a general linear model of repeated measures. Absences of data were not accounted for and were considered missing



data. Statistical analyses were performed using SPSS (version 22.0 or higher; IBM Corp).

### Ethics Approval

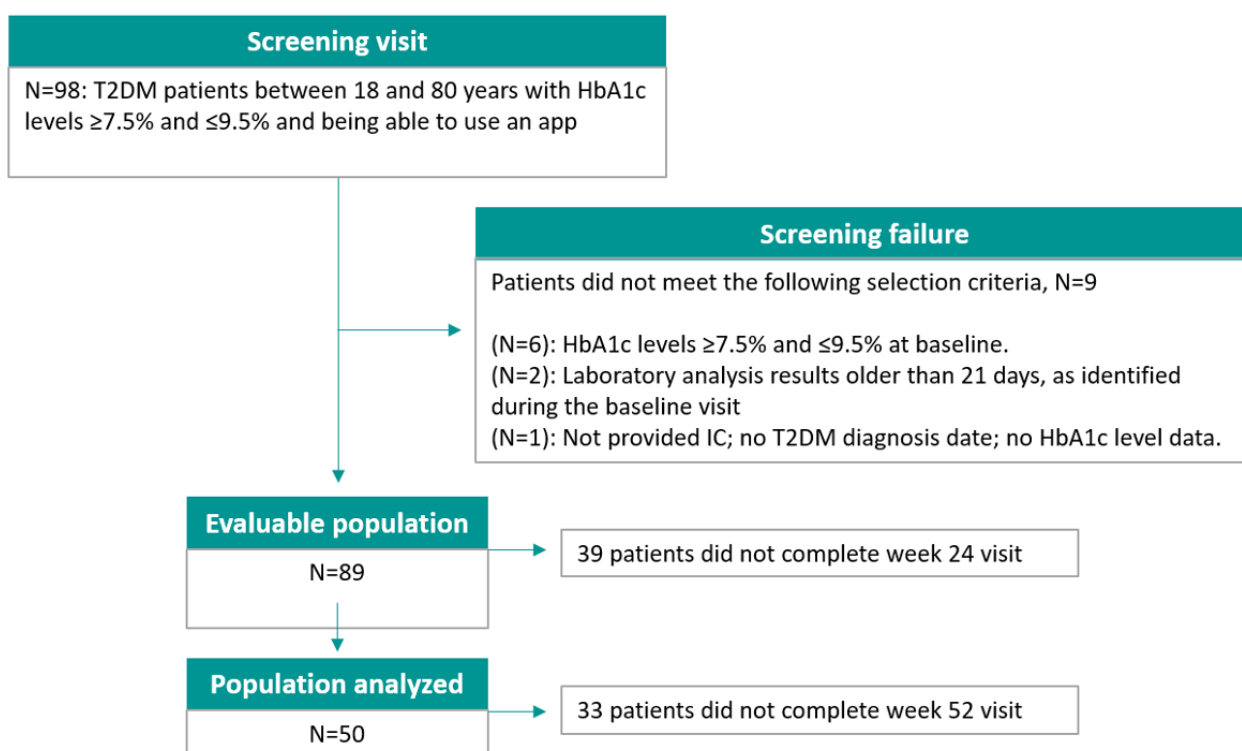
The study was approved by the following ethics committees: Institut Universitari d'Investigació en Atenció Primària Jordi Gol (reference 5OB18/010), General University Hospital of Elda, Central Research Commission of Madrid, Murcian Health Service, and Health Areas of León and Bierzo.

### Results

Due to the COVID-19 pandemic, the study was stopped prematurely (July 2020), with a relevant impact on both the recruitment and follow-up of patients. In addition, the primary hypothesis of the study, which was based on the empowerment

of patients using the DeMpower app, could have been affected by the generally altered lifestyles of the patients during and after the COVID-19 lockdown period, both in the empowered and control groups. At the time of study discontinuation, 98 patients had been recruited in 15 of the 25 participating sites across Spain. Among these, 9 patients were excluded, as they did not meet the selection criteria and 89 were evaluable. Many of the patients were not able to attend visits and procedures due to the lockdown, and finally, 50 patients (33 patients in group 1 and 17 patients in group 2) completed the study visit at week 24 and were considered valid for the final analysis of the main study end points. At week 52, the number of patients remaining in groups 1a, 1b, and 2 were 6, 5, and 6, respectively (Figure 1). No patients abandoned the study due to an inability to adapt to the DeMpower app.

**Figure 1.** Study flowchart. HbA<sub>1c</sub>: hemoglobin A<sub>1c</sub>; IC: informed consent; T2DM: type 2 diabetes mellitus.



The baseline clinical characteristics of the study population are shown in Table 1. The groups were well balanced, without statistically significant between-group differences regarding clinical characteristics or baseline treatments, except for the presence of transient ischemic attack (no patients in group 1 vs 3 patients in group 2,  $P=.04$ ) and the use of glinides (0 patients in group 1 vs 3 patients in group 2,  $P=.03$ ). The mean age of the patients was 64 (SD 8) years, with 25% (13/50) older than 69 years, and 50% (25/50) of all patients were aged between 59 and 69 years. Overall, 66% (33/50) were male and 96% (48/50) were Caucasian; the mean diabetes duration was 10 (SD 6) years, and the mean BMI was 29.7 (SD 4.9) kg/m<sup>2</sup>. Complications associated with diabetes were not observed in 70% (23/33) of the patients in group 1 and 71% (12/17) of the patients in group 2 ( $P>.99$ ). The majority of patients had at least 1 comorbidity (70% vs 59%, respectively;  $P=.53$ ), with

cardiovascular disease being the most common (61% vs 47%, respectively;  $P=.39$ ). At baseline, the mean (SD) HbA<sub>1c</sub> values were 8.2 (0.5) and 8.3 (0.6), respectively ( $P=.57$ ). The most commonly prescribed antidiabetic drugs were metformin (88% vs 100%, respectively;  $P=.29$ ), dipeptidyl peptidase-4 inhibitors (61% vs 41%;  $P=.24$ ), sodium-glucose cotransporter-2 inhibitors (42% vs 53%;  $P=.56$ ), and sulphonylureas (46% vs 18%;  $P=.40$ ).

Regarding the primary metabolic objective, there was a trend toward a higher proportion of people with T2DM achieving HbA<sub>1c</sub> levels  $\leq 7.5\%$  with a reduction of  $\geq 0.5\%$  in HbA<sub>1c</sub> with respect to the baseline value at week 24 (primary outcome) in group 1 compared with that in group 2 (46% vs 18%;  $P=.07$ ), and this reached statistical significance when considering the proportion of people with T2DM achieving HbA<sub>1c</sub> levels  $\leq 7.5\%$  at week 24 (64% vs 24%, respectively;  $P=.02$ ; Figure 2).

When analyzing the percentage of patients with HbA<sub>1c</sub> levels ≤7% at week 24 (36% vs 12%, respectively;  $P=.1$ ) or the proportion of patients controlled according to the individualized HbA<sub>1c</sub> objectives for each patient established by the investigators (67% vs 82%, respectively;  $P=.33$ ), no significant between-group differences were observed. However, more patients in group 1 achieved significant HbA<sub>1c</sub> levels ≤8% at week 24 (85% vs 53%, respectively;  $P=.02$ ; [Figure 3](#)).

HbA<sub>1c</sub> levels from baseline to week 24 significantly decreased to a higher extent in group 1 versus group 2 ( $-0.81$  [ $0.89$ ] vs  $-0.15$  [ $1.03$ ]; mean difference  $-0.66\%$ ;  $P=.03$ ). This statistically significant difference remained after adjusting for changes in antidiabetic treatment, age, sex, duration of diabetes, smoking status, socioeconomic status, educational level, and employment situation ([Figure 4](#)).

No symptomatic and asymptomatic hypoglycemic events ( $\leq 70$  mg/dL) from baseline to week 24 were reported in any of the groups at emergency departments both from primary care centers and hospitals. With regard to antidiabetic drugs, there were no statistically significant differences in treatment between the

groups at week 24. In both groups, there was an overall increase in the prescription of antidiabetic agents at week 24 (Table S1 in [Multimedia Appendix 1](#)).

The evolution of the BMI, systolic blood pressure, diastolic blood pressure, LDL, HDL, and physical activity from the baseline visit to week 24 is shown in Table S2 in [Multimedia Appendix 1](#). Although no statistically significant between-group differences were observed, there was a positive trend for group 1, with relevant reductions in the BMI and blood pressure, and an increase in physical activity.

The MARS-5 responses showed similar adherence to treatment in both groups at week 24, but with a positive trend in group 1. Patient satisfaction (DTSQs) and experience with the health care system (IEXPAC) were positive in both groups, with no significant between-group differences (Table S3 in [Multimedia Appendix 1](#)).

Due to the small number of patients completing the week 52 visit (17/50, 34%), no analysis was performed for the study exploratory end points at this time.

**Table 1.** Baseline sociodemographic characteristics of patients completing 24 weeks of follow-up.

Characteristic	Group 1 (n=33)	Group 2 (n=17)	P value
Age (years), mean (SD)	63.3 (6.4)	64.4 (9.5)	.46
Sex (male), n (%)	22 (66.7)	11 (64.7)	>.99
<b>Race, n (%)</b>			>.99
Caucasian	32 (97)	16 (94.1)	
Other	1 (3.0)	1 (5.9)	
<b>Educational level, n (%)</b>			.32
Primary	10 (30.3)	8 (47.1)	
Secondary	14 (42.4)	3 (17.6)	
Higher education	8 (24.2)	5 (29.4)	
Unknown	1 (3.0)	1 (5.9)	
<b>Professional situation, n (%)</b>			.94
Unemployed	2 (6.1)	1 (5.9)	
Employee	9 (27.3)	4 (23.5)	
Autonomous	3 (9.1)	2 (11.8)	
Retired	17 (51.5)	8 (47.1)	
Other	2 (6.1)	2 (11.8)	
<b>Lifestyle habits, n (%)</b>			.06
Active smoker	8 (24.2)	0 (0.0)	
Ex-smoker	15 (45.5)	8 (47.1)	
Never been a smoker	10 (30.3)	9 (52.9)	
Unknown	0 (0.0)	0 (0.0)	
Time from T2DM <sup>a</sup> diagnosis to study inclusion (years), mean (SD)	10.3 (7.3)	10.6 (4.6)	.47
<b>Complications associated with T2DM disease, n (%)</b>			
None	23 (69.7)	12 (70.6)	>.99
Microalbuminuria	6 (18.2)	1 (5.9)	.40
Peripheral vascular disease	3 (9.1)	1 (5.9)	>.99
Ischemic heart disease	2 (6.1)	1 (5.9)	>.99
Neuropathy	2 (6.1)	2 (11.8)	.60
Stroke	1 (3.0)	3 (17.6)	.11
Retinopathy	1 (3.0)	1 (5.9)	>.99
Transient ischemic attack	0 (0.0)	3 (17.6)	.04 <sup>b</sup>
Heart failure	1 (3.0)	0 (0.0)	>.99
Other complications	2 (6.1)	1 (5.9)	>.99
<b>≥1 comorbidity, n (%)</b>	23 (69.7)	10 (58.8)	.53
Cardiovascular disease	20 (60.6)	8 (47.1)	.39
Musculoskeletal disorder	10 (30.3)	5 (29.4)	>.99
Endocrine disorder	7 (21.2)	3 (17.6)	>.99
Neurological/psychiatric disorder	5 (15.2)	4 (23.5)	.47
Gastrointestinal disorder	3 (9.1)	2 (11.8)	>.99
Respiratory disease	5 (15.2)	2 (11.8)	>.99
Hematological disease	4 (12.1)	0 (0.0)	.29

Characteristic	Group 1 (n=33)	Group 2 (n=17)	<i>P</i> value
Renal disease	2 (6.1)	1 (5.9)	>.99
Infectious disease	2 (6.1)	1 (5.9)	>.99
Cancer	2 (6.1)	2 (11.8)	.60
Autoimmune disease	1 (3.0)	0 (0.0)	>.99
<b>Physical examination, mean (SD)</b>			
BMI (Kg/m <sup>2</sup> )	30.2 (5.3)	28.7 (4.1)	.40
SBP <sup>c</sup> (mmHg)	137 (16.6)	130 (15.8)	.26
DBP <sup>d</sup> (mmHg)	79.5 (9.5)	76.1 (7.5)	.08
<b>Laboratory parameters, mean (SD)</b>			
HbA <sub>1c</sub> <sup>e</sup> (mg/dL)	8.2 (0.5)	8.3 (0.6)	.57
Glucose	173.0 (35.3)	171.0 (38.9)	.84
HDL <sup>f</sup> cholesterol (mg/dL)	47.6 (18.1)	47.4 (11.2)	.58
LDL <sup>g</sup> cholesterol (mg/dL)	96.9 (29.7)	98.5 (34.6)	.85
Individualized HbA <sub>1c</sub> target	7.0 (0.2)	7.2 (0.3)	.05
HbA <sub>1c</sub> (mg/dL), value closest to week 24	7.9 (0.9)	8.2 (1.0)	.56
<b>Antidiabetic drugs<sup>h</sup>, n (%)</b>			
Metformin	29 (87.9)	16 (94.1)	.49
DPP-4 <sup>i</sup> inhibitors	19 (57.6)	8 (47.1)	.48
SGLT2 <sup>j</sup> inhibitors	11 (33.3)	8 (47.1)	.34
Sulfonylurea	14 (42.4)	3 (17.6)	.08
GLP1 <sup>k</sup> receptor agonists	3 (9.1)	1 (5.9)	.69
Glinides	0 (0.0)	3 (17.6)	.03
Glitazones	1 (3)	0 (0.0)	.98

<sup>a</sup>T2DM: type 2 diabetes mellitus.

<sup>b</sup>Italics indicate significant *P* values <.05.

<sup>c</sup>SBP: systolic blood pressure.

<sup>d</sup>DBP: diastolic blood pressure.

<sup>e</sup>HbA<sub>1c</sub>: hemoglobin A<sub>1c</sub>.

<sup>f</sup>HDL: high-density lipoprotein.

<sup>g</sup>LDL: Low-density lipoprotein.

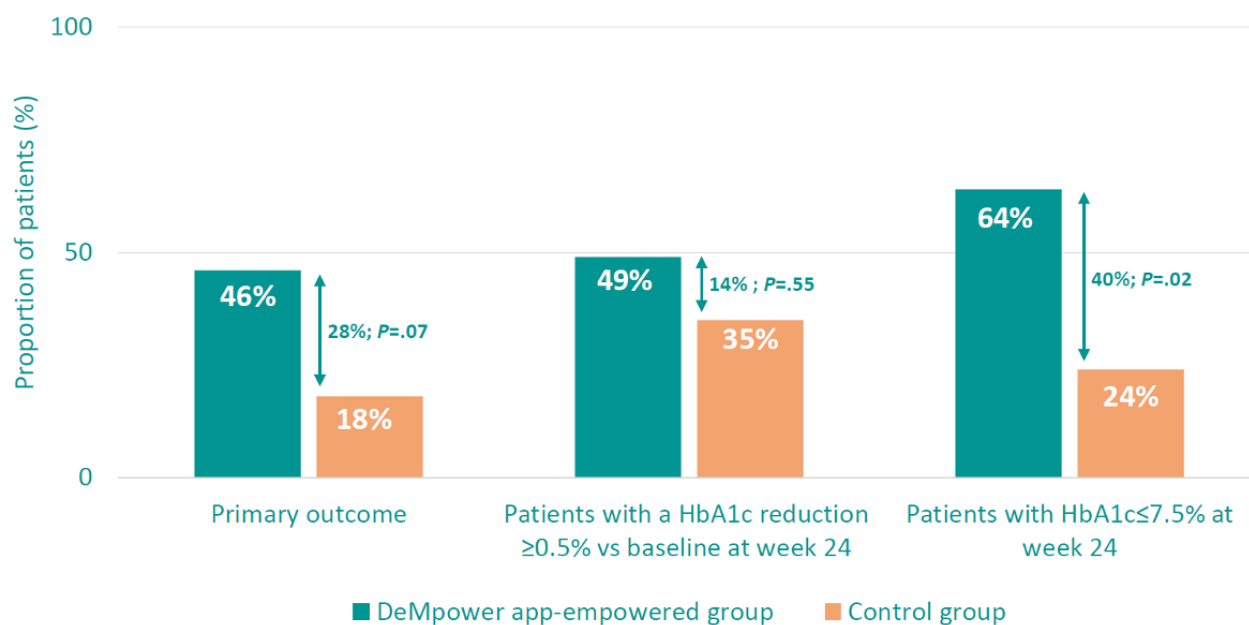
<sup>h</sup>Patients may have been indicated as receiving more than one antidiabetic drug.

<sup>i</sup>DPP-4: dipeptidyl peptidase-4.

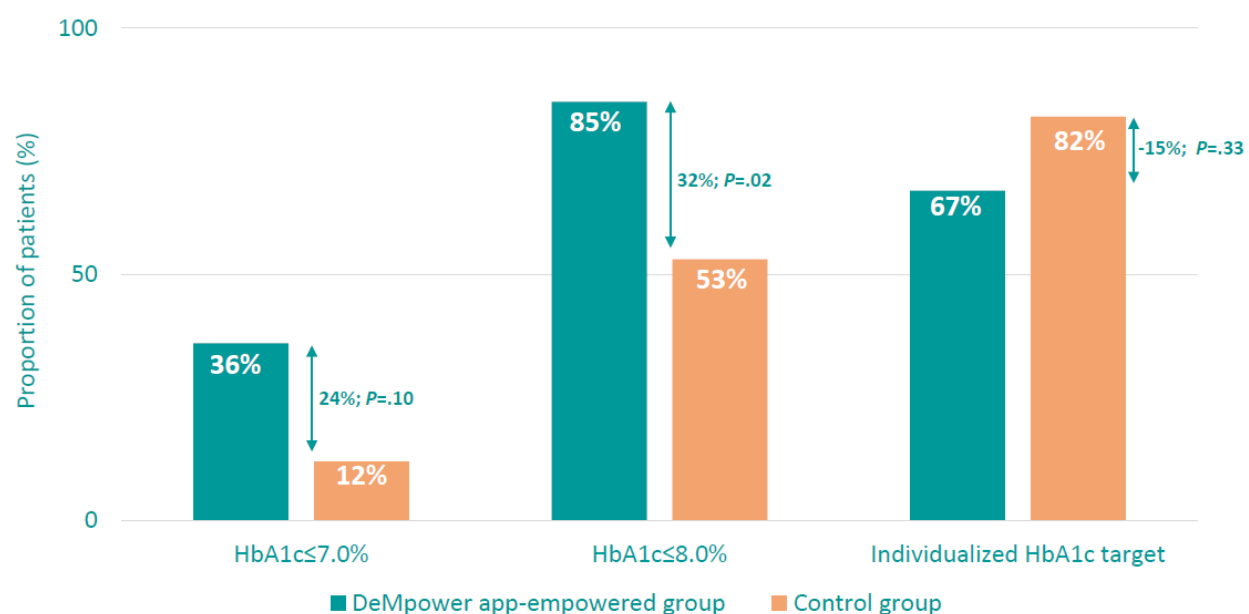
<sup>j</sup>SGLT2: sodium-glucose cotransporter-2.

<sup>k</sup>GLP1: glucagon-like peptide-1.

**Figure 2.** Primary composite outcome and individual components. Primary composite outcome refers to the proportion of patients achieving the study glycemic target ( $HbA_{1c} \leq 7.5\%$  with a reduction in  $HbA_{1c} \geq 0.5\%$  with respect to baseline value) at week 24.  $HbA_{1c}$ : hemoglobin A1c.

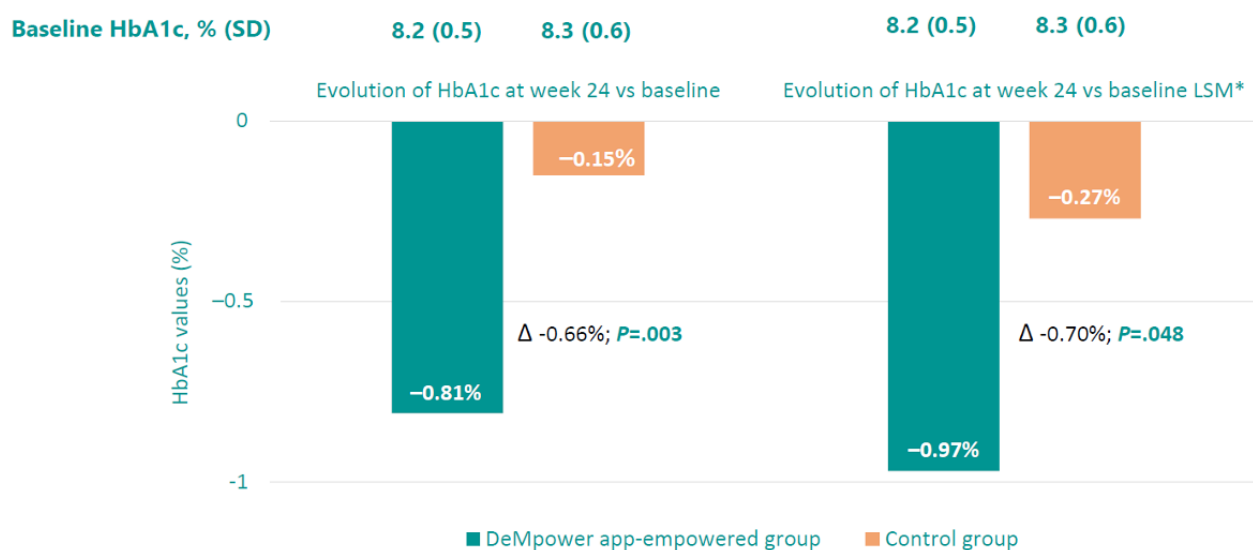


**Figure 3.** Proportion of patients with  $HbA_{1c} \leq 7\%$ ,  $HbA_{1c} \leq 8\%$ , and individualized  $HbA_{1c}$  target established by the investigator at week 24.  $HbA_{1c}$ : hemoglobin A1c.





**Figure 4.** Changes in HbA<sub>1c</sub> from baseline to week 24. HbA<sub>1c</sub>: hemoglobin A<sub>1c</sub>. \*Least square means with adjustments for changes in antidiabetic treatment, age, sex, duration of diabetes, smoking status, socioeconomic status, educational level, and employment situation.



## Discussion

The results from this study suggest that patient empowerment using the DeMpower app might improve metabolic control in people with T2DM who do not achieve HbA<sub>1c</sub> targets with the standard care, possibly leading to a more efficient management of the disease.

The COVID-19 pandemic lockdown had a direct impact on the recruitment and follow-up of patients, reducing the planned study size. In addition, during lockdown, patients were not able to practice outdoor physical activities; some patients might have had uncontrolled dietary habits and physical access to health care providers was limited, leading to impaired metabolic control in both groups. Additionally, this could have also impacted patient-reported outcomes (ie, physical activity, adherence, as well as satisfaction and experience questionnaires). In fact, many research projects unrelated to COVID-19 have been substantially reduced or even suspended due to legal restrictions or logistical, staffing, or operational concerns worldwide, as well as because of lockdowns or restrictions. Thus, a more flexible approach that ensures participant safety is warranted during the COVID-19 pandemic, under the good clinical practice umbrella [38]. In this context, investigating the impact of telemonitoring and telemedicine in patients with chronic conditions such as T2DM should be considered a priority, as it may facilitate better disease control [39,40].

The study groups were well balanced. The majority of patients were aged >60 years, had at least 1 comorbidity, and were taking more than 1 antidiabetic drug. This is in line with the clinical profiles reported in other studies of people with T2DM [10,41,42], indicating that patients included in our study were likely to be representative of the Spanish population with T2DM.

In our study, there was a trend in the primary outcome with a higher numerical proportion of empowered patients achieving the study glycemic target at week 24 compared to those in the control group. The between-group differences were statistically

significant for secondary outcomes such as HbA<sub>1c</sub> levels  $\leq 7.5\%$  and  $\leq 8\%$  at week 24, as well as absolute HbA<sub>1c</sub> reduction at week 24, even after adjusting for several clinical characteristics including treatment modification. In particular, the 0.66% difference in HbA<sub>1c</sub> levels between groups is clinically relevant and was achieved without increasing the risk of hypoglycemia. This is particularly remarkable given that there were no differences regarding the use or modification of antidiabetic drugs between both groups. These results support the clinical utility of the DeMpower app as a home digital patient empowerment and communication tool that might help patients achieve glycemic control that is independent of the antidiabetic treatment. Similarly, previous studies have also shown the benefits of home-based digital patient empowerment tools in the control of T2DM [23-33,43-47]. For example, the ValCrónica study [30] showed that the proportion of people with HbA<sub>1c</sub>  $\geq 8\%$  decreased significantly (by 44%) after 1 year of telemonitoring. In our study, 85% of patients using the digital tool achieved HbA<sub>1c</sub>  $\leq 8\%$ , compared to 53% in the control group (absolute difference 32%; relative difference 60%;  $P=.02$ ). Additionally, meta-analyses of randomized controlled trials on telemedicine interventions have confirmed significant improvements in the management of diabetes compared with standard care [44,45]. The use of home digital tools for people with T2DM empowerment and metabolic control has become even more important during the COVID-19 pandemic, as during this period, metabolic control among people with T2DM has worsened [13-16]. In contrast, glycemic values in people with type 1 diabetes significantly improved during the COVID-19 lockdown, which may be associated with positive changes in self-care and digital diabetes management [16]. This reinforces the importance of improving self-care management using digital tools in T2DM and is in line with the DeMpower study results, suggesting that eHealth and telemedicine could reduce the negative impact of the COVID-19 pandemic and might be relevant in the digital health framework.

People with T2DM often present other comorbidities such as hypertension, dyslipidemia, obesity, and renal or cardiovascular disease [41,42]. Consequently, to reduce the cardiovascular burden in T2DM, it is necessary to implement a comprehensive approach that includes not only glycemic control but also blood pressure, lipid profile, body weight, and physical activity [48]. In our study, there was a positive trend for some of these variables in patients who used the DeMpower app. Additionally, considering that the lockdown during COVID-19 had a negative impact on metabolic and weight control [13-16], it is likely that with a larger sample size, these differences would have reached statistical significance. Besides, a recent meta-analysis of 43 studies reported a positive impact of telemedicine not only on HbA<sub>1c</sub> but also on diastolic blood pressure, weight, and mental and physical quality of life, among people with T2DM [45]. Moreover, in the IDIATel randomized controlled trial [49] that compared telemedicine case management to routine care, greater reductions in LDL cholesterol and systolic and diastolic blood pressure levels were achieved with telemedicine.

Patient satisfaction with treatment is important to improve medication adherence [50]. Although our study did not show significant differences between groups, previous studies have shown an improvement with telemedicine [45]. Finally, the experience of patients regarding the health care attention received, evaluated with the IEXPAC tool, showed that there was opportunity for improvement for both groups, without

significant differences. Similar results have been previously obtained regarding the information that patients receive or can access [19,37].

This study has some limitations. As noted earlier, the most relevant limitation is that the COVID-19 pandemic led to a premature study termination, and consequently, the estimated sample size of 150 patients could not be achieved. This might have impacted the statistical power for the assessment of the main study outcome. As this study was designed to collect information available in routine clinical practice at the participating sites, some data were unavailable, limiting the validity of the study results. Likewise, the appearance of bias derived from the unsuccessful use of digital tools could not be ruled out, but this was expected to be minimized by the selection of patients with a proven ability to use home mobile apps on their smartphones.

In summary, the DeMpower study results strongly suggest that patient empowerment through a home digital tool might lead to more effective metabolic control and consequently to more effective achievement of the clinical objectives in people with T2DM. This study reinforces the importance of using telemedicine and new technologies for patient empowerment and metabolic control, especially in the digital health scenario. Moreover, these findings appear to be crucial during situations with limited patient access to health care and negative health consequences, such as the COVID-19 pandemic.

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## Conflicts of Interest

DOB received consulting fees from MSD and payments for lectures including payments for serving on speaker bureaus from Lilly, Novo Nordisk, and Sanofi Pasteur. CM received fees for participation in review activities such as data monitoring boards, statistical analysis, and end point committees through his institution, Hospital Universitario Virgen Macarena. KFC, MV, CH, CAO, AGG, MC, and GF are full-time employees at MSD Spain. SAM, CB, SC, CG, OB, and AA have no potential conflicts of interest.

Multimedia Appendix 1  
Supplementary information.

[[DOCX File, 484 KB - diabetes\\_v7i4e40377\\_app1.docx](#)]

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## Abbreviations

**DTSQs:** Diabetes Treatment Satisfaction Questionnaire status

**HbA<sub>1c</sub>:** hemoglobin A<sub>1c</sub>

**HDL:** high-density lipoprotein

**IEXPAC:** Instrumento de Evaluación de la Experiencia del Paciente Crónico

**IPAQ:** International Physical Activity Questionnaire

**LDL:** low-density lipoprotein

**MARS-5:** Medication Adherence Report Scale

**T2DM:** type 2 diabetes mellitus

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Original Paper

# Analyzing User Engagement Within a Patient-Reported Outcomes Texting Tool for Diabetes Management: Engagement Phenotype Study

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## Abstract

**Background:** Patient-reported outcomes (PROs) capture patients' views on their health conditions and its management, and are increasingly used in clinical trials, including those targeting type 2 diabetes (T2D). Mobile health (mHealth) tools offer novel solutions for collecting PRO data in real time. Although patients are at the center of any PRO-based intervention, few studies have examined user engagement with PRO mHealth tools.

**Objective:** This study aimed to evaluate user engagement with a PRO mHealth tool for T2D management, identify patterns of user engagement and similarities and differences between the patients, and identify the characteristics of patients who are likely to drop out or be less engaged with a PRO mHealth tool.

**Methods:** We extracted user engagement data from an ongoing clinical trial that tested the efficacy of a PRO mHealth tool designed to improve hemoglobin A1c levels in patients with uncontrolled T2D. To date, 61 patients have been randomized to the intervention, where they are sent 6 PRO text messages a day that are relevant to T2D self-management (healthy eating and medication adherence) over the 12-month study. To analyze user engagement, we first compared the response rate (RR) and response time between patients who completed the 12-month intervention and those who dropped out early (noncompleters). Next, we leveraged latent class trajectory modeling to classify patients from the completer group into 3 subgroups based on similarity in the longitudinal engagement data. Finally, we investigated the differences between the subgroups of completers from various cross-sections (time of the day and day of the week) and PRO types. We also explored the patient demographics and their distribution among the subgroups.

**Results:** Overall, 19 noncompleters had a lower RR to PRO questions and took longer to respond to PRO questions than 42 completers. Among completers, the longitudinal RRs demonstrated differences in engagement patterns over time. The completers with the lowest engagement showed peak engagement during month 5, almost at the midstage of the program. The remaining subgroups showed peak engagement at the beginning of the intervention, followed by either a steady decline or sustained high engagement. Comparisons of the demographic characteristics showed significant differences between the high engaged and low engaged subgroups. The high engaged completers were predominantly older, of Hispanic descent, bilingual, and had a graduate degree. In comparison, the low engaged subgroup was composed mostly of African American patients who reported the lowest annual income, with one of every 3 patients earning less than US \$20,000 annually.

**Conclusions:** There are discernible engagement phenotypes based on individual PRO responses, and their patterns vary in the timing of peak engagement and demographics. Future studies could use these findings to predict engagement categories and tailor interventions to promote longitudinal engagement.

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**International Registered Report Identifier (IRRID):** RR2-10.2196/18554

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## KEYWORDS

user engagement; patient-reported outcomes; mobile health; mHealth; digital health; SMS; type 2 diabetes; health behavior; digital phenotyping

## Introduction

### Background

A patient-reported outcome (PRO) is defined by the National Quality Forum and Food & Drug Administration as a “report of the status of a patient’s health condition that comes directly from the patient without amendment or interpretation of the patient’s response by a clinician or anyone else.” [1,2]. PROs include health-related quality of life [3], adherence to medical regimens, satisfaction with treatment, and elements of disease control [4]. Although innovations in medical technology have allowed the measurement of physical, physiological, or biochemical data with great accuracy, they are not able to provide the patient’s perspectives on their treatment or disease [5]. These data can only be obtained directly from patients [6]. Thus, PROs in clinical trials provide a more holistic assessment of the benefits of the treatment or intervention under investigation [7]. With the advent of patient-centered health care systems, where a patient is considered the center of the health care system [8], patients and patient advocates have called for more patient-centered outcomes reporting (ie, PROs) in combination with other clinical and physiological outcomes [5].

Traditionally, PROs have been assessed using survey instruments [4,9]. However, recent advancements in mobile health (mHealth) technologies have enabled a wide variety [10] of tools and apps that can be used to collect PRO data. With mHealth technologies, PROs can be assessed electronically from PCs, from mobile solutions such as tablet PCs or smartphones using apps or texting tools, or through data entered via web browsers [11]. The use of mHealth technologies to collect PRO data offers several advantages over traditional survey-based methods, including real-time data collection, reduced time for documentation, automated algorithms and calculations, in-home symptom monitoring, immediate transfer of data for clinical use, enhanced patient engagement in care, and more informed clinical decision-making [12-14].

Uncontrolled type 2 diabetes (T2D) is a significant public health problem in the United States, especially among vulnerable populations (eg, low-income, racial, and ethnic minorities) [15,16]. Prior studies have recognized that patients play a central role in the management of T2D (eg, being aware of its signs and symptoms and engaging in daily self-care behaviors), and several national and local organizations have launched initiatives to support the development and use of PROs in the evaluation of T2D patient care [17-21]. However, existing research that incorporates PROs in T2D care has been mostly limited to clinical drug trials examining patient tolerance to new treatment regimens [22]. The few practice-based studies conducted on

T2D used long lists of PRO measures and only had patients report PROs on a single occasion, typically before clinic visits [23,24]. Such reporting increases the risk of a recall bias. To address these shortcomings, a growing number of studies are using mHealth platforms that enable real-time collection of PROs outside the clinical environment [25-31].

### Objective

Analysis of prior mHealth research revealed that most studies did not consider user engagement metrics when evaluating the design implications of the intervention on T2D patients’ health outcomes [30]. Of the few studies that reported engagement data, most were limited by small sample sizes [32] and low response rates (RRs) [33]. Although prior research has found that consideration of user preference and personalization with mHealth PRO interventions are key aspects that influence user engagement [34], there is a lack of consensus regarding best practices for modifying mHealth PRO tools to optimize digital intervention and improve patients’ engagement [35]. Thus, the ideal cadence of PRO collection to facilitate sustained engagement in an intervention is unclear and may vary according to user characteristics [36]. To address these gaps, this study reports on the analysis of longitudinal user engagement data from an ongoing randomized controlled trial (Investigating an mHealth texting tool for embedding patient-reported data in diabetes management [i-Matter]) evaluating the efficacy of a PRO mHealth texting tool for T2D management among 282 patients with uncontrolled T2D [31]. This paper discusses and compares patterns of engagement with the PRO tool among patients randomized to the i-Matter intervention and across sociodemographic characteristics to offer insights for future adaptation of the intervention based on patients’ engagement.

## Methods

### Recruitment

Patients were recruited from a network of primary care practices at NYU Langone Health across New York City’s 5 boroughs and Long Island. The details of our recruitment approach have been reported previously [31]. Briefly, to participate in i-Matter, patients must (1) have a diagnosis of T2D for  $\geq 6$  months, (2) have uncontrolled T2D defined as hemoglobin A1c  $> 7\%$  documented in the electronic health record (EHR) at least twice in the past year, (3) be fluent in English or Spanish, (4) be willing to send and receive text messages, and (5) be  $> 18$  years of age. Patients were excluded if they (1) refused or were unable to provide informed consent; (2) had acute renal failure, end-stage renal disease, evidence of dialysis, renal transplantation, or other end-stage renal disease–related services documented in the EHR; (3) participated in another T2D study;

(4) had significant psychiatric comorbidity or reports of substance abuse (as documented in the EHR); (5) were pregnant or planning to become pregnant within 12 months; or (6) planned to discontinue care at the practice within the next 12 months.

This paper focuses on 61 patients randomized to the i-Matter intervention who have either dropped out of the trial before the 12-month study visit (ie, noncompleters) or completed the trial (ie, completers). We excluded patients who were currently participating in the trial as their data were incomplete and would not provide a comprehensive view of how their engagement with the PRO messages may change over time.

### The i-Matter Intervention

The “Investigating an mHealth texting tool for embedding patient-reported data into diabetes management” (i-Matter) trial is evaluating the efficacy of an innovative mobile PRO system that incorporates patients’ perspective of their disease into the management of T2D in primary care practices. Patients participating in the trial were randomized to the i-Matter intervention or usual care (ie, standard diabetes care by the primary care provider) in a 1:1 ratio by the study statistician. The i-Matter intervention uses text messaging to capture patients’ self-reported PROs in real time, provides data-driven feedback and motivational messages based on responses to the PROs, and creates dynamic visualizations of the PROs that are shared in personalized reports and integrated into the clinical EHR. We are currently conducting a randomized controlled trial to evaluate the efficacy of the i-Matter intervention versus usual care in reducing hemoglobin A1c levels and adherence

to self-care behaviors at 12 months among 282 patients with uncontrolled T2D who receive care in resource-limited primary care practices.

### Description of PRO Messages Embedded in the i-Matter Intervention

The details of the PRO system development have been reported elsewhere [31]. Briefly, we used a mixed method, user-centered design approach to select PROs that were integrated into the i-Matter intervention. Our approach included reviewing the existing literature on PRO measures for T2D, conducting interviews with primary care providers and patients to capture their experiences with T2D, and collecting survey data. These data sources were combined to identify the PROs that would be integrated into a beta version of i-Matter and refined with user testing among patients with T2D. Table 1 lists the final set of PROs, including their timing and response options, which were integrated into the i-Matter intervention. Daily daytime messages included PROs on sleep quality and healthy eating, whereas a daily nighttime message included a PRO on physical activity (Table 1 provides further details). Patients can choose when they would like to receive medication adherence [37] PRO based on their medication regimen in the afternoon, at night, or at both times. The remaining PROs were similarly timed for all patients. In addition, patients can choose one healthy living goal from a selected list of topics identified in user testing (Table 1). Questions on individualized healthy living goals and patients’ diabetes quality of life were sent weekly, and the remaining messages were sent daily. PROs can be sent in either English or Spanish depending on the patients’ language preferences.

**Table 1.** Text (patient-reported outcome) messages in the Investigating a mobile health texting tool for embedding patient-reported data in diabetes management (i-Matter) program, their scheduled time, and accepted response.

Patient-reported outcome question or category	Timing	Valid response
<ul style="list-style-type: none"> <li>Reply with the number that best describes how well you slept last night. Scale: 0 (poor)-10 (excellent) or Sleep quality</li> </ul>	Daily at 9 AM	<ul style="list-style-type: none"> <li>0-10</li> </ul>
<ul style="list-style-type: none"> <li>i-Matter (TM): Other than your regular job, did you do any physical activities like brisk walking for at least 30 minutes today? or Physical activity</li> </ul>	Daily at 8 PM	<ul style="list-style-type: none"> <li>Y, Yes (English only)</li> <li>S, Si, Sí (Spanish only)</li> <li>N, No</li> </ul>
<ul style="list-style-type: none"> <li>Have you taken all of your diabetes medications as prescribed today? or Medication adherence</li> </ul>	Allow patients to decide if they want the message in the 1 PM or 9 PM, or both	<ul style="list-style-type: none"> <li>Y, Yes (English only)</li> <li>S, Si, Sí (Spanish only)</li> <li>N, No</li> </ul>
<ul style="list-style-type: none"> <li>In general, how healthy was your overall diet yesterday? or Healthy eating</li> </ul>	Daily at 11 AM	<ul style="list-style-type: none"> <li>0-10</li> </ul>
<ul style="list-style-type: none"> <li>Custom living goal:               <ul style="list-style-type: none"> <li>1=Lose weight</li> <li>2=Eat more fruit or vegs</li> <li>3=Eat less sweets or carbs</li> <li>4=Have better portion control</li> </ul> </li> </ul>	Weekly at 2 PM	<ul style="list-style-type: none"> <li>0-10</li> </ul>
<ul style="list-style-type: none"> <li>How successful were you in achieving your goal to [custom text healthy goal] yesterday? Healthy living goal</li> </ul>		
<ul style="list-style-type: none"> <li>Reply with the number that best describes how much control you felt you had over your diabetes over the past week. Scale: 0 (poor)-10 (excellent) or Quality of life</li> </ul>	Weekly at 4 PM	<ul style="list-style-type: none"> <li>0-10</li> </ul>

## Measures

### Engagement Metrics

User engagement data were extracted from the patients' responses to the PROs embedded in the texting tool at the end of their participation in the 12-month study. The primary engagement metrics evaluated in this study are listed in [Table 2](#), including the metrics of RR and response time (RT). RR represents the percentage of PRO questions that garnered any valid responses. The RR metric represents patient engagement with the individual PRO questions [36]. The RT of a message was measured as the time difference in seconds between when the PRO message was sent to a patient and the time the patient sent the corresponding response. Only valid responses to the

PROs were used when measuring RT. The RT metric reflects how well the timing of PRO messages integrates into patients' everyday lives, which in turn is expected to affect their level of engagement.

The overall RR and RT were measured by taking the average of the corresponding measures over a time frame, either weekly or monthly. We also measured RRs and RTs by grouping the messages sent at similar times of the day (daytime, nighttime) or times of the week (weekdays and weekends) and those that required similar responses (Yes or No, 1-10). Depending on the patient's decision regarding when to receive the message, the medication adherence PRO was either used once or twice for the nighttime RR and RT measures.

**Table 2.** Engagement measures used to analyze patients' engagement in Investigating a mobile health texting tool for embedding patient-reported data in diabetes management (i-Matter) program.

Engagement measure	Measurement or descriptions
RR <sup>a</sup>	Number of corresponding messages that received a valid response $\times$ 100 number of messages sent by the program with questions on PRO <sup>b</sup>
RT <sup>c</sup>	Difference between the timestamp of an incoming message sent to a patient and the timestamp of corresponding outgoing response in seconds
Weekdays RR	Number of valid corresponding responses received $\times$ 100 number of messages with questions on PRO sent between Monday and Friday
Weekdays RT	Average RT of messages responded by the patients between Monday and Friday every week
Weekends RR	Number of valid corresponding responses received $\times$ 100 number of messages with questions on PRO sent on Saturdays, Sundays
Weekends RT	Average RT of all messages responded by the patients that were sent on Saturdays and Sundays every week
Daytime messages RR	Number of valid corresponding responses received $\times$ 100 number of messages with questions on PRO sent daily at AM (before noon)
Daytime messages RT	Average RT of all messages that were sent before 11:59 AM and were responded to by the patients.
Nighttime messages RR	Number of valid corresponding responses received $\times$ 100 number of messages with questions on PRO sent daily at PM (after noon)
Nighttime messages RT	Average RT of all messages that were sent after 11:59 AM and were responded to by the patients.
Binary messages RR	Average RR of all messages for which accepted responses are Yes, Y, S, Si, Sí, or N, No.
Binary messages RT	Average RT of all messages for which accepted responses are Yes, Y, S, Si, Sí, or N, No.

<sup>a</sup>RR: response rate.

<sup>b</sup>PRO: patient-reported outcome.

<sup>c</sup>RT: response time.

### Demographic Characteristics

At baseline, all patients completed a self-report instrument that was used to collect patient sociodemographic data, including sex, race or ethnicity, age, annual household income, education level, marital status, and employment status.

### Analysis

To analyze user engagement with PRO messages, we first compared the engagement metrics of RR and RT between users who completed the 12-month study (ie, completers) and those who ended their participation before program completion (ie, noncompleters). In addition, we investigated the distribution of dropout times among noncompleters. The goal of this analysis was to identify participants who were likely to drop out of the

program at the early stages and tailor the program to minimize dropouts in future iterations.

We compared the longitudinal data of user engagement from the completer group using latent class trajectory modeling (LCTM). The goal was to classify heterogeneous populations into homogeneous clusters or subgroups with distinct trajectories [38] based on similarities in their engagement behaviors. For the LCTM models, we experimented with user engagement measures at various time intervals, including weekly, biweekly (measured once every 2 weeks), monthly, and bimonthly (once every 2 months). We chose the monthly engagement measures for the final analysis, as they provided a balance between smaller weekly and biweekly units, where the difference in engagement between the classes would be less distinguishable, and the larger

bimonthly engagement measures that would entail smaller sample sizes for trajectories.

Finally, we investigated the difference in engagement between the subgroups identified by the LCTM model from various cross-sections of time and PRO message types. The Shapiro–Wilk normality test was used to evaluate all engagement measures for each group separately before conducting comparisons. We also explored patients' overall sociodemographic characteristics and their distribution among the subgroups. The goal of the analyses was to further characterize the subgroups and identify patients who were likely to be part of a subgroup.

### Ethics Approval

This study was approved by the NYU Langone Health Institutional Review Board (i18-01044).

## Results

### Patient Engagement in the i-Matter Intervention

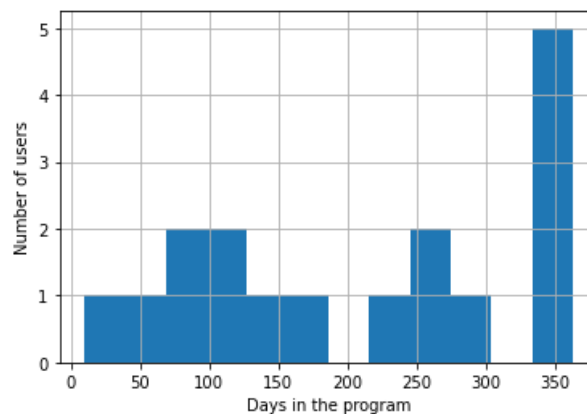
As of April 2022, a total of 61 patients *completed* their participation in the i-Matter intervention. Of the 61 participants,

42 (69%) completed the 12-month program, whereas the remaining 19 (31%) noncompleters ended their participation either by *opting out* on their own (10/61, 16%) or requesting the recruitment team to *disenroll* (9/61, 15%) from the program before the 12-month end point.

### Overall Engagement Metrics in the Noncompleters Group

Figure 1 shows the distribution of the time (in days) when the 19 patients ended their participation before the 12-month study visit. The average participation time in the program was 211 (SD 124.99; range 9-363) days. At least 53% (10/19) of patients dropped out of the program before the average participation time. Of the remaining patients, 4 ended participation in the last week (after 356 days from the day of enrollment) of the program. In all 4 cases, the overall RR was above 70% (mean 85.92%, SD 10.73%; median 90%, IQR 10.34%), suggesting that ending the program could have been unintended.

**Figure 1.** Duration in the program for patients who did not complete (noncompleters) the study.

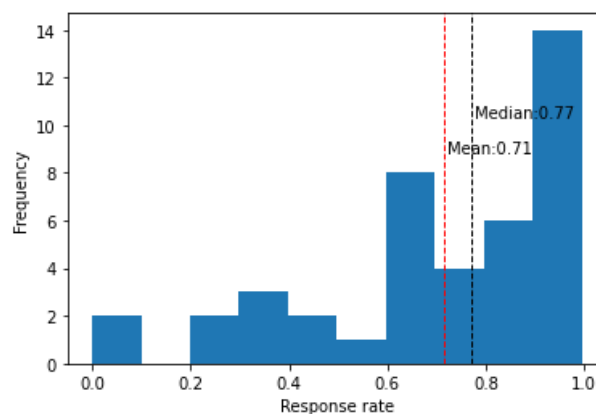


### Overall Engagement Metrics in the Completers Group

The mean RR among the completers was 71.44% (SD 26.50%), and the median was 76.91% (IQR 32.72%). Figure 2 shows the

distribution of RR for this group. Approximately 45% of patients had an RR below the mean value. The distribution of RRs was found to be nonnormal ( $P<.001$ ).

**Figure 2.** Distribution of response rate for the completers group.



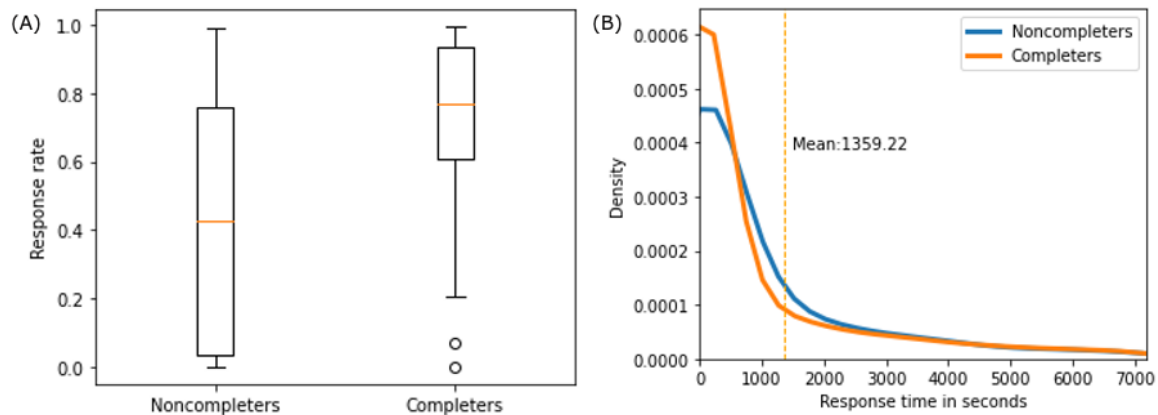


### Comparison in Engagement Metrics Between the Noncompleters and Completers

Figure 3 shows the comparison of PRO engagement metrics between patients who ended the program early (noncompleters) versus those who completed the entire 12 months (completers). The RR of participants (Figure 3A) who completed the program

was much higher (mean 71.44%, SD 26.50%) than that of those who did not (mean 47.40%, SD 37.33%). In addition, the distributions of RTs in the 2 groups in Figure 3B suggest that completers, on average, were quicker (mean 1325, SD 3709 seconds) to respond to PRO messages than the noncompleters (mean 1359 seconds, SD 3754 seconds); however, the difference was not significant because of large variations in the RTs.

Figure 3. Comparison of response rate (A) and response time (B) between the completers and noncompleters group.

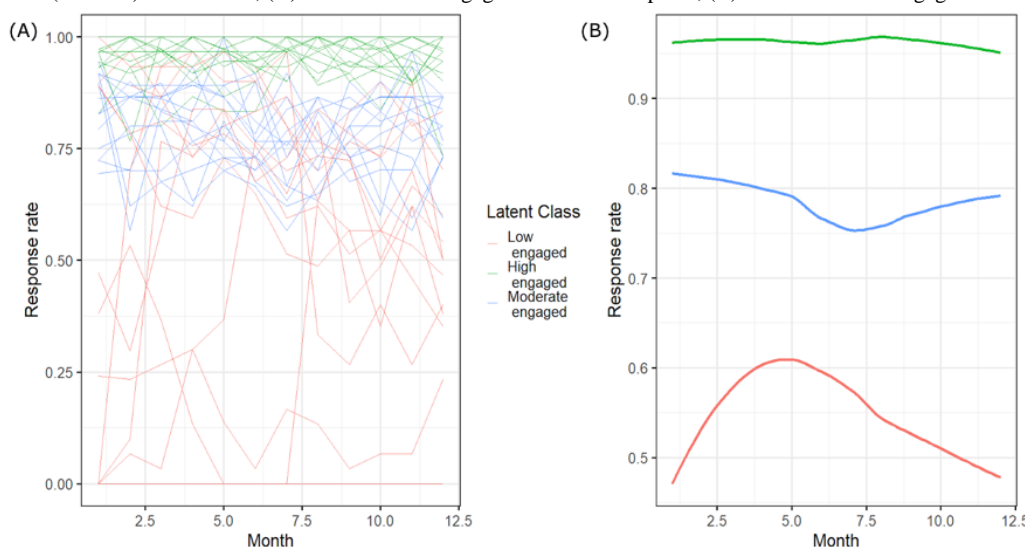


### Description of the Engagement Subgroups Among the Completers

Initially, we constructed a scoping model that provisionally selected a plausible number of classes,  $K=2$ , for the LCTM. In the next step, we refined the preliminary working model by altering the number of classes ( $K=3$ ) and exploring variations in latent class linear mixed models. We capped the number of classes at  $K=3$  because of the sample size (ie, number of patients) in our study. The number of classes for the final model was determined based on the lowest Bayesian information criterion. On the basis of distribution of our outcome variable, RR in the completers group, we investigated both standard linear mixed models (using the *hlme* function) and latent process, latent class mixed models (*lcmm* function). Finally, we performed model adequacy assessments by examining the posterior probability of being assigned to each trajectory class and assigning each individual to the class with the highest probability. An average of these maximum posterior probabilities of assignments above 70% [39] in all classes was

considered acceptable. We tested a total of 11 models (Multimedia Appendix 1), and in the end, a latent class linear mixed model with  $K=3$  classes was chosen as the best fit. The results from the trajectories of the 3 classes are shown in Figures 4A and 4B. We defined the 3 classes as low engaged (red), moderate engaged (blue), and high engaged (green) subgroups. Spaghetti plots of individual-level data illustrate that initial RRs, combined with the timing and direction of changes in the engagement metrics, characterize the subgroups. For example, as shown in Figure 4B, the low engaged subgroup is characterized by the lowest RR at the initial weeks of the intervention, coupled with a sharp increase in RR until the midtrajectory (~5 months), followed by a steady decline in RR for the remainder of patient participation. In contrast, the RR of the moderate engaged subgroup begins above 80%, decreases at the midpoint of the intervention to 75%, and then steadily rises toward the final months to 79%. Finally, the high engaged subgroup showed a consistently high RR across the 12-month study period (Figure 4B).

**Figure 4.** Trajectories of user engagement among completers in the Investigating an mHealth texting tool for embedding patient-reported data in diabetes management (i-Matter) intervention, (A) individual raw engagement in the left panel, (B) smoothed mean engagement in the right panel.



## Comparison of Engagement Subgroups Among the Completers

### Overview

Table 3 displays the RR and RT across the 3 subgroups according to the day of the week and the time of day each PRO message was sent. As the distribution of RTs was found to be significantly nonnormal for the entire population and also for the 3 subgroups individually, we used Kruskal-Wallis 1-way ANOVA to compare engagement among the 3 subgroups, followed by post hoc Dunn tests with Bonferroni adjustments for pairwise comparisons. Overall, the results suggest that patients in the high engaged subgroup had a significantly higher

overall RR (96.27%) than those in the moderate engaged (78.66%) or low engaged (54.35%) subgroups (Table 4). In addition, patients in the high engaged subgroup, on average, took a significantly shorter time (mean 559 seconds, SD 451 seconds) to respond to PRO messages than the moderate engaged (1564 seconds, SD 1138 seconds) or low engaged subgroups (2814 seconds, SD 5115 seconds). The differences in engagement between the 3 subgroups were consistent across most measures, regardless of the day of the week (weekdays and weekends) or timing of the messages (daytime vs nighttime; Table 4). In addition, the RRs of messages sent at night (highlighted in gray) were found to be higher than the overall RR for all 3 subgroups.

**Table 3.** Comparisons of user engagement with text messages between the 3 subgroups ( $P < .05$ ).

Engagement measures (RR <sup>a</sup> , RT <sup>b,c</sup> )	Low engaged (n=12), mean (SD)	Moderate engaged (n=13), mean (SD)	High engaged (n=17), mean (SD)	Difference in distribution, $P$ value
Overall RR (%)	54.35 (31.77)	78.66 (9.14)	96.27 (4.56)	<.001
Overall RT	2814 (5115)	1564 (1139)	559 (451)	<.001
Weekdays RR (%)	54.28 (31.80)	80.29 (10.50)	96.68 (4.32)	<.001
Weekdays RT	2919 (5761)	1581 (1246)	511 (445)	<.001
Weekends RR (%)	54.53 (35.41)	74.41 (16.62)	95.24 (9.35)	<.001
Weekends RT	2034 (3346)	1636 (1783)	694 (852)	<.001
Daytime messages RR (%)	48.32 (34.25)	68.22 (20.04)	93.87 (9.63)	<.001
Daytime messages RT	2814 (5115)	1564 (1139)	559 (451)	<.001
Nighttime messages RR (%)	56.27 (32.27) <sup>d</sup>	83.12 <sup>d</sup> (10.75) <sup>d</sup>	97.02 (4.34) <sup>d</sup>	<.001
Nighttime messages RT	2933 (5357)	1656 (1322)	494 (538)	<.001

<sup>a</sup>RR: response rate.

<sup>b</sup>RT: response time.

<sup>c</sup>All response time values are in seconds

<sup>d</sup>Engagement measures with greater than overall RR.

**Table 4.** Results of post hoc Dunn tests (after Kruskal-Wallis tests) on the extracted measures between the engagement subgroups.

Engagement measures	Pairwise comparison subgroups	z-score	P value	
			Unadjusted	Adjusted
<b>Overall RR<sup>a</sup></b>				
	Low-high	-16.92	<.001	<.001
	Low-moderate	-3.84	<.001	<.001
	Moderate-high	13.14	<.001	<.001
<b>Overall RT<sup>b</sup></b>				
	Low-high	8.24	<.001	<.001
	Low-moderate <sup>c,d</sup>	-0.82	.41	.97
	Moderate-high	-9.33	<.001	<.001
<b>Weekdays RR</b>				
	Low-high	-16.68	<.001	<.001
	Low-moderate	-4.74	<.001	<.001
	Moderate-high	11.92	<.001	<.001
<b>Weekdays RT</b>				
	Low-high	7.87	<.001	<.001
	Low-moderate <sup>c,d</sup>	-1.02	.31	.92
	Moderate-high	-9.16	<.001	<.001
<b>Weekends RR</b>				
	Low-high	-13.71	<.001	<.001
	Low-moderate	-2.73	<.01	<.05
	Moderate-high	11.06	<.001	<.001
<b>Weekends RT</b>				
	Low-high	3.13	<.01	<.01
	Low-moderate	-2.48	<.05	<.05
	Moderate-high	-5.90	<.001	<.001
<b>Daytime messages RR</b>				
	Low-high	-14.42	<.001	<.001
	Low-moderate	-3.17	<.01	<.01
	Moderate-high	11.32	<.001	<.001
<b>Daytime messages RT</b>				
	Low-high	8.24	<.001	<.001
	Low-moderate <sup>c,d</sup>	-0.82	.41	.90
	Moderate-high	-9.33	<.001	<.001
<b>Nighttime messages RR</b>				
	Low-high	-16.62	<.001	<.001
	Low-moderate	-5.24	<.001	<.001
	Moderate-high	11.32	<.001	<.001
<b>Nighttime messages RT</b>				
	Low-high	8.15	<.001	<.001
	Low-moderate <sup>c,d</sup>	-1.28	.20	.61
	Moderate-high	-9.72	<.001	<.001

<sup>a</sup>RR: response rate.

<sup>b</sup>RT: response time.

<sup>c</sup>No significant difference before adjustment.

<sup>d</sup>No significant difference after adjustment.

We also compared user engagement between subgroups for the 6 PRO messages individually. In addition, the PROs were grouped by response type (yes or no as binary, and the remaining messages as a Likert-type scale) and compared separately. As shown in Table 5, a significant difference in the RR was observed for all 6 messages. For example, the mean RRs of sleep quality PRO were 44.84%, 60.44%, and 93.28% in the low engaged, moderate engaged, and high engaged subgroups, respectively. Similarly, RT was also significantly different among the 3 subgroups for all messages, except for physical

activity. Overall, the binary PROs (Yes or No) had a higher RR than the Likert-scale PROs for all 3 subgroups. In fact, patients' RR to binary PRO messages, medication adherence, and diet (healthy eating) were above average for all 3 subgroups. In contrast, patients were consistently less responsive to the Likert-scale PRO on fulfilling a healthy living goal (weekly at 2 PM), with only one of 3 messages receiving any valid response from the low engaged subgroup. Further details of pairwise comparisons of the subgroups are provided in Table 6.

**Table 5.** User engagement and patient-reported outcome message types between the 3 subgroups ( $P < .05$ ).

Engagement measures (RR <sup>a</sup> , RT <sup>b</sup> )	Low engaged (n=12), mean (SD)	Moderate engaged (n=13), mean (SD)	High engaged (n=17), mean (SD)	Difference in distribution, <i>P</i> value
Binary messages RR (%)	57.13 (34.50)	82.93 (11.41)	97.19 (5.14)	<.001
Binary messages RT	3191 (7354)	1630 (1576)	578 (715)	<.001
Likert-scale messages RR (%)	51.12 (31.22)	74.32 (13.11)	95.31 (6.48)	<.001
Likert-scale messages RT	2056 (2797)	1504 (1424)	563 (461)	<.001
Sleep quality RR (%)	44.84 (33.39)	60.44 (22.94)	93.28 (10.17)	<.001
Sleep quality RT	1353 (1500)	1568 (1331)	946 (765)	<.001
Physical activity RR (%)	45.54 (35.32)	70.82 (19.36)	94.95 (9.34)	<.001
Physical activity RT	1183 (1304)	1125 (855)	1005 (1084)	.07
Medication adherence RR (%)	65.03 (36.67) <sup>c</sup>	91.68 (10.93) <sup>c</sup>	98.84 (4.00) <sup>c</sup>	<.001
Medication adherence RT	3097 (7476)	1800 (2256)	250 (865)	<.001
Healthy eating RR (%)	60.23 (34.33) <sup>c</sup>	88.29 (13.42) <sup>c</sup>	98.31 (5.63) <sup>c</sup>	<.001
Healthy eating RT	1867 (3358)	1373 (2073)	195 (503)	<.001
Healthy living goal RR (%)	33.33 (47.30)	64.10 (48.12)	91.18 (28.43)	<.001
Healthy living goal RT	444 (1243)	710 (1260)	772 (1356)	<.001
Quality of life RR (%)	50 (50.17)	85.26 (35.57)	92.65 (26.16)	<.001
Quality of life RT	1187 (2977)	1487 (3518)	250 (1125)	<.001

<sup>a</sup>RR: response rate.

<sup>b</sup>RT: response time.

<sup>c</sup>Patient-reported outcome messages with greater than average response rate.

**Table 6.** Results of post hoc Dunn tests (after Kruskal-Wallis tests) on the patient-reported outcome message types between the engagement subgroups.

Engagement measures	Pairwise comparison subgroups	z-score	P value	
			Unadjusted	Adjusted
<b>Binary messages RR<sup>a</sup></b>				
	Low-high	-15.41	<.001	<.001
	Low-moderate	-4.29	<.001	<.001
	Moderate-high	11.12	<.001	<.001
<b>Binary messages RT<sup>b</sup></b>				
	Low-high	6.39	<.001	<.001
	Low-moderate <sup>c,d</sup>	-1.72	.08	.26
	Moderate-high	-8.40	<.001	<.001
<b>Likert-scale messages RR</b>				
	Low-high	-15.91	<.001	<.001
	Low-moderate	-4.16	<.001	<.001
	Moderate-high	11.76	<.001	<.001
<b>Likert-scale messages RT</b>				
	Low-high	6.13	<.001	<.001
	Low-moderate <sup>c,d</sup>	-1.08	.28	.85
	Moderate-high	-7.44	<.001	<.001
<b>Sleep quality RR</b>				
	Low-high	-14.54	<.001	<.001
	Low-moderate	-2.63	<.01	<.05
	Moderate-high	12.02	<.001	<.001
<b>Sleep quality RT</b>				
	Low-high <sup>c,d</sup>	1.09	.28	.83
	Low-moderate	-3.09	<.01	<.01
	Moderate-high	-4.47	<.001	<.001
<b>Physical activity RR</b>				
	Low-high	-14.80	<.001	<.001
	Low-moderate	-4.22	<.001	<.001
	Moderate-high	10.57	<.001	<.001
<b>Physical activity RT</b>				
	Low-high <sup>c,d</sup>	0.12	.90	.99
	Low-moderate <sup>c,d</sup>	-1.83	.06	.19
	Moderate-high <sup>d</sup>	-2.11	.03	.10
<b>Medication adherence RR</b>				
	Low-high	-13.01	<.001	<.001
	Low-moderate	-6.16	<.001	<.001
	Moderate-high	6.62	<.001	<.001
<b>Medication adherence RT</b>				
	Low-high	7.56	<.001	<.001
	Low-moderate <sup>c,d</sup>	-2.65	.40	.32



Engagement measures	Pairwise comparison subgroups	z-score	P value	
			Unadjusted	Adjusted
<b>Healthy eating RR</b>	Moderate-high	-10.61	<.001	<.001
	Low-high	-14.30	<.001	<.001
	Low-moderate	-6.94	<.001	<.001
<b>Healthy eating RT</b>	Moderate-high	7.09	<.001	<.001
	Low-high	7.35	<.001	<.001
	Low-moderate <sup>c,d</sup>	-1.93	.054	.16
<b>Healthy living goal RR</b>	Moderate-high	-9.62	<.001	<.001
	Low-high	-11.23	<.001	<.001
	Low-moderate	-5.63	<.001	<.001
<b>Healthy living goal RT</b>	Moderate-high	5.38	<.001	<.001
	Low-high	-8.26	<.001	<.001
	Low-moderate	-5.17	<.001	<.001
<b>Quality of life RR</b>	Moderate-high	2.84	<.01	<.05
	Low-high	-9.48	<.001	<.001
	Low-moderate	-7.38	<.001	<.001
<b>Quality of life RT</b>	Moderate-high <sup>c,d</sup>	1.68	.09	.27
	Low-high <sup>c,d</sup>	-1.82	.07	.20
	Low-moderate	-4.27	<.001	<.001
	Moderate-high	-2.78	<.01	<.05

<sup>a</sup>RR: response rate.

<sup>b</sup>RT: response time.

<sup>c</sup>No significant difference ( $P < .05$ ) before adjustment.

<sup>d</sup>No significant difference after adjustment.

### **Comparison of Patient Sociodemographic Characteristics Among the Engagement Subgroups**

We examined patients' sociodemographic characteristics for those who completed the program (n=42) and compared their distribution among the 3 engagement subgroups. In 6.85% (23/336) of cases, at least one of the sociodemographic questionnaires was missing responses. As shown in Table 7, the overall patient sample was mostly female (12/42, 71%), non-Hispanic or Latino origin (22/28, 79%), fluent in English (38/41, 93%), completed a bachelor's degree or above (21/41, 52%), and married or living with a partner (18/41, 44%). The distribution of demographic data further shows that relative to the overall population distribution, a higher proportion of male

Hispanic or Latino origin patients were more high engaged than females and non-Hispanic or Latino origin counterparts. In addition, the high engaged subgroup was composed of mostly older patients with the lowest variations in age range (between 53 and 68 years), and a higher percentage of Hispanic or Latino patients (3/10, 30%) were bilingual (2/16, 13%), and completed at least a graduate-level education (5/16, 31%).

In comparison, the low engaged subgroup was composed primarily of patients who were identified as African Americans (7/12, 58%) and reported the lowest annual income, with one out of every 3 patients earning US \$20,000 or less annually. Finally, marital status was relatively consistent between low-engaged and high-engaged groups.

**Table 7.** Summary of participants' demographics.

Demographics	Overall (n=42)	Low engaged	Moderate engaged	High engaged
<b>Gender, n (%)</b>				
Male	12 (29)	3 (25)	4 (31)	5 (29)
Female	30 (71)	9 (75)	9 (69)	12 (71)
Other or missing	0 (0)	0 (0)	0 (0)	0 (0)
<b>Age (years)</b>				
Range	32-73	45-73	32-68	53-68
Mean (SD)	59.30 (8.37)	59.92 (8.37)	56.33 (9.92)	61.06 (4.23)
<b>Race, n (%)</b>				
African American	20 (48)	7 (58)	6 (46)	7 (41)
White	13 (31)	2 (17)	5 (38)	6 (35)
Other races	3 (7)	2 (17)	1 (8)	0 (0)
Refused	1 (2)	0 (0)	0 (0)	1 (6)
Unknown	5 (12)	1 (8)	1 (8)	3 (18)
<b>Ethnicity, n (%)</b>				
Hispanic or Latino	6 (21)	1 (12)	2 (20)	3 (30)
Not Hispanic or Latino	22 (79)	7 (88)	8 (80)	7 (70)
Missing	14	4	3	7
<b>Language, n (%)</b>				
English	38 (93)	11 (92)	13 (100)	14 (88)
Spanish	1 (2)	1 (8)	0 (0)	0 (0)
Both	2 (5)	0 (0)	0 (0)	2 (12)
Missing	1	0	0	1
<b>Education, n (%)</b>				
Graduate	11 (27)	3 (25)	3 (23)	5 (31)
Bachelor	10 (25)	4 (34)	3 (23)	3 (19)
Associate	2 (5)	0 (0)	1 (8)	1 (6)
Some college or no degree	12 (29)	3 (25)	5 (38)	4 (25)
Technical school	12 (29)	1 (8)	0 (0)	0 (0)
High school or General Educational Development	4 (10)	1 (8)	1 (8)	2 (13)
Grades 1-8	1 (2)	0 (0)	0 (0)	1 (6)
Missing	1	0	0	1
<b>Income per year, n (%)</b>				
<US \$10,000	1 (3)	1 (10)	0 (0)	0 (0)
<US \$20,000	5 (14)	3 (30)	1 (9)	1 (7)
<US \$40,000	10 (28)	4 (40)	2 (18)	4 (27)
<US \$60,000	9 (24)	2 (20)	2 (18)	5 (33)
≤US \$100,000	10 (28)	0 (0)	5 (46)	5 (33)
>US \$100,000	1 (3)	0 (0)	1 (9)	0 (0)
Missing	6	2	2	2
<b>Marital status, n (%)</b>				
Married or partner	18 (44)	5 (42)	7 (54)	7 (44)
Never married	14 (34)	4 (33)	4 (30)	5 (31)

Demographics	Overall (n=42)	Low engaged	Moderate engaged	High engaged
Divorced	6 (15)	2 (17)	1 (8)	3 (19)
Widowed	3 (7)	1 (8)	1 (8)	1 (6)
Missing	1	0	0	1

## Discussion

### Principal Findings

Although achieving glycemic control is of clinical importance for patients with T2D, it is the daily experience of living with T2D that drives patients' perseverance to adhere to treatment regimens and become engaged in their care [40]. This study reports user engagement with PROs in the i-Matter trial, designed to incorporate the collection of real-time PRO data that are meaningful to both patients and providers in the clinical management of T2D. Our retrospective analysis of user engagement found discernible engagement phenotypes based on individual PRO responses: patients who dropped out from the program early (noncompleters) took more time to respond to PRO questions and were less likely to respond than the completers. Among the completers, the analysis of the longitudinal RRs identified 3 subgroups with significant differences in engagement. The completers from the lowest engagement subgroup had a significantly lower RR and longer RT than those from the other 2 completer subgroups. These results suggest that patients who have lower RR in combination with longer RTs are at risk of dropping out of the program or continuing with lower than average engagement with PRO questions. Future analyses will evaluate whether this pattern is associated with poorer adherence to self-management behaviors.

Our analysis further revealed that the engagement phenotypes among completers differed in the timing of peak engagement. The low engaged completers showed an almost normal distribution of average engagement over time, with peak engagement in the middle of the program, followed by a steady decline. The decline in engagement following the peak could be due to fatigue onset among patients from responding to multiple daily text messages across the 12-month study [41]. Further evaluation and analysis are required to determine how to maintain peak engagement in this subgroup in the latter half of the program. The moderate engaged subgroup showed an opposite trend in peak engagement compared with the low engaged subgroup: a decline in engagement in the first 7 months of the program, followed by a steady increase.

The high engaged subgroup consistently showed >90% RR and low RT throughout their participation. They also represent the largest sample among the 3 subgroups. The reasons for high engagement and whether this response pattern leads to better health outcomes (behavioral and clinical) among patients with T2D will be explored in future analyses. The variations in peak engagement timing suggest that longitudinal data on patients' motivations and self-care behavioral activities need to be analyzed for periodic changes and to evaluate their impact on user engagement.

Traditionally, sociodemographic characteristics, including older age, lower income, unemployment status, lower education status, minority racial and ethnic group membership, language barriers, and geographic barriers, have been associated with an elevated risk for poorer health outcomes [42]. Our analysis of the sociodemographic measures also showed that distributions of race, age, language, and income varied between the high- and low engaged subgroups of our intervention. The high engaged completers were predominantly older, of Hispanic descent, bilingual, and highly educated (graduate school or above).

These findings reflect the growing trends in mHealth research, which has shown that behavioral interventions, particularly those that leverage text messaging, have high rates of user engagement among Hispanic individuals with limited English proficiency [43,44]. For example, Cartujano-Barrera et al [44] reported high levels of interactivity (73%) and low disenrollment (20%) with a 12-week smoking cessation intervention delivered via text messaging in a sample of bilingual Hispanic individuals. Similarly, a text messaging intervention designed to improve diabetes management showed high levels of engagement (86% RR to at least one text message) and low dropout rates (6%) among low-income Hispanic patients who were followed in safety-net primary care practices [45]. This is in line with data published by the Pew Research Center [46], which showed higher cell phone ownership and use among Hispanic than among non-Hispanic White patients (100% vs 97%). Data from qualitative evaluations of text messaging studies in Spanish-speaking Hispanic individuals suggest that receiving and responding to text messages serves as a source of emotional support [45] for engaging in self-care behaviors to improve diabetes management. Prior research on disparities in self-care behaviors among patients with T2D reported consistent evidence of no disparities in exercise and some evidence of reverse disparities. Compared with non-Hispanic White patients, Hispanic patients with T2D had healthier diets [47], which likely manifested in higher engagement, especially with Healthy Eating PRO among Hispanic patients. Although our finding that older adults were more likely to be high engagers of the intervention may seem inconsistent with previous research [48-50], recent data show that more than 85% of adults aged  $\geq 50$  years communicate primarily via text messages [51]. Research on barriers to diabetes medication adherence has also found evidence that younger age is associated with motivational and behavioral barriers [37], which could have manifested in lower engagement among younger patients in our intervention.

Our analysis further suggests that African American patients with the lowest annual income are most likely to have low engagement with PRO messages. It is plausible that the initial development of our intervention may not have captured the unique needs and concerns of this patient population. Consequently, the content and delivery of messages may not have been suitable, resulting in low engagement rates. Previous

research has also found barriers to low-income African American patients' engagement in text messaging interventions, including low ownership of personal cell phones, difficulty in responding to text messages, and reporting that the program was not helpful or relevant for improving self-management behaviors [37]. These findings suggest that future text message interventions must consider both the technical elements of the intervention as well as the contextual factors (eg, financial and cultural) that could affect user engagement.

### Limitations

Although this study has many strengths, we note the following limitations that can be considered for future research. First, although our intervention enrolled patients with T2D, it is more common for patients to have 2 or more chronic diseases (ie, multimorbidity) than one disease in isolation (89.3% vs 8.5%, respectively) [52]. Recent research has demonstrated the negative impact of multimorbidity on PROs such as quality life, psychosocial health, self-efficacy, physical function, and self-management behaviors [53]. Thus, future research should examine whether adapting i-Matter for a multimorbid population would improve the engagement of patients and provider management of co-occurring chronic diseases rather than using a single disease focus that can cause inefficiencies and fragmentation in care. Second, we did not examine psychosocial factors that could impact patient participation in the intervention. Their motivation, knowledge, and self-efficacy behaviors before joining the program may affect their engagement with PROs [54]. Future analysis of i-Matter data will examine how user engagement metrics differ based on self-reported diabetes self-care behaviors, medication adherence, self-efficacy, and motivation for diabetes management. We also note a possible limitation of our data analysis because of the small sample size. A larger sample size would provide greater statistical power for detecting statistically significant differences in user engagement

between demographics if there are true differences. Future analyses of i-Matter data will include the remaining patients who completed the trial.

### Conclusions

In summary, we found that patients who dropped out from the intervention early (ie, noncompleters) had a lower RR to PRO questions and took longer to respond to PRO questions than completers. Among completers, analysis of longitudinal RRs identified 3 subgroups of engagement over time. Our results suggest that patient sociodemographics along with RT measures offer good predictability for patients who need further support to stay engaged in the intervention. Future trials should identify these patients early in the intervention and customize PRO messages and their timing to elicit higher engagement.

The i-Matter intervention was designed and developed through active involvement of patients and addresses difficulties with protocol compliance, lack of clinical integration in the EHR, and provider skepticism about the utility of PROs in practice, which were hallmarks of previous trials, thus increasing the likelihood of developing a sustainable approach [55]. Despite these efforts, the results showed that 31.1% of patients dropped out of the intervention before the final 12-month study visit, suggesting room for improvement in the PRO texting tool for future trials. For example, the messages sent during the daytime yielded the lowest engagement from this subgroup, which suggests that further customization of PRO message timing is needed to ensure that the cadence of messages fits within the daily lives of users to increase engagement. This analysis provides insights into how to make PROs more patient-centric in future iterations of the i-Matter intervention. The current research conducting qualitative interviews with patients who complete the program will be used to identify potential motivators that could be integrated into future versions of i-Matter.

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### Conflicts of Interest

AS is a former consultant of the company that developed the digital tool.

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### Multimedia Appendix 1

List of models tested to derive the user engagement classes.

[DOCX File, 13 KB - [diabetes\\_v7i4e41140\\_app1.docx](#)]

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## Abbreviations

**EHR:** electronic health record

**i-Matter:** Investigating an mHealth texting tool for embedding patient-reported data in diabetes management

**mHealth:** mobile health

**LCTM:** latent class trajectory modeling

**PRO:** patient-reported outcome

**RR:** response rate

**RT:** response time

**T2D:** type 2 diabetes

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Original Paper

# Use of Telecommunication and Diabetes-Related Technologies in Older Adults With Type 1 Diabetes During a Time of Sudden Isolation: Mixed Methods Study

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## Abstract

**Background:** The COVID-19 lockdown imposed a sudden change in lifestyle with self-isolation and a rapid shift to the use of technology to maintain clinical care and social connections.

**Objective:** In this mixed methods study, we explored the impact of isolation during the lockdown on the use of technology in older adults with type 1 diabetes (T1D).

**Methods:** Older adults (aged  $\geq 65$  years) with T1D using continuous glucose monitoring (CGM) participated in semistructured interviews during the COVID-19 lockdown. A multidisciplinary team coded the interviews. In addition, CGM metrics from a subgroup of participants were collected before and during the lockdown.

**Results:** We evaluated 34 participants (mean age 71, SD 5 years). Three themes related to technology use emerged from the thematic analysis regarding the impact of isolation on (1) insulin pump and CGM use to manage diabetes, including timely access to supplies, and changing Medicare eligibility regulations; (2) technology use for social interaction; and (3) telehealth use to maintain medical care. The CGM data from a subgroup (19/34, 56%; mean age 74, SD 5 years) showed an increase in time in range (mean 57%, SD 17% vs mean 63%, SD 15%;  $P=.001$ ), a decrease in hyperglycemia ( $>180$  mg/dL; mean 41%, SD 19% vs mean 35%, SD 17%;  $P<.001$ ), and no change in hypoglycemia ( $<70$  mg/dL; median 0.7%, IQR 0%-2% vs median 1.1%, IQR 0%-4%;  $P=.40$ ) during the lockdown compared to before the lockdown.

**Conclusions:** These findings show that our cohort of older adults successfully used technology during isolation. Participants provided the positive and negative perceptions of technology use. Clinicians can benefit from our findings by identifying barriers to technology use during times of isolation and developing strategies to overcome these barriers.

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**KEYWORDS**

type 1 diabetes; older adults; COVID-19; diabetes technology; continuous glucose monitoring; telehealth; diabetes; glucose monitoring; older population; health technology

## Introduction

The use of technology for diabetes management, as well as for communication and social interaction, has become more prevalent over the last decade. However, older adults may be less proficient and equipped to use technology compared to younger generations [1]. In addition, older adults may experience physical and cognitive decline during social isolation and periods of being homebound [2,3], which may further impact their ability to use technology.

Older adults with type 1 diabetes (T1D) are a unique population with challenges related to the management of their diabetes [4-6]. Many of them rely on the use of diabetes-related technologies, such as insulin pumps and continuous glucose monitoring (CGM), to manage diabetes on a daily basis.

The use of insulin pumps and CGM devices has proven to be beneficial in older adults in improving glycemic control and reducing hypoglycemia [7,8]. However, the use of diabetes-related technologies in older adults with T1D is lower than in younger adults with T1D [9,10].

The COVID-19 lockdown triggered a sudden and dramatic change in routine, with self-isolation and a rapid shift to the use of technology for maintaining clinical care and social connections [11]. The lockdown offered a unique opportunity to assess how older adults fared with technology for diabetes management, communication, and social interaction during a time of sudden isolation.

During the lockdown, an ongoing study of older adults with T1D using CGM was paused, providing an important opportunity to examine how isolation affects older adults with T1D using technology. We performed interviews with participants of the study to understand the positive and negative perceptions of technology use in this population during times of isolation. In addition, we examined glucose parameters via CGM in a subpopulation of this cohort with available data to understand the impact of isolation on glycemic control both before and during this period.

## Methods

### Study Design

We performed semistructured interviews with 34 participants from the ongoing study titled “Technological Advances in Glucose Management in Older Adults,” which assessed the use of CGM in older adults with T1D (Clinicaltrials.gov NCT03078491). Interviews were performed between May and August 2020. Each interview lasted 30-60 minutes and was conducted via phone, digitally audio-recorded, and transcribed. Interviews included 4 broad questions with probes, including (1) How are you doing during the COVID-19 pandemic? (2) How are you managing your diabetes during this COVID-19 pandemic? (3) How are you doing using your diabetes technology? and (4) Have you noticed any changes in your emotions during this time? and 23 survey questions. Eligibility criteria for these interviews included enrollment in the

“Technological Advances in Glucose Management in Older Adults” study and willingness and capability to participate. All participants were wearing real-time CGM devices and provided verbal informed consent over the phone.

The interviews were later transcribed, coded using NVivo software (version 12; QRS International), and analyzed using qualitative content analysis by categorizing keywords and phrases to identify themes. We achieved investigator triangulation [12], a process in which more than 1 investigator analyzes the data, through the use of a multidisciplinary team with members experienced in the care of older adults with diabetes. Members included a geriatrician, an endocrinologist, a health informaticist, a psychologist and nurse educator, and research assistants. Interviews were individually coded and then members met via teleconference over a 6-month period to establish group consensus regarding the identification and definition of themes and the selection of examples from transcripts, as well as the status of data saturation. In the results section of this manuscript, the age, gender, and diabetes duration of the participants are provided for each quotation. All names of clinical providers, medical supply companies, and medications and brand names of device companies were omitted and replaced by either initials or generic names within quotations.

CGM data from both before and during isolation were available for 19 (56%) of the 34 individuals interviewed, which included a 2-week period between January and February 2020 (preisolation) and a 2-week period between April and June 2020 (during isolation). A minimum of 192 hours per week of CGM data were required for inclusion in this CGM analysis. CGM metrics, including total percent time in range (defined as total percent time spent between 70 and 180 mg/dL), total percent time spent in hypoglycemia (defined as total percent time spent below 70 mg/dL), total percent time in hyperglycemia (defined as total percent time spent above 180 mg/dL), and coefficient of variation were analyzed. The coefficient of variation (%) was calculated as  $(SD \text{ of glucose} / \text{mean glucose level}) \times 100$  [13].

Descriptive statistics for demographic and clinical data are reported as number (n) and percentage (%) of the cohort for categorical variables. For continuous variables, data are reported as mean (SD) for data with normal distributions and as median (IQR) for data with nonnormal distributions. SAS software (version 9.4; SAS Institute) was used for 2-tailed Student *t* tests for the analysis of CGM metrics. A *P* value of  $\leq .05$  was considered statistically significant.

### Ethics Approval

The Joslin Diabetes Center Institutional Review Board approved the study protocol (CHS #2016-29).

## Results

### Participant Demographics

In all, 34 participants, with a mean age of 71 (SD 5) years and a mean duration of diabetes of 30 (SD 17; range 10-65) years, were interviewed (Table 1).



**Table 1.** Demographics and clinical characteristics of the study population.

Characteristic	Value (N=34)
<b>Demographics</b>	
Age (years), mean (SD; range)	70.9 (4.8; 66-86)
Gender, female, n (%)	18 (53)
Ethnicity, White, n (%)	33 (97)
<b>Marital status, n (%)</b>	
Single	10 (29)
Married	23 (68)
<b>Living status, n (%)</b>	
Private home	18 (53)
Apartment or condo	15 (44)
Currently working, n (%)	8 (24)
Some college or higher level education, n (%)	32 (94)
<b>Diabetes characteristics</b>	
Using a real-time continuous glucose monitor, n (%)	34 (100)
Using an insulin pump, n (%)	20 (59)
Diabetes duration (years), mean (SD; range)	38.0 (17.4; 10-65)
Hemoglobin A <sub>1c</sub> (%), mean (SD)	7.4 (0.93)
<b>Mode of engagement with social networks, n (%)</b>	
Video calls	18 (53)
Phone calls	14 (41)
<b>Connecting with loved ones, n (%)</b>	
More than usual	13 (38)
Less than usual	18 (53)
The same as usual	14 (41)
Had contact with their primary care provider, n (%)	22 (65)
Confident medical needs are being met, n (%)	28 (82)
Had a telehealth visit at the time of interview, n (%)	24 (71)

### CGM Data

We analyzed the CGM data collected from a 2-week period between January and February 2020 (preisolation) and a 2-week period between April and June 2020 (during isolation) from a subpopulation of the study cohort. We analyzed data from 19 (N=34, 56%) participants (mean age 74, SD 5 years; 11/19, 58% female; 12/19, 63% insulin pump users; and mean diabetes duration 38, SD 17, range 14-69 years). The CGM metrics showed that during the lockdown, compared to before the

lockdown, percent time spent in range increased (mean 57%, SD 17% vs mean 63%, SD 15%;  $P=.001$ ) and percent time spent in hyperglycemia (glucose >180 mg/dL) decreased (mean 41%, SD 19% vs mean 35%, SD 17%;  $P<.001$ ). These changes resulted in a reduction of glucose management indicator (mean 7.5%, SD 0.7% vs mean 7.2%, SD 0.6%;  $P=.003$ ) during the lockdown. Our cohort had very little hypoglycemia, which did not change from before to during the lockdown (median 0.7%, IQR 0%-2% vs median 1.1%, IQR 0%-4%;  $P=.40$ ; Table 2).

**Table 2.** CGM<sup>a</sup> metrics from a 2-week period between January and February 2020 (preisolation) and a 2-week period between April and June 2020 (during isolation; n=19). Data are presented as mean (SD) for data with normal distributions and as median (IQR) for data with nonnormal distributions.

CGM metrics	Preisolation	During isolation	P value
Time spent in hypoglycemia <55 mg/dL (%), median (IQR)	0.1 (0-1)	0.1 (0-2)	.40
Time spent in hypoglycemia <70 mg/dL (%), median (IQR)	0.7 (0-2)	1.1 (0-4)	.40
Time spent in the range of 70-180 mg/dL (%), mean (SD)	57 (17)	63 (15)	.001
Time spent >180 mg/dL (%), mean (SD)	41 (19)	35 (17)	<.001
Time spent >250 mg/dL (%), mean (SD)	12 (11)	9 (8)	.08
Glucose management indicator (%), mean (SD)	7.5 (0.7)	7.2 (0.6)	.003
Coefficient of variation (%), mean (SD)	33 (5)	33 (5)	.86

<sup>a</sup>CGM: continuous glucose monitoring.

## Themes

Next, we identified 3 themes regarding the positive and negative perceptions related to the use of technologies for diabetes management, social interactions, and medical care (Table 3).

**Table 3.** Themes and subthemes regarding the impact of isolation during pandemic lockdown on technology use.

Theme, content area	Patient perspective
<b>Use of diabetes-related technologies (pump and CGM<sup>a</sup>)</b>	
Use of CGM to manage diabetes	<ul style="list-style-type: none"> <li>• Able to monitor glucose</li> <li>• Peace of mind, especially overnight</li> <li>• Alarms to help with diabetes management</li> <li>• Able to share data with clinicians</li> <li>• Challenging to keep track of supplies</li> <li>• Fearful of not having sufficient CGM supplies to be able to use CGM device at all times</li> </ul>
Use of insulin pump to manage diabetes	<ul style="list-style-type: none"> <li>• Comfortable adjusting insulin pump settings to address changes in insulin requirements during times of change in daily activity</li> <li>• Concerns about changing to new a device during a challenging time</li> </ul>
Diabetes-related medical supplies	<ul style="list-style-type: none"> <li>• Concerns about receiving supplies in a timely fashion</li> <li>• Appreciated change in Medicare policies to maintain continuity of care</li> <li>• Difficulties in communication with third party suppliers</li> <li>• Frustration with the limited availability of supplies</li> <li>• Delays in shipment</li> </ul>
<b>Use of technology for social interaction</b>	
Social gathering	<ul style="list-style-type: none"> <li>• Help with connecting to family and friends and participation in courses, clubs, and support groups</li> <li>• Lack of in-person interaction</li> </ul>
<b>Use of technology for medical interaction</b>	
Telehealth	<ul style="list-style-type: none"> <li>• Able to connect with medical team</li> <li>• Time saving</li> <li>• Delays in the coordination of care</li> <li>• Lack of physical exam and laboratory data</li> </ul>
Usual care	<ul style="list-style-type: none"> <li>• Provided continuity of care</li> <li>• Experienced delays in care for interventional medicine, such as dental care and eye exam</li> </ul>

<sup>a</sup>CGM: continuous glucose monitoring.

### **Theme 1: Impact of Isolation on the Use of Insulin Pump and CGM to Manage Diabetes, Including Timely Access**

### **to Supplies, and Changing Medicare Eligibility Regulations**

All participants, without fail, had positive perceptions of using CGM during isolation. Several participants reported that using CGM to manage diabetes during a time of lifestyle change

provided reassurance: “I rely on [my CGM] and I’m having it help me get through the night particularly” (72-year-old woman, T1D for 14 years). In addition, the built-in alarms were very important, said one participant: “I forget to take [my insulin]...my CGM is buzzing” (87-year-old man, T1D for 58 years).

A majority (28/34, 82%) of participants reported feeling confident in managing their glucose patterns, even during this time of disruption in daily life, because of CGM.

*Once in a while my blood sugar would go high or low, but not high or low enough to cause any concerns. Sometimes I might forget to take a bolus. So, it might go high, but with the CGM I'm able to take a look and see what's happening and then I can correct for it. [68-year-old man, T1D for 44 years]*

A few participants felt that CGM could be helpful to detect a COVID-19 infection early by showing high glucose readings. One participant noted, “I’m going to assume that if I had a virulent virus, that my blood sugars may easily be affected. If that in fact were the case, I’m speculating now, it—the CGM—would provide an additional level of comfort” (68-year-old man, T1D for 44 years).

Among the participants using insulin pumps (20/34, 59% of this cohort), many reported being comfortable in adjusting insulin pump settings to address changes in insulin requirements during times of change in daily activity: “Actually, it’s better because I’ve managed to adjust the pump now...I’ve been able to deal with the pump settings a lot more easily” (72-year-old man, T1D for 33 years).

However, a major change in pump therapy might be problem, as one person who was planning to change to a different type of pump device reported:

*I've been in touch with my doctor, and I've been in touch with the educators, and we're looking at a new pump. I'm a little concerned about how that's going to work, because there are some things about it that are concerning to me. And I just don't know if I am in the frame of mind to face a new challenge. [69-year-old woman, T1D for 49 years]*

In addition to the benefits of CGM and insulin pump use, participants reported that the ability to share data from these devices with their providers was helpful to guide conversation during medical visits: “Dr. T had me download the [CGM data]...And then, she got those results. And so, we talked about those, and so forth. And I had it in front of me, and she had it. And so, that went well” (75-year-old woman, T1D for 28 years). Another participant said, “These visits, you don’t really have to be there. It’s really a question of talking and reviewing things and answering questions. Telemedicine lends itself very well to that, I think. I was very satisfied we talked” (72-year-old man, T1D for 33 years).

However, many participants worried about the potential loss of CGM supplies, because they rely heavily on CGM data to manage their diabetes. For example, one woman said, “I would say, if you really wanted to get me upset and afraid, take my CGM away. So, I am very dependent on it” (71-year-old woman,

T1D for 14 years). There were also concerns related to supply chain, third party suppliers, and insurance companies regarding timely paperwork processing and supplies shipment during lockdown: “I used to call up and they would say you only get a certain number. They really send me one in a box or something. And then all of a sudden, I’m getting a box of three” (72-year-old woman, T1D for 53 years). Another participant said:

*Insurance has made it extremely difficult to have it work smoothly for getting your supplies. So I'm a little apprehensive that, now that I'll be getting supplies, it looks like, from two different companies and not directly through [pump company] and [CGM company]. And when you have to depend on two supply companies shipping you supplies, and especially after what happened with this virus, you know, shipping isn't what it was. [76-year-old woman, T1D for 53 years]*

A few participants also worried that as they get older, they will have more difficulty keeping up with the processes and regulations of the complex supply system. For example, one person said:

*And now with [CGM], I'm down to my last sensor kit. So I'm finishing the one that I have up, I think this weekend. And so, then I have to order the next one, then make sure they get that shipped out. Like I say, right now I've got my faculty, but 20 years from now, who knows? [77-year-old man, T1D for 18 years]*

Additionally, many participants expressed concerns during the interview regarding adhering to Medicare regulations, as these regulations constantly changed during the pandemic, and participants were not always informed: “With Medicare, you have to be seen every three months and you have to have an A<sub>1c</sub> done. And if these doctor’s offices have been either closed or they don’t call you back and so just trying to coordinate my care has been the biggest issue” (76-year-old woman, T1D 53 years). Some expressed frustration with Medicare rules, overall: “The visit to a doctor every three months, in my opinion, is a waste of money...I talked to the Medicare man about getting the supplies, and he said, ‘Well, the doctor visit is important. We want to make sure that your diabetes hasn’t gone away’” (68-year-old woman, T1D for 51 years).

## **Theme 2: Impact of Isolation on Technology Use for Social Interaction**

The second theme identified was the use of technology as a tool for maintaining social life and connecting with friends and family. More than half (18/34, 53%) of the participants used video call as a way to connect with others and 38% (13/34) reported to be in touch with others more frequently than before lockdown (Table 1). One woman said, “I’m taking courses and things like that. I’m doing some Zoom get-togethers” (72-years old, T1D for 20 years). Another person noted, “we’ve used Zoom to get together with our kids and family, so we do a family Zoom meeting. And the kids are always calling and family FaceTime with our grandkids” (72-year-old man, T1D for 65 years). Many participants reported they were able to maintain

communication and attend religious functions: “I’m playing mahjong with friends online. We go to services from a synagogue online...it’s good to interact” (69-year-old woman, T1D for 49 years). One person reported that she was able to interact remotely using a web-based platform to help out while her daughter worked: “With my granddaughter, oh, we have so much fun. We do FaceTime. I actually call it babysitting” (72-year-old woman, T1D for 20 years).

There was also an increased opportunity to participate in a support group for people using insulin pumps, with an even broader reach than in-person meetings: “I’m part of an insulin pump support group...We’ve actually attracted additional people that not only don’t show up normally for the monthly meetings, but we’ve also gone outside this geographic area” (76-year-old man, T1D for 67 years).

However, other participants reported giving up some of their regular activities, such as playing chess or religious meetings, due to the lack of in-person interactions: “There’s a lot of church groups that you have Zoom meetings, and that’s awkward. I’d rather be meeting in-person instead of Zoom” (71-year-old woman, T1D for 30 years). In fact, a frequent complaint in this cohort of older adults was the lack of physical interaction with their grandchildren: “We have children. We have grandchildren. We’re unable to be around them, and that’s heartbreaking in a lot of ways. We like to see them” (69-year-old woman, T1D for 49 years). Another person said:

*So it’s a whole different thing to worry about when you’re talking with [grandkids] on the phone. How do I engage and help them without being able to sit in the room with them? I have another grandchild...who just had his first birthday party on Zoom. It sucks. [69-year-old man, T1D for 49 years]*

### **Theme 3: Impact of Isolation on Telehealth Use to Maintain Medical Care**

Telemedicine was rapidly implemented at the beginning of the COVID-19 lockdown to provide care when in-person visits were not allowed. At the time the interviews occurred, 71% (24/34) of the participants already had at least one video visit, 65% (22/34) had contact with their primary care provider, and 82% (28/34) reported feeling confident that their medical needs were met (Table 1).

Many of the participants reported that telemedicine was adequate and the delivery of care via telemedicine was able to address their needs. One participant said, “I had [a telemedicine visit] with my allergist and also with my primary care physician, and I came loaded with questions, and I had them all answered. Even if I didn’t like the answers. So the quality of care was good” (72-year-old man, T1D for 65 years). Others voiced that their telemedicine visit with their diabetes team was as good as an in-person visit and may be time- and cost-saving.

*If it’s not a visit to get blood work done, I’d definitely have a conversation over video chat...I like it, because number one, I don’t have to drive into Boston with all the traffic...I think this is a great tool and I’m glad, in a positive way, that COVID actually got this up and running. [69-year-old woman, T1D for 29 years]*

*I had a urinary tract infection and I had a phone conference with my urologist, which I felt was adequate. And treatment was, I don’t think would have been any different than if I sat in his office and waited for 40 minutes, and then spent five minutes with him in person. [68-year-old man, T1D for 42 years]*

However, some participants reported the lack of physical interactions and laboratory data as major drawbacks of telemedicine. One man said, “I think these telemeetings...[My provider] couldn’t take blood pressure, or anything like that...And I’m thinking, ‘Yeah, well, that’s not very useful’” (72-year-old man, T1D for 31 years). Another man said, “One of the things they’re supposed to do is check my feet...They want to see how my balance is when I’m walking or how stable I am...I just don’t have those words and terminology to relay the information to them” (69-year-old man, T1D for 49 years). One person reported, “I really don’t see any value for me personally, in telemedicine. Unless I’m having a real problem, I feel like I can manage the diabetes myself...in my particular situation, I didn’t opt for any telemedicine visits” (76-year-old man, T1D for 67 years).

Some participants voiced concerns regarding remote visits for diabetes management due to their inability to change insulin pump settings without hand-on assistance from their provider.

*I think I really prefer seeing my diabetes caregivers in person and making changes to my treatment, my CGM and my pump because I still don’t feel capable of making those changes myself when things are not going smoothly, and that’s a worry. [79-year-old woman, T1D for 58 years]*

COVID-19 imposed delays in medical care requiring in-person visits, such as surgery, dental care, and eye care, which telemedicine could not address. One woman noted, “I should’ve had a cochlear implant surgery. And that’s been put on hold” (72-year-old woman, T1D for 60 years). Another woman said, “my dental stuff, I’m not in any pain or anything but I knew I needed to do that at some point, so the COVID is standing in my way, in part, for that” (73-year-old woman, T1D for 24 years). “I was due for an eye exam and that was put on hold” (76-year-old woman, T1D for 53 years), stated one woman.

## **Discussion**

This study shows that older adults with T1D were able to continue to use diabetes-related technologies, such as insulin pump and CGM, during a time of isolation, to maintain their diabetes management. However, the participants described barriers to and enablers of technology use that have not yet been described in the literature. Although pandemics are rare, sudden isolation can occur in the lives of older persons due to the loss of a significant other, acute illness, or decline in cognitive or functional status. Understanding how older persons with T1D interact with technologies may help clinicians to develop age-specific pathways to support this unique population during times of sudden isolation.



All of the participants in our study voiced that the use of CGM was beneficial during the lockdown. This finding is important, considering that the adoption of CGM in older adults has lagged behind the adoption in the younger population. A recent study of a large cohort from the T1D Exchange (2016-2018) showed that only 34% of adults aged >50 years with T1D were using personal CGM [14]. A majority (22/34, 65%) of our cohort in this study had strong positive perceptions about the benefits of readily available data and alarms from CGM. Participants reported that being able to share CGM data with clinicians during telemedicine visits was helpful to assess glucose patterns (time in range and time spent in hyperglycemia and hypoglycemia). Such information can be very valuable during a remote visit, to provide actual information on glycemic control, when laboratory data, such as Hemoglobin A<sub>1c</sub>, are unavailable [15]. Furthermore, the CGM metrics collected in a small subgroup of participants did not show a worsening of glycemic control during a lockdown, which is consistent with other reports in adults with T1D [16]. Thus, all of these findings, taken together, support the benefits of CGM use in older adults with T1D, even during a time of isolation.

We also found that the reliability of timely access to supplies for CGM and insulin pump was concerning for many of the participants. Most participants reported some concerns with shipment arrival and the quantity of supplies shipped. This issue was a nationwide problem at the beginning of the pandemic when shipping companies got overwhelmed by the increased volume of shipment [17]. Fortunately, only a few people experienced actual delivery delays; however, their anxiety remained a concern. Similarly, until the COVID-19 lockdown, Medicare required patients with T1D to be seen in-person every 3 and 6 months for pump and CGM, respectively. Medicare addressed and modified the rules very early in the pandemic; however, not all participants were aware of these changes. These findings highlight the issues older adults face with accessing current regulatory and administration information with the use of diabetes technology. In addition to assistance with the use of technology, this population would benefit from structured assistance with regulatory and administrative tasks.

The use of technology to communicate with others is a recent advancement and not all older adults are proficient in its use [1]. Most of our interviewees felt that communication technology was helpful to keep in contact with family and

friends. Many of the participants in our cohort reported enrolling in new social events held remotely during the COVID-19 lockdown, such as book clubs, support groups, or happy hours. These findings are consistent with another population-based representative survey conducted in older adults during the COVID-19 lockdown, showing their ability to use technology to mitigate social isolation [18]. However, several participants reported missing physical contact with their young grandchildren and were not engaged in remote socialization. Our findings further highlight the results from a recent study showing persistent loneliness in older adults who face barriers to technology-based social interactions [19]. Increasing isolation in older adults during COVID-19 has been associated with a worsening in mental and physical health in some studies [20]. Thus, assisting older adults with T1D to overcome barriers to communication technology use during isolation and promoting in-person interaction as much as possible is an important intervention to maintain their mental health.

The majority of our participants voiced that the use of web-based technologies for telemedicine lessened the negative impact of isolation on their health care. Several recent studies have shown that telehealth visits have been as beneficial as in-person visits to manage diabetes in people with both T1D and type 2 diabetes [16,21,22]. The CGM data from our cohort support these findings. However, in-person visits remain important for subspecialties such as dentistry, podiatry, and ophthalmology, as well as laboratory data for routine clinical care. Overall, our study supports the benefits of the use of telemedicine for older persons with T1D using CGM for the management of diabetes.

The limitations of the study included the homogeneity of our participants. Almost all participants are non-Hispanic White, with high levels of education, and universally use CGM; thus, our results may not be generalizable to all older adults with T1D.

In conclusion, our cohort of older adults with T1D using CGM were able to use technologies to maintain their diabetes management, social interactions, and medical care during isolation. The participants provided both the positive and negative perceptions of technology use, which can help clinicians identify barriers to technology use and strategies to overcome these barriers in their patient population during isolation from any cause.

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## Conflicts of Interest

MM is a consultant for Sanofi. SH is an employee and shareholder at Pfizer. All other authors declared no other conflicts of interest.

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## Abbreviations

**CGM:** continuous glucose monitoring

**T1D:** type 1 diabetes

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Original Paper

# The Use of Information and Communication Technology–Based Self-management System DialBeticsLite in Treating Abdominal Obesity in Japanese Office Workers: Prospective Single-Arm Pilot Intervention Study

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## Abstract

**Background:** Making lifestyle changes is an essential element of abdominal obesity (AO) reduction. To support lifestyle modification and self-management, we developed an information and communication technology–based self-management system—DialBeticsLite—with a fully automated dietary evaluation function for the treatment of AO.

**Objective:** The objective of this study was to evaluate the preliminary efficacy and feasibility of DialBeticsLite among Japanese office workers with AO.

**Methods:** A 2- to 3-month prospective single-arm pilot intervention study was designed to assess the effects of the intervention using DialBeticsLite. The information and communication technology system was composed of 4 modules: data transmission (body weight, blood pressure, blood glucose, and pedometer count); data evaluation; exercise input; and food recording and dietary evaluation. Eligible participants were workers who were aged  $\geq 20$  years and with AO (waist circumference  $\geq 85$  cm for men and  $\geq 90$  cm for women). Physical parameters, blood tests, nutritional intake, and self-care behavior were compared at baseline and after the intervention.

**Results:** A total of 48 participants provided completed data for analysis, which yielded a study retention rate of 100%. The average age was 46.8 (SD 6.8) years, and 92% (44/48) of participants were male. The overall average measurement rate of DialBeticsLite, calculated by dividing the number of days with at least one measurement by the number of days of the intervention, was 98.6% (SD 3.4%). In total, 85% (41/48) of the participants reported that their participation in the study helped them to improve their lifestyle. BMI, waist circumference, and visceral fat area decreased significantly after the intervention ( $P < .001$ ). In addition,

the daily calorie intake reduced significantly ( $P=.02$ ). There was a significant improvement in self-care behavior in terms of exercise and diet ( $P=.001$ ).

**Conclusions:** Using DialBeticsLite was shown to be a feasible and potentially effective method for reducing AO by providing users with a motivational framework to evaluate their lifestyle behaviors.

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## KEYWORDS

abdominal obesity; self-management; telemedicine; mobile phone

## Introduction

### Background

Obesity is a global public health problem because of its high prevalence and associated morbidity and mortality [1]. In particular, abdominal obesity (AO), which is defined by intra-abdominal fat deposition, is associated with an increased risk of multiple chronic diseases such as cardiovascular disease, atherosclerosis, and type 2 diabetes.

Evidence from preceding studies strongly supports the benefits of lifestyle changes—diet and exercise—as effective means to reduce AO [2-4]. However, behavioral interventions can be difficult to achieve in wide-scale clinical practice because of limited resources and inadequate professional support [5,6]. In addition, it is often challenging to maintain obesity reduction with behavioral lifestyle changes over a long period [7,8].

As such, interventions that use information and communication technology (ICT) show great promise in terms of effectiveness and scalability. Given that weight loss has been shown to improve through the use of ICT interventions, the authors of this study sought to investigate the utility of ICT tools as a means of providing behavioral intervention to those with AO [9,10]. We previously reported that the self-management ICT system “DialBetics” improved glycemic control in patients with type 2 diabetes [11]. The system was shown to be a feasible and an effective tool for improving hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) by providing patients with real-time support based on their measurements. Furthermore, we have developed the self-management ICT system “DialBeticsLite” to provide a similar approach to addressing AO. The upgrade from DialBetics to DialBeticsLite includes fully automated instant calculation and evaluative feedback on nutrient intake, which replaced the manual calculation of nutritional values by dietitians, which took 1 to 2 days. This intervention assists patients to practice lifestyle self-management through daily self-monitoring of blood pressure (BP), blood glucose, pedometer count, body weight (BW), exercise, and diet.

Systematic reviews reported that the use of mobile health (mHealth) showed a modest short-term effect on BW and BMI in adults with obesity [12], and internet-based interventions have a significant and promising effect on waist circumference (WC) change [13]. Nevertheless, these studies did not further investigate the effect of mHealth lifestyle interventions on visceral fat area among the population with AO. Excess visceral fat area is a well-known risk factor for the development of diabetes mellitus and onset of cardiovascular disorders [14].

### Goal of This Study

In this study, we performed a pilot study to test DialBeticsLite in a population with AO. This study aimed to evaluate the effects of a lifestyle intervention using ICT-based self-management systems on physical and metabolic parameters, including visceral fat area, as well as self-care behavioral parameters in participants with AO.

## Methods

### Design

A prospective single-arm pilot study using the intervention DialBeticsLite was conducted.

### Ethics Approval

The study was approved by the institutional review board of the Graduate School of Medicine, the University of Tokyo (approval numbers: 3283-(10) and 11475) and was carried out in accordance with the Declaration of Helsinki.

### Participants

Japanese office workers who were aged  $\geq 20$  years; with AO (WC  $\geq 85$  cm for men and  $\geq 90$  cm for women), which was determined at routine health checkups held at work sites in the year before this study; and willing to use the ICT system were eligible for the study. The WC cutoff points were chosen based on the recommendation of the Japanese Committee of the Criteria for Metabolic Syndrome, which adopts cutoffs of WC  $\geq 85$  cm for men and  $\geq 90$  cm for women [15]. Those who received any medications for the treatment of hypertension, dyslipidemia, or diabetes were excluded. The applicants provided written informed consent before study participation. As literature that focuses on mHealth interventions for visceral fat area reduction is scarce, we have no information on the effect size for sample size calculation. Therefore, we recruited at least 55 patients as a suitable sample size for a pilot feasibility study based on recommendations in the literature [16].

### Interventions

#### Educational Group Session

Before using DialBeticsLite, the participants attended an educational group session at the University of Tokyo Hospital. The research team, consisting of nurses, diabetologists, and dietitians, gave a 40-minute lecture about diet and exercise therapy. The research team trained all the 48 participants in the use of DialBeticsLite and ensured that they could use the app and devices competently. The participants were college educated and used cell phones for calls and SMS text message exchanges

daily; none of them had difficulties in using DialBeticsLite and measurement devices. They were allowed to contact the research team if they encountered any issues during the use of the app and devices.

**Use of DialBeticsLite**

The participants used DialBeticsLite for 2 or 3 months (61 days, March 1 to April 30, 2017, for the participants from company X and 93 days, May 22 to August 22, 2017, for those from company Y). Both companies had different time availabilities for study participation owing to unavoidable job circumstances. The DialBeticsLite system is outlined in Figure 1.

At home, the participants measured their blood glucose, BP, and BW upon waking in the morning and blood glucose and BP at bedtime. They wore a pedometer and measured their number of daily steps and the calories consumed during the activity. Blood glucose was measured by the participants who were willing to do so. The participants transferred measured data from each device to the smartphone by near field communication or Bluetooth; all data were sent to the server directly following measurement, excluding pedometer counts, which were sent at least once a day at bedtime.

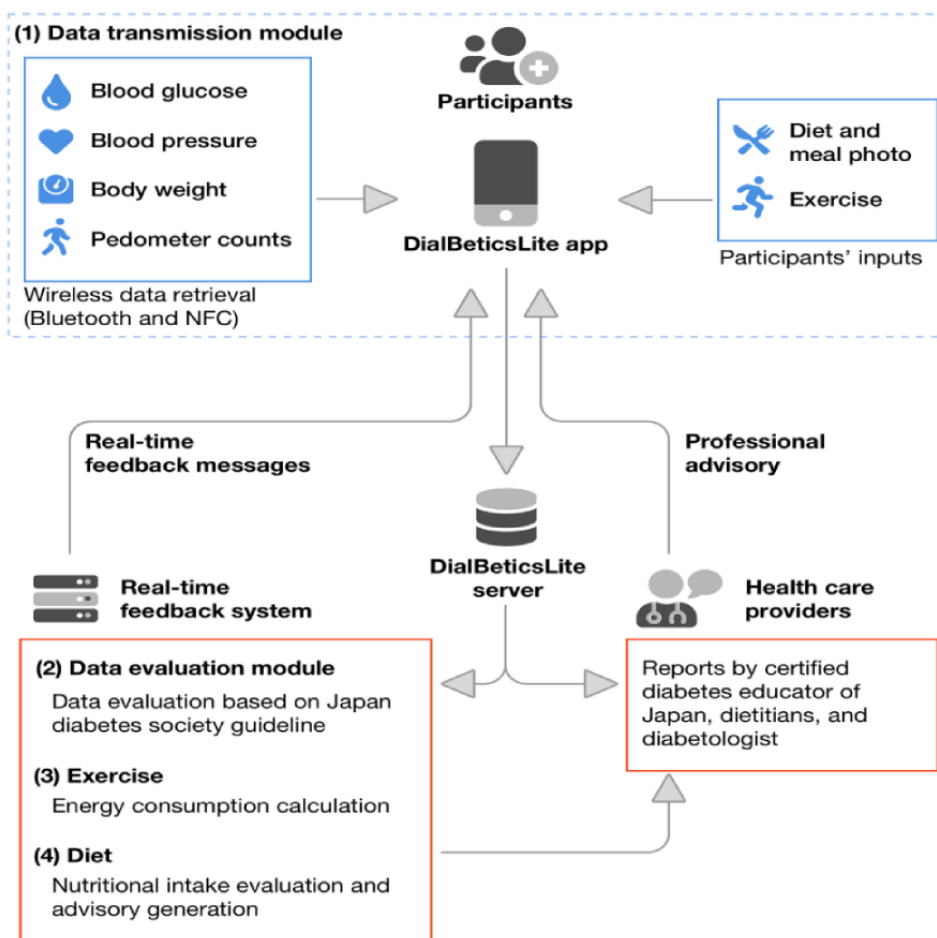
The data were automatically evaluated according to the Japan Diabetes Society guideline’s target values [17]: optimally, glucose level below 110 mg/dL before breakfast and below 140

mg/dL at bedtime and BP below 125/75 mm Hg. The number of daily steps was evaluated according to the Japanese official physical activity guidelines for health promotion, with a target of ≥8000 steps per day [18]. DialBeticsLite then determined whether each reading satisfied the guidelines [17,18] and immediately sent those results to each participant’s smartphone.

Dietary information (food names and quantity of each meal with photos) and exercise information (type of exercise and its duration) not counted by a pedometer were inputted by the participants and sent to the server; specific advice on diet modification was sent back to each participant immediately after the input. The participants were provided with a set of devices for the study: a smartphone (Galaxy Note3 SC-01F [Samsung]), a Bluetooth-enabled BP monitor (HEM-7271T [Omron]) and scale (HBF-255T [Omron]), a near field communication-enabled glucometer (MS-FR201B [Terumo]), and a pedometer (MT-KT02DZ [Terumo]).

The system triggered alerts if a participant recorded no data for more than 3 days; the alerts could be checked on the administrator screen. The nurse emailed (after 1 week of inactivity) or called (after 2 weeks of inactivity), encouraging the participants to restart measurements. If a participant recorded no data (measured data, food, or exercise) for 3 weeks, we designated the participant as a dropout.

**Figure 1.** Data transmission module, data evaluation module, exercise, and nutritional evaluation function of DialBeticsLite. NFC: near field communication.





### **Report From Health Care Providers**

The participants received a specific feedback report from the research team at the end of the study. The nurses and dietitians of the study team drafted the *Advice From Healthcare Providers* and physicians of the team reviewed and approved them before distributing them to the participants. The report was based on measured data, and recorded data were provided, including measurement rates, target achievement rates, averages of measured values, lifestyle evaluations, and suggestions for further improvement ([Multimedia Appendix 1](#)).

### **Data Collection and Outcomes Measure**

#### **Total Measurement Rate, Food Recording Rate, and Exercise Input Rate**

We assessed the total measurement rate, food recording rate, and exercise input rate of the DialBeticsLite users in this study. The total measurement rate, measurement rate for each parameter (blood glucose, BP, BW, and pedometer counts), exercise input rate, and food recording rate were each calculated. The total measurement rate was calculated by dividing the number of days with at least one measurement by the number of days of the intervention (ie, 61 or 93 days). Similarly, the measurement rate for each parameter was calculated by dividing the number of days on which that parameter was measured by the total number of intervention days.

#### **Changes in Physical and Metabolic Parameters**

All participants underwent physical measurements and blood tests at the time of the educational group session, which immediately preceded the start of the study and happened after 2 or 3 months of the use of DialBeticsLite, by a trained nurse or clinical laboratory technician, with the exception of BP. The BP of the patients were measured at home at baseline and after the intervention. The participants' height, BW, BP, WC, and visceral fat area were measured. Visceral fat area was measured by differentiating visceral fat and abdominal subcutaneous fat using dual bioelectrical impedance analysis, which measures the bioelectrical impedance of the entire abdomen and its surface with a dual current path [19] (DUALSCAN, HDS-2000 [Fukuda Colin]). It has been reported that the estimation of visceral fat area by dual bioelectrical impedance is significantly correlated with that by the gold standard method measured by x-ray computed tomography [20]. We calculated BMI from height and BW. The blood test results included the levels of fasting plasma glucose, HbA<sub>1c</sub>, total cholesterol, triglyceride, and high-density lipoprotein cholesterol.

#### **Changes in Behavioral Parameters**

To assess the changes in nutritional intake, we asked the participants to fill in a paper-based 7-day meal record at the beginning of the study (within 2 weeks before the use of DialBeticsLite) and the end of the study (within 1 month after the use of the system). The participants recorded the ingredients and their portion size for the food and drinks they consumed for breakfast, lunch, dinner, and in between meal–snacks on a record sheet. The researchers briefed the participants on the correct filling of the dietary record before the study. Dietitians calculated the nutritional intake (total energy [kcal],

carbohydrate [g], protein [g], lipid [g], dietary fiber [g], and salt [g]) from the record.

The Japanese-Translated Summary of Diabetes Self-Care Activities (J-SDSCA) measure was included in the questionnaires at baseline and after the intervention to evaluate changes in self-care behaviors [21]. We used only 2 subscales of the J-SDSCA, namely diet and exercise. The J-SDSCA was developed to assess self-care activities for patients with diabetes, but because there is no standardized questionnaire to evaluate self-care activities for people with AO, we used the J-SDSCA for this study.

We compared the mean number of daily steps between the first 7 days and last 7 days of the DialBeticsLite use period. When the participants recorded the number of steps  $\geq 2$  times on the same day, the last recorded data were defined as the total number of steps for that day.

#### **Usability of DialBeticsLite**

We conducted a usability survey for DialBeticsLite after the intervention using the same questionnaire as that in the previous DialBetics study [11]. After the intervention period, the research team informed the participants to attend a wrap-up session in the hospital and asked them to fill out a usability survey. There were 15 statements in this survey, and each statement had a “yes” or “no” option. The research team, which consisted of 1 endocrinologist, 1 cardiologist, 2 nurses, and 2 dietitians, confirmed the face validity of the survey to investigate the usability of DialBeticsLite.

#### **Statistical Analysis**

Data are presented as mean (SD) for parametric variables or median (IQR) for nonparametric variables. Changes in physical and metabolic parameters, the mean daily intake of energy and each nutrient calculated from the 7-day meal record, and the mean number of daily steps were compared using the paired, 2-tailed *t* test for parametric variables or the Wilcoxon signed-rank test for nonparametric variables. Changes in the J-SDSCA scores were compared using the Wilcoxon signed-rank test. Changes in the level of AO were compared using the McNemar test. *P* values of  $<.05$  were considered statistically significant. Statistical analyses were performed using SPSS for Windows (version 25.0; IBM Corp).

## **Results**

### **Overview**

A total of 56 individuals from 2 companies participated in this study. After completion of the study, we found that 8 participants had already received medication for hypertension, dyslipidemia, or diabetes; they were excluded from the analyses because they did not meet our eligibility criteria. Finally, 48 participants ( $n=18$ , 38% from company X and  $n=30$ , 62% from company Y) were included in the analyses. There were no dropouts.

The average participant age was 46.8 (SD 6.8; range 32–62) years, and 92% (44/48) of participants were male. The median WC was 95.0 (IQR 91.0–102.5) cm in men and 98.0 (IQR

91.5-102.3) cm in women. The median visceral fat area was 112.0 (IQR 90.0-147.0) cm<sup>2</sup>.

### Measurement and Recording Rates

The measurement rates are presented in Table 1. The total measurement rate was 98.6% (SD 3.4%). Of the 48 participants, 32 (67%; n=18, 38% from company X and n=14, 29% from

company Y) measured blood glucose; the measurement rates of blood glucose before breakfast and at bedtime were 84.5% (SD 24.4%) and 74.4% (SD 27.1%), respectively. The measurement rates of BP before breakfast and at bedtime were 83.9% (SD 20.7%) and 62.2% (SD 32.1%), respectively. The measurement rates of BW, pedometer count, exercise input, and food input were 90.8% (SD 10.7%), 91.1% (SD 16%), 12.5% (SD 19.2%), and 88.5% (SD 20.1%), respectively (n=48).

**Table 1.** The measurement rate of each feature in DialBeticsLite.

Variables	Measurement rates (%), mean (SD)
The total measurement rate (n=48)	98.6 (3.4)
<b>Blood glucose (n=32)</b>	
Before breakfast	84.5 (24.4)
At bedtime	74.4 (27.1)
<b>Blood pressure (n=48)</b>	
Before breakfast	83.9 (20.7)
At bedtime	62.2 (32.1)
Body weight (n=48)	90.8 (10.7)
Pedometer count (n=48)	91.1 (16.0)
Exercise input (n=48)	12.5 (19.2)
Dietary record input (n=48)	88.5 (20.1)

### Changes in Physical and Metabolic Parameters

Changes in the physical parameters between baseline and after using DialBeticsLite are presented in Table 2. BW and median BMI significantly decreased from 82.6 (SD 13.1) to 79.0 (SD 12.9) kg ( $P<.001$ ) and 27.0 (IQR 25.5-31.1) to 26.3 (IQR 24.1-29.4) kg/m<sup>2</sup> ( $P<.001$ ), respectively. WC and visceral fat area also significantly decreased from 95.0 (IQR 91.0-102.5) to 91.7 (IQR 87.0-97.8) cm ( $P<.001$ ) and from 112.0 (IQR 90.0-147.0) to 92.0 (IQR 68.3-113.8) cm<sup>2</sup> ( $P<.001$ ), respectively. The prevalence of AO was significantly reduced

by 13% after using DialBeticsLite (before, n=48 vs after, n=42;  $P=.03$ ).

After using DialBeticsLite, the participants exhibited significant reductions in systolic and diastolic BP, from 131.8 (SD 14.7) to 126.6 (SD 14.3) mm Hg ( $P=.02$ ) and from 88.1 (SD 11.5) to 84.7 (SD 10.2) mm Hg ( $P=.02$ ), respectively. Fasting blood glucose levels and HbA<sub>1c</sub> significantly declined from 90.0 (IQR 85.0-95.0) to 87.0 (IQR 80.3-93.5) mg/dL ( $P=.01$ ) and from 5.6% (IQR 5.3%-5.8%) to 5.4% (IQR 5.2%-5.6%;  $P<.001$ ), respectively. Total cholesterol lowered from 215.5 (IQR 188.0-234.3) to 194.5 (IQR 175.5-218.0) mg/dL ( $P<.001$ ).

**Table 2.** Changes in physical parameters, blood pressure (BP), glucose, and lipid metabolism before and after the DialBeticsLite intervention.

Variables	Baseline measurements (n=48)	Measurements after the intervention (n=48)	P values
<b>Physical parameters</b>			
Body weight (kg), mean (SD)	82.6 (13.1)	79.0 (12.9)	<.001 <sup>a</sup>
BMI (kg/m <sup>2</sup> ), median (IQR)	27.0 (25.5-31.1)	26.3 (24.1-29.4)	<.001 <sup>b</sup>
Waist circumference (cm), median (IQR)	95.0 (91.0-102.5)	91.7 (87.0-97.8)	<.001 <sup>b</sup>
Visceral fat area (cm <sup>2</sup> ), median (IQR)	112.0 (90.0-147.0)	92.0 (68.3-113.8)	<.001 <sup>b</sup>
<b>Home BP (n=43)</b>			
Systolic BP (mm Hg), mean (SD)	131.8 (14.7)	126.6 (14.3)	.02 <sup>a</sup>
Diastolic BP (mm Hg), mean (SD)	88.1 (11.5)	84.7 (10.2)	.02 <sup>a</sup>
<b>Glucose and lipid metabolism</b>			
Fasting plasma glucose (mg/dL), median (IQR)	90.0 (85.0-95.0)	87.0 (80.3-93.5)	.01 <sup>b</sup>
HbA <sub>1c</sub> <sup>c</sup> (%), median (IQR)	5.6 (5.3-5.8)	5.4 (5.2-5.6)	<.001 <sup>b</sup>
Total cholesterol (mg/dL), median (IQR)	215.5 (188.0-234.3)	194.5 (175.5-218.0)	<.001 <sup>b</sup>
HDL <sup>d</sup> cholesterol (mg/dL), mean (SD)	50.0 (11.3)	48.9 (12.3)	.23 <sup>a</sup>
Triglyceride (mg/dL), median (IQR)	120.5 (78.3-215.3)	110.5 (68.3-165.0)	.06 <sup>b</sup>

<sup>a</sup>Paired, 2-tailed *t* test for parametric variables.

<sup>b</sup>Wilcoxon signed-rank test for nonparametric variables.

<sup>c</sup>HbA<sub>1c</sub>: hemoglobin A<sub>1c</sub>.

<sup>d</sup>HDL: high-density lipoprotein.

### Changes in Behavioral Parameters Between Baseline Measurement and Postintervention Measurement

Changes in the nutritional intake based on the 7-day food records are presented in Table 3. The daily energy intake significantly declined from a median of 1953 (IQR 1790-2395) to 1877 (IQR 1690-2153) kcal ( $P=.02$ ). The daily intake of protein and carbohydrates significantly decreased from 71.4 (IQR 63.5-86.4) to 66.4 (IQR 57.2-79.6) g ( $P=.002$ ) and from 227.7 (IQR 198.4-277.6) to 216.3 (IQR 181.6-250.5) g ( $P=.03$ ), respectively, whereas no significant reduction was observed in the fat ( $P=.12$ ) or salt ( $P=.11$ ) intake. The daily fiber intake significantly declined from 14.2 (IQR 12.6-16.7) to 12.1 (IQR 10.8-13.9) g ( $P=.001$ ).

Changes in lifestyle based on the J-SDSCA are summarized in Table 4. The number of days the participants ate >300 g of vegetables significantly increased from 2.0 (IQR 1.0-3.0) to 4.0

(IQR 2.0-5.8) days per week ( $P<.001$ ), whereas there was no change in the number of days per week the participants ate high-fat foods or the number of days per week their nutrient intake was distributed evenly throughout the day (eg, eating 3 well-balanced meals). The number of days they did at least 30 minutes of physical activity, including walking, increased significantly from 2.0 (IQR 1.0-3.0) to 3.0 (IQR 2.0-6.0) days per week ( $P<.001$ ). In addition, the number of days per week they participated in a specific exercise session (such as swimming, walking, or biking) significantly increased ( $P=.02$ ). As for the total scores, specific diet and exercise significantly improved from 7.0 (IQR 5.0-9.0) to 8.0 (IQR 6.0-10.8;  $P=.01$ ) and from 2.5 (IQR 1.0-4.8) to 6.0 (IQR 3.0-7.0;  $P=.001$ ), respectively.

The mean number of daily steps underwent no significant change between the first 7 days and last 7 days of using DialBeticsLite (8074, SD 3522 to 8700, SD 4240 steps;  $P=.32$ ).

**Table 3.** Changes in the nutritional intake before and after the DialBeticsLite intervention.

	Baseline measurements (n=47), median (IQR)	Measurements after the intervention (n=47), median (IQR)	P values <sup>a</sup>
Energy (kcal/day)	1953 (1790-2395)	1877 (1690-2153)	.02
Protein (g/day)	71.4 (63.5-86.4)	66.4 (57.2-79.6)	.002
Lipid (g/day)	72.2 (58.6-91.8)	66.6 (54.7-80.7)	.12
Carbohydrate (g/day)	227.7 (198.4-277.6)	216.3 (181.6-250.5)	.03
Dietary fiber (g/day)	14.2 (12.6-16.7)	12.1 (10.8-13.9)	.001
Salt intake (g/day)	10.0 (8.4-11.5)	9.3 (8.5-10.4)	.11

<sup>a</sup>Wilcoxon signed-rank test for nonparametric variables.

**Table 4.** Changes in the J-SDSCA<sup>a</sup> score before and after the DialBeticsLite intervention.

Questions	Baseline measurements (n=48), median (IQR)	Measurements after using DialBeticsLite (n=48), median (IQR)	P values <sup>b</sup>
<b>Specific diet</b>			
On how many of the last 7 days did you eat approximately >300 g vegetables? (days per week)	2.0 (1.0-3.0)	4.0 (2.0-5.8)	<.001
On how many of the last 7 days did you eat high-fat foods such as red meat or full-fat dairy products? (days per week)	3.0 (2.0-4.0)	2.5 (2.0-4.0)	.22
On how many of the last 7 days did you distribute all nutrients evenly through the day? (days per week)	0.0 (0.0-2.75)	1.0 (0.0-3.0)	.23
Total score	7.0 (5.0-9.0)	8.0 (6.0-10.8)	.01
<b>Exercise</b>			
On how many of the last 7 days did you participate in at least 30 minutes of physical activity? (total minutes of continuous activity, including walking; days per week)	2.0 (1.0-3.0)	3.0 (2.0-6.0)	<.001
On how many of the last 7 days did you participate in a specific exercise session (such as swimming, walking, or biking) other than what you do around the house or as part of your work? (days per week)	1.0 (0.0-2.0)	1.5 (0.0-3.0)	.02
Total score	2.5 (1.0-4.8)	6.0 (3.0-7.0)	.001

<sup>a</sup>J-SDSCA: Japanese-Translated Summary of Diabetes Self-Care Activities.

<sup>b</sup>Wilcoxon signed-rank test for nonparametric variables.

### Comparison of the Outcomes Between the 2 Companies

The use period of the system was different between the 2 companies; however, the reductions in BW (−3.9% for company X, 95% CI −7.7% to −1.5% vs −2.6% for company Y, 95% CI −7.3% to −0.9%); WC (−5.3% for company X, SD 4.6% vs −3.3% for company Y, SD 5.3%); and visceral fat area (−20.9% for company X, SD 14.2% vs −13.6% for company Y, SD 24%) at the end of the intervention were greater, although not significantly so, in company X ( $P=.46$ ). The measurement rates of blood glucose before breakfast (88.1%, SD 25.8% for company X and 79.4%, SD 27.8% for company Y;  $P=.37$ ); blood glucose at bedtime (81.6%, SD 24.3% for company X and 65.9%, SD 29.6% for company Y;  $P=.11$ ); BW (97.2%, SD 4.9% for company X and 90.2%, SD 11% for company Y;  $P=.004$ ); BP before breakfast (91.3%, SD 21.3% for company X and 82.9%, SD 17.8% for company Y;  $P=.15$ ); BP at bedtime

(80%, SD 24.1% for company X and 54.4%, SD 32% for company Y;  $P=.005$ ); and daily steps (93.5%, SD 13% for company X and 91.3%, SD 17.9% for company Y;  $P=.66$ ) were higher, especially for BW, among the participants from company X than among those from company Y in the first 2 months of the study.

### Usability of DialBeticsLite

The results of the usability survey are summarized in [Table 5](#). The results showed that 85% (41/48) of the participants felt that using DialBeticsLite had improved their lifestyle and self-management skills. In total, 88% (42/48) of the participants responded that using the system and improving their lifestyle gave them a sense of security. On average, the participants spent 15.7 minutes per day using the system, and 88% (42/48) of them reported that the system was worth using for the amount of time they spent.

**Table 5.** Usability survey results.

Statement or question	Response	
	Yes, n (%)	Others, mean (SD)
1. I used the blood sugar monitor with no problem. (n=32)	24 (75)	N/A <sup>a</sup>
2. I used the sphygmomanometer with no problem. (n=48)	47 (98)	N/A
3. I used the pedometer with no problem. (n=48)	44 (92)	N/A
4. The interface of the system was easy to use. (n=47)	21 (45)	N/A
5. The instructions were easy to understand. (n=47)	45 (96)	N/A
6. The devices caused me physical discomfort. (n=48)	7 (15)	N/A
7. It was difficult to incorporate the system into daily practice. (n=48)	19 (40)	N/A
8. Any technical problems were resolved within 24 hours. (n=43)	22 (51)	N/A
9. Using the system and improving my lifestyle gave me a sense of security. (n=48)	42 (88)	N/A
10. I found the advice from the system useful. (n=46)	18 (39)	N/A
11. Participation in the study helped me to improve my lifestyle and self-management skills. (n=48)	41 (85)	N/A
12. Using the system took too much of my time. (n=48)	13 (27)	N/A
13. Using the system caused me some problems. (n=48)	13 (27)	N/A
14. How much time did you spend using the system? (minutes; n=48)	N/A	15.7 (8.0)
15. Is the system worth using for the time you spent? (n=48)	42 (88)	N/A

<sup>a</sup>N/A: not applicable.

## Discussion

### Principal Findings

The intervention using the ICT-based self-management system “DialBeticsLite” to support participants with AO yielded high continuous measurement rates, and 88% (42/48) of the participants reported that the system was worth using for the time they spent, demonstrating that DialBeticsLite is a feasible AO treatment solution (Table 5). After the intervention, which consisted of the initial 40-minute educational session and 2 to 3 months of use of DialBeticsLite, BW, BMI, WC, visceral fat area, systolic BP, and diastolic BP all improved (Table 2). The prevalence of AO reduced by 13% (6/42) in this sample ( $P=.03$ ).

To the best of our knowledge, this is the first study to document the effects of a lifestyle intervention using an ICT-based self-management system on several parameters, including visceral fat area, in participants with AO. Previous studies have examined the effects of ICT-based systems in patients with obesity but focused on body mass without collecting data on body composition, such as visceral fat area [9,10]. Our results, which showed decreases in BW mediated by an ICT-based self-management system, are consistent with previous studies in patients with obesity, which showed a 1.9 to 4.8 kg decrease in BW or >5% reduction in the initial BW using other intervention methods for 3 months, such as internet-based programs [9,10]. In addition to decreases in BW, visceral fat area decreased significantly in this study, suggesting that a decrease in visceral fat area contributed to a decrease in BW. The daily energy intake also decreased, and the total score for diet as measured by the J-SDSCA increased significantly; it is presumed that the decrease in daily energy intake led to the loss

of BW, BMI, WC, and visceral fat area. Greater reductions in BW, WC, and visceral fat area among participants from company X than in those from company Y may be attributed to the higher measurement rates in company X. Even though the HbA<sub>1c</sub> levels of the participants were within the normal range at the study onset, HbA<sub>1c</sub> was further reduced significantly after the intervention by 0.2%. This can be attributed to the overall effect of lifestyle changes and daily blood glucose monitoring supported by DialBeticsLite. DialBeticsLite incorporated feedback and monitoring as a behavior change technique, and a study had proven that automated personalized feedback through mHealth leads to lifestyle behavior change [22].

The measurement rates remained high over the study period (Table 1) compared with the previously reported studies in which ICT-based systems were introduced without any in-person interaction. Our previous study that was conducted entirely remotely using a self-management smartphone app for patients with type 2 diabetes and prediabetes showed a rapid decline in retention rates in the absence of intervention by medical professionals [23]. In this study, the in-person educational session on ICT system use by our research team for the study participants at baseline and reminders from our research team prompting participants to resume measurement when they stopped measurement for more than a week may have helped maintain better measurement and recording rates in this study. Relationships with health care providers have been shown to increase patients' willingness to achieve goals [24], and our study showed that real-time feedback from the app coupled with targeted support from health care providers for patients who are prone to disengage from the use of mHealth is feasible, which leads to improved lifestyle habits and clinical outcomes. In



addition, the recruitment of company employees may have created a sense of obligation among participants to complete the study, resulting in a better retention rate. Nevertheless, the short study duration in this study did not permit investigation of long-term retention and engagement with the intervention. To boost scalability to a wider network of users and reduce the burden on health care providers, unsupported mHealth may be necessary, which warrants the need to explore options of human-like features and experiences in the mHealth intervention, such as the use of chatbot and web-based coach [25].

The present findings regarding dietary intake suggest that more personalized feedback is necessary to improve the diet. The daily dietary fiber intake declined significantly (Table 3), presumably because of the decrease in the total dietary intake. Given that previous national health and nutrition examination surveys reported that the intake of dietary fiber declined along with decreased total energy intake [26], it is difficult to increase the intake of fiber under restricted total energy intake. In addition, the daily salt intake of the study participants was 9.3 g per day after the intervention (Table 3), which is still very high compared with the recommendation of a maximum intake of 6 g per day for adults by the Japanese Society of Hypertension [27]. Providing meaningful information to the users through the intervention about salt or dietary fiber intake is expected to increase their awareness of these detrimental behaviors. The current intervention provides the same automated feedback to the users regardless of their understanding of the intake levels and dietary sources of each nutrient. Therefore, the improvement of automatic feedback such that it is tailored to match the levels of each user's knowledge and interest in diet and nutrition should be considered in the future.

### Limitations

Several limitations to the present findings have to be considered. First, this was a small pilot study with 48 participants with the mean age of 46.8 (SD 6.8; range 32-62) years, and most participants were male (n=44, 92%). The gender distribution corresponded to the prevalence of metabolic syndrome according to the criteria set by the Japanese Committee of the Criteria for Metabolic Syndrome, which is significantly higher in men than in women (12.1% vs 1.7%) [28]. Moreover, the higher affinity for ICT use among men may have partly contributed to the gender disparity in our study population [29].

Second, the duration of intervention by the system was short (61 and 93 days); therefore, we were unable to assess the

long-term effects and use patterns of the system. Third, in this study, it was not possible to determine whether the improvements in physical parameters such as BW, BMI, WC, visceral fat area, and systolic and diastolic BP were the effects of "DialBeticsLite" itself; the educational session at baseline might have affected the subjects' behavior. Nevertheless, given the fact that all participants reported being motivated by the sense of security using the system imparted, there is a strong possibility that using the system raised their awareness of newer methods of self-management based on ICT.

As data from 2 groups (participants from company X and those from company Y) were collected from different periods and seasons, there is a possibility of bias, as the frequency of walking activities varied according to the outdoor temperature (step counts) and seasonal variation may influence BP and dietary intake. This was unavoidable, as both companies had different time availabilities to participate in the study owing to different job natures.

We also could not avoid potential recall bias and input of socially acceptable information when participants self-reported their dietary record; nevertheless, we tried to reduce the bias by instructing patients to report their diet immediately after each meal. At the time of the study, no validated questionnaire was available in the literature to test the usability of this mHealth app, and we sought to reduce the bias by establishing the face validity of the questionnaire.

Finally, this study adopted a pre-post study design, which may be subject to other confounders; thus, the results should be interpreted with caution. The participants were those who were willing to participate in the study and were not randomly chosen. Considering these limitations, the study findings must be validated in a larger randomized controlled trial with a longer duration, and we are currently conducting a randomized controlled trial to examine whether DialBeticsLite is effective in improving parameters related to metabolic syndromes.

### Conclusions

In conclusion, DialBeticsLite was shown to be a feasible and potentially effective tool for improving AO by providing patients with real-time support based on their measurements and inputs of BW, BP, pedometer count, blood glucose, exercise, and dietary intake. Preliminary findings showed that DialBeticsLite significantly reduced the BW, BMI, WC, and visceral fat area of patients with AO. A larger randomized controlled trial with a longer duration to further validate these findings is in progress.

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### Authors' Contributions

KW, SY, SK, TT, RN, and KO conceived and designed this study. YK, KW, KM, and SK collected and analyzed the data. YK, KW, SY, TS, KU, HW, and KT drafted and revised the manuscript.

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## Conflicts of Interest

This study was conducted at the Department of Ubiquitous Health Informatics, which was engaged in a cooperative program between the University of Tokyo and NTT DOCOMO, Inc, the sponsor of the study. KW, SY, KM, and SK were members of the Department of Ubiquitous Health Informatics when the study was conducted. TT and RN belonged to NTT docomo Inc.

## Multimedia Appendix 1

An overview of a feedback report from health care providers to the users of DialBeticsLite. Under “measurement data,” the percentages shown represent the average measurement rate over the intervention period. Under “achievement status of treatment goal,” the percentages shown represent the achievement rate of target blood glucose, blood pressure, and pedometer count.” Data are presented as mean (SD) or median (IQR).

[[PNG File , 426 KB - diabetes\\_v7i4e40366\\_app1.png](#) ]

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## Abbreviations

**AO:** abdominal obesity

**BP:** blood pressure

**BW:** body weight

**HbA<sub>1c</sub>:** hemoglobin A<sub>1c</sub>

**ICT:** information and communication technology

**J-SDSCA:** Japanese-Translated Summary of Diabetes Self-Care Activities

**mHealth:** mobile health

**WC:** waist circumference

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Original Paper

# Modified e-Delphi Process for the Selection of Patient-Reported Outcome Measures for Children and Families With Type 1 Diabetes Using Continuous Glucose Monitors: Delphi Study

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## Abstract

**Background:** Type 1 diabetes (T1D) management is complex and associated with significant psychosocial burden. Continuous glucose monitors (CGM) can improve disease management and outcomes and introduce new or exacerbate existing psychosocial concerns. Patient-reported outcome measures (PROMs) can be used to capture this information, but there is no consensus on which PROMs should be used in pediatric CGM research.

**Objective:** Here we describe the process to (1) identify PROMs that could be used to assess the impact of CGMs on pediatric patients with T1D, (2) implement a modified electronic Delphi (e-Delphi) methodology to arrive at an expert consensus on which PROMs are most suitable for clinical and research applications, and (3) establish a periodicity table for the administration of PROMs over time in a real-world evidence study.

**Methods:** To identify appropriate PROMs for pediatric patients and families with T1D and CGMs, we conducted an asynchronous, e-Delphi process with a multidisciplinary group of experts from around the country. We identified candidate instruments through a literature review. The 3-round e-Delphi process was conducted via a study website, email, and web-based forms. Participants provided opinions on the usefulness of instruments, age validation, feasibility, time, and frequency of administration.

**Results:** In total, 16 experts participated in the e-Delphi process; 4 of whom consistently participated in all 3 rounds. We identified 62 candidate instruments, which were narrowed down to 12 final PROMs across 5 domains: diabetes distress and burden (n=4), autonomy (n=2), quality of life (n=1), psychosocial (n=3), and technology acceptance (n=2). A quarterly administration schedule was developed to reduce burden on participants.

**Conclusions:** PROMs can provide critical insights into the psychosocial well-being of patients. The specific measures identified in the paper are particularly well suited for pediatric patients with T1D using CGMs. Clinical implementation could help health care providers, patients, and families to engage in more comprehensive disease management.

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## KEYWORDS

type 1 diabetes; diabetes; diabetic; juvenile; pediatrics; paediatrics; child; youth; continuous glucose monitor; glucose; monitoring; patient reported; outcome measure; PROM; Delphi; disease management; self-management; measurement; instrument

## Introduction

Type 1 diabetes (T1D) impacts nearly 1.6 million Americans, including approximately 187,000 children and adolescents [1]. The advancement of diabetes technology, specifically continuous glucose monitors (CGM), has made self-management and home monitoring more feasible and accessible [2,3]. Disease

management can be complex and includes the management of blood sugar levels with insulin, diet plans, exercise, and a coping lifestyle to prevent complications [1]. This complexity can lead to distress, depression, anxiety, eating disorders, poor treatment satisfaction, and adherence in patients and their families [1,4]. Therefore, chronic disease management requires an integrated approach with routine management as well as proactive risk



assessment. Patient-reported outcome measures (PROMs) can facilitate systematic assessment of patients' and parents' perception of a child's overall well-being and deeper understanding of the patient experience. The Center for Devices and Radiological Health, part of the US Food and Drug Administration (FDA), has emphasized the use of PROMs in medical device evaluation and regulatory decisions to support claims in approved medical product labeling in pre- and postmarket medical device-related clinical studies [4-8].

There have been several PROMs developed for patients with diabetes, though they are rarely implemented outside of research settings [9]. The Department of Public Health of the University of Oxford has published a list of recommended PROMs for use in the management of diabetes after structured systematic review in 2006 and 2009 [10]. The FDA has qualified the Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) questionnaires as a medical device development tool to assess the impact of automated insulin dosing (AID) systems on psychosocial functioning and quality of life (QoL) [11]. For pediatric patients, it is not as simple as reusing adult instruments. Pediatric PROMs need to be designed to capture a parent or caretaker's perspective, consider parent-child dynamics, and accommodate a broad neurodevelopmental spectrum and varying age-appropriate literacy and numeracy skills [12,13]. These psychometric challenges, along with overall less funding and focus on pediatric research compared to adults [14-16], have contributed to a lag in the development and adoption of pediatric PROMs.

Since 2018, we have been working on an FDA-funded real-world evidence study focused on children with T1D using CGMs, with the ultimate goal of creating a real-time, prospective database of patients using medical devices that can be used for clinical, operational, research, and regulatory purposes. One key component of the project is to aggregate data from several sources, including the electronic health record (EHR), medical devices, and the patients themselves. To that end, we have leveraged a number of technologies, including Cerner's population health management platform, HealtheIntent, to ingest clinical data, integration engines to ingest CGM data directly into the EHR [17], and REDCap to collect patient-reported outcomes [18,19]. Here we describe our process to (1) identify PROMs that could be used to assess the impact of CGMs on pediatric patients with T1D, (2) implement a modified electronic Delphi (e-Delphi) methodology to arrive at an expert consensus on which PROMs are most suitable for clinical and research applications, and (3) establish a periodicity table for the administration of PROMs over time in our real-world evidence study. The Delphi technique, developed in the 1950s, is a structured process that leverages the judgment of experts through a series of rounds that integrate controlled feedback to develop consensus on a specific topic [20-22]. The overarching goal of this Delphi process is the creation of a battery of PROMs to facilitate patient-provider interaction and individualized patient-centered care, which can reflect measurable changes in population health over time.

## Methods

### PROMs Identification and Literature Review

We collaborated with a medical librarian to systematically search PubMed (National Library of Medicine), Embase (Elsevier), Web of Science (Clarivate Analytics), Engineering Village (Elsevier), and ClinicalTrials.gov (National Library of Medicine) to identify relevant publications related to PROMs, CGMs, and pediatrics (referring to individuals aged 0-18 years). We ran a series of searches using a combination of controlled vocabulary (when available) and keywords to capture multiple facets of PROMs which included the following: PROMs, questionnaires, pain, sleep and fatigue, stigma, self-efficacy and relationships, physical activity, stress, cognition, and emotions. The queries were not limited by publication date.

Because this study focused on CGMs and PROMs, studies focused on insulin pumps, AIDs, and other diabetes technologies were excluded. Search results underwent title and abstract screening for relevance, and full-text review was conducted by 2 independent researchers to identify relevant PROMs. This process was facilitated by the medical librarian, and a third researcher was available to adjudicate as needed. Citations in included papers were also reviewed for eligibility. Exclusion criteria were as follows: duplicate instruments, inability to find the full text of the instruments, instruments that were not validated, older versions of PROMs, and instruments that were too long to administer in a clinical setting. All PROMs were grouped by the study team into one of 5 domains: autonomy, psychosocial factors, diabetes distress and burden, general health and QoL, and technology and acceptance.

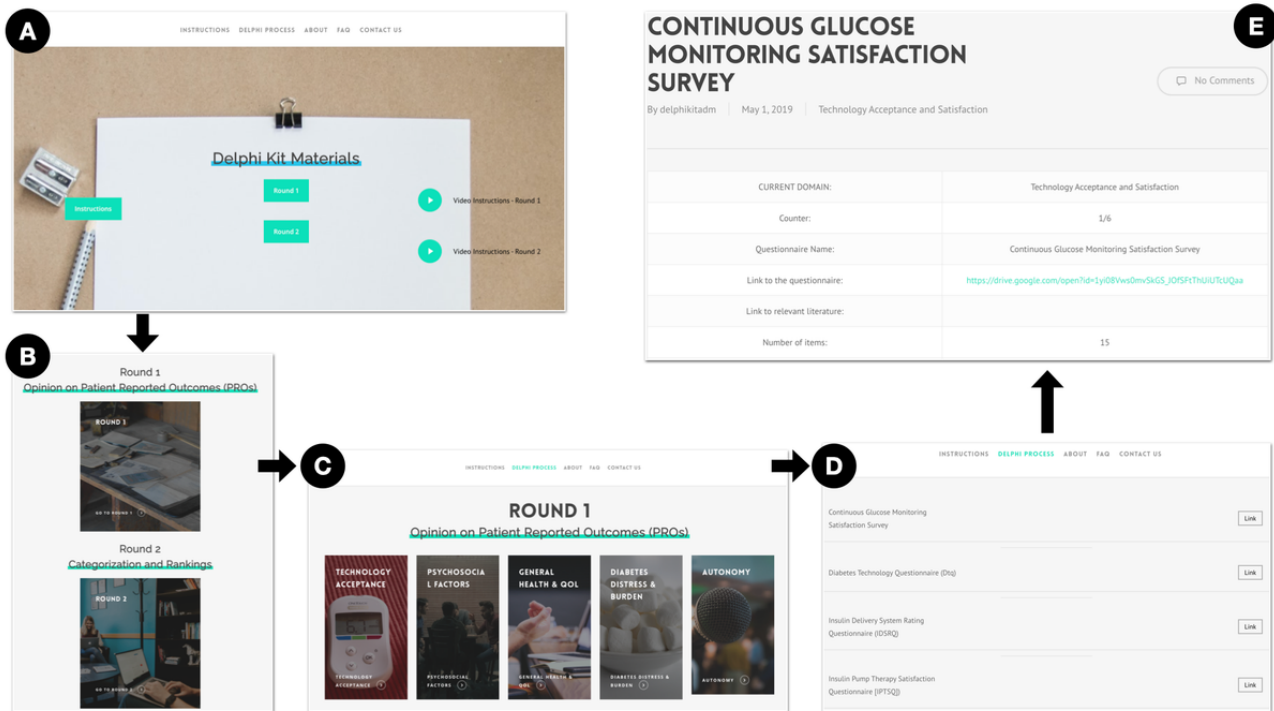
### Delphi Expert Panel Recruitment

Potential participants were identified by the study team using purposive sampling without quotas. Participants were eligible if they were directly involved in the care or support of pediatric patients with T1D using CGMs, including experienced clinicians, researchers, psychologists, health educators, and device developers. Participants were recruited by email invitation describing the aims of the study, purpose of the PROMs, study design, participation details, and anticipated time commitment. Snowball recruitment was used to identify additional participants beyond the first round of invitations.

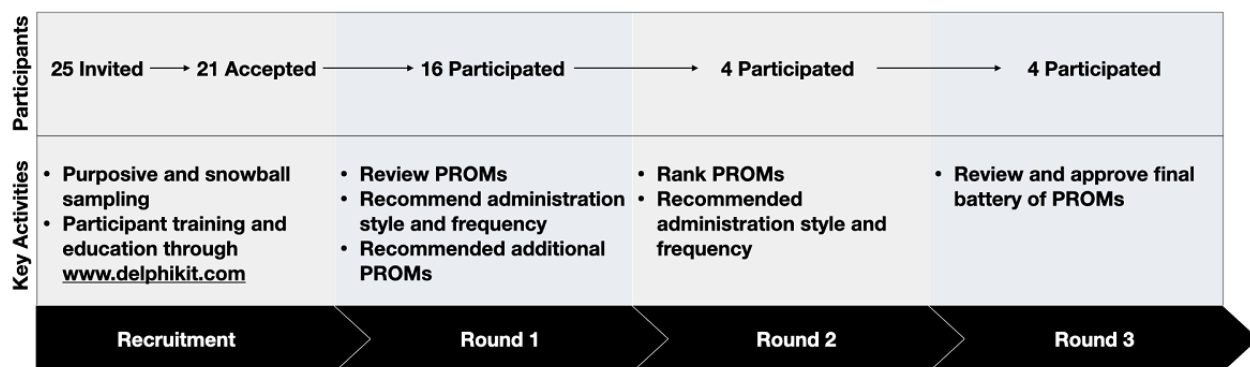
### e-Delphi Process

All parts of the e-Delphi process were conducted asynchronously and on the internet. The website and web-based data collection tools are hosted on the Delphi Kit website (Figure 1) [23]. Delphi panelists were sent instructions and a video explaining how to use the website. The e-Delphi process consisted of 3 rounds of feedback that needed to be provided on the internet (Figure 2). During each round, participants were given a 4-week period and reminders to nonresponders were sent weekly. Participants who failed to respond despite 3 email reminders were defined as withdrawals. Participants could also withdraw on their own request if they could not commit the time. Data collected up to that point was included for analysis. Demographics were collected from all Delphi participants.

**Figure 1.** Overview of the Delphi Kit website [23] used for organizing the Delphi process and collecting data. The website included multiple pages encompassing information on the Delphi process, description of the study, instructions for participants, survey pages, and the first 2 rounds of the electronic Delphi process. (A) The home page, (B) the Delphi process page, (C) the round 1 page, (D) the technology acceptance domain page, and (E) the Continuous Glucose Monitoring Satisfaction Survey page.



**Figure 2.** Key activities and engagement of participants across each stage of the electronic Delphi process. PROM: patient-reported outcome measure.



In the first round, the Delphi website included detailed information about each instrument with a description, number of items, link to the full text questionnaire, and references. Participants were shown all included PROMs and were asked to provide their opinion on each instrument, and if they had any experiences administering it in clinical or research settings. They were also asked if the instrument should be administered at a specific time or milestone during the study, or if it should be administered like an ecological momentary assessment—a brief, repeated instrument, typically triggered by a specific event, completed by the subject in their natural environment [24]. Finally, participants were asked to suggest other instruments not included in round 1. The research team reviewed and categorized the responses from round 1 and refined the list of PROMs for round 2. In round 2, participants were asked to rank the remaining instruments within each domain on the basis of multiple factors, including robustness of the research data obtained using the instrument, the importance or relevance of

the concept or phenomenon being addressed, feasibility of administering the instrument, and overall burden on patients and providers. They were also asked to suggest how often each instrument should be administered or if they should be administered after specific clinical events (hospitalization, emergency room visit, new prescription, etc). An open-ended question for general feedback was included as well. We reviewed all responses and further refined the list of PROMs for round 3. In round 3, the final list of PROMs along with their proposed administration frequency and timeline was sent to all reviewers for feedback. Instruments were evaluated on the basis of multiple factors, including the number of items, ease and time of completion, age range, parent versus self-report, and availability (ie, cost of proprietary instruments). The participants and the responses were anonymized to each other.

**Ethical Considerations**

This study is not considered human subjects research; therefore, no consent was obtained and no ethics approval was required.

**Results**

**e-Delphi Process and Results**

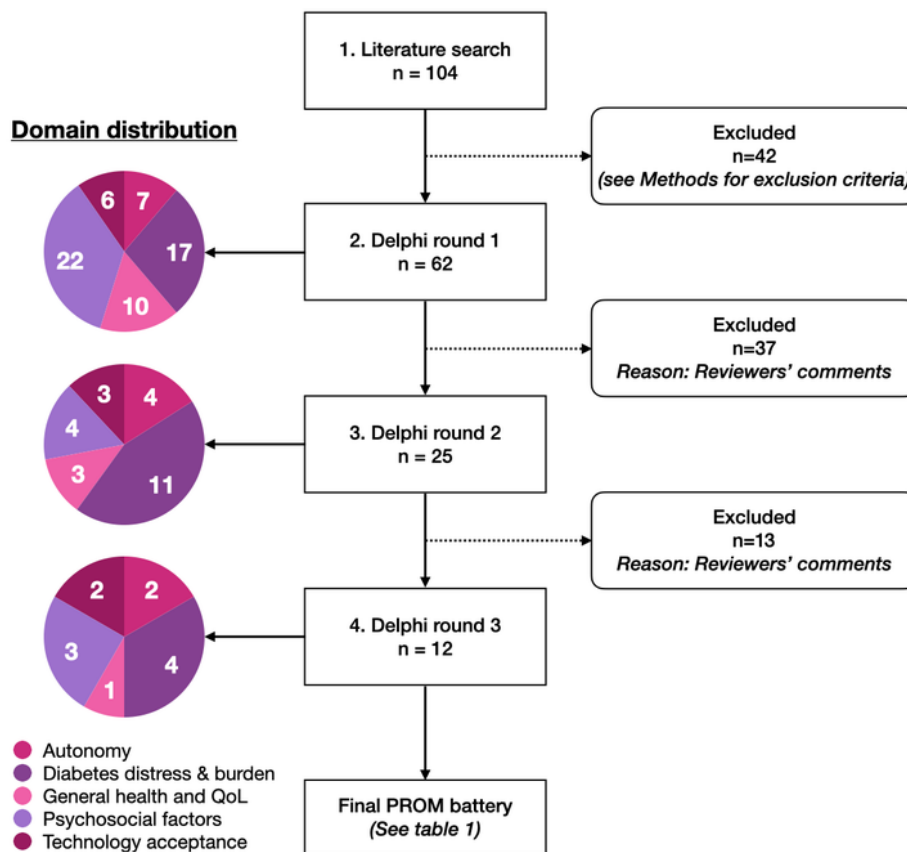
A total of 25 participants were invited to participate in the Delphi process, of whom 21 agreed to participate (Figure 2). There was participant attrition after each round; only 4 participants completed the third and final rounds. The core research team (JE, JR, and PS) reviewed and integrated all responses after each round.

**e-Delphi Process**

Our literature review identified a total of 104 relevant articles. After applying all of the exclusion criteria, 62 unique PROMs

were included in round 1. Figure 3 shows the flow of PROMs across rounds and how they are distributed across domains. In round 1, all participants reviewed the instruments and references. In total, 37 PROMs were excluded on the basis of feedback, primarily owing to lack of fit, unfamiliarity, being too lengthy, or being too difficult to administer in a real-world setting. The core research team reviewed all the feedback and identified 25 PROMs for round 2. During this round, participants were asked to rank the remaining PROMs. Based on these rankings, the core research team finalized a list of 12 instruments planned for the study. In round 3, the final list was shared with participants along with the planned administration frequency and modality (Table 1). All Delphi participants agreed with the proposed schema in round 3. A comprehensive list of all PROMs considered all 3 rounds, citations, and additional literature can be found on the Delphi Kit website.

**Figure 3.** Modified Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram describing the different rounds of the electronic Delphi process and the number of patient-reported outcome measures selected by domain distribution: autonomy, diabetes distress and burden, general health and quality of life, psychosocial factors, and technology acceptance. PROM: patient-reported outcome measure; QoL: quality of life.



**Table 1.** The final list of patient-reported outcome measures selected from the e-Delphi process for patients and families with type 1 diabetes using continuous glucose monitors.

Domain and instrument	Items, n	Age (years)	Scheduled
<b>Diabetes distress</b>			
<b>Problem Areas in Diabetes scale</b>			Annually, emergency department visit, and hospitalization
Child	20	8-11	
Youth	26	>12	
Parent	26	Not restricted	
Diabetes Distress Scale	17	>18	
<b>Hypoglycemia Fear Survey</b>			Hospitalization
Child	25	6-18	
Parent	28	Not restricted	
<b>Blood Glucose Monitoring Communication questionnaire</b>			Hospitalization and emergency department visit
Child	8	8-18	
Parent	8	Not restricted	
<b>Autonomy</b>			
Diabetes Knowledge Test	19	12-18	Baseline and transitional milestones
The Mercy What I Know About Diabetes	23	>18	
<b>General health and quality of life</b>			
<b>Type 1 Diabetes and Life measures</b>			Annually
Child	21	8-11	
Adolescent	23	12-17	
Parent	22	—	
<b>Psychosocial</b>			
Patient Health Questionnaire-9	9	>12	Annually
<b>Diabetes Family Responsibility Questionnaire</b>			Annually
Child	17	8-18	
Parent	17	Not restricted	
<b>Diabetes Strengths and Resilience Measure</b>			Annually
Child	12	9-12	
Adolescent	12	13-17	
Young adult	16	18-22	
<b>Technology acceptance</b>			
<b>Diabetes Technology Attitude</b>			Annually
Youth	5	>12	
Parent	5	Not restricted	
Glucose Monitoring Satisfaction Survey	15	>12	Baseline

The PedsQL 3.2 Diabetes module [25] was selected for inclusion in round 1, but reviewers reported concerns with validity, reliability, and length; hence, it was replaced by the Type 1 Diabetes and Life (T1DAL) measures [26] during round 2 on the suggestion of one of the Delphi participants and was approved by the other participants in round 3. One of the Delphi participants was a subject matter expert on adolescents with

diabetes and suggested during round 2 that the Problem Areas in Diabetes scale (PAID) was more geared toward the pediatric population and the Diabetes Distress Scale (DDS) is a more suitable instrument for adolescents. Therefore, we added the DDS for patients older than 18 years. The Diabetes Technology Attitude survey was selected over the FDA-recommended INSPIRE Questionnaires [11] because of the latter's focus on



AID systems. In total, 7 out of 12 instruments were selected to be administered annually. To minimize the burden on patients and parents and reduce survey fatigue, all instruments are staggered across quarters so that families complete no more than 3 surveys at a time. A brief description of each domain is presented here, and a detailed description of each of the 12 instruments is provided in [Multimedia Appendix 1](#).

### Diabetes Distress and Burden Domain

T1D can cause significant distress for patients and their families, particularly as it relates to diabetes regimen-specific duties including continuous glucose monitoring and adherence to meal, physical activity, and treatment management plans [27]. Social distress, diabetes-related fears, coping lifestyle, and financial burden also play a role in the overall psychosocial burden of diabetes. This distress and burden can manifest in the form of anger, guilt, frustration, denial, loneliness, and fear of hypoglycemia [28]. Thus, it can negatively affect the functioning, QoL, and ultimately glycemic control, leading to further deterioration of mental and physical health [29]. The purpose of this domain is to identify the emotional and psychosocial needs of patients and caregivers, create opportunities to discuss them with providers, and engage appropriate support mechanisms. Our Delphi panel selected 4 instruments, including the PAID [28,30], DDS [31], Hypoglycemia Fear Survey [32], and Blood Glucose Monitoring Communication questionnaire [33] to assess the distress in patients with T1D. The PAID will be administered annually to children (aged 8-12 years), youths (aged 12-17 years), and their parents. DDS will be administered annually to patients older than 18 years of age. The Hypoglycemia Fear Survey and Blood Glucose Monitoring Communication questionnaire will be triggered with events such as diabetes-related hospitalization or emergency department visits when patients may experience increased anxiety related to monitoring. Details regarding age validation and administration are described in [Table 1](#).

### Autonomy Domain

Effective diabetes self-management (DSM) can prevent or delay diabetes-related complications. Autonomous motivation is important in adopting and maintaining DSM practices that improve glycemic control [34,35]. DSM requires continual improvement of disease-related knowledge in patients as well as maintaining engagement, skills, and self-efficacy [36]. DSM was identified as the principal construct to assess for this domain. The Delphi panel chose the Diabetes Knowledge Test [37] for the 12-18-year age group and The Mercy What I Know About Diabetes [38] for patients older than 18 years. DSM behaviors and perceived autonomy can change over time and also depend on support from family and health care providers [34]. Therefore, the group decided to administer these instruments at baseline and transitional milestones.

### General Health and QoL Domain

T1D requires a daily execution of complex tasks owing to frequent glucose monitoring, insulin injection, dose adjustments, and carbohydrate estimation [39]. Long-term treatment management brings on physical and psychological hardship and impacts the QoL of individuals with T1D [40]. QoL-related

PROMs in this domain assess developmentally appropriate emotional, physical, and social well-being and treatment satisfaction, and can help clinicians provide early intervention and health education, and prevent disease-related complications. The group chose to administer the TIDAL measures [26,41] annually to assess QoL in all age groups.

### Psychosocial Domain

Depression and anxiety are much more common in children with T1D, which negatively impact social life and well-being [42]. The American Diabetes Association has published evidence-based guidelines to help providers implement psychosocial assessments into the care of patients with diabetes and their families [43]. Patient-centered psychosocial care requires interactive communications, problem identification, psychosocial screening, diagnostic evaluation, and cognitive, behavioral, and social intervention to optimize health outcomes [43,44]. Positive and supportive parenting styles have been shown to improve QoL in patients with T1D [45]. This domain includes instruments to assess both risk and protective factors, as well as family dynamics. Select instruments include the Patient Health Questionnaire-9 for patients older than 12 years [46], the Diabetes Family Responsibility Questionnaire for children aged 8-18 years and their parents [47,48], and the Diabetes Strengths and Resilience Measure for all age groups [49-51]. All instruments in this domain will be administered annually at different time points.

### Technology Acceptance Domain

This is a critical but often neglected domain of T1D management. Medical devices including CGMs and insulin pumps are critical components of T1D management. However, patients often reported the barriers when using these devices on a daily basis. The most common barriers are related to the physical experience of these devices, including the hassle of wearing them, not wanting to wear them, and not liking how devices look on their bodies [52]. Given the potential of CGMs to improve glycemic control, it is important to assess and address barriers to device uptake. The Delphi panel selected the Glucose Monitoring Satisfaction Survey [53] to be administered at baseline and the Diabetes Technology Attitude [52] annually among all parents and children aged 12 years and older. Of note, we did not identify any CGM-specific instruments.

## Discussion

### Principal Findings

Pediatric patients with T1D and their families face a lifetime of lifestyle and behavior modifications, medical therapies, and complex treatment regimen to prevent T1D complications and mortality [54]. CGM can make self-management and correction simpler [2], but many patients feel distress related to the multitude of self-care responsibilities to optimize glycemic control, resulting in low self-efficacy and reduced self-care [55]. PROMs can give providers a structured method to evaluate the burden on patients, the impact of technology, and opportunities to identify patients who may benefit from additional support. The intersection of technology, patient behaviors, and PROMs has seen increased attention, with large



national registries such as the BETTER Patient Engagement registry in Canada and the T1D Exchange registry in the United States, featuring these concepts prominently in their publications [56,57].

In 2017, the National Institute of Diabetes and Digestive and Kidney Diseases and the American Diabetes Association cosponsored a 2-day workshop to identify research priorities related to patient-reported outcomes for patients with diabetes and published their conclusions in 2019 [58]. The authors identified a number of themes relevant to pediatric diabetes, including shared disease management between parents and children, the transition to self-management as children age, the overall burden of disease with a focus on psychosocial impact, and the importance of including self-reported instruments, when possible, over parent proxy instruments. Another central theme identified in the paper was that it would be impossible to select a single approach to the development and selection of patient-reported outcomes for all uses; rather, it would be important to rely on contextual factors and to consider specific goals. We applied several of these themes to our own work, prioritizing self-reported outcomes over parent proxy when possible and ensuring that we included multiple options for assessing the psychosocial impact of T1D. The iterative comments from our Delphi participants also highlight the same point acknowledged by the workshop: there is no universal set of PROMs; rather, the specific goal and population should drive the selection of tools. Through this effort, because this study was undertaken as part of an FDA-funded real-world evidence demonstration project, we explicitly sought to identify a series of PROMs that could encompass the complex, holistic, and multifactorial perceptions of patients and families living with diabetes across a number of domains [59].

To our knowledge, this is the first attempt to leverage a systematic process to generate a list of PROMs specifically for pediatric patients with T1D using CGMs. In 2009, the Patient-Reported Outcome Measurement Group of the University of Oxford Department of Health published a structured review of PROMs for diabetes [10]. This review did not focus on pediatric patients or CGM users, but it identified 9 PROMs that could be used in pediatric patients with diabetes (4 generic and 5 diabetes-specific). While many of these instruments were included in round 1 in this study, none of them were present in our final list. This may be in part owing to the 10-year gap between the 2 projects and the development of new tools in the interim, such as the T1DAL. The National Institutes of Health also organized a group discussion of psychology experts to recommend a list of PROMs for T1D across all age groups for internal use (unpublished, personal correspondence). They organized 20 diabetes-specific and 15 “other relevant” instruments into 4 domains: diabetes distress and burden, psychosocial attitudes toward automated insulin delivery, hypoglycemia (worries, Fear, behavior, and confidence), and technology acceptance and satisfaction. Overall, 5 out of 12 of our final instruments were also featured on their list.

There were a number of strengths to our approach. This was an asynchronous and digital process where we involved a large variety of stakeholders from different fields. The decision process was transparent, technologically sophisticated, and very

well documented. Of note, we conducted our asynchronous digital process prior to the COVID-19 pandemic, which, in many ways, prepared us for some of the unique workflow adaptations that we undertook after March 2020. All of the final instruments included in this study have been used in research settings, some having been used quite extensively. Ultimately, we prioritized instruments that were relatively short, easy to administer electronically, and those that address tangible clinical concepts so that the battery of surveys could be useful to clinicians and researchers focused on clinical, translational, and implementation research. [Multimedia Appendix 1](#) provides descriptions of each instrument and a summary of the underlying evidence to support clinicians and researchers interested in implementing PROMs in their practice. One strength of the Delphi process is that the responses are weighted equally, providing controlled feedback on group opinions and reducing subjective bias.

### Limitations

There were also several limitations to our study. The Delphi process can be quite time-consuming and laborious for participants. Participant attrition in our own study was quite high; only 1 in 5 participants made it to the final round. The final 4 participants were 2 pediatric endocrinologists and 2 pediatric psychologists specializing in the care of children and adolescents with T1D. This group was reasonably representative of the initial panel of participants, although notably lacking dietitians and industry representatives. Though we did not formally collect data on why participants did not complete the process, anecdotally, many of them cited that the project was time-consuming. In the future, it would be important to address engagement and retention through decreased time burden and increased engagement and compensation. Many participants reported not being familiar with the included instruments prior to the Delphi process; however, given their expertise in the field, we believe that their recommendations are still valid and helpful. Our study was specifically focused on pediatric patients with T1D using CGMs; hence, our findings may not be generalizable to other populations, such as adults with T1D or children with type 2 diabetes or to explore outcomes for patients with insulin pumps or automated insulin dosing systems. Lastly, identifying PROMs is only the beginning of this process; patients and providers will need training and education on the importance and role of PROMs and how to administer and complete the instruments, interpret the instruments, and incorporate them into interactional decision-making with patients and families. It should be noted that patients or patient representatives did not participate in this Delphi process, although patients were involved in the development of many of the instruments selected for this study. This decision was made on the basis of the need for Delphi participants to have extensive subject matter expertise in research methods and experience with reading and reviewing of medical literature to evaluate the PROMs. Our initial goal was to work with clinical and research experts to develop a curated library of PROMs that future studies could select from. These studies would then involve patients or a community advisory board in selecting the PROMs from the curated library, which are most appropriate for the population and the study aims. Our implementation strategy includes the administration

of these surveys at home, in the clinic, and shortly after hospitalization or emergency department visits using REDCap and obtaining feedback from the patients. We plan to administer all PROMs electronically along an adaptive schedule to minimize patient burden and refusal, similar to Corathers et al [4]. We have also developed capabilities to display REDCap PROM data in HealtheIntent alongside clinical data. The interactional dashboard that includes all of these sources will enable the visualization and analysis of individual patients as well as cohort-level data from medical records, devices, and patients.

## Conclusions

PROMs can provide critical insights into the psychosocial well-being of patients, and their role in both clinical care and

research is becoming more important. National registries, federal agencies, and philanthropic organizations have all placed increased focus on the use of PROMs to measure care quality and patient engagement in their care. This study is the first to provide guidance and resources for clinicians and researchers on selecting PROMs that are specific for CGM use among pediatric patients with T1D. Future studies will need to focus on refining and expanding this battery of instruments with additional concepts. The selection of specific PROMs from this list should be made in collaboration with patients and patient representatives to ensure that they are fit for purpose and appropriate for the population of interest.

## Acknowledgments

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## Authors' Contributions

PS designed the study, performed data collection and review, and drafted the manuscript. JKR designed the study, reviewed the instruments, and edited the manuscript. JE conceived the study, designed and supervised the study, and drafted the manuscript. The study was presented at American Academy of Pediatrics (AAP) Meeting in October 2021: Payal Shah, Jennifer K Raymond and Juan Espinoza. Modified E-delphi Process for Selection of Patient-reported Outcomes (PRO) for Children and Young Adults with type-1 Diabetes and Their Families. Session: Section on Advances in Therapeutics and Technology Program. Presented at AAP, October 8-11, 2021.

## Conflicts of Interest

JE is a paid consultant at AI Health. AI Health played no role in the design, execution, analysis, or write-up of this work. AI Health did not play a role in the decision to publish this manuscript and had no editorial input.

## Multimedia Appendix 1

A brief description of the final patient-reported outcome measures selected from the e-Delphi process for patients and families with type 1 diabetes using continuous glucose monitors.

[DOCX File, 18 KB - [diabetes\\_v7i4e38660\\_app1.docx](#) ]

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## Abbreviations

**AID:** automated insulin dosing

**CGM:** continuous glucose monitor

**DDS:** Diabetes Distress Scale

**DSM:** diabetes self-management

**e-Delphi:** electronic Delphi

**EHR:** electronic health record

**FDA:** Food and Drug Administration

**INSPIRE:** Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations

**PAID:** Problem Areas in Diabetes scale

**PROM:** patient-reported outcome measure

**QoL:** quality of life

**T1D:** type 1 diabetes

**T1DAL:** Type 1 Diabetes and Life



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Review

# Smartphone Apps for Surveillance of Gestational Diabetes: Scoping Review

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## Abstract

**Background:** Developments and evolutions in the information and communication technology sector have provided a solid foundation for the emergence of mobile health (mHealth) in recent years. The cornerstone to management of gestational diabetes mellitus (GDM) is the self-management of glycemic indices, dietary intake, and lifestyle adaptations. Given this, it is readily adaptable to incorporation of remote monitoring strategies involving mHealth solutions.

**Objective:** We sought to examine and assess the available smartphone apps which enable self-monitoring and remote surveillance of GDM with a particular emphasis on the generation of individualized patient feedback.

**Methods:** Five databases were searched systematically for any studies evaluating mHealth-supported smartphone solutions for GDM management from study inception until January 2022. The studies were screened and assessed for eligibility of inclusion by 2 independent reviewers. Ultimately, 17 studies were included involving 1871 patients across 11 different countries. The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) conceptual framework was adhered to for data extraction and categorization purposes.

**Results:** All studies analyzed as part of this review facilitated direct uploading of data from the handheld glucometer to the downloaded patient-facing smartphone app. Glycemic data were captured by all studies and were reassuringly found to be either improved or noninferior to extant models of hospital-based care. Feedback was delivered in either an automated fashion through in-app communication from the health care team or facilitated through bidirectional communication with the app and hospital portal. Although resource utilization and cost-effective analyses were reported in some studies, the results were disparate and require more robust analysis. Where patient and staff satisfaction levels were evaluated, the response was overwhelmingly positive for mHealth smartphone-delivered care strategies. Emergency cesarean section rates were reduced; however, elective cesarean sections were comparatively increased among studies where the mode of delivery was assessed. Most reviewed studies did not identify any differences in maternal, perinatal, or neonatal health when app-based care was compared with usual in-person review.

**Conclusions:** This comprehensive scoping review highlights the feasibility, reliability, and acceptability of app-assisted health care for the management of GDM. Although further exploration of the economic benefit is required prior to implementation in a real-world clinical setting, the prospect of smartphone-assisted health care for GDM is hugely promising

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**KEYWORDS**

gestational diabetes; digital health; mHealth; telemedicine; diabetes; apps; smartphone; remote feedback

## Introduction

Positive exploitation of the exponential growth and development seen in the information and communication technology (ICT) sector in the last decade has provided novel solutions to operational challenges such as overcrowding and staff shortages within the health care arena. Telemedicine has emerged as one such advancement and has seen rapid diffusion for the management of chronic diseases in particular. Diabetes is one such condition that has proven to be readily adaptable to self-management and remote monitoring.

Mobile health (mHealth) is a facet of telemedicine focusing on the use of mobile phone technology to facilitate exchange of health information between the patient and the caregiver. Increasingly, apps downloaded by the patient-user to personal handheld smart devices, such as phones or tablets, are used as data-capturing tools, conduits to share and exchange health information, and repositories of disease-specific information and education [1]. There are an estimated 3.8 million smartphone users in Ireland, representing an increase of 16.8% since 2018. Smartphone penetration rates Europewide reflect this trend, with projected ownership rates of 87%, 92%, and 94% by 2025 in France, Germany, and the United Kingdom, respectively [2].

This review sought to evaluate the smartphone apps that have been developed for gestational diabetes mellitus (GDM) to promote patient-centered care through the surveillance of markers of glycemic control, such as blood glucose levels, diet, exercise, and weight management. mHealth promotes a precision medicine model of care by maintaining channels of communication between patients and their health care professional while focusing the onus of disease management on the patients themselves. Such responsibility has been shown to foster improved patient compliance and satisfaction levels and represents an exciting new chapter in GDM care [3]. Demonstration of improved glycemic control has been shown from use of smartphone app-based interventions for adults with type 2 diabetes mellitus [4]. Treatment strategies for GDM and type 2 diabetes mellitus are similar, encompassing medical nutrition therapy, lifestyle modifications, and self-assessment

of daily blood glucose levels, such that the patient with GDM is perfectly poised to benefit from app-assisted care.

Previous reviews have examined mHealth in the context of all types of diabetes rather than a specific focus on GDM [5]. Leblalta et al [6] addressed all digital health interventions available to support women with GDM, including models of web-based care that have arguably become outdated. We sought to refine this existing knowledge by exploring further and assessing the surveillance strategies and capabilities afforded by smartphone apps for women with GDM.

## Methods

### Search Strategy

A comprehensive literature search was conducted following consultation with a reference librarian. With the aim of evaluating smartphone apps used for the surveillance of GDM, we reviewed the following medical databases: PubMed, Embase, CINAHL, Web of Science, and the Cochrane library. All peer-reviewed literature in the English language and published between January 1990 and January 2022 was searched. Prior to 1990, the mobile phone was far more primitive and not capable of the technological features this review aimed to assess. The incorporation of ICT into health care management represented an area of rapid development during this time, with telemedicine emerging as a potentially feasible pathway for management of chronic diseases in 1990 [7]. Inclusion and exclusion criteria for this scoping review are presented in [Table 1](#) using the population-concept-context framework recommended by the Joanna Briggs Institute (JBI) methodology for scoping reviews. We also considered the PICO (patient/population, intervention, comparison, and outcomes) framework for systematic reviews in establishing our research question ([Table 2](#)). Medical subject headings were used where possible in our database searches. "Gestational Diabetes" was used in combination with each of the search terms outlined in [Multimedia Appendix 1](#). The JBI reviewers manual was adhered to in the development of our scoping review protocol, which is available on request from the corresponding author (SS).

**Table 1.** Inclusion and exclusion criteria following the population-concept-context criteria recommended by the Joanna Briggs Institute.

	Inclusion criteria	Exclusion criteria
Population	GDM <sup>a</sup>	Type 1 diabetes mellitus, type 2 diabetes mellitus
Concept	Smartphone apps associated with a hospital-based clinical portal facilitating remote monitoring	Smartphone apps for personal surveillance of GDM but with no oversight from the obstetric diabetes team through a hospital clinical portal
Context	Surveillance of at least 1 element of GDM care (glycemic indices, diet, exercise, weight, blood pressure)	Surveillance of additional parameters not primarily involved in GDM care (eg, psychological assessment, remote management of a separate obstetric condition)

<sup>a</sup>GDM: gestational diabetes mellitus.

**Table 2.** Characteristics of studies evaluating smartphone app–assisted care for GDM and the provision of remote feedback.

Article information	Type of trial	Participants, n	GDM <sup>a</sup> diagnosis	Glycemic targets	Self-monitoring schedule	Details of smartphone app–assisted technology
Calle-Pascual et al, Spain (2010) [8]	Prospective randomized interventional study	100	Carpenter Couston criteria; <28 weeks' gestation	Fasting <95 mg/dl; 1-h postprandial <120 mg/dl	6× a day	Infrared enabled transfer of SMBG <sup>b</sup> from glucometer to smartphone app (preinstalled), with captured data then transferred to a central hospital database (Eminens Conecta Plus Web Application); bidirectional communication between patient and HCP <sup>c</sup>
MacKillop et al, UK (2018) [9]	Randomized controlled trial	206	Fasting >5.6 mmol/l; postprandial >7.8 mmol/l <35 weeks' gestation	Fasting <5.3 mmol/l; 1-h postprandial; 7.8 mmol/l; 2-h postprandial <6.4 mmol/l	6× a day, 3 days a week	Bluetooth-enabled transfer of SMBG from glucometer to smartphone app (GDm-Health), with captured data transferred to a secure website. Review of website 3 × a week by the specialist midwife; unidirectional communication of staff to patient only
Guo et al, China (2018) [10]	Randomized interventional study	124	IADPSG <sup>d</sup> criteria; 24-28 weeks' gestation	Unspecified	6× a day, 3 days a week reducing to 2 days a week if control demonstrated	Automatic data upload from glucometer to app (Dnurse); HCP review of uploaded data from app to doctor-facing version of Dnurse; HCP able to communicate with patient to adapt medical guidance; unidirectional communication of staff to patient only
Al-ofi et al, Saudi Arabia (2019) [11]	Randomized open-label control study	60	IADPSG criteria; 24-28 weeks' gestation	Fasting <5.1 mmol/l; postprandial <8.5 mmol/l	4× a day	Glucometer linked to smartphone app (Glucomail) enabling easy transfer of data to the app, with captured data then transferred to a secure hospital-based system; an immediate alert is generated to the HCP if above-threshold levels are recorded, allowing for further action to be taken; unidirectional communication of staff to patient only
Yew et al, Singapore (2021) [12]	Randomized controlled trial	340	WHO <sup>e</sup> 2013 criteria (endorsed IADPSG criteria); 12-30 weeks' gestation	Fasting <5.5 mmol/l; 2-h postprandial <6.6 mmol/l	7× a day, 2-3 times a week	Smartphone-based lifestyle coaching program associated with a secure web app (Habits-GDM); app-compatible glucometer to transfer SMBG values; bidirectional communication between patients and HCP
Borgen et al, Norway (2019) [13]	Randomized controlled trial	238	2-h OGTT <sup>f</sup> >9 mmol/l; <33 weeks' gestation	Unspecified	Unspecified	Bluetooth-enabled transfer of SMBG values from glucometer to app (Pregnant+); automated color-coded feedback in direct response to glycemic control; no in-app communication between patient and HCP
Sung et al, South Korea (2019) [14]	Randomized controlled trial	21	2-step approach IADPSG criteria or Carpenter Couston criteria; <30 weeks' gestation	Unspecified	4× a day	Bluetooth-enabled transfer of SMBG values from glucometer to smartphone app; automatic transfer of data by a wireless network captured in the app to a secure server; bidirectional communication between HCP and patient; HCP sends tailored medical and nutritional guidance from the server to the app
Miremberg et al, United States (2018) [15]	Randomized controlled trial	120	2-step process Carpenter Couston criteria; <34 weeks' gestation	Fasting <95 g/dL; 1-h postprandial <140 g/dL	4× a day	Delivery of personalized feedback from the HCP secure database to the patient's app (Glucose Buddy) regarding self-management, glycemic control, and follow-up scheduling; bidirectional communication between the HCP and the patient.

Article information	Type of trial	Participants, n	GDM <sup>a</sup> diagnosis	Glycemic targets	Self-monitoring schedule	Details of smartphone app-assisted technology
Poulter et al, Australia (2021) [16]	Intervention study	100	IADPSG criteria; 24-30 weeks' gestation	Fasting <5 mmol/l; postprandial <6.7 mmol/l	4× a day	Bluetooth-enabled glucometer to upload SMBG data to the app (NET Health) which are automatically sent to a secure central server, with the software server automatically flagging the above-threshold glycemic values; unidirectional communication of the HCP to patients through the in-app interface
Rigla et al, Spain (2018) [17]	Pilot study	20	NDDG <sup>g</sup> criteria; <34 weeks' gestation	Unspecified	4× a day	Bluetooth-enabled glucometer facilitating transfer of SMBG to the app (MobiGuide) with subsequent transfer of the data to a specifically designed decision support software, with the HCP using a web-based app to visualize all the patient data; no feedback between staff and patients through the app/server system
Varnfield et al, Australia (2021) [18]	Feasibility study	40	IADPSG criteria; 24-28 weeks' gestation; (if RF <sup>h</sup> at earlier OGTT in T1, with repeat at 24-28 weeks if normal)	Fasting <5 mmol/l; - h postprandial <7.4 mmol/l; 2-h postprandial <6.7 mmol/l	4× a day	Bluetooth enabled glucometer facilitating transfer of SMBG values to the app (MoTHER); automatic transmission of app data to the clinician web portal which is reviewed weekly by the HCP; no in-app communication between HCP and patients
Khalil et al, France (2019) [19]	Qualitative study	15	Unspecified	Unspecified	6× a day reducing to 3 × a day if stable BGL <sup>i</sup>	Bluetooth-enabled glucometer to facilitate transfer of SMBG to the app (MyDiabby); color-coded (green, orange, red) automated feedback reflecting glycemic control and customized alert system at the server/HCP end of the solution; bidirectional communication between HCP and patients
Moazen et al, Austria (2021) [20]	Pilot study	27	Unspecified	Unspecified	4× a day	Bluetooth-enabled glucometer to facilitate transfer of SMBG to the app (DiabCare); data are transferred from the app to an online data management system accessible by the health care team; bidirectional communication between HCP and patients.
Seo et al, South Korea (2020) [21]	Case series study	4	Diagnosed following OGTT at 24-28 weeks' gestation	Unspecified	Unspecified	Bluetooth-enabled glucometer to facilitate transfer of SMBG to the app; transfer of data captured by the app via wireless network to the study server; personalized and automated feedback; bidirectional communication between HCP and patients
Wickramasinghe et al, Australia (2019) [22]	Randomized crossover study	10	Diagnosed following OGTT at 26-28 weeks' gestation	Unspecified	4× a day	Bluetooth-enabled glucometer to facilitate transfer of SMBG to the app (Diamond solution); data captured by the app are reviewed on a secure platform by the HCP who responds to the patient with recommendations; unidirectional communication of the HCP to patient through the in-app interface
Yang et al, China (2018) [23]	Pilot intervention study	157	WHO 2013 criteria (endorsed IADPSG criteria)	Fasting <5.3 mmol/l; 1-h postprandial <7.8 mmol/l; 2-h postprandial <6.7 mmol/l	10× a day	Smartphone app using a WeChat system to which blood glucose, blood pressure, and weight are uploaded; data are subsequently uploaded to a cloud platform and are evaluated by the HCP through the HCP's own WeChat interface; unidirectional communication of HCP to patient through the WeChat system



Article information	Type of trial	Participants, n	GDM <sup>a</sup> diagnosis	Glycemic targets	Self-monitoring schedule	Details of smartphone app-assisted technology
Tian et al, China (2020) [24]	Randomized controlled trial	309	IADPSG criteria; <31 weeks' gestation	Fasting <5.3 mmol/l; 1-h post-prandial <7.8 mmol/l; 2-h post-prandial <6.7 mmol/l	5× a day for 6 days in a 2-week block	Smartphone app using a WeChat system to which blood glucose, diet, exercise and weight are uploaded; unidirectional communication of HCP to patient only; peer-to-peer communication

<sup>a</sup>GDM: gestational diabetes mellitus.

<sup>b</sup>SMBG: self-monitored blood glucose

<sup>c</sup>HCP: health care provider.

<sup>d</sup>IADPSG: International Association of Diabetes in Pregnancy Study Group.

<sup>e</sup>WHO: World Health Organization.

<sup>f</sup>OGTT: oral glucose tolerance test.

<sup>g</sup>NDDG: National Diabetes Data Group.

<sup>h</sup>RF: risk factors.

<sup>i</sup>BGL: blood glucose level.

## Outcome Measures

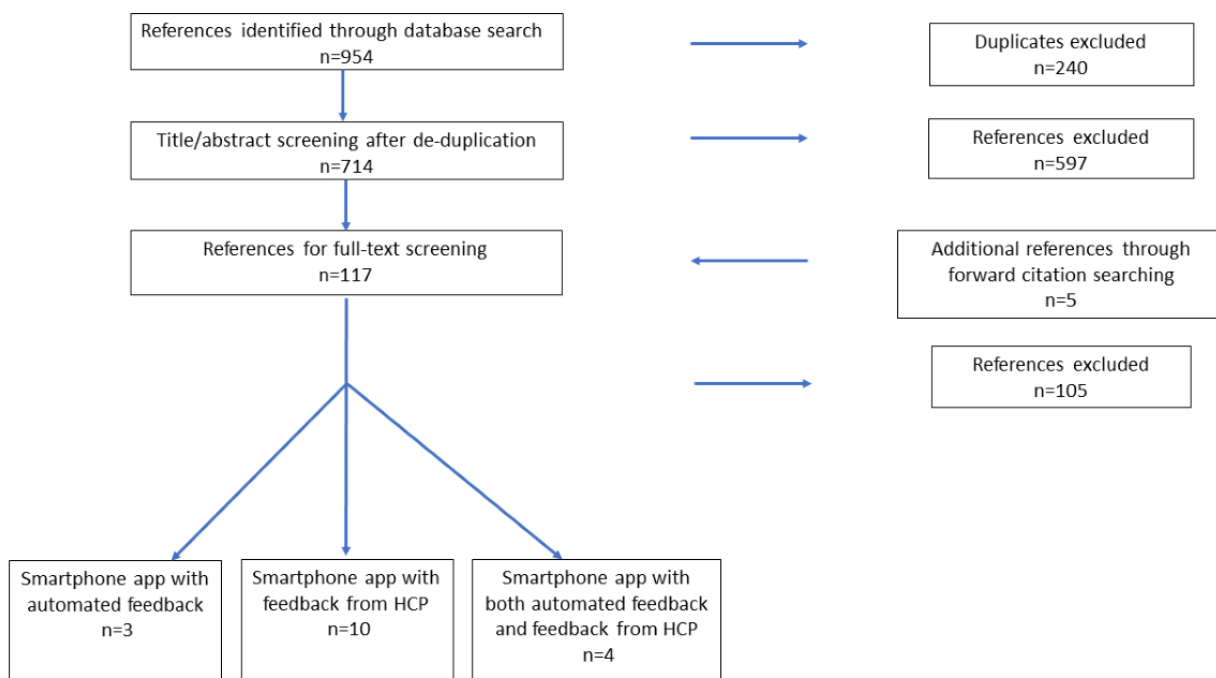
The primary outcome of this review was assessment and achievement of glycemic control following adoption of app-assisted health care delivery focusing on personalized or automated feedback of at least 1 component of standard GDM surveillance. Secondary outcome measures included patient and staff satisfaction levels and the cost-effectiveness of app-based interventions.

## Screening

Guidelines from the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for

Scoping Reviews) were adhered to during the literature search and screening process [25]. Retrieval of titles from database searching as described in the previous section was performed independently by 2 authors (SS and EC). These same 2 authors independently screened the titles and abstracts generated by the search to assess fulfilment of the study inclusion criteria. Relevant studies meeting the inclusion criteria were selected for review in this study. A third reviewer (FB) was available to oversee discussions pertaining to discrepancies which were solved by consensus opinion. The initial search strategy yielded 954 articles which were subsequently refined such that 15 articles were included in the final review. A schematic representation of the screening process is depicted in Figure 1.

**Figure 1.** PRISMA flow diagram describing the systematic literature search for studies examining the effect of smartphone app-assisted care associated with remote feedback for GDM.



## Data Extraction

A data extraction form was developed to collate and record information from each article that would later inform data synthesis. Similar to the screening process described above, the PRISMA-ScR conceptual framework was employed to achieve extraction and categorization of data while subsequently facilitating inferences and conclusions to be drawn from it. The data extraction form was designed to capture the following three criteria: (1) publication characteristics, including authorship, study title, year of publication, journal of publication, and country of origin; (2) characteristics of the app-assisted care program and details of any remote monitoring systems; and (3) study outcomes, including achievement of glycemic control, staff and patient-user satisfaction, and cost-effectiveness.

The data extraction tool was sampled on a random subset of 3 papers and was later refined to ensure all desired elements were captured.

## Synthesis of Results

Following data extraction, a validation check was completed, after which the data from each article were summarized and presented in narrative fashion. Key characteristics of the smartphone app-assisted interventions were recorded along with outcome data, which were subcategorized as follows:

**Textbox 1.** Reasons for study exclusion following full-text review.

### Excluded studies following full-text review

- Phone use but not use of a smartphone app (n=18)
- Description of software development (n=18)
- Web-based interventions only (n=19)
- Smartphone apps that functioned as a repository only (n=6)
- Poster abstract only (n=4)
- Not assessing gestational diabetes mellitus (n=3)
- Secondary analyses (n=26)
- Inaccessible (n=8)

There were 17 studies included in this review, the characteristics of which are represented in [Table 2](#). The included studies were published between 2010 and 2022, with the majority (16/17, 94%) published during or since 2018. The studies were conducted across 11 countries, with 7 from Asia, 6 from Europe, 3 from Australia, and 1 from the United States. There were 10 randomized controlled trials (RCTs), 5 pilot intervention studies, 1 qualitative study, and 1 case series. The number of participants ranged from 4 participants in the case series to 340 in the largest of the RCTs (mean 111; median 100).

## Description of the Smartphone-Assisted Remote Monitoring Solutions for Surveillance of GDM

All included studies reported direct uploading of data from the glucometer to the smartphone app. Although one early study used infrared transfer of data, Bluetooth-enabled transfer of glycemic indices was the most common approach. All studies involved the use of a smartphone app. Study participants were provided with a smartphone on which the study app was

preinstalled in 2 studies, but in all other cases, the patient's personal smartphone was used. Pervasive management solutions compatible with several operating systems, such as Android and iOS, were used in 13 studies [[10-16,18-20,22-24](#)].

The aim of this scoping review was to give a transparent, systematic overview of existing remote management strategies involving smartphone app-assisted care for GDM management. As such, neither methodological quality nor risk of bias was critically appraised as part of the review.

## Results

The electronic database search yielded 954 results. Subsequent removal of duplicates resulted in 714 articles for title and abstract screening. A further 597 references were then excluded, as they did not meet the inclusion criteria. The remaining 117 articles were subject to full-text screening. An additional 5 studies obtained following forward citation searching were also screened by full-text review. This process resulted in the exclusion of 105 articles. Excluded studies included those describing the use of mobile phone technology without specific use of a smartphone app, descriptions of software and technological architecture development, and studies relating solely to web-based interventions ([Textbox 1](#)). Ultimately, 17 articles were included in the final review.

The most commonly captured variable in the smartphone apps was glycemic data, which all 17 described app-assisted care programs had the capability of performing. Other tracked variables included dietary and lifestyle information, weight, medication dosing, blood pressure, ketonuria, and heart rate.

Automatic transfer of data captured in the app was sent to a secure hospital-based server through a wireless network in 14 of the reviewed studies. Of the remainder, 2 studies used the WeChat app to allow cloud storage of patient data only accessible to the research team [[23,24](#)]. One app-assisted care pathway was not linked with a hospital-based server and thus did not have real-time remote monitoring capabilities [[13](#)].

## Description of Personalized Health Care Provider–Delivered Feedback

Bidirectional communication of data, questions, and advice was available between patients and their obstetric diabetes teams in 8 of the reviewed smartphone app–linked telemedicine systems [8,12,14,15,19–21,24]. A further 6 of the reviewed studies demonstrated the capability of in-app communication delivered from a member of the health care delivery team to the patient [9–11,16,22,23]. The 3 remaining studies provided automated feedback to the patient [13,17,18].

## Description of Automated Feedback and Messaging

The generation of automatic feedback by the server to the app in specific response to uploaded patient data was noted in 4 studies [10,13,17,19]. In 2 studies, this feedback was represented pictorially in a color-coded traffic light system, with green icons signifying a normal result and red icons signifying an above-threshold glucose result [13,19]. A patient-facing alert in the form of a pop-up message was generated in the setting of above-threshold readings in the other 2 studies [10,17]. Patients were prompted and directed toward a questionnaire link for completion to elaborate on potential causative lifestyle factors.

A further 4 studies issued in-app educational information and motivational pop-up messages. Although these were not specifically tailored to a woman's uploaded app data, they served to reinforce the monitoring strategies for GDM and highlight the importance of achievement of appropriate glycemic control [11,14,18,21]. One study reported the generation of in-app prompts reminding participants to capture a 7-point capillary glucose profile on any 2 days of the week [12].

## Outcomes

### Glycemic Indices

Glycemic indices were the most commonly reported upon clinical outcome data. Improved management of glycemic indices by app users was demonstrated in 9 studies [10–12,15,20–24], while noninferior glycemic control, manifested by self-monitored finger prick blood indices or hemoglobin A1C, was noted in a further 2 studies [8,9]. Moreover, 2 studies assessed app-assisted care based on postnatal assessment of glycemic control [13,14]. Although lower rates of insulin resistance were demonstrated by one of these studies, this did not reach statistical significance. The second study assessing a 2-hour postnatal oral glucose tolerance test did not report any significant difference when compared with the control group.

### Resource Utilization and Cost Analysis

Resource utilization was reported in 4 studies, the majority of which (n=3) reported a reduction in unscheduled hospital attendances by app-using participants [8,10,16]. One study reported the converse, with an increased number of low-utility clinic visits when an app-assisted pathway of care for GDM was compared with a historical control [18]. The authors surmised that this might be explained by an increased level of self-monitoring prompting patients with above-threshold readings to present for review. Cost-effectiveness of smartphone

app–assisted care delivery was considered in 2 studies [9]. No significant cost saving was demonstrated in the economic analysis of one study, whereas the other study reported a cost saving of Aus \$23 (US \$15.32) per patient reflected by 37 minutes of total clinician time saved in the app-using group compared with the control group.

### Satisfaction With Smartphone App–Assisted Care

Patient satisfaction was explored in 6 of the studies [9,16–19,22]. A further 2 studies reported increased compliance levels with self-monitoring schedules, and satisfaction could be inferred from such usage behavior [10,15]. Staff satisfaction with this remote model of care provision was evaluated in 3 studies, and all were overwhelmingly in favor of the transition [18,19,22].

### Maternal, Perinatal, and Neonatal Outcomes

Data pertaining to maternal, perinatal and neonatal outcomes were reported in 11 of the 17 (65%) reviewed studies [8–13,15–17,23,26]. One RCT found that women in the app-assisted care delivery group had fewer cesarean sections than did the comparator group ( $P=.005$ ) [9]. In another study which reported no difference in mode of delivery between an app-using group and a historical control cohort, the authors did note fewer emergencies but a greater number of elective cesarean sections among the app-using women [18]. An increase in elective cesarean sections was similarly noted in another study, and this was associated with a  $P$  value of  $<.05$  [23]. Two studies reported reduced weight gain while another study reported reduced blood pressure in their respective intervention groups [10,11,17]. No differences in maternal or perinatal outcomes were demonstrated across the other studies. The results of the majority of studies looking at neonatal outcomes were noninferior for app use compared with standard care, but one study did demonstrate fewer composite adverse neonatal outcomes among app-using participants ( $P=.006$ ) [12].

## Discussion

This scoping review provides a comprehensive overview of the availability and functionality of smartphone apps capable of the generating remote feedback in the surveillance of women with GDM. We have noted that app-assisted care is noninferior to standard clinic-based care in terms of glycemic treatment targets, and in fact, half the reviewed studies identified an improvement in overall glycemic control [10–12,15,20–24]. Such evidence demonstrates the feasibility of adopting app-assisted health care for GDM.

If the adoption and diffusion of app-assisted platforms as a viable aspect of surveillance are to be successful, patient and staff satisfaction and acceptability levels must be high. Continued use of novel solutions in health care management, such as smartphone apps, requires accessible, easily interpretable, and aesthetically pleasing interfaces. Additionally, behavioral intention has been highlighted as a significant determinant of ongoing health technology use and engagement by the patient [27]. Other factors that should be taken into consideration in the development and dissemination stage of artificial intelligence–assisted technologies are personal innovativeness or the willingness to engage in a new health

solution as well as performance and effort expectancy [27-29]. In this review, we have shown that over half of the reviewed studies (10/17, 58 %) did not seek to assess patient or staff satisfaction levels, although we acknowledge that secondary analyses might have explored these themes. Three studies did assess patient compliance with the mandated monitoring schedule and thus satisfaction can be inferred, although not proven, from continued usage behavior in these studies [10,15,24]. Where satisfaction was assessed, all studies reported positive experiential expressions from the app-using groups [9,16-19,22]. Such expressions included reassurance that blood glucose levels were being reviewed frequently, and often in real time, by the obstetric diabetes team and feelings of self-efficacy, autonomy, and convenience. Satisfaction among staff users of the app-linked technologies was only assessed in 3 studies. Effective and time-efficient management was the most commonly identified theme. Ensuring collaboration and endorsement between all stakeholders in a novel ICT-based health intervention is crucial to its success. Cognitive trust has been found to be an impacting factor on the behavioral intentions of physicians' use and endorsement of app-assisted health care [30]. Robust RCTs prior to mass product circulation will contribute to allaying trust concerns with the technology.

The impact of resource utilization and economic benefit have been promoted as hugely beneficial effects of telemedicine, and by extension, so have mHealth management strategies [31,32]. These themes were only explored in 5 of the studies [8-10,16,18]. A statistically significant reduction in resource use by app-using women was noted by one study, and this reduction resulted in an overall cost saving for the hospital [16]. An analysis by another study, however, did not report significant cost savings [9]. Finally, one study reported an increase in the number of low-utility clinic visits among app users compared with a historical control group [18]. This may be a result of increased compliance with self-monitoring leading to a greater numbers of hyperglycemic episodes that need to be evaluated. This particular study did not offer feedback relating to uploaded glycemic indices or lifestyle patterns, and addition of these capabilities to the app technology would likely have an impact on requirement for in-person hospital review. Such

considerations should be given due attention during early iterations of the app development phase.

The evidence collated in this review demonstrates achievement of equivalent or improved glycemic control, confirms noninferior maternal and neonatal outcomes, and highlights the potential for reduced resource utilization and economic efficiency among women availing of app-assisted health care delivery for GDM. The transition towards incorporation of mHealth technologies such as smartphone apps has been welcomed by women with GDM who have shown high levels of satisfaction with a self-monitored remote management strategy. Key to the success of such smartphone apps is the maintenance of communication between the patient and her obstetric diabetes team. To optimize this alliance, a bidirectional communication strategy, as described in 8 of the studies in this review, would likely help to obviate the requirement for many women with well-controlled GDM to attend the hospital for in-person review without impacting on their sense of team involvement or hospital oversight. The resource implications of such a strategy are not limited to the hospital infrastructure alone, with benefits envisaged for the patient through the potential avoidance of financial and time constraints associated with frequent hospital attendances.

Given the rapid expansion of the telehealth sector, this review of app-assisted health care facilitating remote feedback in the setting of GDM is timely and judicious. However, to allow for comprehensive knowledge acquisition of the potential benefits and drawbacks of telemedicine and mHealth management of GDM, further research is still required. For instance, only 1 study in this review adapted a smartphone app for a culturally diverse audience [13]. In an era of great ethnic diversity within populations, absence of such a feature could be an exclusory factor. Further, patients who are willing to partake in research studies are more likely to be health and eHealth literate which may introduce bias into the study cohorts. Finally, the impact of app-assisted health care and remote surveillance needs robust health economic assessments to enable the refinement of existing technology such that app-assisted systems can viably become integrated into routine medical practice.

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## Conflicts of Interest

None declared.

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Multimedia Appendix 1

Search terms.

[DOCX File, 42 KB - [diabetes\\_v7i4e38910\\_app1.docx](#) ]

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## Abbreviations

**GDM:** gestational diabetes mellitus

**ICT:** information and communication technology

**JBI:** Joanna Briggs Institute

**mHealth:** mobile health

**PICO:** patient/population, intervention, comparison, and outcomes

**PRISMA-ScR:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

**RCT:** randomized controlled trial

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