JMIR Diabetes

Contents

Original Papers

Original Paper

The Effect of a Cellular-Enabled Glucose Meter on Glucose Control for Patients With Diabetes: Prospective Pre-Post Study

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This is a corrected version. See correction statement: https://diabetes.jmir.org/2020/3/e21993/

Abstract

Background: Diabetes is a global epidemic affecting approximately 30 million people in the United States. The World Health Organization recommends using technology and telecommunications to improve health care delivery and disease management. The Livongo for Diabetes Program offers a remote monitoring technology with Certified Diabetes Educator outreach.

Objective: The purpose of this study was to examine health outcomes measured by changes in HbA_{1c}, in time in target blood glucose range, and in depression symptoms for patients enrolled in a remote digital diabetes management program in a Diabetes Center of Excellence setting.

Methods: The impact of the Livongo for Diabetes program on hemoglobin A_{1c} (HbA_{1c}), blood glucose ranges, and depression screening survey results (Patient Health Questionnaire-2 [PHQ-2]) were assessed over 12 months in a prospective cohort recruited from the University of South Florida Health Diabetes Home for Healthy Living. Any patient ≥18 years old with a diagnosis of diabetes was approached for voluntary inclusion into the program. The analysis was a pre-post design for those members enrolled in the study. Data was collected at outpatient clinic visits and remotely through the Livongo glucose meter.

Results: A total of 86 adults were enrolled into the Livongo for Diabetes program, with 49% (42/86) female, an average age of 50 (SD 15) years, 56% (48/86) with type 2 diabetes mellitus, and 69% (59/86) with insulin use. The mean HbA_{1c} drop amongst the group was 0.66% (P=.17), with all participants showing a decline in HbA_{1c} at 12 months. A 17% decrease of blood glucose checks <70 mg/dL occurred concurrently. Participants with type 2 diabetes not using insulin had blood glucose values within target range (70-180 mg/dL) 89% of the time. Participants with type 2 diabetes using insulin were in target range 68% of the time, and type 1 diabetes 58% of the time. Average PHQ-2 scores decreased by 0.56 points during the study period.

Conclusions: Participants provided with a cellular-enabled blood glucose meter with real-time feedback and access to coaching from a certified diabetes educator in an outpatient clinical setting experienced improved mean glucose values and fewer episodes of hypoglycemia relative to the start of the program.

KEYWORDS

diabetes; blood glucose; blood glucose meter

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Introduction

Diabetes mellitus is now considered an epidemic, as global prevalence approaches 500 million people with the disease [1]. Approximately 30 million people have diabetes in the United States, and 84 million are at a high risk of developing the disease within 5 years [2]. Poor control of diabetes is shown to be related to a lack of knowledge around blood glucose (BG) monitoring, proper nutrition, and medication self-management [3]. A lack of consistent access to educational resources and episodic communication with providers may be responsible for poor outcomes in daily self-management [4,5].

In an effort to improve diabetes care and outcomes, the World Health Organization (WHO) recommends the use of mobile telecommunications in the health care setting to improve health care delivery and disease management [6]. Multimedia technologies have also been shown to increase patient satisfaction, access, adherence, and cost effectiveness [7-10]. Specifically, when electronic glucose monitoring is combined with personalized feedback or expert coaching, Hemoglobin A_1c (HbA_{1c}) levels improve significantly [11-16]. Access to a cellular-connected glucose monitor with real-time feedback from certified diabetes educators (CDEs) decreased the likelihood of experiencing hypoglycemia or hyperglycemia up to 18% monthly, and it also decreased HbA_{1c} by 1% every 3 months and nearly 2% over 12 months [11,13,15]. Technology-facilitated care has also been significantly associated with depression remission, depression free days, and increased satisfaction of care [17,18].

The purpose of this study was to examine health outcomes measured by changes in HbA_{1c}, time in the target BG range, and depression symptoms for patients enrolled in a remote digital diabetes management program in a Diabetes Center of Excellence setting.

Methods

Study Design

This was a prospective study that investigated the impact of the Livongo for Diabetes program on HbA_{1c} and the proportion of BG checks in range for patients with diabetes mellitus at the University of South Florida Diabetes Home for Healthy Living (USF DHHL). The Livongo for Diabetes program is a digital chronic condition management program that combines: (1) a Food and Drug Administration–cleared, cellular-enabled, two-way messaging glucometer that measures blood glucose and delivers personalized digital coaching messages (see Multimedia Appendix 1); (2) free unlimited blood glucose test strips; and (3) unlimited access to CDEs for goal setting and behavioral and lifestyle education based on the American Diabetes Association's (ADA) Standards of Medical Care and the American Association of Diabetes Educator's (AADE) Diabetes Education Prompt Deck and Educator Guide [19,20].

Personalized digital coaching methods are delivered algorithmically on the meter to members based on diabetes type, medication use, and clinical guidelines. Immediately following each BG check, members receive context-specific feedback based on the BG value measured, as well as BG trends and patterns established with repeated meter usage. This feedback is delivered through messages less than 140 characters in length and based on ADA and AADE recommendations.

The CDEs also provided 24 hours a day, 7 days a week, 365 days a year call support for members with BG readings of <50 mg/dL or >400 mg/dL, within 3 minutes of transmitted blood glucose, to provide ADA-recommended, nonmedication-related interventions to effect their BG (ie, "drink 8 ounces of orange juice to bring your BG values up and recheck BG in 15 minutes").

In addition to the Livongo glucometer and access to CDEs, participants had access to a mobile phone application on iOS and Android, and a web portal available through traditional web browsers that tracked historical BG readings, provided reminders for BG checking, and allowed members to send Health Summary Reports of BG readings to care providers, family members, and friends (see Multimedia Appendix 2).

Participants

A convenience sample of participants were enrolled from the USF DHHL clinic from February 2015 to February 2016. All participants recruited for the study were established patients of the clinic with elevated HbA_{1c} who were receiving their usual care. Patients were eligible if they were at least 18 years of age, diagnosed with type 1 or type 2 diabetes mellitus, and proficient in English. Patients were excluded from the study if they did not have a baseline HbA_{1c} value and at least one other HbA_{1c} value within the study period for comparison, did not have a follow-up visit, and never activated the device (Figure 1). In addition, patients who died during the study were also excluded due to unavailable health information because of closed medical records.

The study protocol was approved by the University of South Florida Institutional Review Board (Protocol #PRO00016476). Verbal and written informed consent were obtained prior to participant's enrollment in the study. Study procedures were conducted in compliance with the Declaration of Helsinki.

Figure 1. Study population. *Valid baseline hemoglobin A_{1c} (HbA_{1c}) values defined as HbA_{1c} test taken within 90 days before registration date and 45 days after registration date.
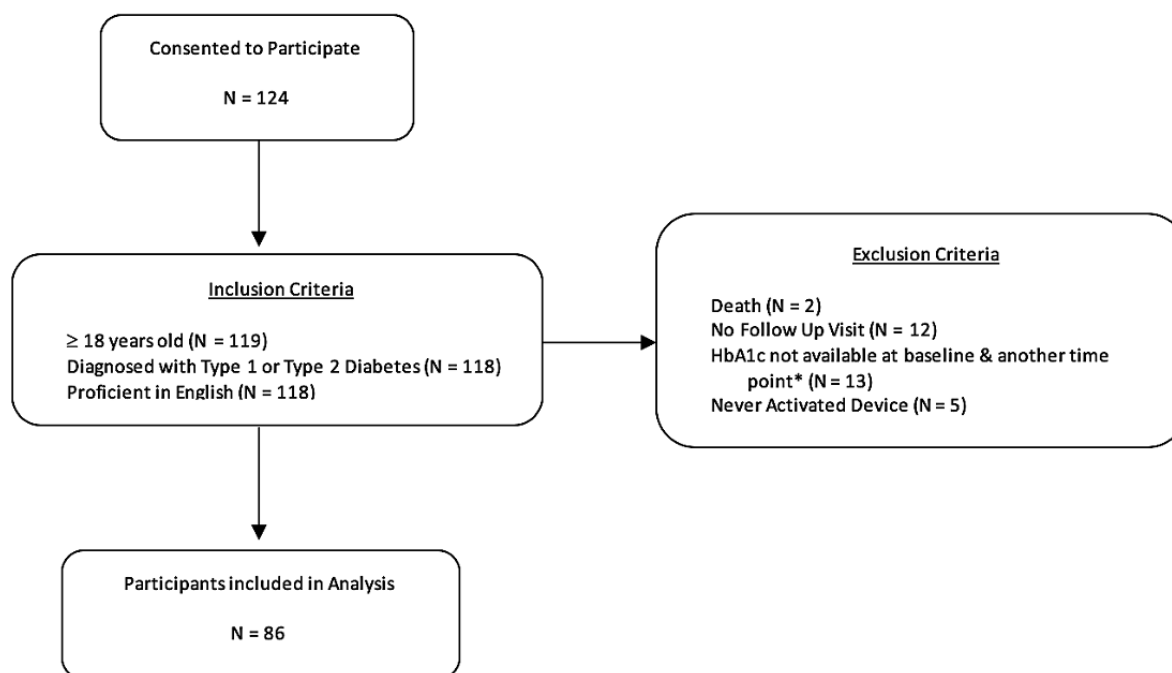
Measures

Blood Glucose

Blood glucose values were captured remotely in real-time from the cellular-connected Livongo glucose meter provided to participants. Target BG range was defined between 70 and 180 mg/dL. Additionally, BG values of <70 mg/dL and >180 mg/dL were defined as low and high, respectively.

Hemoglobin A_{1c}

HbA_{1c} was measured at the DHHL clinic using the Siemens DCA Vantage Analyzer. Eligible study participants were required to have recorded HbA_{1c} values within 3 months prior to their Livongo program registration date and at least one subsequent HbA_{1c} value for comparison during the 12-month study period. HbA_{1c} was measured at every subsequent clinic visit as clinically indicated for one year.

Patient Health Questionnaire

Patient Health Questionnaire-2 (PHQ-2) is a validated, patient-reported outcome tool that assesses the frequency of depressed mood and anhedonia over the past two weeks as a screen for depression. The ADA recommends that providers

consider annually screening all people living with diabetes for depression, as they have up to a 35% higher incidence of depressive symptoms than those without diabetes [15,21]. A PHQ-2 score ranges from 0-6, where a score of 3 or higher indicates further evaluation for depression should be pursued. Participants were asked PHQ-2 survey questions within one month of program enrollment and again at the end of the study period.

Statistical Analysis

Summarizing statistics were computed for demographic characteristics. Outcome variables were computed between baseline and subsequent clinic visits. The nonparametric Wilcoxon rank sum test was used to compare continuous variables, and Fisher's exact test was used for categorical data comparisons.

Results

Baseline Characteristics

Baseline characteristics are presented in Table 1. Nearly half of the participants were female, with a mean age of 50 (SD 15) years, and were diagnosed with type 2 diabetes (56%; 48/86).

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Table 1. Demographic characteristics.

Characteristics	Type 1 diabetes (n=38)	Type 2 diabetes		Overall population (N=86)
		Insulin use (n=21)	No insulin use (n=27)	
Gender, female, n (%)	20 (52.6)	12 (57.1)	10 (37)	42 (48.8)
Age (years)				
Mean (SD)	39.3 (11.3)	57.1 (12.1)	59 (12.1)	49.8 (15.0)
Median (IQR[a])	38.0 (15.3)	55.0 (16.0)	62.0 (14.0)	49.5 (24.8)
Body mass index				
Mean (SD)	28.0 (5.3)	36.8 (10.7)	31.0 (4.4)	30.8 (7.2)
Median (IQR)	26.0 (7.4).	32.6 (6.7)	30.7 (4.1)	30.4 (6.6)
Race, n (%)				
White	6 (15.8)	1 (4.8)	2 (7.4)	9 (10.5)
Hispanic	1 (2.6)	0 (0)	0 (0)	1 (1.2)
Black	3 (7.9)	1 (4.8)	1 (3.7)	5 (5.8)
Other	28 (73.7)	19 (90.5)	24 (88.9)	71 (82.6)
Daily blood glucose checking frequency				
Mean (SD)	1.3 (1.3)	1.2 (1.0)	1.0 (0.9)	1.2 (1.1)
Median (IQR)	0.8 (1.8)	1.0 (1.2)	0.8 (1.0)	0.8 (1.6)
Insulin use, n (%)				
Once a day	29 (76.3)	19 (90.5)	0 (0)	48 (55.8)
More than once a day	9 (23.7)	2 (9.5)	0 (0)	11 (12.8)
No use	0 (0)	0 (0)	27 (100)	27 (31.4)
Self-reported blood pressure category, n (%)				
High	13 (34.2)	8 (38.1)	5 (18.5)	26 (30.2)
Normal	24 (63.2)	13 (61.9)	18 (66.7)	55 (64.0)
Unknown	1 (2.6)	0 (0)	4 (14.8)	5 (5.8)
Smoker, n (%)				
Never smoked	32 (84.2)	17 (81.0)	23 (85.2)	72 (83.7)
No, quit on given date	2 (5.3)	1 (4.8)	0 (0)	3 (3.5)
Yes, not trying to quit	4 (10.5)	3 (14.3)	4 (14.8)	11 (12.8)

[a]IQR: interquartile range.

Hemoglobin A$_{1c}$

Mean HbA$_{1c}$ improved from baseline in all participants throughout the intervention, and within each diabetes type. Statistically significant improvements were seen in all participants from baseline to 3 months (0.8%; P=.02). Additionally, insulin users, whether with type 1 or type 2 diabetes, experienced a greater decrease in HbA$_{1c}$ than noninsulin users, at both 3 months (0.8%; P=.04) and 6 months (1.0%; P=.05). While HbA$_{1c}$ improved from baseline to 12-months, it was not statistically significant at any time point for participants with type 1 diabetes, type 2 diabetes, or participants with no insulin usage, whether with type 1 or type 2 diabetes. Further details about changes in HbA$_{1c}$ over the 12-month intervention by subgroups are reported in Figures 2-6.

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Figure 2. Change in hemoglobin A_{1c} (HbA$_{1c}$) from baseline by timepoint for all participants.
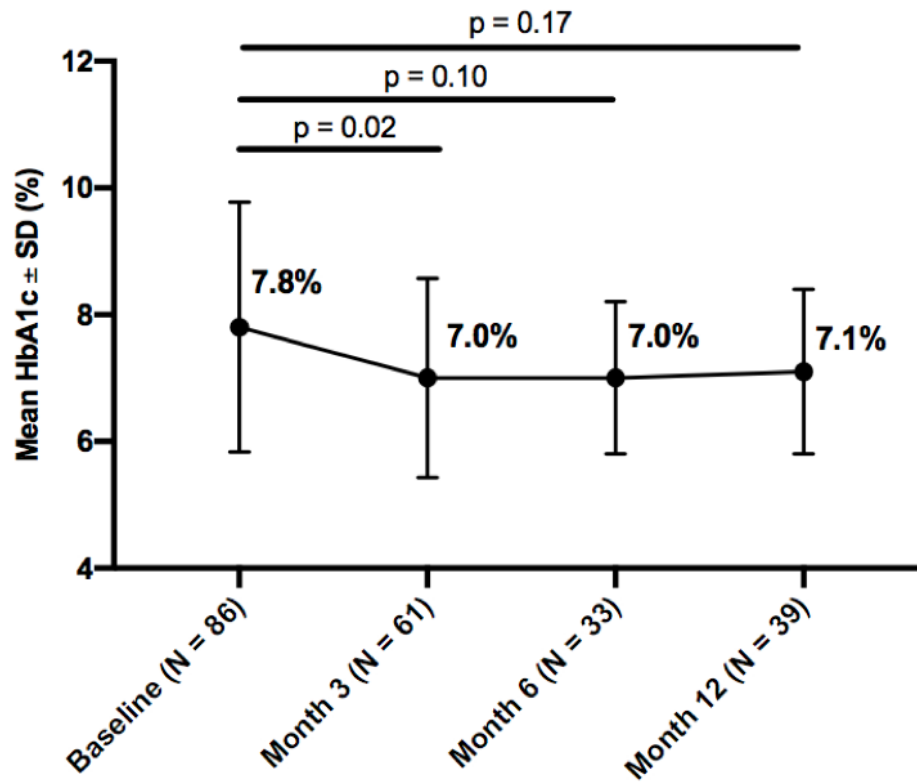

Figure 3. Change in hemoglobin A_{1c} (HbA$_{1c}$) from baseline by timepoint for type 1 diabetes.
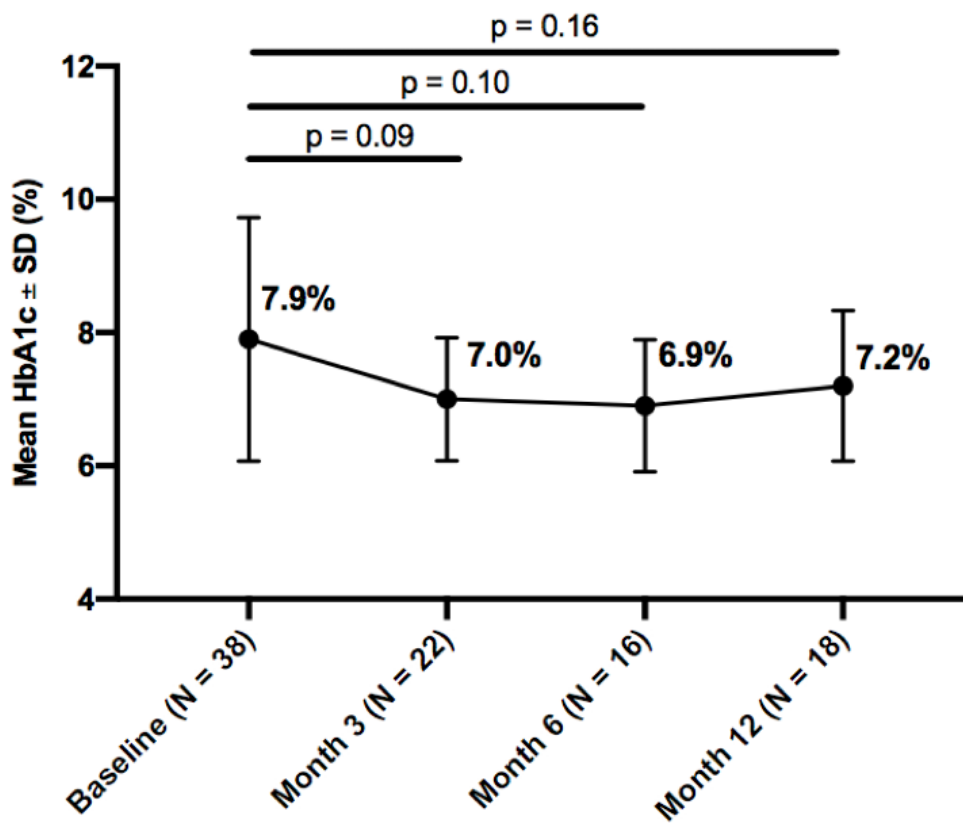
Figure 4. Change in hemoglobin A$_{1c}$ (HbA$_{1c}$) from baseline by timepoint for type 2 diabetes.
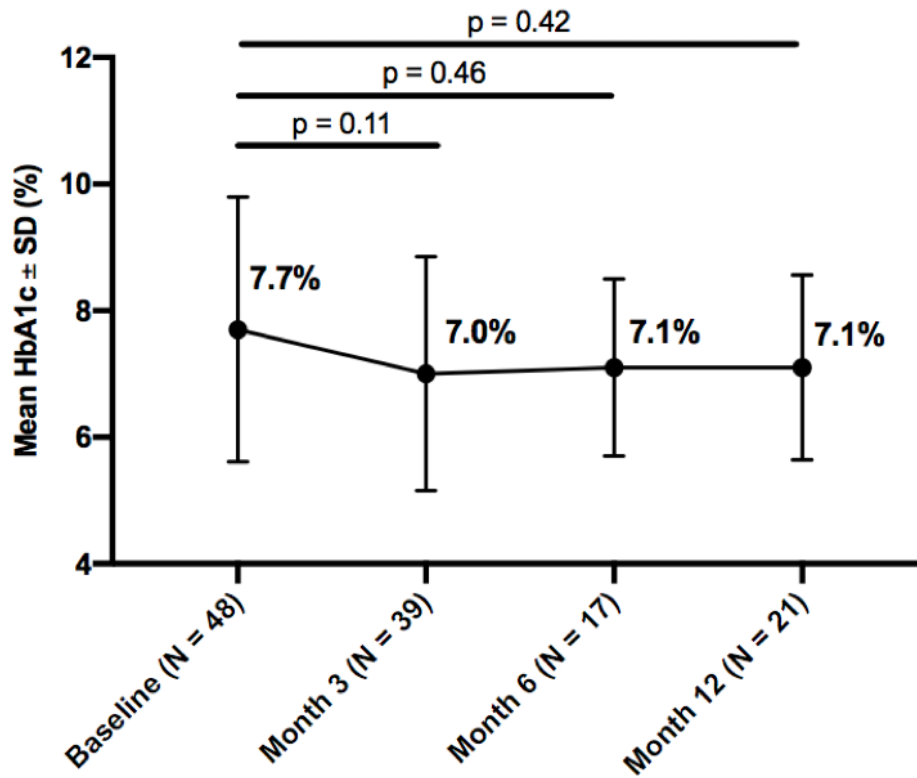

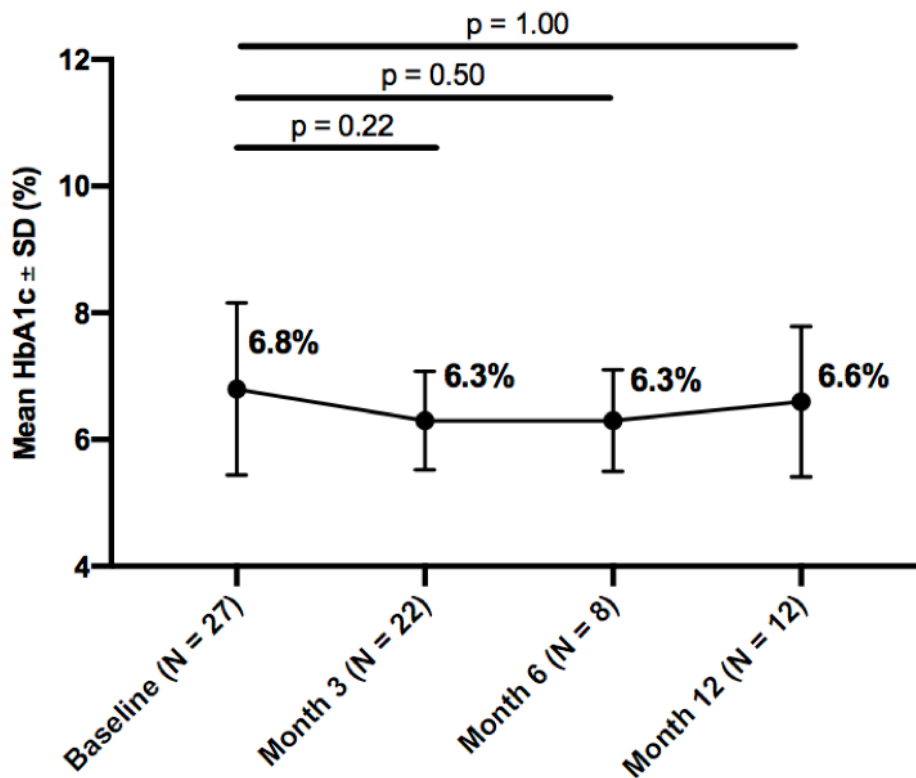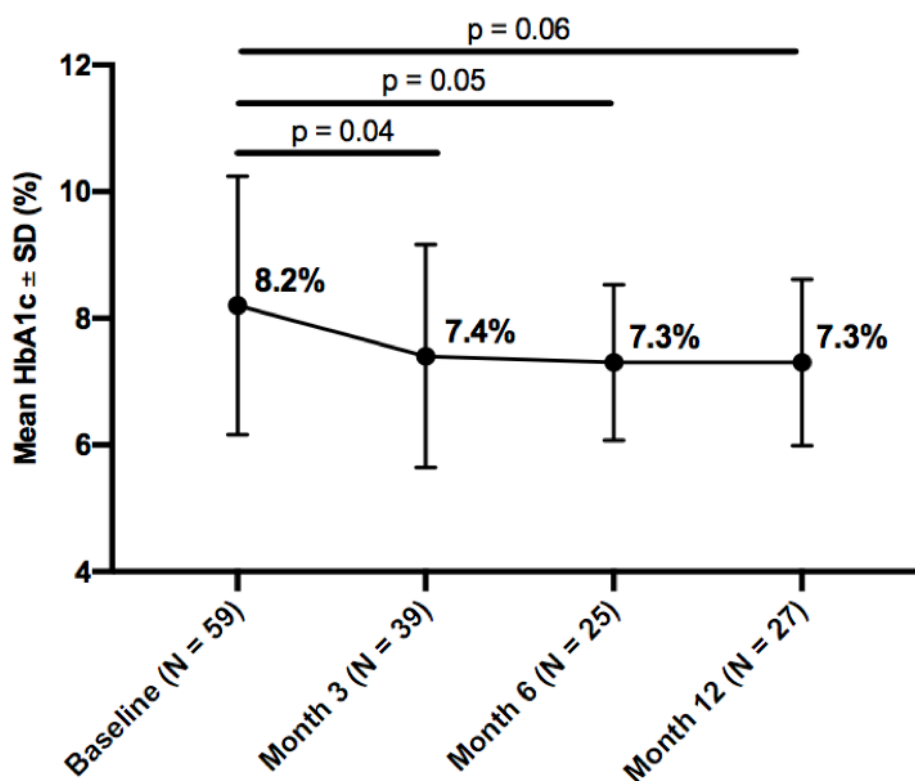**Figure 5.** Change in hemoglobin A$_{1c}$ (HbA$_{1c}$) from baseline by timepoint for type 2 diabetes without insulin use.

Figure 6. Change in hemoglobin A_{1c} (HBA_{1c}) from baseline by timepoint for all participants with insulin use.


Percent of Blood Glucose Checks Within Target Range

Blood glucose values were analyzed by BG range categories, and by diabetes type, for all participants during the study period. Median BG checking frequency ranged from 0.8 to 1.0 times per day depending on diabetes type and insulin use. Participants with type 2 diabetes using insulin had the highest BG checking frequency at approximately 1.0 (SD 1.2) times per day, while participants with type 2 diabetes not using insulin checked an average of 0.8 (SD 1.0) times per day and participants with type 1 diabetes were at 0.8 (SD 1.8) checks per day.

Patients with type 2 diabetes not using insulin had the highest percentage of BG checks within the target range of 70-180mg/dL (89.0%; SD 15.9), compared to participants with type 2 diabetes on insulin (68.1%; SD 28.1) and type 1 diabetes (57.9%; SD 22.5) throughout the 12 months.

When comparing percentage of BG checks in range in the first three months of the study versus the last three months, all participants decreased their percentage of BG checks that were <70 mg/dL from 4.9% to 4.1% (P=.56; see Figure 7). Though not statistically significant, participants with type 1 diabetes experienced a slight decrease in percentage of BG checks over 400 mg/dL from 1.8% to 1.5% (P=.81). Similarly, participants with type 2 diabetes using insulin had a nonsignificant decrease in percentage of BG checks greater than 180 mg/dL from 33.5% to 25.9% (P=.43). Participants with type 2 diabetes not using insulin showed no significant improvements for BG time in range. Further comparison of BG checks in range by diabetes type from 0-3 months to 9-12 months is shown in Multimedia Appendix 3.

Figure 7. Percent blood glucose (BG) checks in range by diabetes type and insulin use.
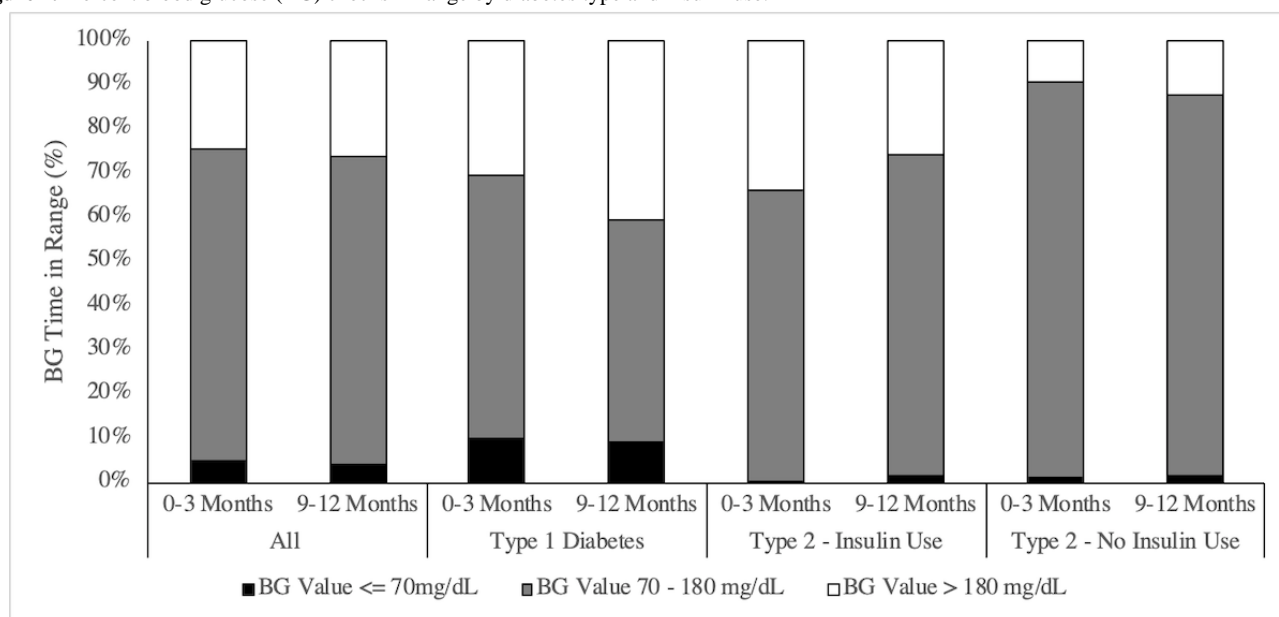
Depression Screening

Over the intervention period, there was a statistically significant decrease in mean PHQ-2 score (P=.04) among all participants. Average baseline PHQ-2 score (N=40) was 0.83. Postintervention score (N=19) was 0.26. While both baseline and postintervention scores were <3, showing an unlikelihood for depression symptoms, participants still showed a statistically significant decrease from baseline to 12 months. When analyzing PHQ-2 score by diabetes type and insulin usage, participants using insulin showed a statistically significant decline in PHQ-2 score (1.03 to 0.19; P=.01), while type 1, type 2, and participants not using insulin saw a nonstatistically significant improvement in scores.

Discussion

Principal Findings

The results of this study in an outpatient diabetes clinic provide evidence that access to a cellular-enabled BG meter connected to CDEs with real-time personalized recommendations can improve HbA_{1c}. This improvement was significant since our study showed that with lower HbA_{1c}, participants also had increased BG values within target range, with a decrease in hypoglycemic events at 12 months. Furthermore, study participants had improved depressive symptom scores as measured by PHQ-2 surveys. Overall, a connected BG meter with personalized feedback and access to CDEs improved diabetes care at 12 months.

The ADA and WHO recognize digital health and technology advances can support and enhance the delivery of health services [6,19]. Specifically, the ADA's 2019 Standards of Medical Care includes recommendations for diabetes technology recognizing digital self-management solutions for improvement in HbA_{1c}, especially when paired with a health care team, individualized feedback, patient generated historical health data, and education [19]. Additionally, the ADA recommends patients receive

ongoing education and evaluation of glucose data to adjust therapy and self-care in relation to individual needs [19,22]. With the growing global epidemic of diabetes linked to a lack of knowledge around BG monitoring, self-management, education, and episodic communication with health care providers, testing a cellular-enabled BG meter with BG checking reminders, personalized digital coaching, access to CDEs, and historical BG reporting was critical to understand the benefit of including digital diabetes solutions related directly to issues increasing diabetes prevalence, in addition to a diabetes clinic's standard care [1-5].

Using a cellular-connected BG meter provides health care professionals with instant access to patient-generated BG readings, allowing for faster change in care plan, education, and outcomes. In addition, a patient's care team can provide a more personalized and proactive plan, with tailored education through the system's generated insights of historical BG data and two-way communication with CDEs available through the Livongo meter [23]. Viewing a patient's BG values within low, normal, or high ranges over a week or month allows for a timelier response in condition management versus waiting 3 months for a change in HbA_{1c}. In addition, two individuals with the same HbA_{1c} could have very different time in BG ranges, which would impact desired treatment plan. Without the ability to view historical BG readings in a timely manner, an important aspect of an individual's personalized care plan could be overlooked as it would not be reflected in HbA_{1c}. As such, our study supports previous findings that access to a cellular-connected glucometer and CDE coaching decreases hypoglycemic episodes and leads to a decrease in HbA_{1c} up to 1% in 3 months [11,13,15]. Also, having access to a program like Livongo for Diabetes can provide continued BG monitoring, education, and coaching for individuals with diabetes who choose to not follow up with their health care team as recommended.

Combining digital health tools with human coaching for individuals with diabetes has also improved depressive

symptoms, as measured by PHQ scores [17,18,24]. By incorporating technology and access to real-time support from CDEs into diabetes care, the challenges of self-management that can increase depressive symptoms, such as support, emotional burden, and access to education and management, are addressed in a more timely manner focused on the patient's personalized needs [17,25]. The addition of coaching offers reinforcement of education, accountability, and creation of problem-solving skills to overcome behavioral and cognitive barriers for successful self-management [25].

The Livongo for Diabetes program has also been shown to provide cost savings to its users [26,27]. In 2019, Livongo users had a 21.9% decrease in spending compared to nonusers, translating to $88 per month. Specifically, a 10.7% reduction was observed in diabetes-related medical spending, and a 24.6% reduction in spending for office-based services [27]. While historically offering ongoing human coaching can be costly, the Livongo for Diabetes program has provided a return on investment for its users while improving clinical outcomes.

Limitations and Future Research

The limitations of this study include the lack of a control group and the small sample size for subgroup comparisons. Authors assume the dramatic decline in sample size is related to a physician leaving the clinic, resulting in a lack of follow up from that physician's patients since patients come to the clinic to see specific providers. In addition, participants for this study were recruited at a Diabetes Center of Excellence, which provides access to the highest level of diabetes care. The BG checking frequency was unexpectedly low in the type 1 diabetes population. This finding may be a result of continuous glucose monitor use in this population, which requires two BG checks for calibration. Neither this information nor the use of non-Livongo BG meters were captured as part of the study.

Finally, changes in medication use, weight, knowledge of diabetes self-management, coaching interactions, and other factors that might influence BG control were not captured as part of this study. Further investigations will be required to see if findings would be applicable to the general population and to better understand the drivers of improved glucose control.

Despite the small sample size, this study provides a glimpse of how adding a new product into the market, or with standard care, can improve patient outcomes even in centers of excellence. This is an important contribution to the literature and for larger population studies in the future.

Conclusions

Participants provided with a cellular-enabled BG meter with real-time feedback and access to CDE coaching in a diabetes center of excellence experienced a reduction in HbA$_{1c}$, fewer hypoglycemic episodes, and a significant reduction in PHQ-2 scores. These results support evidence that the addition of diabetes digital health solutions can improve diabetes care. Further studies should be conducted to assess a larger population with the addition of coaching interactions, medication use, education, and self-management behaviors.

Multimedia Appendix 1
Livongo Diabetes Glucose Meter.
[PNG File 777 KB - diabetes_v4i4e14799_app1.png]

Multimedia Appendix 2
Livongo diabetes smartphone app.
[PNG File 4676 KB - diabetes_v4i4e14799_app2.png]

Multimedia Appendix 3
BG checks in range by diabetes type from 0-3 months to 9-12 months.
[PDF File (Adobe PDF File)56 KB - diabetes_v4i4e14799_app3.pdf]

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Abbreviations

AADE: American Association of Diabetes Educator
ADA: Americans with Disabilities Act
BG: blood glucose
CDE: certified diabetes educator
HbA$_{1c}$: hemoglobin A$_{1c}$
HSR: health summary report
PHQ: Patient Health Questionnaire
USH DHHL: University of South Florida Diabetes Home for Healthy Living
WHO: World Health Organization

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Original Paper

Understanding the Adoption and Diffusion of a Telemonitoring Solution in Gestational Diabetes Mellitus: Qualitative Study

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Abstract

Background: Women with gestational diabetes mellitus (GDM) require regular follow-ups and overall management to normalize maternal blood glucose and improve pregnancy outcomes. With the advancements made in the digital field, telemedicine is gaining popularity over traditional health care approaches in different medical fields. As for GDM, telemonitoring solutions seem to improve women's quality of life and enhance self-management.

Objective: The aim of this study is to understand, from patients' and health care professionals' (HCPs) perspectives, what drives the adoption and diffusion of a telemonitoring solution (myDiabby) in a context where telemonitoring activities are still not compensated like traditional follow-ups.

Methods: The study was conducted in 12 diabetes services in France using myDiabby for monitoring and managing patients with GDM. A qualitative research approach was adopted for collecting and analyzing data. A total of 20 semistructured interviews were conducted with HCPs working in different health structures in France, and 15 semistructured interviews were conducted with patients who had been using myDiabby. Data were analyzed using a thematic analysis approach.

Results: Different determinants need to be taken into consideration when adopting an innovative health technology. By drawing on the diffusion of innovation theory, a set of factors associated with the technology (the relative advantages, compatibility, ease of use, testability, and observability of the telemedicine platform) has been identified as affecting the adoption and diffusion of telemonitoring solutions in French diabetes services. In addition, data analysis shows a set of environmental factors (the demographic situation of HCPs, the health care access in rural communities, and the economic and political context in France) that also influences the spread and adoption of telemonitoring systems in French hospitals.

Conclusions: Even though telemonitoring activities are still not remunerated as traditional follow-ups, many French HCPs support and encourage the adoption of telemonitoring systems in GDM. As for patients, telemonitoring systems are perceived as a useful and easy way to monitor their GDM. This study contributes to recognizing the value of telemonitoring interventions in managing GDM and considering the expansion of telemonitoring to other chronic conditions.

Introduction

Background

Gestational diabetes mellitus (GDM) is defined as glucose intolerance first recognized during pregnancy [1]. The increasing prevalence of obesity and the advanced maternal age seem to increase the number of women with GDM [2,3]. This prevalence varies depending on the screening criteria; GDM is estimated to occur during 6% to 15% of pregnancies [4]. According to the new criteria defined by the International Association of Diabetes and Pregnancy Study Groups, GDM is estimated to occur in 14% pregnancies in France and represents one of the most frequent pathologies during pregnancy [5].

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Many perinatal and postpartum complications are associated with GDM [6,7]. Adverse outcomes include the development of type 2 diabetes and cardiovascular disease in the mothers, preterm delivery, shoulder dystocia, stillbirths, clinical neonatal hypoglycemia, hyperbilirubinemia, and cesarean deliveries [3,6,8]. The World Health Organization recommends universal screening of all women for GDM at 24 to 28 week's gestation [9]. Women with GDM require regular follow-ups and overall management to normalize maternal blood glucose and improve pregnancy outcomes [10-13]. However, an intensive surveillance in GDM can be costly and labor intensive [3]. It represents a real burden for health professionals and patients. Owing to the increasing number of women with GDM requiring regular follow-ups, along with the shortage of health care professionals (HCPs), telemedicine interventions can reduce outpatient clinic visits and provide better overall management for patients with GDM [14,15]. With the advancements made in the digital domain, telemedicine is gaining popularity over traditional health care approaches in different medical fields. Although a growing number of research studies highlighted the value of telemonitoring for managing diabetes and addressed its feasibility and acceptability among health professionals and patients, results are still modest. Besides, few studies have used qualitative approaches to examine in-depth factors that influence the adoption and diffusion of telemonitoring solutions in French health establishments and among patients.

Therefore, this study aimed at understanding, from patients' and HCPs' perspective, what drives the adoption and diffusion of myDiabby (a telemonitoring platform) in French health care centers where telemonitoring of women with GDM is still not compensated.

Telemedicine in Gestational Diabetes: Related Work

Some research studies focused on examining the feasibility and the acceptance of telemedicine systems for managing GDM [16-20]. The literature review shows a high degree of acceptance of telemedicine interventions in GDM. The use of telemedicine seems to improve patient satisfaction regarding access to care [19,21], reduce the need for outpatient clinic visits [16,19], and enhance patient-caregiver information exchanges [22]. In addition, the use of telemedicine solutions seems to increase the efficacy of health care providers [21,23,24]. It also seems to improve patients' self-efficacy in managing their diabetes [16,25] and is cost saving [26]. Patients with GDM feel supported with telemedicine solutions and are willing to use them again [17,27].

Despite the underlined acceptance and satisfaction regarding the use of telemonitoring systems in GDM, factors that drive their adoption and diffusion in health establishments are less investigated. Previous studies mainly focused on telemedicine outcomes (feasibility, satisfaction, and clinical outcomes) without providing an in-depth analysis of how telemonitoring systems are adopted and diffused, particularly in France. In this respect, this study will draw on the diffusion of innovation theory to examine factors that drive the adoption and diffusion of myDiabby in French health care centers where telemonitoring activities are still not remunerated.

The Diffusion of Innovation Theory

The diffusion of innovation theory offers an appropriate lens for examining factors that influence the adoption and diffusion of an innovation in specific context settings. An innovation is defined as *an idea, practice, or project that is perceived as new by an individual or other unit of adoption* [28]. Therefore, it is not necessarily invented recently. If individuals perceive it as new, then it is still an innovation for them. Rogers [28] highlighted 5 key attributes of an innovation that influence its likelihood of adoption and diffusion in a specific context. These attributes are relative advantage, perceived compatibility, complexity, trialability, and observability. Relative advantage is the extent to which an innovation is perceived better than the idea it supersedes [28]. Innovations are adopted when users perceive them as a better option than the ones they currently have or use. Perceived compatibility is the degree to which an innovation is perceived by the potential adopters to be consistent with their existing values and current needs. In other words, an innovation has a greater chance to be adopted and diffused when it is aligned with the cultural norms and adopters' needs. Complexity is the extent to which an innovation is perceived to be difficult to understand and use [28]. This attribute is also found in the technology acceptance model under the perceived ease of use. Innovations that are difficult to use will be adopted more slowly than the ones that are perceived to be less difficult and complicated. A high degree of complexity can lead to a high degree of frustration among potential adopters. Trialability is the possibility to experiment and test an innovation before committing to it. Innovations with higher trialability are more likely to be adopted by individuals [29]. They allow the potential user to try out an innovation and return to pre-existing situation without much cost. Finally, observability is the degree to which the results of an innovation are visible to potential users. High visibility and demonstrability of the benefits of an innovation encourage more individuals to adopt it [29].

According to Rogers and Singhal [28], other determinants also influence the spread and the adoption rate of an innovation: the communication channels, the social system, and the characteristics of the adopters. The communication channels are crucial to diffuse the information about the perceived advantages of an innovation. They can create or change people's attitudes toward an innovation. Communication channels can include any mean (newspaper, television, reports, and intrapersonal communication) through which people diffuse and obtain information about the innovation and its benefits. As for the social system, it is defined as a "set of interrelated units engaged in joint problem-solving to accomplish a common goal." The social system affects individuals' attitudes toward an innovation. As for the characteristics of the adopters, individuals can be categorized into 5 groups: innovators (first group to adopt an innovation), early adopters, earlier majority, later majority, and laggards (the strongest resisters to the adoption of an innovation).

Even though previous studies have used the diffusion of innovation theory as a theoretical lens to examine the adoption of health care information technologies [30,31], these studies rarely addressed the context of GDM [32], even less in France. Therefore, this study used the diffusion of innovation theory to

understand what drives French hospitals to adopt and diffuse myDiabby.

Methods

Research Settings

myDiabby health care is a telemonitoring platform that offers a new solution for monitoring and managing GDM. It replaces paper diary records and allows patients to manually enter their blood sugar level in the system or have their data transferred directly from the glucometer to the app (via Bluetooth). myDiabby includes a color coding (green, orange, and red) that helps patients understand their blood glucose concentration. Patients can also enter their dietary records and privately share their concern(s) and question(s) with their health care team. As for HCPs, myDiabby allows them to telemonitor their patients' data (blood glucose level) via a customized alert system, adjust or prescribe insulin doses, and privately chat with their patients. myDiabby is implemented in 230 French health centers. A total of 360 new patients are telemonitored via myDiabby every month.

In general, patients diagnosed with GDM are invited to a therapeutic education session in the health center of their region. During this session, the health care team (the diabetes specialist, the midwife, and the nurses) meets with the patients, provides them with explanations regarding their pathology, and answers their questions and concerns. The therapeutic education session is also the occasion to raise patients' awareness regarding the need for self-monitoring and managing their diabetes. During this session, the health care team provides their patients with a glucometer, introduces them to the myDiabby health care platform, and gives them secured personal access to the telemonitoring platform. Patients are supposed to test and enter their blood sugar level 6 times per day (before and after breakfast, before and after lunch, and before and after dinner). However, those with stable blood glucose levels can decrease their test and data entry to 3 times per day. Although some patients prefer entering their data manually to be more aware of their results, others do it manually, especially when their Bluetooth does not work properly.

Nevertheless, the use of myDiabby has not eliminated phone interactions. Health care team members still contact their patients (via phone) to follow-up with those who have not entered their data for 2 days in a row or to discuss changes in their treatment decision.

Data Collection

The qualitative research was conducted in 12 diabetes services in France using myDiabby platform for monitoring and managing patients with GDM. Among the 12 diabetes services, 11 are attached to public health centers and 1 is a private diabetes clinic. Each diabetes service has its own organization, coordination procedures, patient education process, and telemonitoring protocol. HCPs do not follow any standardized protocol for viewing patients' data in the system and responding to them via the app. They have developed their own "practice" for telemonitoring patients and managing their GDM.

Data collection took place from January 2018 to May 2018. A set of semistructured interviews was performed with patients and health professionals working in 12 different health care centers in France.

On the one side, interviews were scheduled with HCPs to understand in depth their perspectives regarding the adoption and diffusion of myDiabby. The sample includes HCPs working in French diabetes services (public or private) and having experience in both traditional follow-ups and telemonitoring. Therefore, 32 HCPs from 18 different diabetes services that use myDiabby and other telemonitoring platforms were contacted. Personalized emails were sent to them, explaining the purpose of the study and inviting them to participate in the study. A total of 20 HCPs (8 diabetes specialists, 8 educational nurses, 2 dietitians, 1 gynecologist, and 1 midwife) from the 12 diabetes services showed interest in participating in the study and agreed on being contacted. A total of 5 HCPs did not respond to the emails, and 7 highlighted their lack of availability. In all, 20 participants gave their oral consent to be interviewed. Interviews lasted between 35 and 45 min. A saturation in the gathered data was reached after 20 interviews.

On the other side, interviews were also scheduled with a convenience sample of patients who have previously had or currently have GDM. The sample included women who have been diagnosed with GDM and have used a glucometer and myDiabby during at least 1 pregnancy. The decision of including pregnant women with active GDM and women who already delivered helped increase the sample and gain more insights into their perceptions of the telemonitoring platform. Women who were diagnosed with diabetes before their pregnancy were excluded from the study.

Women with GDM were identified from the list of patients of HCPs who had already been interviewed. Given the nature of this study and the no risks associated, this research did not require an Institutional Review Board approval (according to the French law "JARDE"). However, the purpose of the research was explained to patients before getting their approval and oral consent to participate in the study. HCPs elucidated the reasons why these patients were asked to be part of the study, the possible discomforts they may feel during the interview, and their possibility to pass on answering any question or to even quit the conversation. They also made it perfectly clear that they were not part of the research team and that they had no interest in it. This way, patients did not feel pressured to participate. In total, 15 patients agreed on participating in the study and gave their verbal consent. Interviews lasted an average of 30 min and were recorded with the consent of the participants.

Data Analysis

Before starting the analysis, transcripts were translated to English by a third party. For analyzing the collected data, we adopted an interpretive approach. We began with multiple readings of the transcribed interviews to understand the context and projects in which the respondents were involved. Although we adopted an open-coding approach to identify key categories in each transcribed word, sentence, or paragraph, Rogers' theoretical lens guided us in analyzing the data. Early descriptive codes were identified with little or no inference beyond the

piece of data. Therefore, data were summarized and segmented. A set of deductive themes, such as "relative advantage of myDiabby," "compatibility of myDiabby," and "ease of use of myDiabby," has been identified and justified verbatim. Besides, more advanced codes or pattern codes emerged inductively, such as "the impact of the demographic context of French health care professionals" and "the context of pregnancy." Themes were defined and justified verbatim [33,34]. The coding process was done by a coder who has expertise in qualitative research. However, the same data have been analyzed twice in an interval of 7 months. This helped compare the results and evaluate their consistency over time.

Results

Relative Advantage of myDiabby

From Health Care Professionals' Perspective

According to the interviewees, the use of myDiabby for monitoring GDM offers a set of significant advantages compared with traditional follow-ups.

The use of myDiabby enabled regular follow-ups and improved patient care by being more reactive:

> *Today they [patients] have closer follow-ups.* [Diabetes specialist_4]

> *We used to have random follow-ups whereas now we are way more reactive. We put them under treatment sooner.* [Diabetes specialist_1]

Regular follow-ups seemed beneficial for controlling women's glycemic level and weight:

> *Frankly, we have a better follow-up now. Plus, with the hypoglycemic and hyperglycemic alerts, we can directly identify patients that need to be taken in charge immediately.* [Nurse_5]

> *Women has less tendency to gain weight as the follow-up is more frequent.* [Diabetes specialist_1]

> *Women have also lost weight due to regular follow-ups.* [Dietician_2]

In addition, the use of myDiabby empowered women to self-manage their GDM:

> *myDiabby helped patients self-manage their health.* [Nurse_2]

Therefore, patients spent less time commuting and waiting in doctors' offices to show their glucose level:

> *Patients commute less. And, we barely see those who have stable blood glucose levels.* [Gynecologist_1]

> *Patients spend less hours waiting in our office* [Nurse_2]

In addition, telemonitoring brought HCPs closer to patients. According to the former, myDiabby helped them interact more often with their patients:

> *We were really surprised with how close we felt with our patients. We got to know them better.* [Nurse_1]

> *The communication is better now. It's more spontaneous. We have a more trustworthy relationship.* [Nurse_6]

Even though our participants all agreed on the relative advantages of telemonitoring, a few underlined the need of sustaining human contact with their patients, beyond their virtual desktops:

> *It is important to keep on seeing our patients or having them on the phone at least.* [Nurse_2]

> *myDiabby doesn't totally replace human contact.* [Diabetes specialist_6]

From Patients' Perspective

The use of myDiabby was perceived by patients as more reassuring and more useful than traditional follow-ups:

> *I knew there was always someone controlling my results, and ready to address my questions.* [Patient_3]

> *I felt safe when using myDiabby.* [Patient_5]

> *Health professionals can get my blood results in-real time, which is very useful.* [Patient_2]

> *I can directly get in contact with them and have quick answers.* [Patient_6]

According to the participants, myDiabby decreased the stress and anxiety related to manage their diabetes:

> *I knew that health providers would contact me in case my glycemic values were high.* [Patient_2]

> *It simplified my daily life and decreased my anxiety. All I had to worry about was my blood glucose test* [Patient_7]

It also empowered them as they felt more autonomous to self-manage their health, and it made their life easier:

> *Technologies help us being more autonomous. We feel more responsible.* [Patient_1]

> *I really appreciate being self-sufficient.* [Patient_2]

> *We feel more free and autonomous.* [Patient_9]

> *I don't see myself going to the hospital every other week to control my glycemic calendar.* [Patient_2]

> *It is a real blessing to exchange virtually with health providers. I don't have to commute.* [Patient_4]

That said, a few patients evoked the need of seeing their health care team when they are under insulinotherapy:

> *Insulinotherapy necessitates physical contact. I need to see my doctor, ask questions...I feel less reassured if I do it through distance.* [Patient_1]

> *I need to see my doctor when an insulinotherapy is required.* [Patient_7]

Compatibility

From Health Care Professionals' Perspective

Data analysis showed that myDiabby was consistent with HCPs' vision and practices:

For me it doesn't make any sense to ask these women to commute so I can check their blood glucose. [Diabetes specialist_2]

Technologies are the future. We are going to use more applications and technologies very soon. [Diabetes specialist_4]

We use technologies in everything now...everyone is connected in some way. [Nurse_2]

From Patients' Perspective

According to the patients we interviewed, technologies are becoming part of everyone's life. Regardless of their sociodemographic background, age, and social status, almost everyone has access to the internet, downloads, and uses apps on mobile phones and tablets. Therefore, myDiabby is aligned with people's lifestyles:

Nowadays, everyone has an iPhone and access to the Internet. [Patient_4]

Therefore, the use of myDiabby or any other telemonitoring system is consistent with their way of living.

Complexity Associated With the Use of myDiabby

From Health Care Professionals' Perspective

Complexity is the extent to which an innovation is perceived to be difficult to understand and use. It can be a barrier to the adoption of a technology and its diffusion. In this study, HCPs highlighted the ease of use of myDiabby. The intuitive aspect of this telemedicine platform encouraged them to progressively adopt it and integrate it in their practices:

myDiabby is fabulous, very intuitive. I tried two different platforms that weren't user-friendly at all. This one is very simple. [Diabetes specialist_1]

The interface of myDiabby is very intuitive. [Diabetes specialist_3]

It is user-friendly, easy to appropriate. [Diabetes specialist_2]

From Patients' Perspective

As for the patients we interviewed, they had the same opinion regarding the ease of use of myDiabby:

myDiabby is very easy. [Patient_2]

Honestly I didn't have any trouble when I started using it, it is very simple. [Patient_4]

It is really easy, I can manually enter my data, modify them. [Patient_14]

The perceived ease of use of myDiabby seemed to affect patients' attitude toward telemonitoring. They seemed more inclined to use telemonitoring systems during their pregnancy.

Trialability of myDiabby

From Health Care Professionals' Perspective

Data analysis showed that the possibility to test myDiabby before committing to it had a positive impact on HCPs' perceptions toward its adoption:

At first, our nurses were slightly reserved regarding the use of myDiabby, but once they tried it, they were very happy. [Diabetes specialist_3]

When we first introduced the platform to the patients, some of them [patients] remained reserved regarding its use. But once they started using it, they were satisfied and happy. [Nurse_4]

In the beginning we tried it on a few patients, and after three weeks it was adopted and used by almost everyone. [Nurse_6]

In addition, HCPs were more likely to adopt the platform as they were able to customize it according to their needs:

We are able to customize it. It's a real pleasure. [Diabetes specialist_1]

The development team is very responsive and reactive. myDiabby evolves according to our requirements. [Gynecologist_1]

From Patients' Perspective

The patients we interviewed were given the chance to choose between myDiabby and traditional follow-ups. After attending the educational workshop and getting secure access to myDiabby, patients were able to try myDiabby and decide whether to continue using it. Their positive experience with it seems to encourage its adoption and use:

I remember the first times I had to enter my data after each glucose test... I thought it was going to be complicated and that I should go back to the paper diary records. but rapidly I got used to it... if I'm ever pregnant again and have diabetes, I would ask to be telemonitored. [Patient _5]

Observability

From Health Care Professionals' Perspective

The observed benefits have encouraged other health specialists to adopt myDiabby:

Midwives are now interested in using myDiabby. It is starting to expand progressively within our structure. [Diabetes specialist_3]

Our gynaecologists are now using myDiabby. They leave us messages on patients' weight or any related health problems. [Diabetes specialist_1]

In addition, the participants emphasized the impact of the observed benefits on patients' attitudes regarding the adoption of myDiabby:

Our patients are willing to use it again. [Nurse_2]

Some of them [patients] would never go back to traditional follow-ups. [Nurse_6]

During their second pregnancy our patients use the application without even questioning it. [Nurse_7]

From Patients' Perspective

Patients expressed their tendency to share their positive feedback with their surroundings:

I was talking to my sister about how simple it was to be telemonitored. [Patient_15]

I would encourage my friend to use it if she had to... [Patient_12]

Beyond these factors that are directly associated with the telemonitoring technology, environmental factors seem to play an important role in encouraging telemonitoring over traditional methods: the demographic context of French health professionals, the geographic context, the pregnancy context, and the economic and political context.

The Demographic Context of Health Professionals

In France, the number of HCPs working in diabetes care is disproportional to the number of patients with GDM. Therefore, the implementation of innovative ideas for managing patients with GDM is encouraged. According to our participants, telemonitoring helped them address this issue:

We have a mismatch between the number of patients with gestational diabetes and the number of health care professionals. We had 580 patients with gestational diabetes in 2017. [Diabetes specialist_2]

We had to find another way to take care of our patients, otherwise, we wouldn't be able to meet patients' needs. [Diabetes specialist_8]

The Geographic Context and Health Care Access

Telemedicine seemed useful for patients living in rural areas. As mentioned previously, many patients have long hours of commuting to visit their HCPs and show their blood glucose values. Therefore, commuting is "exhausting," especially for pregnant women. For this reason, women tend to prefer virtual follow-ups over traditional ones:

Some of our patients drive 100 kilometers in order to come to the hospital. [Diabetes specialist_3]

The Context of Pregnancy

Pregnancy can be critical for patients with GDM. In this respect, telemonitoring is helpful, as it enables regular follow-ups and encourages women to self-monitor their diabetes during their pregnancy (which is usually limited to a few months). Besides, women feel more responsible in the context of pregnancy, as their baby is also impacted by their medical condition:

Pregnancy is the ideal context; women have three months to self-manage their diabetes. Hence, they will invest themselves and do whatever it takes to protect their baby. [Diabetes specialist_8]

The Economic and Political Context

Despite the positive feedback regarding myDiabby, the participants (mostly HCPs) reported a few barriers that constrain the diffusion of telemonitoring solutions in French health centers. As telemonitoring of GDM is still not recognized as a medical "practice" in France, HCPs are unable to dedicate specific hours for telemonitoring activities. They do it for free, in addition to their work:

We do it during our working time. I do it sometimes at my house at 10pm. [Diabetes specialist_4]

It is not recognized as a medical act and it is not included in our job description. [Nurse_4]

Given this situation, many health professionals do not use it despite the perceived advantages:

It decreases the number of medical acts that can be billed. [Diabetes specialist_5]

Liberal doctors prefer earning money which is understandable. [Midwife_1]

The actual care policy emphasizes money over quality of care. [Nurse_2]

However, even though telemonitoring is still not valued and recognized as a medical "practice," many HCPs still encourage its adoption. Some of them have even suggested the expansion of myDiabby to diabetes 1 and 2:

It can be beneficial in diabetes 1 and 2 as it happens that we don't see some patients for 5 years. [Diabetes specialist_7]

It is probably interesting to use mydiabby during a specific period—after a surgery for instance—and on specific profiles. [Gynecologist_1]

Discussion

Principal Findings

The findings underline patients' and HCPs' preferences for virtual follow-ups over traditional ones. The relative advantages, perceived ease of use, observed benefits, trialability, and compatibility of myDiabby with participants' vision and needs have encouraged the use of this telemonitoring system for managing GDM:

If we decide to take the platform from them [patients], believe me, they [patients] will be very unhappy. [Diabetes specialist_3]

It is becoming rare to have patients who prefer physical consultations only. [Diabetes specialist_6]

That said, the characteristics of the adopters (innovators or early adopters) have also affected the adoption level of myDiabby. However, these participants have also tried other telemonitoring systems without diffusing them within their services. This could lead us to assume that the characteristics of the innovation itself have played a major role in encouraging its adoption.

Beyond the characteristics of myDiabby, data analysis shows that other factors have also influenced the spread and adoption of telemonitoring activities in French diabetes services. The context of having diabetes during pregnancy, the demographic situation of HCPs, the health care access in rural communities, and the economic and political context in France seem to encourage telemonitoring activities in French hospitals. Findings show that telemonitoring solutions are becoming inevitable in an environment where the number of patients with GDM is getting higher every year. Even though telemonitoring of GDM in France is still not recognized as a medical practice, HCPs seem to support it and encourage it.

Conclusions

The diffusion of telemonitoring solutions in French health centers is still under investigation. Few papers have examined what drives French HCPs to adopt telemonitoring systems in a context where telemonitoring activities are not compensated.

This research paper highlights different determinants that should be taken into consideration when adopting a digital health solution. By drawing on the diffusion of innovation theory, the study emphasizes the innovation attributes that have encouraged the adoption and diffusion of myDiabby. However, beyond these attributes, addressed in previous papers, the research also shows the role of environmental factors in encouraging the adoption and diffusion of telemonitoring solutions. Therefore,

this study offers a complementary theoretical perspective toward the adoption and diffusion of telemonitoring solutions in the context of GDM. Nevertheless, this research presents 2 major limitations. First, the number of interviews is limited. More interviews should be performed with patients and HCPs to generalize the findings. Second, participants (patients and HCPs) in this study can be classified in the "innovators" or "early adopters" category. This can constitute a potential bias in the results that are very positive. Even though the purpose of the study was to understand what motivates individuals to adopt telemonitoring systems, it would have been more interesting to include nonusers and resisters to the adoption of telemonitoring solutions.

Conflicts of Interest

None declared.

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Abbreviations

GDM: gestational diabetes mellitus
HCP: health care professional

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