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Changes in Glycemic Control Among Individuals With Diabetes Who Used a Personalized Digital Nutrition Platform: Longitudinal Study

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Abstract

Background: Diabetes-related costs are the highest across all chronic conditions in the United States, with type 2 diabetes accounting for up to 95% of all cases of diabetes. A healthy diet is strongly associated with lowering glycated hemoglobin A_{1c} (HbA_{1c}) levels among individuals with diabetes, which can help curtail other health complications. Digital health platforms can offer critical support for improving diet and glycemic control among individuals with diabetes. Less is known about the characteristics of people with diabetes who use digital health platforms (specifically, a platform that integrates personalized healthy meal plans and food ordering) and changes in their HbA_{1c} levels.

Objective: The aim of this study is to characterize Foodsmart users with diabetes and evaluate the longitudinal impact of Foodsmart—a personalized digital nutrition platform with meal planning, food ordering, and nutrition education features—on changes in HbA_{1c} levels.

Methods: We retrospectively analyzed data collected from 643 adults with at least two self-reported HbA_{1c} entries in the Foodsmart platform between January 2016 and June 2021. Participants self-reported their HbA_{1c} levels, height, weight, health conditions, and diet in a 53-item food frequency questionnaire. Diabetes was defined as $HbA_{1c} \geq 6.5\%$. We analyzed distributions of characteristics by baseline diabetes status and examined the association of characteristics with the likelihood of having diabetes at baseline. To evaluate the change in HbA_{1c} levels among Foodsmart users, we calculated mean changes (absolute and percent) in HbA_{1c} among participants with diabetes and by length of follow-up. We also compared changes in HbA_{1c} and weight between participants with diabetes at baseline who achieved a normal HbA_{1c} level and those who did not.

Results: We found that 43.5% (280/643) of the participants with at least two HbA_{1c} level entries had diabetes at baseline. Participants with diabetes at baseline were more likely to be male, have a higher weight and BMI, report high blood pressure, and have a poorer diet in comparison to participants without diabetes. Using a multivariable logistic regression model, we found that being male and obese were statistically significantly associated with baseline diabetes. Among participants with diabetes at baseline, HbA_{1c} was reduced, on average, by 0.46%. In addition, 21.4% (60/280) of participants with diabetes achieved a normal HbA_{1c} level (<6.5%) in their last HbA_{1c} level entry; this percentage increased with longer follow-up time (39% [7/18] at >24 months). In a sensitivity analysis, users with an $HbA_{1c} \geq 7.0\%$ at baseline had an average absolute change of –0.62% and 31.2% (62/199) of these participants achieved HbA_{1c} levels of less than 7.0%.

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Conclusions: This study assessed characteristics of individuals enrolled on the Foodsmart platform with HbA$_{1c}$ levels and found that users with diabetes had lower HbA$_{1c}$ levels over time and a sizable percentage of participants were successful in achieving normal levels.

Introduction

Over 34 million individuals in the United States have diabetes, comprising 13% of US adults [1]. In 2018 alone, 1.8 million new cases were diagnosed [1]. Diabetes-related costs are the highest of any condition in the US health care system, with the cost of care increasing each year [2]. Recent estimates state that direct medical costs of diabetes and related complications amount to approximately $237 billion each year, accounting for one of every seven health care dollars spent [3]. Notably, type 2 diabetes accounts for 90%-95% of all cases in the United States [1].

For adults with diabetes, the body either does not produce enough insulin or its cells are insulin resistant [4]. Because insulin facilitates the uptake of sugar into cells from the bloodstream, diabetes results in elevated levels of blood glucose. Diabetes is defined by high blood sugar, or hyperglycemia, and glycemic control is fundamental to diabetes management [5]. Type 2 diabetes can also occur due to drug-induced hyperglycemia, which is often caused by beta blockers, thiazide diuretics, corticosteroids, and others [6]. In the long-term, high levels of blood glucose can lead to macrovascular (heart disease, stroke, poor blood circulation) and microvascular (loss of sight, nerve damage, and kidney disease) damage [7]; these health issues lead to greater health care costs. By controlling their blood sugar, however, patients can limit the effect of these negative health consequences [7]. A healthy diet is a critical component in this treatment plan; this includes a meal plan of healthy carbohydrates and fats as well as fiber-rich foods, while limiting foods that are high in trans fats, sodium, and added sugars [8]. Generally, healthy diets for those with diabetes or hyperglycemia are nutrient rich and low in fat and calories. The incorporation of this type of diet for those with type 2 diabetes has been shown to decrease individuals' glycated hemoglobin A$_{1c}$ (HbA$_{1c}$) levels, a measure of one's mean blood glucose levels over the prior three months [9,10]. Despite evidence of the benefits of a healthy diet, there are many barriers to adopting and sustaining these changes in one's diet, such as lack of time, financial resources, accessibility, and information [11]. Previous studies have shown that lower income neighborhoods have an increased exposure to advertisements for tobacco and alcohol, and are more likely to be food deserts, with less access to healthy foods [12,13]. A study conducted in the United Kingdom found that while many participants understood what a healthy diet was, they found it difficult to achieve due to lack of time, advertising, community norms, and conflicting advice from professionals [14]. Furthermore, dietary habits are also shaped by education and nutritional and cooking knowledge, as well as motivation and convenience [15].

Foodsmart is a meal planning platform that addresses access to affordable and healthy foods to enable its users to develop healthy eating habits. The Foodsmart platform improves its participants' health by providing users with a basic understanding of their current diet and potential areas for improvement. It also supplies participants with personalized recipe recommendations and facilitates the purchasing of healthy options through ad-free online ordering of groceries, meal kits, and prepared foods at discounted prices. Previous research has shown that Foodsmart members with obesity have achieved weight loss that has been sustained over the time during which they used the platform [16].

Previous studies have shown that digital nutritional and dietary interventions can improve glycemic control among individuals with type 2 diabetes [17-19]. One digital low-carbohydrate intervention (with comprehensive diabetes and nutritional education and a social support component) was associated with a mean absolute decrease of 1.17% in HbA$_{1c}$ levels after one year [17]. In another study, a dietary intervention that included both a low-carbohydrate Mediterranean diet and a low-fat diet that was conducted over the course of four years showed that changes in one's diet can lead to sustained differences in HbA$_{1c}$ levels [18]. Another study's intervention aimed to encourage participants to adopt a plant-based diet and engage in regular exercise through a digital intervention paired with specialized human support, resulting in a mean change in HbA$_{1c}$ of –0.8% within 12 weeks [19]. In a systematic review of internet interventions, the majority of web-based interventions also focused on the glucose monitoring process and on insulin titration, while very few focused on lifestyle modification, behavior theory, and education with tailored feedback [20,21]. Of the 9 studies that fit the review's criteria and did promote behavior change, 6 of them targeted healthy eating, which further validates the effect of diet on diabetes [21]. Foodsmart differs from these interventions in its complete digital interface, personalization of meal planning, and online food ordering system. The platform alters the food purchasing environment by integrating recipe recommendations into a grocery list, removing online advertisements for unhealthy options, and providing discounts and price comparisons, all of which ease the process of behavior change. By assisting participants through the process of making healthy, sustainable behavior changes, Foodsmart may, in turn, be able to assist users living with diabetes in reducing their HbA$_{1c}$ levels. Given the complexities

of healthy eating, especially among people with diabetes, we wanted to characterize users with diabetes who used Foodsmart.

The main objectives of this study were to better understand and characterize participants with diabetes compared to participants without diabetes and evaluate changes in HbA_{1c} levels, weight, and nutrition quality over time among Foodsmart participants with diabetes through its features including nutritional assessment, personalized meal planning, and altered food environment for grocery purchasing.

Methods

Study Sample

As of June 2021, 10,197 participants (aged >18 years and living in the United States) of Foodsmart who enrolled since January 2016 had entered a plausible value for HbA_{1c} (HbA_{1c} >3% or HbA_{1c} <15%). Of those, 643 Foodsmart participants had entered at least two HbA_{1c} entries, with the first and last entry at least 30 days apart. The final sample size was 643 participants who had at least two reports of HbA_{1c}.

Foodsmart

Foodsmart is a digital nutrition platform that encourages sustained behavior change through nutrition education and personalized meal planning, and promotes healthy eating and nutrition through online grocery and food ordering integration. Foodsmart has two components, FoodSmart and FoodsMart, to help users learn how to eat healthy to meet their nutrition targets and order affordable, tasty, and healthy food online, respectively.

The FoodSmart component provides participants with digital dietetics information on how to better plan meals to meet their nutrition targets. Once participants enroll, they are prompted to fill out the Nutriquiz, an online dietary assessment. Participants report their usual dietary intake and meal planning habits and based on the responses, the assessment provides specific dietary recommendations and a tailored meal plan. Participants can retake the Nutriquiz assessment at any time to track their progress toward their health goals.

The second component is FoodsMart, an online food purchasing environment that promotes buying healthy groceries and meals. Personalized meal plans are converted into a grocery list and integrated into online ordering and delivery of meal kits, prepared foods, and groceries. Participants are encouraged to purchase healthy options that align with their preferences and personalized meal plan. Customized grocery discounts for healthier food options and budget-based purchasing that compares prices across integrated grocery partners help participants save money and further encourage participants to choose healthy food options.

Foodsmart is available through health plans and employers and can be accessed via the web or iOS or Android operating systems.

Measurements of HbA_{1c} and Weight

On the Foodsmart platform, participants were able to enter biometrics such as height, weight, HbA_{1c}, blood pressure, and lipids, and were able to update their biometrics at any time. Given the potential for error when entering self-reported metrics, the following values were considered as incorrect entries and were replaced with a missing value: HbA_{1c} ≤3% or ≥15%, BMI ≤15 kg/m^2 or ≥50 kg/m^2, and weight ≤27.2 kilograms or ≥181.1 kilograms. We only included participants who reported an HbA_{1c} measurement at least twice, and we used the first (baseline) and last (end) values entered. Length of follow-up was calculated as the number of months between the date of the first value and the date of the last value. We defined HbA_{1c} ≥6.5% as the cutoff for diabetes as defined by the American Diabetes Association [22]. The same method was applied to the end HbA_{1c} value to assess diabetes status at the end of follow-up. Since a glycemic target of HbA_{1c} <7% is recommended for nonpregnant adults, as defined by the American Diabetes Association, we used the cutoff of 7% for sensitivity analyses [5]. Changes in HbA_{1c} were calculated by subtracting the first reported value from the end value. Percent change was calculated by dividing the change in HbA_{1c} by the first HbA_{1c} entry.

Baseline BMI was calculated as the first weight entry in kilograms divided by height in meters squared (kg/m^2). Participants' baseline BMI was categorized as normal BMI (BMI <25 kg/m^2), overweight (25-29.9 kg/m^2), or obese (BMI ≥30 kg/m^2). Participants were also able to report any conditions they currently had (eg, high blood pressure, high cholesterol) in the Nutriquiz.

Dietary Assessment

Participants self-reported their usual dietary intake and habits in Foodsmart. Upon enrollment, participants were prompted to fill out a 53-item food frequency questionnaire called Nutriquiz (adapted from the National Cancer Institute Diet History Questionnaire I [23]). Demographic information (age, sex, height), weight, and daily dietary intake (added sugars, fiber, fruits, vegetables, whole grains, fats, proteins, water, and sodium) were also obtained using the Nutriquiz.

Based on responses from the Nutriquiz, a score (Nutriscore) was calculated to assess overall diet quality, which is based on the Alternative Healthy Eating Index-2010 and the Commonwealth Scientific and Industrial Research Organization Healthy Diet Score [24,25]. Participants were assigned a total Nutriscore from 0 to 70 based on the sum of scores for 7 components: fruits, vegetables, protein ratio (white meat/vegetarian protein to red/processed meat), carbohydrate ratio (total fiber to total carbohydrate), fat ratio (polyunsaturated to saturated/trans fats), sodium, and hydration (percent of daily fluid goal). Each of the components was scored from 0 to 10, with 10 being optimal. Change in the Nutriscore was calculated as a participant's last Nutriscore minus the participant's first Nutriscore. A positive change in Nutriscore indicates the participant improved their dietary quality.

Statistical Analysis

We used descriptive analyses to examine the baseline demographic characteristics, HbA_{1c} levels, and diet quality of the study population as a whole and according to whether

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participants had diabetes at baseline or not. We reported categorical variables as number of participants (percentage of study population) and continuous variables as mean (SD). We used chi-square tests to assess whether categorical variables are independent of baseline diabetes status, and two-sample t tests to evaluate differences in continuous variables.

Univariate and multivariable logistic regression were used to estimate the odds ratios (ORs) and 95% CIs of having diabetes at baseline. The multivariable logistic regression model was mutually adjusted for gender, age category, baseline BMI category, baseline Nutriscore, high blood pressure, and high cholesterol.

Among participants who had diabetes, we calculated the mean changes in HbA_{1c} overall and by time of follow-up (>6 months, >12 months, >24 months). We used paired t tests to test whether the changes were statistically significant. Additionally, we calculated the mean percent change for HbA_{1c}. In a sensitivity analysis, we used a threshold of $HbA_{1c} \geq 7\%$ to calculate mean changes in HbA_{1c}.

We also calculated the percentage of participants with diabetes at baseline who returned to normal HbA_{1c} levels by the end of follow-up, and stratified by follow-up length. We conducted a sensitivity analysis using a threshold of $HbA_{1c} \geq 7\%$.

To further explore the performance of HbA_{1c}, we examined changes in weight and HbA_{1c} stratified by whether participants with diabetes at baseline achieved normal HbA_{1c} levels ($HbA_{1c} \geq 6.5\%$) by the end of follow-up.

We considered P values less than .05 to be significant for all tests. R Studio (version 1.4.1106) and R (version 4.0.5; R Foundation for Statistical Computing) were used for all analyses.

The study was declared exempt from institutional review board oversight by the Pearl Institutional Review Board given the retrospective design of the study and the less than minimal risk to participants.

Results

Participant Characteristics

Baseline characteristics of the total study sample and those stratified by baseline diabetes status are shown in Table 1. We found that 43.5% (280/643) of participants had diabetes at

baseline. There were 643 participants included in the analysis, of which 64% (411/643) were female and 61% (391/643) were between 40 and 59 years old (Table 1). The mean weight was 93.9 (SD 23.8) kilograms, the mean baseline Nutriscore was 31.4 (SD 8.5) points, and the mean change in the Nutriscore was 3.2 (SD 7.1) points. The mean follow-up length was 10.4 (SD 7.1) months and ranged from 1 to 38 months. Compared to participants who did not have diabetes, participants who did have diabetes were significantly more likely to be male, to have a higher weight and BMI, to have a lower baseline Nutriscore, and to self-report having high blood pressure. Participants with diabetes at baseline were also more likely to have a higher increase in Nutriscore, a longer follow-up duration, and self-reported high cholesterol compared with participants without diabetes at baseline, although the differences were not statistically significant.

To better understand what type of participant was likely to have diabetes at baseline, we examined the association between baseline characteristics and odds of having diabetes in univariate and multivariable logistic regression models (Table 2). In the univariate regression models, participants who were female were 40% less likely to have diabetes at baseline than participants who were male (OR 0.60, 95% CI 0.43-0.82, P=.002). Participants classified in the overweight BMI category were 86% more likely to have diabetes at baseline than participants classified in the normal BMI category (OR 1.86, 95% CI 1.10-3.19, P=.02). Participants classified in the obese BMI category were 151% more likely to have diabetes at baseline than participants classified in the normal BMI category (OR 2.51, 95% CI 1.58-4.09, P<.001). Participants who self-reported having high blood pressure were also 46% more likely to have diabetes at baseline than participants who did not self-report having high blood pressure (OR 1.46, 95% CI 1.06-1.99, P=.02). Participants with a higher baseline Nutriscore were less likely to have diabetes at baseline (OR 0.98, 95% CI 0.96-1.00, P=.03).

After adjusting for all other variables in the multivariable logistic regression model, we found that being female was associated with 44% lower odds of having diabetes at baseline (OR 0.56, 95% CI 0.39-0.79, P=.001). Additionally, participants who were obese were 134% more likely to have diabetes at baseline than those in the normal BMI category (OR 2.34, 95% CI 1.40-3.97, P=.001).

Table 1. Baseline characteristics of total study sample and by baseline diabetes status.

Characteristic	Total participants		Participants without diabetes		Participants with diabetes		P value[a]
	Sample size, n	Values	Sample size, n	Values	Sample size, n	Values	
Female, n (%)	643	411 (64)	363	251 (69)	280	160 (57)	.002
Age (years), n (%)							.65
<40	643	35 (5)	363	19 (5)	280	16 (6)	
40-59	643	391 (61)	363	216 (60)	280	175 (63)	
≥60	643	217 (34)	363	128 (35)	280	89 (32)	
Weight (kg), mean (SD)	637	93.9 (23.8)	362	90.3 (23.5)	275	98.4 (23.4)	<.001
Change in weight (kg), mean (SD)	466	–1.7 (8.0)	265	–0.8 (8.3)	201	–2.9 (7.6)	.005
BMI category, n (%)							<.001
Normal	643	106 (17)	363	77 (21)	280	29 (10)	
Overweight	643	158 (25)	363	93 (26)	280	65 (23)	
Obese	643	360 (56)	363	185 (51)	280	175 (62)	
Missing	643	19 (3)	363	8 (2)	280	11 (4)	
Baseline HbA$_{1c}$ (%), mean (SD)	643	6.6 (1.4)	363	5.8 (0.5)	280	7.8 (1.5)	<.001
Follow-up duration (months), mean (SD)	643	10.4 (7.1)	363	10.1 (7.0)	280	10.7 (7.3)	.34
High blood pressure, n (%)	147	47	70	44	78	53	.02
High cholesterol, n (%)	209	57	92	54	120	61	.10
Baseline Nutriscore (0-70), mean (SD)	643	31.4 (8.5)	363	32 (8.5)	280	30.5 (8.5)	.03
Change in Nutriscore, mean (SD)	601	3.2 (7.1)	337	3.0 (7.1)	264	3.4 (7.0)	.46

[a]Chi-square tests and two-sample t tests were used to test differences for categorical and continuous variables, respectively.

Table 2. Association between baseline characteristics and likelihood of diabetes at baseline in univariate and multivariable logistic regression models.

Parameter	Univariate odds ratio (95% CI)	P value	Multivariable odds ratio (95% CI)	P value
Gender (female)	0.60 (0.43-0.82)	.002	0.56 (0.39-0.79)	.001
Age (years)				
<40	1 (reference)		1 (reference)	
40-59	0.96 (0.48-1.95)	.91	0.84 (0.41-1.78)	.65
≥60	0.83 (0.40-1.71)	.60	0.72 (0.34-1.57)	.40
Baseline BMI category				
Normal	1 (reference)		1 (reference)	
Overweight	1.86 (1.10-3.19)	.02	1.64 (0.96-2.85)	.08
Obese	2.51 (1.58-4.09)	<.001	2.34 (1.40-3.97)	.001
High blood pressure	1.46 (1.06-1.99)	.02	1.18 (0.83-1.69)	.36
High cholesterol	1.32 (0.96-1.81)	.09	1.13 (0.80-1.60)	.48
Baseline Nutriscore (0-70)	0.98 (0.96-1.00)	.03	0.99 (0.97-1.01)	.47

Changes in HbA$_{1c}$ Levels

Figure 1 presents the mean and percent changes in HbA$_{1c}$ levels among participants who were classified as having diabetes for the overall group and by length of follow-up, at >6, >12, and >24 months. The mean changes in HbA$_{1c}$ overall and at >6, >12, and >24 months were –0.46, –0.37, –0.45, and –0.70 points, respectively. Percent changes in HbA$_{1c}$ overall and at >6, >12, and >24 months were –6%, –5%, –6%, and –9%, respectively. All changes were statistically significant (P<.05) using paired t tests. For users with an HbA$_{1c}$ ≥7.0%, mean change in HbA$_{1c}$ was –0.62 points (P<.001), and percent change was –7.6%.

Figure 1. Mean change in HbA$_{1c}$ among participants who had diabetes at baseline. Bars represent average HbA$_{1c}$ change. Line represents average HbA$_{1c}$ percent change.
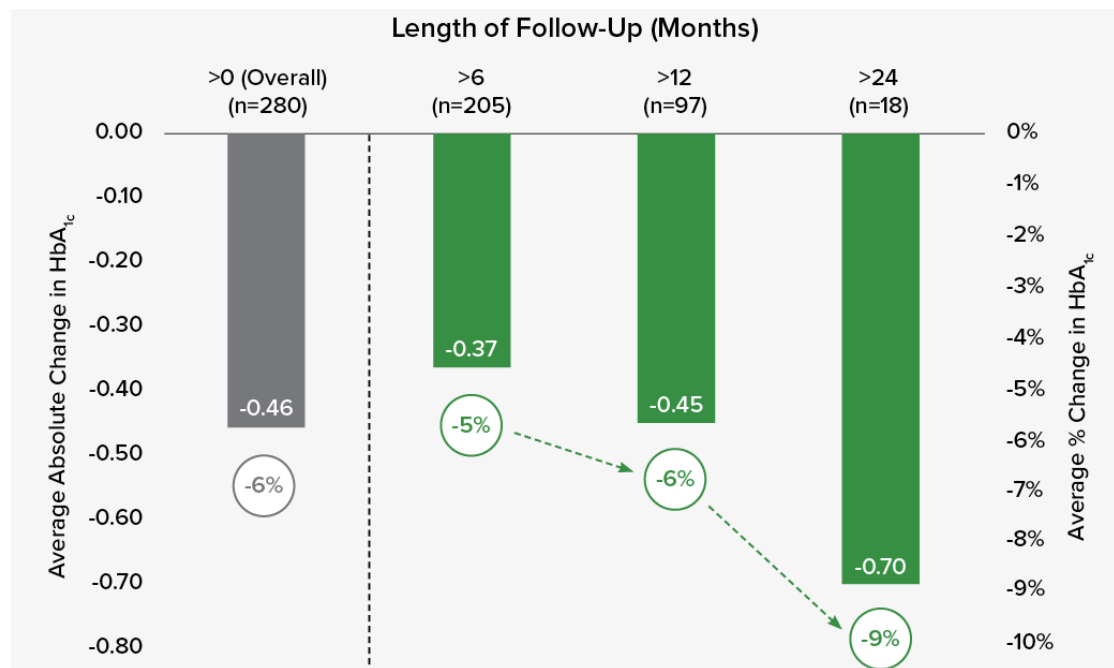
We calculated the percentage of participants with diabetes at baseline who achieved a normal (<6.5%) HbA$_{1c}$ level overall and by cumulative length of follow-up time. Among all participants with diabetes, 21.4% (60/280) achieved normal HbA$_{1c}$ levels, using a threshold of 6.5%. Among participants whose follow-up time was longer than 6, 12, and 24 months, the percentage of participants who achieved normal HbA$_{1c}$ levels was 21.0% (43/205), 22% (21/97), and 39% (7/18), respectively. In a sensitivity analysis, for participants with an HbA$_{1c}$ ≥7%, 31.2% (62/199) of them achieved an HbA$_{1c}$ level less than 7%.

To better understand how weight and HbA$_{1c}$ changed according to end diabetes status, we examined changes in weight and HbA$_{1c}$ stratified by whether participants with diabetes at baseline achieved normal HbA$_{1c}$ levels (Table 3). Reductions in weight and HbA$_{1c}$ were greater for those who achieved normal HbA$_{1c}$ levels at the end of follow-up versus those who did not.

Table 3. Change in biometrics stratified by whether participants with diabetes at baseline achieved a normal HbA$_{1c}$ level.

Biometrics	Diabetes to normal	Diabetes to diabetes
Weight change (kg)	–4.1	–2.5
HbA$_{1c}$ change (%)	–1.7	–0.1

Discussion

Principal Findings

In this study of 643 participants who used the Foodsmart platform, we found that 43.5% (280/643) had diabetes at baseline, as defined by their baseline HbA$_{1c}$ level. Foodsmart participants with diabetes at baseline were more likely to be male and have a higher weight and BMI. On average, HbA$_{1c}$ decreased by 0.46% among participants with diabetes over a mean duration of follow-up of 10.7 (SD 7.3) months. Among participants with diabetes at baseline, 21.4% (60/280) of those participants achieved a normal HbA$_{1c}$ level by the end of follow-up. These findings suggest that use of the Foodsmart platform may be associated with improved glycemic control among users with diabetes.

In line with our findings, prior studies evaluating the association between diet interventions and clinical biomarkers showed that various nutrition therapies significantly improved glucose regulation and reduced HbA$_{1c}$ levels in patients with diabetes mellitus. For instance, Esposito et al [18] conducted a randomized trial to evaluate the effects of a low-carbohydrate Mediterranean diet versus a low-fat diet on HbA$_{1c}$ levels among individuals with type 2 diabetes. The trial was conducted in Italy and included 215 participants with type 2 diabetes who were classified as obese, had never previously taken antihyperglycemic medication, and had HbA$_{1c}$ less than 11%. After two years, those on the low-carbohydrate Mediterranean diet had a decrease in HbA$_{1c}$ of 1.1%, while those on the low-fat diet had a decrease of 0.5%. In our study, participants who had a follow-up time period greater than 2 years were observed to have a 0.7% decrease in HbA$_{1c}$. Esposito et al [18] also found that, at the end of their study, 37% and 24% of participants returned to normal HbA$_{1c}$ levels (using a threshold of 7%) after following the Mediterranean and low-fat diet, respectively. In our study, 31% of participants returned to normal HbA$_{1c}$ levels

(using a threshold of 7.0%). The effects of the low-carbohydrate Mediterranean diet were likely greater than what was observed with Foodsmart because the trial had more specific and stringent guidelines for the participants' diets than there were with Foodsmart, as participants can make changes that best fit their lifestyles. Therefore, with assistance from Foodsmart in making flexible dietary changes, participants can see changes in their HbA_{1c} levels that are similar to that of a strict low-fat diet.

In our study, we found that men were more likely to have diabetes, which is in line with a previous study conducted by Nordström et al [26]. The authors analyzed data from The Healthy Aging Initiative, a population-based prospective study of men and women 70 years of age or older in northern Sweden, and found a significantly greater prevalence of diabetes in men than women. They hypothesized that this was due to differences in visceral fat mass among men and women and found that when visceral fat mass was adjusted for, male sex was no longer associated with diabetes. Therefore, their findings suggest that differences in the prevalence of diabetes between males and females may be due to differences in visceral fat mass, which is known to be a strong predictor of diabetes [27,28]. Additionally, we found that people with diabetes were more likely to be obese, which has been established by several studies that have found obesity to be a risk factor for diabetes [29-32]. Finally, we found that there was greater weight change among those who achieved normal HbA_{1c} levels. This is consistent with findings from Gummesson et al [33], who conducted a systematic review aimed at understanding the association between weight loss and HbA_{1c} for overweight and obese patients with type 2 diabetes. They found a dose-response relationship between weight loss and reduction in HbA_{1c} in their participants, which may explain why we see a larger weight change for those who have a greater reduction in HbA_{1c} and return to normal levels in our study.

Patients with diagnosed diabetes incur mean medical expenditures of $16,750 per year, of which about $9600 is attributed to diabetes [3]. Glucose-lowering drugs such as sodium–glucose cotransporter 2 (SGLT2) inhibitors and glucagon-like peptide 1 (GLP-1) receptor agonists account for a large proportion of these expenditures, with an estimated mean annual cost of $2727 per patient [34]. Significant savings can be achieved if patients meet the target American Diabetes Association HbA_{1c} level of <7% [5,22]. A 1%, 1.25%, or 1.5% reduction in HbA_{1c} for a commercially insured patient could result in savings of $801, $1033, and $1266 per patient per year, respectively [35]. In this study, participants with diabetes at baseline who achieved an end normal HbA_{1c} level reduced their HbA_{1c} by 1.7% on average, achieving a clinically significant change of 0.5% [36]. Given the high cost of medications, prevention and management of diabetes through eating healthier could be an attractive, low-cost alternative. Unfortunately, we do not know whether participants were on glucose-lowering medications before or during enrollment on the Foodsmart platform. Despite this, we can estimate the difference in costs between prescription medications and Foodsmart. Improved glucose management would cost $327 more per person with diabetes annually relative to current care, largely due to use of antihyperglycemic medications [37]. In comparison, as of 2021, the Foodsmart platform on average costs $12.30 per eligible member annually. Using the results above, a 1% reduction in HbA_{1c} would cost $26.98 on average. On the other hand, using metformin or liraglutide (a GLP-1 receptor agonist) to reduce HbA_{1c} levels by 1% would cost on average $120 and $8640, respectively. Given that the cost of metformin is 4 times higher than the cost of using Foodsmart, and assuming participants on the Foodsmart platform were not on glucose-lowering medication, the cost of a digital platform like Foodsmart would be significantly more affordable than standard treatment with diabetes medications [38-40].

There are some important limitations to note for this study. The first is that HbA_{1c} levels were self-reported and were not clinically validated. However, these values should still be fairly accurate, particularly for participants with diabetes who used the app to track their HbA_{1c} levels. Since participants were not required to enter HbA_{1c} levels, we have reason to believe people who did—in particular, participants with diabetes—had purposefully entered their HbA_{1c} levels rather than entering an arbitrary HbA_{1c} level, which would lead to greater inaccuracy. Additionally, follow-up time was based on when the biometrics were entered, but did not necessarily line up with when the labs were conducted. Another issue is potential selection bias for participants with diabetes who choose to use the platform and are included in the study. For example, those with diabetes who use the app, particularly as a tracker, might be more inclined to want to make changes to their lifestyle. They may have made changes outside of what they did in the app that resulted in changes in HbA_{1c}. Therefore, we cannot definitively conclude that Foodsmart's platform caused these changes in HbA_{1c}, but there could be an association between using the platform and HbA_{1c} changes. A randomized controlled trial must be conducted to determine if there is a causal link. In addition, there are other potential factors influencing diabetes status at baseline and changes in HbA_{1c} that we might not be able to evaluate because certain types of data are not collected in the Foodsmart app. For example, we do not have participants' personal or family medical histories to understand their influence on diabetes status [41]. We are also unable to assess how the use of diabetic medications may influence HbA_{1c}, as well as other medication-induced fluctuations in HbA_{1c}. However, either prevalence of use of these medications or the incident hyperglycemia as a result of these medications in the US population is fairly rare [42]. Some other influencing factors for HbA_{1c} that we did not collect include sleep and amount of exercise [43,44]. We also did not account for socioeconomic factors, such as educational level, which might confound the associations seen and the accuracy of the self-reported biometrics, as stated earlier [45]. Additional studies are required to obtain more information about these covariates. We also did not account for the frequency of use of the Foodsmart platform, which could affect the associations found. Finally, due to missing data for several biometrics (such as BMI) and only single values input for HbA_{1c}, our study had a small sample size relative to the total number of participants who use the Foodsmart platform.

This study also has many strengths. To our knowledge, this is the first study that evaluated the real-life impact of behavior change with online food ordering, diet, and meal planning through a digital intervention and its impact on diabetes and HbA$_{1c}$ levels. Using Foodsmart's large user base, this study was able to draw real-world associations between changes in dietary habits and HbA$_{1c}$ levels and the use of a commercial digital health platform. Furthermore, participants on the Foodsmart platform had a broad range of durations of enrollment; this allowed us to measure changes in HbA$_{1c}$ over different lengths of time, including time spans of greater than 2 years.

Conclusions

This study evaluated changes in self-reported HbA$_{1c}$ levels among participants with diabetes who were using a digital nutrition intervention with personalized recipe recommendations, meal planning, food ordering, and grocery discounts and price comparisons. Future research through a randomized controlled trial will be needed to assess the causal effect of the Foodsmart platform on dietary changes and improvements in HbA$_{1c}$ levels, the difference in cost between pharmaceutical and digital interventions, and which specific components of the dietary score are associated with a reduction in HbA$_{1c}$ levels.

Acknowledgments

Authors' Contributions

BS acquired data, analyzed the data, interpreted the results, and drafted the manuscript. EAH designed the study, interpreted results, and drafted the manuscript. SB interpreted results and drafted the manuscript. KC acquired data. JL and JS interpreted results. All the authors reviewed and approved the final version of the manuscript and take responsibility for the manuscript.

Conflicts of Interest

BS, EAH, SB, JL, KC, and JS are employees of Foodsmart. EAH, JL, KC, and JS own Foodsmart stock.

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Abbreviations

GLP-1: glucagon-like peptide 1
OR: odds ratio
SGLT2: sodium–glucose cotransporter 2

Original Paper

Blood Glucose Monitoring and Sharing Amongst People With Diabetes and Their Facilitators: Cross-sectional Study of Methods and Practices

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Abstract

Background: The last two decades have witnessed a burgeoning rise in the prevalence of diabetes globally. It has already reached epidemic proportions in Saudi Arabia, with reported high risk among women. As a result, diabetes monitoring and self-management programs are being highly prioritized for diabetes control and management.

Objective: To investigate measuring and sharing practices of the self-monitoring of blood glucose (SMBG) among patients with type 1 or 2 diabetes using insulin.

Methods: A cross-sectional study was conducted on a sample of 203 patients attending primary care clinics at a tertiary care center. The questionnaire assessed the measuring, recording, and sharing of SMBG practices of patients having diabetes with their physicians. The methods used for recording and sharing were categorized into paper-based and electronic-based. In addition, the determinants of the different methods used and frequency of sharing were analyzed.

Results: The overall monitoring prevalence was 95% (193/203), and 57% (117/203) of participants shared the SMBG results. Among the 193 individuals that performed self-monitoring, 138 (72%) performed daily monitoring, and 147 (76%) recorded their blood sugar levels. Almost 55% (81/147) used paper-based materials like notebooks and paper for recording, while the rest (66/147, 45%) used digital devices like laptops and smartphones. A shift towards the use of digital devices and smart applications was observed in patients below 50 years of age. The digitally recorded blood glucose measurements were being shared thrice more often than the recordings made on paper or in notebooks (OR [odds ratio] 2.8; P=.01). Patients >50 years of age (OR 2.3; P=.02), with lesser formal education, married (OR 4.2; P<.001), with smaller family size (OR 2.6; P=.01), having type 2 diabetes (OR 4.1; P<.001) and any comorbid conditions (OR 2.6; P=.01) were associated with higher odds of using paper-based sharing methods. Only the female gender and type 2 diabetes were associated with increased frequency of sharing, while uncontrolled diabetes, the presence of other comorbidities, and duration of diabetes did not show any influence.

Conclusions: Good monitoring and optimal sharing practices were found. Sharing using electronic devices can be emphasized. Diabetes self-management programs can incorporate the use of digital technology in training sessions. Digital literacy and its applications in health care may enhance SMBG practices resulting in better diabetes control.

Introduction

Optimal glycemic control is central to the management of both type 1 and type 2 diabetes. Poor glycemic control has been causally associated with microvascular and macrovascular complications. Hence it is imperative to target and maintain optimum diabetes control [1-3]. Regular monitoring of blood glucose levels is an integral part of diabetes management [4]. Clinical monitoring of glycated hemoglobin levels (HbA_{1c}) that determine the 3-month average blood glucose status and daily home monitoring of the capillary blood glucose levels called self-monitoring of blood glucose (SMBG) are the two principal methods of monitoring blood glucose levels [5]. According to the 2012 American Diabetes Association (ADA) guidelines, SMBG is recommended at least thrice daily for those on multiple insulin therapy and a minimum once daily for noninsulin users [6]. Diabetes management reached a significant milestone with the introduction of glucometer-based SMBG. Short-term benefits of regular monitoring of glucose levels include hypoglycemia prevention and the proven benefit to the physicians in adjusting the insulin doses. Scientific evidence suggests there is a substantial reduction in diabetes-related complications due to the long-term benefits of regular blood glucose monitoring [7-10].

Furthermore, in addition to monitoring, the practice of sharing blood glucose levels with the physicians is highly recommended by the consensus of organizations such as the ADA, International Diabetes Federation, and European Association for the Study of Diabetes in the holistic management of hyperglycemia [11-13]. However, the frequency of monitoring can be individualized according to the patient's glycemic status, presence of other comorbidities and diabetes-related complications, lifestyle, and type of drugs administered [14]. Regular monitoring and sharing have been associated with significant predictors like motivation from the physician and family, fear of hypoglycemia, and the desire for good glycemic control [15]. Sharing SMBG results, in addition to HbA_{1c}, has been the basis for drug dosing and physicians' decision-making [14,15]. The frequency of SMBG monitoring and sharing influence the progressive monitoring behavior that ultimately has a profound impact on glycemic control. Technological advancements in monitoring devices have simplified the process of monitoring and sharing. Digital devices like smartphones, with specific health apps installations and glucometers linked to smart devices, offer a conducive medium for effortless and error-free sharing of measurements.

Scientific literature reporting SMBG practices among insulin users is often sparse in Saudi Arabia. Our study investigated the frequency of blood glucose monitoring and the methods adopted to measure, record, and share SMBG results by patients with diabetes and on treatment with insulin. We hypothesized that at least 50% shared the results with their physicians, and 50% of the patients used paper-based methods for recording and sharing. The associated factors that determine the sharing practices were also investigated. Additionally, the physicians' advice on results-sharing and their perceptions on the adequacy of SMBG results in adjusting insulin dose was also determined. The results would provide a comprehensive understanding of the prevailing patient practices related to SMBG that may identify determinants of good monitoring and sharing practices. Moreover, the findings may suggest the improvement of diabetes education programs by adopting changing trends in digital technology use and facilitating patient empowerment in optimum diabetes management.

Methods

Study Design

A cross-sectional study design was incorporated to investigate the measurement of SMBG among patients with diabetes using insulin. The study was conducted from November 2019 until April 2020. Patients with a known diabetes diagnosis and on insulin treatment formed the primary sampling unit. The patients were identified from the appointment list on the hospital's electronic health records at the primary care clinics, family medicine clinics, and specialized diabetes care centers of the university hospital. During the first 4 months of the study period, data was collected at the clinics, transitioning to telephone surveys during COVID-19 restrictions during March and April 2020. A well-trained team was involved in the data collection. Patients with cognitive impairment, pregnant women, and those requiring hospitalization were excluded. The selected patients' physicians were also interviewed to assess the advice and use of shared SMBG results.

Blood Glucose Measurements of Patients

Every patient with diabetes is usually provided with a glucose self-monitoring kit, including a diary, to maintain the self-management plan provided by the university hospital at the time of the first diagnosis or during the first follow-up visit. The patients record the SMBG results according to their preference and convenience using the given diaries or digital devices. Paper-based methods consisted of blood glucose readings measured and shared via diaries, notebooks, or paper, while smartphones, laptops, and glucometers were categorized as digital or electronic methods.

Study Questionnaire and Sample Size

The questionnaire was comprised of two parts. The first section included questions regarding patient demographics, history of diabetes, and SMBG practices that were administered to the patients. The second part of the questionnaire included 4 questions were addressed to the patient's attending physician, relating to the physician's advice on sharing SMBG results and the use of results in adjusting the patient's insulin dose. In addition, a pilot test was conducted on 20 subjects (excluded from the sample) attending primary care clinics to estimate the interview time, ensure comprehensibility, and test logistics. A sample size of 203 was obtained using the formula for a single proportion $N=z^2$ x P x $(1-P)/\delta2$, where P=75%, the proportion that shared the SMBG results during the pilot test, z=90% CI, and P=.05.

Ethical Considerations

A consent form was attached to the questionnaire explaining the research purpose, research benefits, a statement of confidentiality, and a guarantee of participants' right to drop out of the study at any stage. Participating in this study was nonobligatory, and no rewards were given to participants upon completing the questionnaire. Study approval was obtained by the department's ethics committee (reference number CMED 305-F 14-2018-19).

Data Analysis

Descriptive statistics such as mean and standard deviation were derived for continuous variables. Frequency and percentage were computed for binary and categorical data. Bivariate statistical analysis was carried out using appropriate statistical tests based on the type of study and outcome variables. Pearson's chi-square test was used to test the differences in observed frequencies between the two groups, paper-based and electronic-based, considering the different categorical variables in 2 x 2 table. A P value of <.05 was used to report the statistical significance. The odds ratio (OR) and upper and lower 95% CI were taken from the risk estimate.

Results

The final sample included 203 participants. The mean age of the study participants was 51.8 years (SD 16.6). Type 2 diabetes was predominant (155/203, 76%). The mean HbA_{1c} was 9.5%, and the majority (193/203, 95%) of the participants showed poor glycemic control (HbA_{1c} >7%). Table 1 illustrates the demographic characteristics of the study participants. Chronic diseases were reported in more than half (119/203, 58.6%) of the study participants. The most prevalent comorbidity was hypertension (90/203, 44.3%), followed by dyslipidemia (42/203, 20.7%). Other commonly reported comorbidities were thyroid disorders, mainly hypothyroidism, with asthma and kidney diseases accounting for 20% (40/203).

Table 2 displays the frequency of measuring, recording, and sharing of the SMBG results. A majority of participants (193/203, 95%) reported measuring their blood glucose levels. Almost 81% (156/197) measured themselves, and 19% (37/197) sought family assistance. Of the 193 individuals, 147 (76%) recorded the measurements, and among those who recorded, 117 (79%) shared the readings with their physicians. More than half of the participants (65/117, 55.6%) preferred paper-based methods like notebooks and paper sheets, while the rest (52/117, 44.4%) used digital devices like glucometers, mobile phones, laptops, and smartphone apps to share SMBG results. Significance testing with increased frequency of sharing showed only female participants and patients with type 2 diabetes were significantly associated with increased sharing (data not shown).

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Table 1. Sociodemographic and clinical characteristics of patients with diabetes on insulin therapy.

Variable	Frequency (N=203)
Age (in years), n (%)	
≤50	87 (42.9
>50	116 (57.1)
Gender, n (%)	
Female	109 (53.7)
Male	94 (46.3)
Nationality, n (%)	
Saudi	193 (95.1)
Non-Saudi	10 (4.9)
Education, n (%)	
School education	137 (67.5)
Advanced education	66 (32.5)
Employment status, n (%)	
Employed	55 (27.1)
Retired	48 (23.6)
Not employed	100 (49.3)
Marital status, n (%)	
Married	150 (73.9)
Not married	53 (26.1)
Monthly family income, n (%)	
USD <2666	122 (60.1)
USD >2667	81 (39.9)
Family members, n (%)	
≤6	103 (50.7)
>6	100 (49.3)
Type of diabetes, n (%)	
Type 2	155 (76.4)
Type 1	48 (23.6)
Duration of diabetes (years), n (%)	
≤10	73 (36)
>10	130 (64)
HbA_{1c}[a] , n (%)	
Uncontrolled (>7.0 %)	193 (95.1)
Controlled	10 (4.9)
Other chronic diseases	
Yes	119 (58.6)
No	84 (41.4)
HbA_{1c}, mean (SD)	9.5 (1.8)

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

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Table 2. Frequency of self-monitoring of blood glucose practices.

Variables	Frequency (N=203)
Measuring, n (%)	193 (95.1)
Recording (n=193), n (%)	147 (76.2)
Sharing (n=147), n (%)	117 (79.6)
# of times shared (n=117), n (%)	
Daily	25 (21.4)
Week	17 (14.5)
Monthly	36 (30.8)
Every 3 months	39 (33.3)
Methods of sharing (n=117), n (%)	
Notebook for recording blood glucose results	49 (41.9)
Paper	16 (13.7)
Glucometer	15 (12.8)
Laptop or Smartphone	20 (17.1)
Smart Applications	17 (14.5)

Table 3 illustrates the determinants of the methods used for sharing. Patients aged >50 years were twice as likely to use paper-based methods (OR 2.3; P=.02) for recording and sharing the measurements. Being married increased the odds of using paper-based methods for sharing SMBG results by 4 times (OR 4.2; P<.001). Small family sizes (less than 6 family members) were also associated with the increased use of the paper-based methods (OR=2.6; P=.01). In addition, type 2 diabetes and the presence of any chronic ailment were associated with a greater likelihood of using paper methods. Although not reaching the level of statistical significance, those attaining formal education were twice as likely to rely on paper-based methods for recording and sharing the results with their physicians.

Furthermore, digitally recorded blood glucose results were shared almost three times more frequently than those recorded on paper or notebooks (OR 2.8; P=.01). Other characteristics such as gender and HbA_{1c} were not significantly correlated with the methods of sharing.

Additionally, physicians' role in patients' SMBG practices was also analyzed. Most of the patients' physicians (196/203, 96.6%) encouraged them to monitor their blood glucose levels regularly. In addition, almost 97.4% (114/117) of the physicians checked the SMBG results before adjusting the insulin dose. On the other hand, 60% (112/203) of the physicians perceived that SMBG measurements were adequate to adjust the patients' insulin dose.

Table 3. Determinants of paper-based and electronic methods of sharing.

Variable	Paper-based sharing, n	Electronic-based sharing, n	χ^2 value	P value	OR	95% CI
Age (years)			4.86	*.02* [a]	2.3	1.1-4.8
>50	42	23				
≤50	23	29				
Gender			1.17	.27	0.6	0.3- 1.3
Male	26	26				
Female	39	26				
Education			3.47	.06	2.0	0.9-4.4
School education	47	29				
Advanced education	18	23				
Employment status			0.00	.97	0.9	0.4- 2.3
Not employed	32	27				
Employed	18	15				
Marital status			11.77	*<.001*	4.2	1.8-9.8
Married	54	28				
Not married	11	24				
Monthly family income (Saudi Riyal)			0.17	.67	1.1	0.5-2.4
USD <2666	40	30				
USD >2667	25	22				
Family members			6.36	*.01*	2.6	1.2-5.5
≤6	39	19				
>6	26	33				
Type of diabetes			9.55	*<.002*	4.1	1.6-10.4
Type 2	57	33				
Type 1	8	19				
Duration of diabetes (years)			0.27	.59	1.2	0.5-2.6
≤10	23	16				
>10	42	36				
HbA$_{1c}$ [b]			_ [c]	.23	0.2	0.1-1.6
Controlled (<7)	2	5				
Uncontrolled	63	47				
Other chronic diseases			6.12	*.01*	2.6	1.2-5.6
Yes	47	26				
No	18	26				
Times they share			6.24	*.01*	2.8	1.2- 6.4
>1 Month	28	11				
≤1 Month	37	41				

[a]P values in italic indicate differences between variables are statistically significant.

[b]HbA$_{1c}$: glycated hemoglobin levels.

[c]Cell count less than 5 did not give the chi-square constant.

Discussion

Principal Findings

The measuring, recording, and sharing of SMBG practices in patients with diabetes using insulin were investigated. Some of the major findings of this study show that 95% (193/203 of the total study population monitored their blood glucose at any given time, and 72% (138/193) performed daily monitoring. Among those who monitored, close to 76% (147/193) recorded the measurements, of which 79% (117/147) shared it with their physicians. But the overall prevalence of sharing in the total sample was 57.6% (117/203) only. The majority of the participants (81/147, 55%) used notebooks or paper for recording SMGB readings, although smart applications were also frequently used. Being >50 years of age, with lesser formal education, married, with smaller family size, with type 2 diabetes, and the presence of comorbidities were significant determinants for using paper-based methods to share SMBG results. The majority of the physicians (196/203, 96.6%) constantly encouraged their patients to share the results, and most of them perceived that SMBG results are adequate for optimizing insulin doses.

Empirical evidence from studies worldwide suggests frequent monitoring of blood glucose to be significantly associated with effective glycemic control; hence, regular monitoring and sharing are highly recommended by the consensus [16-19]. Many international studies point towards a higher prevalence of daily blood glucose monitoring compared to sharing the results. For example, a nationwide Norwegian survey reported 70% of the patients practicing SMBG and less than 50% performing daily monitoring [20]. Another research from the United States noted 86% of insulin-users practice SMBG [21], while a regional study from Oman demonstrated a lower rate of 36%; nevertheless, all of them showed a lesser prevalence of results-sharing with physicians [22]. On the contrary, compared to these studies, our results reflect the higher prevalence of monitoring practices; however, sharing SMBG results with physicians was considered optimal.

Monitoring and sharing are two interlinked practices of diabetes self-management. Monitoring helps patients track their glycemic levels daily, plan nutritional and activity routines, and improve their quality of life, whereas sharing helps physicians optimize insulin doses. Physician's motivation, in addition to diabetes self-management training and education programs, support the importance of monitoring and sharing practices. Our results showed that 93.6% (190/203) of the patients were encouraged by the physicians to monitor their glycemic status regularly, and 96.6% (196/203) were motivated to share the results. The encouraging attitude of the physicians reflected the high rate of monitoring; however, it did not effectively impact the rate of sharing. Of the 79% (117/147) who shared the SMBG results, 64% (75/117) shared once every month or more, and 21% (25/117) shared daily.

Further analysis showed an increased frequency of sharing to be associated with type 2 diabetes and being a woman. Although the presence of other comorbidities was not associated with increased sharing, patients in the "no comorbidity" group shared more often daily and weekly. Other variables like uncontrolled diabetes or longer duration of diabetes also did not influence sharing frequency. A similar regional study from Western Saudi Arabia demonstrated a prevalence rate of 70 % for measuring SMBG, with only 22% sharing the results with their physicians [23]. Our results showed higher rates of compliance when compared to the other regional literature. These are some important findings of our research which, if further investigated, might shed light on the causal reasons for frequent sharing that can be henceforth applied to augment effective diabetes management.

Furthermore, this study noted a slight preponderance towards the use of paper-based methods for sharing the results. However, the characteristics defining the method of use were unambiguous. Patients with higher age and those with lesser education preferred paper-based methods to digital devices. The other determinants like being married and the presence of comorbidities are also associated with age. One of the main reasons for the preponderance of paper-based methods could be related to the ease and comfort in recording the results right away. Since the patients are provided with a glucometer kit and notebook, many patients preferred saving the results in the notebook instantaneously compared to laptops or smartphones.

In the era of a digital revolution, the use of smartphones and digital devices is ubiquitous. One might expect a high dependency on smartphone applications for health-related information-sharing between patients and physicians. Our study has observed a transitional trend in the method of sharing, where the younger and more educated subjects preferred digital devices. Previous research has shown that uptake and sustained use of digital devices and applications for monitoring health depends on a number of factors like literacy, age, cognitive abilities, type and features of applications, and complexity of use [24]. Wildenbos et al [25] demonstrated poor usability and feasibility in using digital applications for health monitoring among older adults. Besides, complications in operations have largely contributed to aiding the discontinued use of digital applications for health benefits [26]. The findings from these studies establish the evidence in favor of predominant digital nonuse among senior people and the digitalization of younger patients, demonstrating consistency with our results. Identifying an emerging shift towards the use of digital technology in health care and contemplating the barriers of its application demonstrates the need to revise and reframe the structure of the standard diabetes education programs. Patient education programs could include training sessions demonstrating the use of digital devices and their applications in diabetes management.

Another key finding of the study is the adequacy of the shared blood glucose measurements in adjusting and customizing insulin doses. Almost 93% (188/203) of the physicians perceived shared results were adequate for optimizing the insulin dose. This is a major clinical use of SMBG. A recent review based on evidence from 26 studies found SMBG to be highly beneficial in titrating insulin doses. It has the potential to influence the physicians' decision-making [27] as well as patients. Furthermore, some trials have demonstrated structured diabetes control programs achieving targeted glycemic control by using daily blood glucose monitoring results as a basis to

self-adjust insulin dose in poorly or uncontrolled type 2 diabetes patients [28].

Finally, another interesting finding showed that those who used digital devices shared results three times more often than those who used paper methods. One of the reasons for using digital devices could be a relatively simpler and quicker process. Moreover, although not significant, the number of patients with uncontrolled diabetes in the device-using group was lesser than those in the paper-based group. In addition, the presence of comorbidities was significantly lesser in the device-using group. However, the role of confounders like age cannot be ruled out. Hence, digital devices can be considered as one of the facilitators of good sharing practices. Moreover, measurements from the digital devices can be synced, and the data can be stored in other devices for future reference. An Australian mobile health pilot program for diabetes control demonstrated digital device use and subsequent digital training to impact patients' self-management of diabetes substantially [29]. With this additional evidence, we highly recommend prioritizing digital literacy in diabetes self-management training and education programs.

However, the study does contain certain limitations. Limited generalizability is one of the study's major limitations since the research was conducted at a single tertiary care government referral center. The smaller sample size is also a potential limitation.

Conclusions

To our knowledge, this is the first study reporting the methods and determinants of the sharing practices of SMBG among insulin users in Saudi Arabia. The findings have good research and clinical implications. Future research exploring individual factors for patient preferences and monitoring adherence and detailed analyses of SMBG barriers are highly recommended. Furthermore, determinants, barriers, and facilitators of sharing and the effect of sharing on the disease status must be explored to understand the effective role of sharing SMBG results fully. However, this study provides resourceful literature and highlights the essentials of SMBG results sharing practices while recognizing the importance of the types of methods preferred that can substantially increase good practices. With diabetes beginning to affect more and more younger people, and owing to the widespread use of smartphones and other digital devices, digitalization can be considered one of the methods to increase diabetes monitoring. Numerous health applications in smartphones have been developed to assist in maintaining physical fitness, general health, and specific disease control like obesity and diabetes. Smartphone applications related to diabetes control and built-in glucometer software technologies enable users to keep track of their blood glucose and assist in optimum diabetes management through lifestyle modification strategies. Hence diabetes education and self-management programs can consider redesigning the curriculum to include training in the use of smartphone applications in diabetes self-management.

Authors' Contributions

AJ, ST, MB, and NS contributed to the conception and design of the study and data interpretation. WB, SA, AA, MA, NA, and SO participated in data acquisition and statistical analysis. ST assisted in the analysis and drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ADA: American Diabetes Association
OR: odds ratio
SMBG: self-monitoring of blood glucose

Original Paper

A Novel Mobile Health App to Educate and Empower Young People With Type 1 Diabetes to Exercise Safely: Prospective Single-Arm Mixed Methods Pilot Study

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Abstract

Background: Empowering young people with type 1 diabetes (T1D) to manage their blood glucose levels during exercise is a complex challenge faced by health care professionals due to the unpredictable nature of exercise and its effect on blood glucose levels. Mobile health (mHealth) apps would be useful as a decision-support aid to effectively contextualize a blood glucose result and take appropriate action to optimize glucose levels during and after exercise. A novel mHealth app acT1ve was recently developed, based on expert consensus exercise guidelines, to provide real-time support for young people with T1D during exercise.

Objective: Our aim was to pilot acT1ve in a free-living setting to assess its acceptability and functionality, and gather feedback on the user experience before testing it in a larger clinical trial.

Methods: A prospective single-arm mixed method design was used. Ten participants with T1D (mean age 17.7 years, SD 4.2 years; mean HbA$_{1c}$, 54 mmol/mol, SD 5.5 mmol/mol [7.1%, SD 0.5%]) had acT1ve installed on their phones, and were asked to use the app to guide their exercise management for 6 weeks. At the end of 6 weeks, participants completed both a semistructured interview and the user Mobile Application Rating Scale (uMARS). All semistructured interviews were transcribed. Thematic analysis was conducted whereby interview transcripts were independently analyzed by 2 researchers to uncover important and relevant themes. The uMARS was scored for 4 quality subscales (engagement, functionality, esthetics, and information), and a total quality score was obtained from the weighted average of the 4 subscales. Scores for the 4 objective subscales were determined by the mean score of each of its individual questions. The perceived impact and subjective quality of acT1ve for each participant were calculated by averaging the scores of their related questions, but were not considered in the total quality score. All scores have a maximal possible value of 5, and they are presented as medians, IQRs, and ranges.

Results: The main themes arising from the interview analysis were "increased knowledge," "increased confidence to exercise," and "suitability" for people who were less engaged in exercise. The uMARS scores for acT1ve were high (out of 5) for its total quality (median 4.3, IQR 4.2-4.6), engagement (median 3.9, IQR 3.6-4.2), functionality (median 4.8, IQR 4.5-4.8), information (median 4.6, IQR 4.5-4.8), esthetics (median 4.3, IQR 4.0-4.7), subjective quality (median 4.0, IQR 3.8-4.2), and perceived impact (median 4.3, IQR 3.6-4.5).

Conclusions: The acT1ve app is functional and acceptable, with a high user satisfaction. The efficacy and safety of this app will be tested in a randomized controlled trial in the next phase of this study.

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KEYWORDS

mobile health app; exercise; acT1ve; type 1 diabetes; young people; blood glucose level

Introduction

Managing blood glucose levels during and after exercise is challenging for young people with type 1 diabetes (T1D). Despite the many physical and psychological health benefits of regular exercise, many individuals do not meet physical activity recommendations of at least 60 min/day of moderate to vigorous activity [1,2]. A recent survey based on self- and parent-report revealed that 28% of youth with T1D aged 9 to 17 years were insufficiently active [3]. Among the multiple barriers to engaging in a physically active lifestyle, T1D-specific major barriers include fear of hypoglycemia and insufficient knowledge of managing diabetes around exercise [4-6]. Empowering individuals with T1D to manage their blood glucose levels during exercise is a complex challenge faced by health care professionals, as many factors can influence an individual's glycemic response to exercise, such as exercise type, intensity, and duration [7,8]; fitness levels; insulinemic state [9]; environmental conditions; and anxiety and stress levels [10]. Technological advances in diabetes management, such as insulin pumps and continuous glucose monitoring (CGM) systems, have aided in the management of diabetes during and after exercise for people with T1D [8]; however, managing the level of blood glucose around physical activity remains one of the biggest challenges to overcome due to the often unpredictable nature of exercise and its effect on blood glucose levels [11].

Key professional societies and organizations have published recommendations for the prevention of exercise-related hypoglycemia based on previous clinical studies and expert opinions [12-14]. However, these recommendations can be challenging to follow, and are often located in medical journals and not readily accessible to the general T1D community and clinicians alike. In addition, health care professionals believe that the lack of formal education in exercise metabolism, and limited time and resources to do so are common barriers to providing guidance around exercise management [15]. Therefore, adolescents and young adults with T1D may benefit from having access to decision-support aids to effectively contextualize a blood glucose result and take appropriate action to optimize glucose levels during and after exercise.

Current care models provide very limited physical activity support to people with T1D. Previous research conducted by our team proposed that providing exercise guidelines in a mobile health (mHealth) app would be useful as a decision-support aid around exercise management for adolescents and young adults with T1D [6]. Global use of mHealth apps is on an exponential rise, and these tools provide a useful platform to deliver health behavior interventions [16-18]. In particular, mHealth apps for diabetes self-management are promising and proliferating at a very high rate [17,18], since diabetes (and in particular T1D) is well suited to smartphone-based support given the use of technology around glucose monitoring, insulin dosing, and carbohydrate counting.

Recent reviews of the literature [19-25] revealed that insulin/medication recording features were found frequently in these apps, as were carbohydrate logs, diet recording features, and physical activity tracking features. Personalized feedback or advice based on patient data, typically insulin dosage suggestions, was also available in 17% of the apps reviewed [21]. However, personalized education is an underrepresented feature, with none of these apps providing personalized advice around exercise.

T1D mobile phone–based interventions hold great promise, but few studies have shown definitive proof of improved health outcomes in this population [26]. Recently, improvement in glucose monitoring and significant improvement in HbA_{1c} [27] in youth with T1D have been reported with the Bant app, which provides personalized feedback by tracking meals, blood glucose, physical activity, and weight data, and is designed primarily for young people with T1D. Since mHealth apps can provide real-time support to their users in addition to traditional clinical counselling, we attempted to develop an exercise app to address the exercise management needs of adolescents and young adults with T1D.

Based on recent consensus exercise guidelines [12-14], "acT1ve," a novel mHealth app, was developed in collaboration with researchers, young people with T1D, and the digital health company Curve Tomorrow, according to a user-centered design (UCD) process that engages end users to ensure app effectiveness [28]. acT1ve uses an exercise advisor algorithm developed in house, consisting of 240 possible pathways depending on user inputs. Participants are prompted to answer questions about the type, intensity, and duration of physical activity they are about to complete; duration since the last insulin bolus; and their current blood glucose levels, with this information then used to provide them with a personalized insulin dose and carbohydrate advice for exercise lasting up to 60 minutes (Figure 1). In addition, acT1ve provides more information on hypoglycemia treatment, pre-exercise and postexercise insulin and carbohydrate advice, and an educational food guide that highlights the importance of low and high glycemic index foods in the context of exercise management.

Figure 1. Example screenshot from acT1ve of the carbohydrate and insulin dose recommendation based on information provided by the participant.
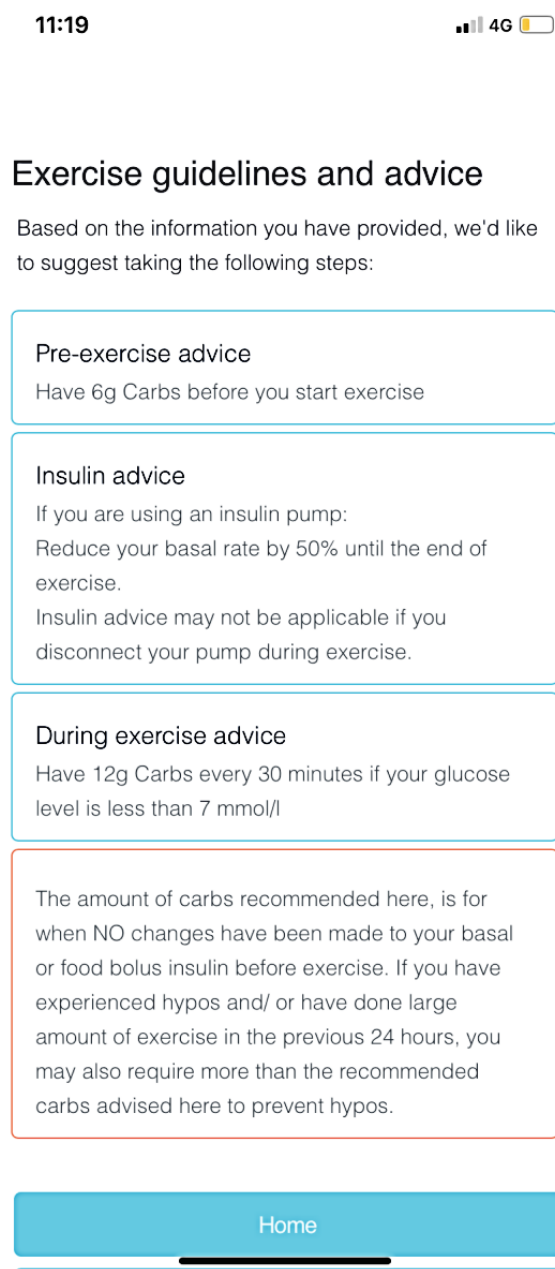
The aim of this study was to pilot acT1ve in a free-living setting with adolescents and young adults with T1D to assess its acceptability and functionality and to gather feedback to improve the user experience of the app before testing it in a larger clinical trial. Here, mainly viewed from a technological perspective, this study served the following two purposes: (1) to determine whether the app is usable and accepted by users; and (2) to test the deployment of the app before it is rolled out for a larger clinical trial.

Methods

Participants

Adolescents and young adults who were aged 12 to 25 years with a diagnosis of T1D for more than 6 months, were on multiple daily injections (MDIs) or continuous subcutaneous insulin infusion (CSII), were exercising regularly (at least twice per week), were competent in English, and had a smartphone were eligible to participate. Recruitment was performed through the Western Australian Children's Diabetes Database and Perth Children's Hospital diabetes clinics. The study was advertised on websites and social media. Eligible participants were provided with study information at their clinic visits and via email. Participants provided consent in accordance with the Child and Adolescent Health Human Research Ethics Committee, registered with the National Health and Medical Research Council's Australian Health Ethics Committee. Parental consent was also obtained for participants under the age of 18 years. The goal of the recruitment was to have enough participants till saturation was attained. Recruitment ceased when saturation was achieved with 10 participants.

Methods and Measures

This study was based on a mixed methods prospective single-arm pilot design to assess the acceptability of the acT1ve intervention. Participants visited the research facility on 2 occasions. On the first occasion, the following demographic and descriptive characteristics of the participants were collected: age, sex, duration of diabetes, HbA_{1c}, insulin therapy, and exercise patterns. Then, participants were shown how to install acT1ve onto their smartphones. Once installed, participants set up their profile and followed the in-built on-boarding process that guided them through the different sections and functions of acT1ve before leaving the research facility.

Participants were then advised to continue exercising (at least) twice a week over the following 6 weeks with acT1ve, but were otherwise free to use the app as they pleased for their exercise management. Once per week during this 6-week period, the study coordinator contacted study participants and/or their parents/guardians to ensure that the participants were not experiencing more hypoglycemia than usual, remind them to use acT1ve and exercise regularly, troubleshoot any technical problems, and obtain any interim comments or feedback that participants may have had. Study data and survey responses were collected and managed using institutional review board–approved Research Electronic Data Capture (REDCap) [29].

User Mobile Application Rating Scale Survey

At the end of this 6-week period, participants returned to the research facility and completed the user Mobile Application Rating Scale (uMARS) survey [30]. The uMARS is used to assess the overall quality of mHealth apps, and provides a 20-item measure that includes 4 objective quality subscales, namely engagement, functionality, esthetics, and information quality, and 1 subjective quality subscale. Another subscale, consisting of 6 items, is added to measure users' perceived impact of the evaluated app [30]. Responses are scored on a 5-point Likert-type scale (1, inadequate; 2, poor; 3, acceptable; 4, good; 5, excellent) [31]. A score of 3 or above was considered acceptable. More specifically, the subscales are as follows: engagement subscale with 5 items assessing entertainment, interest, customization, interactivity, and target group appeal; functionality subscale with 4 items assessing app performance, ease of use, navigation, and gestural design; esthetics subscale with 3 items measuring layout, graphics, and visual appeal; information subscale with 4 items measuring quality and quantity of the written and visual information in addition to the credibility of the source; subjective quality measure with 4 items assessing recommendation and usage of the app, payment, and star rating; and perceived impact measure with 6 items assessing the awareness of the importance of exercise management, an increase in knowledge/understanding of blood glucose management, attitudes toward improving this health behavior, an increase in intention/motivation to address this health behavior, a change in health behavior, and the encouragement of help-seeking behavior, should the participant need it.

Interview

Participants lastly completed an interview that consisted of both structured and semistructured questions. The interview questions (Multimedia Appendix 1) were designed to gain an understanding of participants' experiences during the study period to determine if and how any key aspects of acT1ve could be improved, and to investigate whether the use of the app resulted in any improvements in their enjoyment, confidence, frequency, and duration of exercise. Additionally, participants were asked about their overall impressions of the app, and whether they would use it again and recommend it to their peers. All interviews were audio recorded for transcription and analysis. The app was deleted from each participant's phone at the end of the study period.

Statistical Analysis

Qualitative Analysis

Two qualitative approaches were utilized. Qualitative content analysis was used deductively to analyze the responses to the structured questions, which asked directly about changes in exercise frequency and enjoyment, app useability and acceptability, app recommendation to others, and suggestions for improvement of the app features. This process involves reading and reviewing the data to identify and quantify the content and explore usage rather than meaning. Open coding and categories were created to explain the data [32]. Additionally, thematic analysis was used inductively to identify and report patterns throughout the interview transcripts and determine themes, according to the coding framework outlined by Braun and Clark [33]. Interview transcripts were independently read and reread by 2 researchers, important and relevant codes were identified, and the codes were further explored and clustered to develop themes to explain the data. Any discrepancies were discussed with the research team until a consensus was reached.

Quantitative Analysis

The uMARS was scored for the 4 quality subscales described above (engagement, functionality, esthetics, and information), and a total quality score was obtained from the weighted average of the 4 subscales. Scores for the 4 objective subscales were determined by the mean score of each of the individual questions. The perceived impact and subjective quality of acT1ve for each participant were calculated by averaging the scores of their related questions, but were not considered in the total quality score. All scores have a maximal possible value of 5, and they are presented as medians, IQRs, and ranges.

Results

Demographics

Ten individuals (8 females and 2 males) were enrolled in this study. They had a mean age of 17.7 (SD 4.2) years, T1D duration of 7.2 (SD 4.8) years, and HbA_{1c} of 54 (SD 5.5) mmol/mol (7.1%, SD 0.5%), and engaged in physical activity for 4.5 (SD 2.9) hours per week. Five participants used CSII and 5 used MDIs. Seven of the 10 participants used a CGM system to monitor their glucose levels. Among the 10

participants, 5 had prior experience with using an exercise-based mobile app; however, none of these were diabetes specific. All 10 participants had acT1ve installed on an Apple iPhone. No participants stopped using the app before the end of the 6-week period.

Weekly contacts with the participants provided information on technical issues and higher than normal hypoglycemia experienced by participants. Two participants experienced a technical error when recording feedback on the app on 1 occasion only. Of the 10 participants, only 2 reported hypoglycemia events after exercise related to app use. One participant followed only 1 of the 2 insulin strategies suggested

by the app after exercise. The other participant, who would normally remove the pump while running, continued to use the pump with a reduction in the basal insulin rate as suggested by the app and experienced hypoglycemia.

Qualitative Analysis: Thematic

The 3 main themes identified from the postintervention interview transcripts were "increased knowledge" (information), "increased confidence to exercise" (confidence), and "suitability for people who are less engaged in exercise" (suitability). These 3 themes and interrelated subthemes are shown in the thematic map (Figure 2), and are discussed below, accompanied by selective illustrative quotations.

Figure 2. Thematic map of the interview analysis showing 3 overarching themes and the interrelation of subthemes.
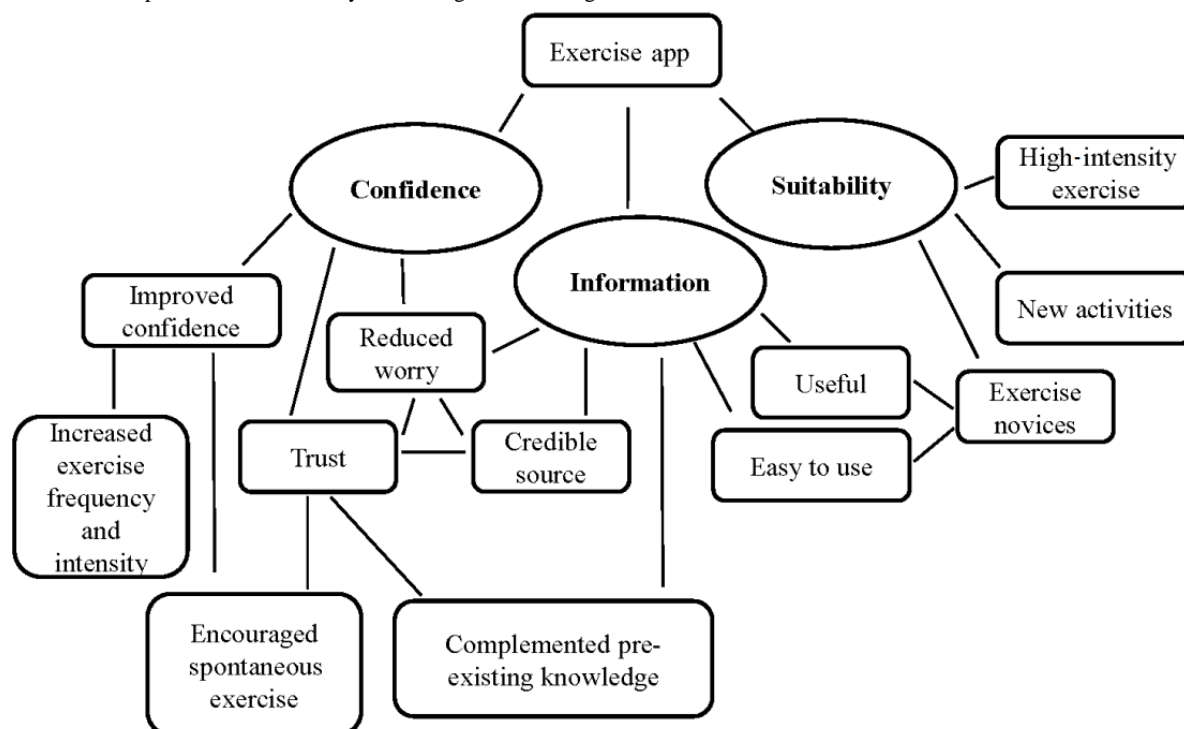
Information

Some participants commented that the specific information they received from the app was useful in providing new practical information and was credible.

> I was like, ok so I should be having this much to eat before, ok, reduce basal here, and stuff like that. Guidance was helpful. [Participant #10]

> I think the main thing that I really liked was taking into account how much insulin you've got on board, how long ago was your bolus, that's the thing that people really use and really like. [Participant #2]

> It gave me information that I hadn't (previously) been given. [Participant #9]

> I knew the advice it was giving me was legitimate and from like doctors and stuff. [Participant #5]

Some participants noted how the information enabled them to keep stable blood glucose levels when physically active.

> Normally I would be going inside for a low treatment every 10 minutes, but I was barely going low when I had the app. [Participant #7]

Participants also commented on how the information provided by the app complemented their pre-existing knowledge.

> You pick and choose or use their information, take it your own way. Which I think is really good as well, because people should come up with their own things. [Participant #2]

While most participants found the information they received from the app useful, some individuals commented that the amount of information provided was too much to read and absorb, the information did not always work for them, or the information was repetitive.

> Fun to use, but a lot of info, a lot of reading, which I'm happy to do, but it is a bit of information overload. [Participant #1]

Confidence

The second theme identified was related to the feeling of increased confidence to exercise while using the app. Participants began to trust the information they received from the app, which contributed to improve confidence and lessen worry, particularly in relation to hypoglycemia while physically active.

> *Before having this app, I would hesitate before exercising, just because I was worried about my level because I didn't feel as confident in like knowing how much to eat or how giving insulin would affect my levels after exercise, but using this app just gave me a bit more confidence.* [Participant #3]

> *After I worked out, using the advice the first time, it worked really well for me. So I knew that I didn't have to worry about going low during the exercise and even afterwards, I know I'd have a good sleep.* [Participant #4]

> *I felt like I didn't need to guess, and felt more assured in what I was doing to prepare for exercise; because information was coming from the app, it was probably going to work.* [Participant #3]

One participant (participant #1) commented that using the app was like "having a security blanket."

Participants stated they became more confident with the app the more they used it, and this led to the participants learning to trust the app over time.

> *At the start, I would switch between following and not following [the advice provided], but towards the end I always followed it.* [Participant #7]

Suitability

With respect to app suitability for people who are less engaged in exercise, participants commented on the types of activities and who they thought the app would be especially useful for. Some participants acknowledged it being useful mainly for high-intensity activity or when undertaking a new activity.

> *I'd use it for things that are new. Once I've used it enough, and get an idea, I probably wouldn't have to use it. But I probably would still use it just to make sure I'm doing the right thing.* [Participant #5]

> *The app would be particularly suitable for people who aren't really into exercise yet or who have the fear of what happens if they go low during or after physical activity.* [Participant #4]

> *...it might be useful for other people who "struggle with sport".* [Participant #9]

Qualitative Analysis: Content

Content analysis was used to explore specific predetermined items, namely exercise frequency and enjoyment; app useability and acceptability; recommendation of the app to others; and suggestions for improvement of the app.

Exercise Frequency and Enjoyment

Six participants commented that using the app had encouraged them to increase their amount of exercise, engage in more spontaneous exercise, and/or increase the intensity of their usual exercise regime during the 6-week study period.

> *I don't think I did anything new, just did more of what I usually do [more intense/longer].* [Participant #3]

While 1 participant commented that exercise was more enjoyable while using the app "because it took the stress away" (participant #4), the other participants reported that their enjoyment of exercise had not changed during app usage.

> *It made me want to exercise, which is good, I think it was more comfortable to exercise rather than more enjoyable.* [Participant #2]

Useability and Acceptability

All participants felt that acT1ve was generally straightforward and easy to use, with 4 of the 10 participants feeling confident after the first time of use. Other participants had to use the app on several occasions to become confident with it, with 9 of the participants acknowledging that there were enough instructions within the app to get started.

> *Very easy and straight forward. I had no issues with it at all in regards to finding where I had to go.* [Participant #1]

> *Just easy to use and worked 90% of the time.* [Participant #7]

Participants felt that the convenience of having the app's information on a phone was excellent, with 3 participants choosing to use acT1ve in conjunction with their own methods of glycemic management, using the app as a guide.

Recommendation

Overall, acT1ve was well liked by participants, who all stated that they would recommend it to friends and other people with T1D, and suggested that it might also help others such as teachers or sport coaches.

> *100% I have a lot of friends in the same boat as me, so it will be a hit I'm sure.* [Participant #1]

> *I'd recommend to heaps of people. Even just having an exercise app, everyone wants one just to use, and its good specifically type 1. So it you can log exercise, look at what you've done, but it's nice that it's just for my diabetes as well.* [Participant #2]

Participants reported that they would use it again themselves if it was available.

> *Why? Because it's a good app, with good information that worked for me.* [Participant #8]

Suggestions for Improving the App

The interview also gave participants the opportunity to provide valuable feedback and suggestions for improving the app prior to its roll out for a larger trial. Their suggestions included a help section on how to use the app for those who may need extra guidance, added information for longer duration of exercise,

minimization and simplification of some of the information, suggestions for data sharing and social interaction features, and suggestions for improving esthetics, including more color, personalization for notifications, profile pictures, and *emojis*.

> *Really good, gives a lot of information and will help with exercise and give people confidence. Wouldn't say 5 because it can be confusing sometimes, could see people having an issue or rushing through information and not really reading it. Lack of color is a minus, especially for kids, is something that should be incorporated.* [Participant #2]

> *I like the app and it had good information, I just think it could do with more personalization on the user's behalf, eg, choosing your own emoji, and notifying you with how much exercise you've done, with more visuals.* [Participant #8]

Quantitative Analysis

Sports Logged by Participants

Over 6 weeks, participants used acT1ve to obtain exercise management advice for their sports/activities 134 times in total (mean 13.4, SD 7.2 times per participant). Walking, running,

and team sports accounted for just over half (51%, 68/134) of the activities logged by participants. Swimming, cycling, and strength training accounted for 18% (24/134) of the activities logged. Other activities like group workout, vaulting, cardio, dance, pilates, yoga, rock climbing, golf, athletics, and skipping accounted for the remaining 31% (42/134) of the activities logged.

uMARS

The uMARS total quality median score (out of 5) was 4.3 (IQR 4.2-4.6) (Figure 3), and the objective quality subscale scores were 3.9 (IQR 3.6-4.2) for engagement, 4.8 (IQR 4.5-4.8) for functionality, 4.3 (IQR 4.0-4.7) for esthetics, and 4.6 (IQR 4.5-4.8) for information (Table 1). The median scores for all subjective quality items were above 4 (Table 2), with the exception of "payment" (asks participants how likely they are to pay for acT1ve). The median scores for all perceived impact items (where a score of 1=strongly disagree and a score of 5=strongly agree) were 4 or above (Table 2), with the exception of "knowledge," with a score of 3.5 (IQR 3.2-4.6). Lower scoring items were customization (median 3.0, IQR 3.0-3.0) in the engagement subscale and payment (median 3.0, IQR 2.0-3.8) in the subjective quality measure.

Figure 3. Aggregate participant (n=10) scores (median, IQR, and range) of the 4 user Mobile Application Rating Scale quality subscales (engagement, functionality, esthetics, and information) and the total quality score.
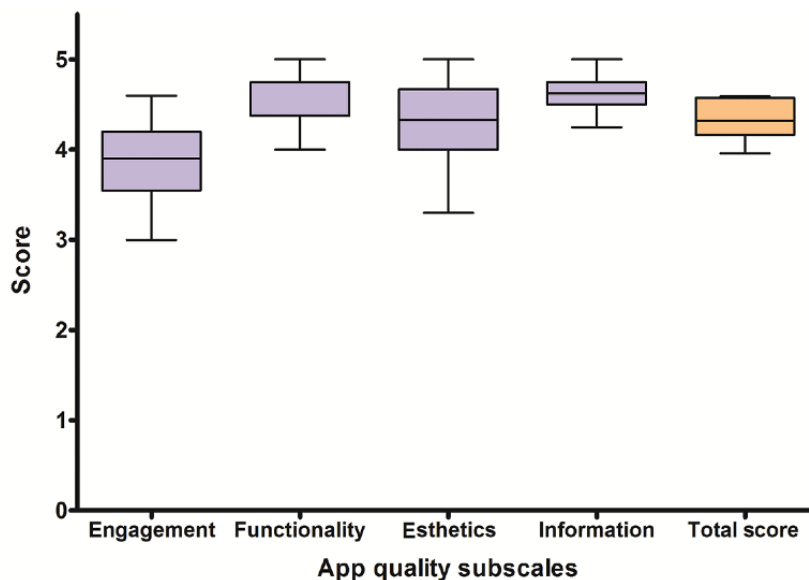
Table 1. Objective quality and total quality scores in the user Mobile Application Rating Scale (uMARS) evaluation.

Measure, subscale, and item	Score, median (IQR)
Objective quality	
Engagement	3.9 (3.6-4.2)
Entertainment	4.0 (3.3-4.0)
Interest	4.0 (4.0-4.8)
Customization	3.0 (3.0-3.0)
Interactivity	4.0 (4.0-4.0)
Target group appeal	4.0 (4.0-5.0)
Functionality	4.8 (4.5-4.8)
Performance	5.0 (5.0-5.0)
Ease of use	4.0 (4.0-5.0)
Navigation	5.0 (4.0-5.0)
Gestural design	5.0 (4.0-5.0)
Esthetics	4.3 (4.0-4.7)
Layout	5.0 (4.0-5.0)
Graphics	5.0 (4.2-5.0)
Visual appeal	4.0 (3.3-4.0)
Information	4.6 (4.5-4.8)
Quality information	5.0 (4.0-5.0)
Quantity information	4.5 (4.0-5.0)
Visual information	4.5 (4.0-5.0)
Credibility	5.0 (5.0-5.0)
Total quality	4.3 (4.2-4.6)

Table 2. Subjective quality and perceived impact scores in the user Mobile Application Rating Scale (uMARS) evaluation.

Measure and item	Score, median (IQR)
Subjective quality	4.0 (3.8-4.2)
Recommend	5.0 (4.0-5.0)
Usage	4.5 (4.0-4.8)
Payment	3.0 (2.0-3.8)
Star rating	4.0 (4.0-4.8)
Perceived impact	4.3 (4.0-5.0)
Awareness	4.0 (4.5-4.8)
Knowledge	3.5 (3.0-5.0)
Attitudes	4.5 (3.3-5.0)
Intention to change	4.0 (4.0-4.8)
Help seeking	4.0 (4.0-4.8)
Behavioral change	4.0 (3.3-5.0)

Discussion

Principal Findings

mHealth apps can provide real-time support to users, in addition to traditional clinical counselling. In order to find out if mHealth apps can provide people with T1D with real-time support during exercise, we piloted acT1ve, a novel mHealth app, to assess its acceptability and functionality, and gather feedback to improve the user experience of the app before testing it in a larger clinical trial. We found that acT1ve was functional and acceptable, with high user satisfaction.

The qualitative and quantitative analyses of this study provided important insights into the perspectives of participants in relation to the functionality and usability of the app. The information provided by the app was found to be relevant, appropriate, and clear, with a simple and easy flow of presentation. Participants felt they received adequate information to guide their diabetes management and enable them to maintain stable blood glucose levels during physical activity. This reduced their worry about their glucose levels and provided them with trust and confidence to be more physically active. Trust was gained because the information came from a credible source and complemented their pre-existing knowledge.

Many participants felt the information received from the app was beneficial, and acknowledged that it would be helpful for high-intensity exercise, when undertaking a new activity, for people struggling with sports, and for those who have fear of exercise-related hypoglycemia. These findings are not surprising since these situations are very challenging for exercise management in T1D. Indeed, the unpredictability of glycemic responses during a new activity and the variable glycemic response during and after high-intensity activities depending on the prevailing insulin levels [34,35] increase the complexity of exercise management [12-14]. Hence, having an exercise advisor app available during physical activities was reported to be useful. Unlike the diabetes education information currently available in approximately 35% of apps accessible for diabetes self-management [25], acT1ve provides real-time decision support around exercise. As reported by Lum et al [36], of the approximately 370 diabetes apps that met the researchers' criteria for blood glucose self-management, the majority did not provide real-time decision support or situation-specific education on blood glucose self-management. Only 10% of apps educated users on blood glucose management [36], and none educated users on maintaining stable glycemia around exercise.

acT1ve was found to be engaging, informative, and functional with appropriate esthetics. The participants liked the design of the app and found it acceptable and useful. They indicated that they would likely continue to use it long term and also recommend it to friends and other people with T1D. It has been established that for a user to adopt and frequently use a smartphone app long term, the user must consider it both usable and useful [37,38]. A recent review [39] examining evidence supporting commercially available apps for diabetes self-management and a detailed assessment of app features, privacy/security, and usability found variable results on app usability. Of the 5 apps available for usability testing for T1D, 1 was acceptable, 3 were marginal, and 1 was not acceptable [39]. Though these results suggest that patients may have had a difficult time using some of these apps, our results are not comparable, since usability was assessed not by patients using the app, but by reviewers rating each available app using the System Usability Scale (SUS), which includes 10 Likert-like items [40]. They used guidance from Bangor et al [41] to interpret SUS ratings (≥70 B, acceptable; 50-69 B, marginal; <50 B, not acceptable). Chavez et al [42] used uMARS to analyze the 89 most popular free English language diabetes apps and found that while this subset of mHealth apps ranked

"acceptable-good" in engagement, functionality, and esthetics, they ranked "poor-acceptable" in information, app quality, and app subjective. In contrast, acT1ve received high scores for each of the uMARS subscales and its overall quality. The 2 lower scoring items were customization in the engagement criteria and payment in the subjective quality criteria. The lack of customization features in acT1ve settings and preferences that end users would have liked, for example, sound, content, and notifications, needs improvement in the future iterations of acT1ve. Moreover, individuals would be more likely to use acT1ve if it is freely available.

acT1ve has great scope to be a promising tool to support exercise management for youth with T1D since the assessment of practices around exercise in these individuals has shown that there is a lack of understanding, awareness, and adherence to clinical recommendations around exercise [43]. Despite several studies showing an increase in the frequency of hypoglycemia during and after exercise, many youth are not adjusting insulin for exercise [43]. In a recent study, MacMillan et al [44] examined patients', parents', and providers' perceptions of physical activity support in youth with T1D, and found that all of them spoke of limited physical activity encouragement in the current care model. For this reason, they proposed interventions that included education to "build confidence in the patient to participate in physical activity" and inclusion of technology in the interventions to provide in-person support [44]. The use of a diabetes-related smartphone app as an adjunct to usual care combined with weekly text message support from a health care professional has been shown to significantly improve glycemic levels in adults with T1D [45].

The recent consensus report from the joint European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group highlights the potential value of digital apps for diabetes self-management [46]. Though an exercise advisor app for T1D has recently been designed [47] and there are increasing numbers of apps designed to give guidance to patients with T1D during exercise [48], to our knowledge, the benefits of a smartphone app have not been tested with respect to its effectiveness at supporting diabetes self-management around exercise in adolescents and young adults with T1D. Our results show that acT1ve has the potential to facilitate glycemia management during exercise and to support the needs of youth with T1D by providing personalized guidance on insulin dosing and carbohydrate intake strategies, and by improving their knowledge and confidence around exercise management.

Limitations

Despite its many benefits, there are some limitations with acT1ve. For instance, acT1ve was tested only on Apple iOS; however, consumers use a variety of mobile technological platforms. While acT1ve was also compatible with Android devices, iOS appeared to be the dominant operating system in the target group of the study. Another limitation was that even though this app was developed by adopting the UCD process, acT1ve did not include all the features recommended by the end users in the design process due to budget limitations. This was evident in the uMARS evaluation, where a lower score was

given for elements in the engagement criteria like customization and participant feedback for improvement of the app. Some of the suggestions like the help section on how to use the app for those who may need extra guidance, the shortening and simplification of some of the information it provides to avoid confusion, and the improvement of esthetics have all been considered in the amended version of the app. Other desirable features like activity tracker, data sharing options, integration with real-time CGM, social engagement, and interactions with other technological tools like music apps could have further improved its interactivity and will be considered in future iterations of the app. Since the scores from the uMARS do not necessarily reflect the real impact in terms of behavior change and health outcomes, further studies are needed to assess the efficacy, safety, and clinical significance of acT1ve for diabetes self-management around exercise.

Since the aim of this study was to test the usability and acceptability of the app, only patients who were exercising at least two or more times per week were enrolled in the study without accounting for the wide range of HbA$_{1c}$, different activity levels of patients, or their barriers to exercise. All these variables will be addressed by conducting a randomized controlled trial in the next phase of this study.

Conclusions

This study suggests that our novel mHealth app acT1ve is informative, functional, and acceptable, and that users were satisfied with using it. Our app may thus provide a promising intervention for exercise management for adolescents and young individuals with T1D. The app was well received by all users and was found to be simple to use with easy-to-follow advice and smooth functioning. The end users reported less anxiety about exercising, knowing credible advice was readily available. Self-management is the key to diabetes care, and managing glucose levels around exercise has been an ongoing challenge for young people with T1D. Our findings suggest that acT1ve may be a valuable addition or supplement to diabetes management around exercise for adolescents and young adults with T1D. However, additional work is needed to assess the efficacy, safety, and clinical significance of this app.

Authors' Contributions

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

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview questions.
[DOCX File , 29 KB - diabetes_v6i4e29739_app1.docx]

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Abbreviations

CGM: continuous glucose monitoring
CSII: continuous subcutaneous insulin infusion
MDIs: multiple daily injections
mHealth: mobile health
SUS: System Usability Scale
T1D: type 1 diabetes
UCD: user-centered design
uMARS: user Mobile Application Rating Scale

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Original Paper

Differences in Secure Messaging, Self-management, and Glycemic Control Between Rural and Urban Patients: Secondary Data Analysis

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Abstract

Background: Rural patients with diabetes have difficulty accessing care and are at higher risk for poor diabetes management. Sustained use of patient portal features such as secure messaging (SM) can provide accessible support for diabetes self-management.

Objective: This study explored whether rural patients' self-management and glycemic control was associated with the use of SM.

Methods: This secondary, cross-sectional, mixed methods analysis of 448 veterans with diabetes used stratified random sampling to recruit a diverse sample from the United States (rural vs urban and good vs poor glycemic control). Administrative, clinical, survey, and interview data were used to determine patients' rurality, use of SM, diabetes self-management behaviors, and glycemic control. Moderated mediation analyses assessed these relationships.

Results: The sample was 51% (n=229) rural and 49% (n=219) urban. Mean participant age was 66.4 years (SD 7.7 years). More frequent SM use was associated with better diabetes self-management (*P*=.007), which was associated with better glycemic control (*P*<.001). Among rural patients, SM use was indirectly associated with better glycemic control through improved diabetes self-management (95% CI 0.004-0.927). These effects were not observed among urban veterans with diabetes (95% CI –1.039 to 0.056). Rural patients were significantly more likely than urban patients to have diabetes-related content in their secure messages (*P*=.01).

Conclusions: More frequent SM use is associated with engaging in diabetes self-management, which, in turn, is associated with better diabetes control. Among rural patients with diabetes, SM use is indirectly associated with better diabetes control. Frequent patient-team communication through SM about diabetes-related content may help rural patients with diabetes self-management, resulting in better glycemic control.

KEYWORDS

diabetes; secure messaging; rural; self-management; patient portal; urban; data; access; risk; portal; eHealth; digital health; messaging; support; accessible; cross-sectional; veteran

Introduction

Background

Over 30 million people in the United States have been diagnosed with type 2 diabetes [1]. Poor glycemic control, defined as hemoglobin A_{1c} (HbA_{1c}) > 8% (64 mmol/mol) [2], in patients with type 2 diabetes is a risk factor for the development of diabetes-related complications including retinopathy, neuropathy, heart disease, stroke, blindness, kidney failure, and lower limb amputations [3]. Costs for diabetes care are high and rising [4,5]. Within the United States, total costs have been estimated at US $465.2 billion, including morbidity, mortality, and medical costs [6]. Glycemic control is the primary therapeutic objective for the prevention of diabetes-related complications [7].

Diabetes Management in Rural Populations

Diabetes is a nationwide epidemic, though difficulty managing this complex, chronic condition varies across the United States [8]. Management is markedly more difficult in rural communities with limited access to health information and specialty care [9,10]. Diabetes is nearly 10% more prevalent in rural than in urban areas, likely owing to greater risk factors including lower income, older age, and higher body mass index [11]. In addition, individuals living with diabetes in rural areas face numerous barriers (limited availability of diabetes education [12], reduced cell phone coverage and internet access [13], transportation barriers, and lengthy travel distances [14,15]), preventing patients from accessing health care [16]. The Veterans' Affairs (VA) Office of Rural Health estimates nearly 5 million veterans live in rural areas where access to care can be difficult [17], and that almost 40% of Veterans Health Administration (VHA) patients with diabetes live in rural areas [18].

Promise of Patient Portals

Diabetes self-management behaviors (eg, medication adherence, diet, physical activity, and monitoring blood glucose levels [19]) are consistently linked to achieving glycemic control. Accessible communication, via face-to-face visits or technology, with providers is essential to foster patients' disease self-management [20]. Access to diabetes self-management education and ongoing support can be improved by using digital health solutions [21]. Previous research highlights the benefits of using web-based patient portals, suggesting that increased access to information and support may engage patients in the management of their disease and improve health outcomes [22,23]. Considering the access challenges rural patients face, virtual care services may be even more critical in this population for effective diabetes self-management. Features such as secure messaging (SM) in the VHA web-based patient portal My HealtheVet (MHV), are fundamental to the goal of increasing access to care. SM can be used in lieu of telephone or in-person visits, or to provide additional opportunities for patient-provider communication between visits. Previous coding of SM content revealed wide variety in how it is used, including self-management behaviors such as medication renewal/refill requests, scheduling, referrals, and discussing medication or health issues [24,25].

Research to date suggests that SM use is associated with higher odds of meeting HbA_{1c} control targets, with increased odds of control for every additional message sent per year [26], and with more years of use [27]. SM use may support improved diabetes self-management, though the exact mechanism among these 3 constructs has not been established. It is also unclear to what extent patient characteristics, such as where they live, may play a role in the effectiveness of SM. SM is potentially more beneficial for rural patients with reduced access to in-person care, though it is also possible that it may be less helpful or accessible for those in rural areas with more limited internet access [28-30].

This Study

This study examined and compared the benefits of sustained SM use for rural and urban patients with diabetes. Rural patients with diabetes are less likely to engage in self-management behaviors, have worse glycemic control, and more limited access to health care. Therefore, they may depend more on accessible communication to help manage their disease. This study uses a framework that was initially developed to evaluate how the BlueButton within the MHV patient portal can support key stakeholder (eg, patients') experiences, processes of care (eg, patient-team communication, self-management, and care coordination), and health outcomes, and understanding how contextual characteristics (eg, environment or setting in which patients seek and receive health care) shape use of the technology [31]. We have adapted this framework to evaluate other MHV features including SM.

This study had 3 objectives. We sought to investigate whether diabetes self-management mediates the relationship between SM use and glycemic control (objective 1). Additionally, we sought to understand if this mediation was conditional on the patient's environment (eg, where the patient lived; objective 2). Finally, we wanted to understand how patients are using SM for diabetes management (objective 3).

Methods

Study Design and Recruitment

This retrospective observational, cohort, sequential, explanatory, mixed methods (QUAN qual) study included US veterans living with type 2 diabetes. Table 1 specifies the timeline and sources of sampling and data collection. All participants experienced uncontrolled diabetes in 2012 (defined as mean HbA_{1c}>8.0% and less than 25% of the year with an HbA_{1c}<8.0%). All participants were sustained users of MHV between 2013 and 2017, defined as having used the portal repeatedly (used prescription refills, viewed or downloaded their health information, and used SM at least twice a year for 2 years between 2013 and 2015) and recently (sent at least 4 SMs between January 2016 and June 2017). Seeking a diverse sample of users who were either in good or poor control of their HbA_{1c}, we randomly selected a sample of 500 patients who had achieved good HbA_{1c} control in 2016 (defined as mean HbA_{1c}<8.0% for 75% of the year or more) and 500 who remained in poor HbA_{1c} control in 2016 (defined as mean

HbA$_{1c}$>8.0% for 75% of the year or more). We mailed the randomly selected participants (N=1000) surveys in November 2017, and an additional 200 surveys at the beginning of 2018.

Quantitative methods were used to examine the associations among SM use in 2017, diabetes self-management between November 2017 and February 2018, mean glycemic control in 2018, and differences between rural and urban patients. Data on patients' use of the MHV patient portal, their glycemic control, in-person health care utilization, and demographic variables were obtained from the VHA Corporate Data Warehouse (CDW) and merged with survey responses.

Qualitative methods were used to further understand how participants were using SM for diabetes self-management. Purposeful sampling was used to identify 40 survey respondents to participate in semistructured interviews about their diabetes management and technology use. In the survey, participants were asked an open-ended survey question, "Can you tell us about an 'A-Ha!' Moment when you realized you could use the MHV portal to better manage your diabetes?" We selected interviewees to represent a variety of responses to this and other survey items about MHV use, including those who used a variety of MHV portal features, those with controlled and uncontrolled diabetes, urban and rural patients, and those with or without comorbid mental health diagnoses. Women and minority veterans were oversampled to broaden the representation of patient demographics. More details regarding our survey sampling methodology [25] and qualitative sampling methodology [32] are available elsewhere. This study was approved by the local institutional review board.

Table 1. Study timeline and data sources.

Year	Sampling: diabetes control	Sampling: portal use	Mixed methods data sources	Constructs (source)	Covariates (source)
2012	100% Uncontrolled diabetes	Repeated portal use[a]	—[b]	—	—
2013	—	Repeated portal use[a]	—	—	—
2014	—	Repeated portal use[a]	—	—	—
2015	—	Repeated portal use[a]	—	—	—
2016	50% Achieved control/50% remained uncontrolled	Current portal use[c]	—	—	—
2017	—	Current portal use[c]	• Quantitative: survey[d] • Quantitative: corporate Data Warehouse (CDW)	• Rurality (CDW) • SM use (CDW) • Diabetes self-management (Survey)	• In-person health care Utilization (CDW) • Income (survey) • Race (survey)
2018	—	—	Qualitative: semistructured interviews	Hemoglobin A$_{1c}$% time in control (CDW)	—

[a]Defined as having used prescription refills, having viewed or downloaded their health information, and having used secure messaging at least twice a year for 2 years between 2013 and 2015.

[b]—: Not available.

[c]Defined as having sent at least 4 secure messages between January 2016 and June 2017.

[d]Disseminated at the end of 2017 or in early 2018.

Measures

Rurality

We identified rurality on the basis of zip codes recorded in the patient's address data from the CDW. The VA uses the Rural-Urban Commuting Areas (RUCA) system to define patient residence as either urban (at least 30% of the population residing in an urbanized area as defined by the Census Bureau), highly rural (less than 10% commutes to any community larger than an urbanized cluster), or rural (land areas not defined as urban or highly rural). RUCA codes are created using a validated algorithm developed by the US Department of Agriculture–Economic Research Service to classify US census tracts using measures of population density, urbanization, and daily commuting [33]. Patients who live in rural and highly rural areas were combined and categorized as "rural." Living in a rural area was assigned a value of 0 and living in an urban area was assigned a value of 1.

SM

Patients' use of SM was quantified in 2017, the year prior to survey data collection, to enable us to evaluate the association between SM use (in 2017) and subsequent diabetes management (in late 2017/early 2018) and glycemic control (in 2018). We counted how many months of the year a patient sent at least one SM. SM use had a possible range of 0 to 12, where 0 reflected no months of SM use, and 12 reflected sending at least one secure message every month of the year.

To further understand patients' use of SM, we coded the qualitative content of each SM in accordance with published coding methods [34], which have previously been used to code SM [24]. In addition, we coded each message using binary indicators for whether the messages were related to each of the

following health topics: diabetes-related content, blood pressure, cholesterol, physical activity, diet/nutrition, and mental health. All messages were double-coded by 2 of 3 trained research team members who met regularly to discuss questions, reach agreement on any coding discrepancies, and refine the coding categories. Message codes were collapsed at the thread; that is, if a patient engaged in at least one message about diabetes, the entire message thread was coded as such. Patients were coded as having either engaged in at least 1 thread about a health topic or none. Additionally, as part of the larger study, we conducted qualitative interviews with 40 of the survey respondents [32]. We examined these interviews to further understand rural patient's perceptions and use of SM.

Diabetes Self-management

Diabetes self-management behaviors were measured with the Diabetes Self-Management Questionnaire (DSMQ) [35]. The DSMQ is a global measure of diabetes self-management comprising 16 items to assess activities related to glycemic control in patients with diabetes (eg, "I strictly follow the dietary recommendations given by my doctor or diabetes specialist"; "I do regular physical activity to achieve optimal blood sugar levels"; and "I keep all of my doctors' appointments recommended for my diabetes treatment"). The questionnaire asks participants to rate each item on a scale from 0 (does not apply to me) to 3 (applies to me very much). From the 16 items, a composite score was calculated as the average of 4 subscales, including glucose management, dietary control, physical activity, and health care use, and could range from 0 to 10. Higher values indicate greater engagement in self-management. The DSMQ has been shown to be significantly correlated with HbA_{1c} levels [35].

Glycemic Control

Glycemic control was defined as the estimated percentage of time in control (TIC) over the course of 2018 based on HbA_{1c} measurements (A_{1c}%TIC). Patients' HbA_{1c} measurements for 2018 were obtained from the CDW. We calculated A_{1c}%TIC using the Rosendaal method [36], using linear interpolation to assign a value to each day between patient's successive HbA_{1c}

measurements. After interpolation, the percentage of 2018 during which the interpolated HbA_{1c} values within the region of control (ie, $HbA_{1c} < 8.0\%$) were calculated.

Covariates

Covariates included age (measured in years), annual income in late 2017 or early 2018, and in-person health care utilization in 2017. Annual income was self-reported on a 16-category scale ranging from less than US $5000 to more than US $150,000. We dichotomized annual income using a median split of less than US $35,000 (46% of the sample) and US $35,000 or more (53.6%). The number of days a patient had a VA primary care visit in 2017 was used to measure in-person health care utilization.

Analyses

We performed 2-tailed t tests, chi-square tests, and correlation analyses to examine differences between rural and urban participants and relationships between covariates and model measures. Moderated mediation was used to address the first 2 study objectives. Moderated mediation (Figure 1) estimates the indirect effect (SM use on A_{1c}%TIC through diabetes self-management; research objective 1), and whether this indirect effect is conditional on values of a moderator (rurality; research objective 2). Analyses were conducted using Hayes' PROCESS model in the SAS Enterprise Guide [37]. Moderation of the mediation model by rurality was assessed by calculating the index of moderated mediation [38] between rurality and the indirect effect between SM months in 2017 and A_{1c}%TIC in 2018. The index of moderated mediation with a dichotomous moderator is defined as the difference in the indirect effects, or mediated effects, between the 2 levels of the moderator (rural and urban). The test of this index is assessed by generating a bootstrap 95% CI of the difference in indirect effects across moderator groups. Effects were considered significant if the 95% CI did not include 0.00 ($P < .05$). Qualitative analysis of the SM was used to further understand the nature of the secure message content and patient perceptions of SM (research objective 3).

Figure 1. Moderated mediation between secure messaging (SM) use in 2017 and percent time in control of hemoglobin A_{1c} in 2018 (A_{1c}%TIC), via diabetes self-management, moderated by rurality. Numbers represent parameter estimates. Model adjusts for age, gender, and income. *95% CI does not include 0.00 and $P < .05$.
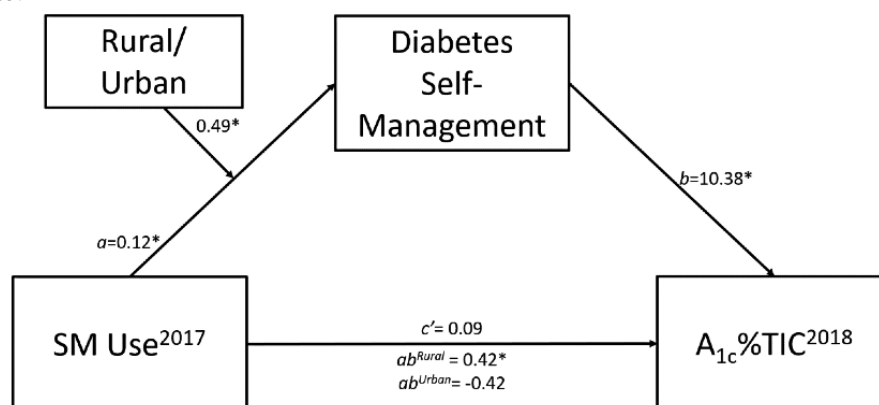
Results

We mailed 1200 surveys and received 448 (37%) responses. Table 2 describes the respondent sample in 2017, of whom just over half (51%) lived in rural areas. Most (94%) were male, and just over half (54%) reported an annual income above US $35,000. The mean age of survey respondents was 66.4 years (SD 7.5 years, range 34-88 years). In-person health care utilization ranged from 0 to 54 in-person visits; 52% (n=231) of the sample had 8 (median) or fewer in-person visits. As a population, they spent approximately half of their time in control

in 2018 (mean A_{1c}%TIC 52.6%, SD 43.6%, range 0%-100%). Their use of SM ranged from 0 to 12 months (mean 6.7 months, SD 3.1 months) in 2017. On average, patients reported relatively high levels of diabetes self-management (mean 7.9, SD 0.9, range 5.5-9.5). Rural and urban veterans were similar in income, age, A_{1c}%TIC, in-person health care utilization, diabetes self-management score, and number of months using SM. SM use was significantly correlated with more in-person health care utilization (r=0.7, P<.001). Diabetes self-management was significantly correlated with a higher A_{1c}%TIC in 2018 (r=0.21, P<.001).

Table 2. Respondent characteristics by rurality (N=446).

Characteristics	All	Rural (n=228)	Urban (n=218)	P value[a]
Male, n (%)	418 (94)	214 (94[b])	204 (94[c])	0.90
Income <US $35,000, n (%)[d]	207 (46)	111 (49[b])	96 (44[c])	0.33
Age, mean (SD)	66.4 (7.5)	66.3 (7.3)	66.5 (7.7)	0.82
2017 In-person primary care visits, mean (SD)	10.1 (7.8)	9.5 (7.0)	10.6 (9.5)	0.12

[a]Rural vs urban respondents.

[b]Percentage values are based on a total value of 228 respondents.

[c]Percentage values are based on a total value of 218 respondents.

[d]Income from the survey was for late 2017 or early 2018 based on when respondents completed their survey.

Diabetes Self-management

More months using SM was significantly and positively associated with greater diabetes self-management (B=0.12, 95% CI 0.033-0.212; P=.007; a in Figure 1). Rurality influenced the strength of the relationship between SM use and diabetes self-management (B=–0.08, 95% CI –0.138 to –0.026; P=.005). When we examined the conditional effects of SM on diabetes self-management for rurality, there was a trend to a significant positive relationship between SM and diabetes self-management for rural patients (B=0.04, 95% CI –0.001 to 0.083; P=.06) and a trend toward a negative relationship between SM and diabetes self-management among urban patients (B=–0.04, 95% CI –0.080 to 0.002; P=.06).

Glycemic Control

Patients who reported greater diabetes self-management had significantly higher A_{1c}%TIC (ie, more time in control of their

diabetes throughout the year; B=10.38, 95% CI 5.539-15.217; P<.001; b in Figure 1). There was no direct effect of SM use on A_{1c}%TIC (B=0.09, 95% CI –1.463 to 1.651; P=.91; c' in Figure 1). However, there was a conditional indirect effect between SM use and A_{1c}%TIC, via diabetes self-management for rural patients (B=0.42, 95% CI 0.004-0.927; Table 3 and ab^{Rural} in Figure 1). This conditional indirect effect represents the change in A_{1c}%TIC for every month of SM use, mediated by diabetes self-management. Among urban patients, there was no indirect effect between SM use and A_{1c}%TIC via self-management (B=–0.42, 95% CI –1.039 to 0.056; ab^{Urban} in Figure 1). The index of moderated mediation (ie, the difference between rural and urban indirect effects) was significant (index=–0.85, 95% CI –1.64 to –0.23).

Table 3. Moderated mediation analyses.

	B (95% CI)	P value
Model to predict diabetes self-management		
Constant	5.81 (4.82 to 6.81)	<.001
Secure messaging use during 2017	0.12 (0.03 to 0.21)	.007
Rurality	0.49 (0.08 to 0.90)	.02
Secure messaging use during 2017*Rurality	–0.08 (–0.13 to –0.03)	.005
Secure messaging use during 2017*Rural	0.04 (0.00 to 0.08)	.06
Secure messaging use during 2017*Urban	–0.04 (–0.08 to 0.00)	.06
Age	0.02 (0.01 to 0.03)	.003
In-person primary care visits in 2017	0.01 (–0.01 to 0.02)	.29
Income (reference=<US $35,000)	0.16 (–0.01 to 0.34)	.08
Model to predict the percent time in control of hemoglobin A_{1c} in 2018		
Constant	–19.13 (–69.74 to 31.49)	.46
Direct effect of secure messaging use during 2017 on the percent time in control of hemoglobin A_{1c} in 2018	0.09 (–1.46 to 1.65)	.91
Diabetes self-management	10.38 (5.54 to 15.22)	<.001
Age	–0.17 (–0.75 to 0.41)	.56
In-person primary care visits in 2017	0.11 (–10.70 to 6.72)	.65
Income (reference=<US $35,000)	–1.99 (–10.70 to 6.72)	.65
Indirect effects of Rurality on the percent time in control of hemoglobin A_{1c} in 2018		
Rural	0.42 (0.01 to 0.92)	—[a]
Urban	–0.42 (–1.03 to 0.05)	—

[a]—: not determined.

Sensitivity Analysis

This study modeled SM use in 2017 and A_{1c}%TIC in 2018. Had we examined both SM use and glycemic control in the same year, we would have risked potentially having some participants with SM data toward the end of the year and HbA_{1c} measurements in the beginning of the year. These data would not be consistent with the hypothesized temporal nature of the analysis. However, as sensitivity analysis, we compared SM use in 2017 and 2018. SM use in 2017 and 2018 were significantly correlated (r=0.53, P<.001). Additionally, we ran the moderated mediation model using both SM use and A_{1c}%TIC in 2018. A similar pattern of results occurred in a moderated mediation analysis that examined both SM use and A_{1c}%TIC simultaneously in 2018. Further information is included in Multimedia Appendix 1.

SM Content

Qualitative analysis of the SM content revealed that significantly more rural participants (77%, n=177) discussed diabetes-related content in at least one SM thread than urban participants (67%, n=146; P=.01). There were no other significant differences between the proportion of urban and rural participants who engaged in at least one thread related to other health topics codes. Semistructured interviews with a subset of survey respondents further expanded on how rural patients perceived SM and were using SM (Table 4). Patients consistently expressed how SM helped them communicate with their clinical teams. Rural patients indicated that SM was a convenient tool to support tasks pertinent to effective diabetes self-management. For example, one patient reported that SM was a more reliable form of communication than through a cell phone to set up appointments or medication renewal requests. Patients also indicated they were able to use SM to communicate their diabetes-related equipment needs with their clinical team. Patients also reported that SM allowed them to communicate with various members of their clinical team.

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Table 4. Qualitative themes and representative quotes.

Communication theme	Quote
Reliability	*Cellphones don't work real [sic] well around here, you have to be in certain areas. There's lots of dead spots, like hundreds of miles of it…It works better for [hospital] to use secure messaging to set up appointments. I've used them to talk to [the clinic], I've used them to talk to my provider a couple of times when I needed prescriptions changed or stuff like that.* [Rural male, 69 years]
Communicate needs rapidly	*I've got central tremors and…I'm shaking and I can't get the syringe in the bottle you know. So I just sen[t]… a SM. I said Dr. [name] I want to get pens again I can't do it. Within 48 hours, I'm serious, literally. I had pens delivered to my front door you know. Just absolutely wonderful as far as I'm concerned.* [Rural male, 54 years]
Facilitates communication with team	*Once I tried to message them or if I sent a message to the nursing staff then the next time I got on there, there was a connection for me to, you know, to send a message directly to my pharmacist...* [Rural female, 65 years]

Discussion

Principal Findings

In a population of veterans with diabetes, we examined the relationship between the use of SM and percent time in glycemic control, whether diabetes self-management behaviors mediated this relationship, and if the use of SM is beneficial for those both living in urban and rural areas. This study leveraged mixed methods to quantify these relationships through a moderated mediation analysis, examine how patients with diabetes use SM through a message content analysis, and learn from patients through qualitative interviews. Moderated mediation analysis revealed that the relationship between the use of SM, diabetes self-management, and A_{1c}%TIC was influenced by rurality. Among rural patients, increased use of SM was associated with a higher A_{1c}%TIC through diabetes self-management. The mediation of SM and A_{1c}%TIC through diabetes self-management was not found among urban patients. This finding does not indicate that SM is not necessarily beneficial for urban patients; rather, it indicates that SM may help support rural patients' diabetes self-management efforts to a greater extent than among urban patients. In addition to the challenges of effective diabetes management, rural patients face additional barriers including limited access to diabetes education and clinical services, limited cell phone coverage and internet access, limited transportation, and long travel distances [39]. It is possible that the enhanced clinical access afforded by SM may not influence self-management among urban patients who do not face the same access barriers as their rural counterparts [10]. SM offers rural patients means to overcome many of these barriers.

Our quantitative analysis included all SM communication (ie, not just diabetes-specific SM) as many different subjects, such as messages about hypertension or physical activity, are likely to be helpful for diabetes management. We used qualitative analyses to further explore the ways in which rural patients leverage SM for diabetes self-management. Rural patients were more likely than their urban counterparts to communicate via SM with their health care team about diabetes-related content, which may be associated with more effective diabetes management efforts. While messages about other health topics may be just as important for diabetes management, there were no significant differences in the frequency in which these other

health topics were discussed between rural and urban patients. Additionally, participant interviews revealed insights into some of the benefits SM affords rural participants, such as SM being a more reliable and convenient means to communicate with various members of their clinical team to engage in activities important for diabetes management (eg, appointment requests, medication renewals, and equipment requests).

This relationship between increased health care team access and greater self-management aligns with previous research; a systematic review evaluating technology-enabled diabetes self-management support concluded that 2-way communication between the patient and clinical team was an essential component for improved HbA_{1c} [40]. Patients who use web-based portals and SM can communicate with their team more regularly, as needed, and potentially reduce the need for in-person visits. Reports on the relationship between SM and in-person health care utilization are inconsistent. For example, we found that greater use of SM was positively associated with more in-person health care utilization, whereas other recent work has found that use of SM was associated with a decrease in in-person utilization [41]. It is difficult to disentangle if patients are using SM in place of in-person care, or if they are using SM because of an upcoming or recent in-person visit (eg, following up on a new medication). Owing to this potential confounder, we included in-person primary care visits as a covariate in our model to control for health care utilization and possible confounding by indication.

Implications

More consistent use of SM, particularly SM related to diabetes, can help overcome commonly reported regional disparities in diabetes self-management and glycemic control. Despite the benefits of SM for diabetes self-management and glycemic control in rural veterans with diabetes, rural patients are less likely to manage personal health information on the internet or communicate through the internet with their providers [30]. External support from a patient's clinical team has been identified as a key facilitator of diabetes self-management [39], though such support is less available for patients with limited access to in-person visits. Fortunately, virtual modalities such as web-based patient portals and features including SM can provide easily accessible support for effective diabetes self-management. It is critical to identify methods that will promote patients' use of web-based portals for better chronic

disease management. Technology-based approaches and interventions are widely accepted for promoting diabetes self-management in rural communities [42]. Additionally, we previously found that as little as one team-initiated secure message was significantly associated with better diabetes self-management [25]. Providers may find that encouraging patients, particularly rural patients, to use SM may significantly improve their diabetes self-management and outcomes.

SM has the potential to reach an ever-increasing number of patients. As of July 2021, 3.7 million veterans (more than half of active VA patients) were registered portal users, of which 1.4 million were active users of SM. Increasing SM use can be considered a high-reach, light-touch intervention with the potential to improve population health. Understanding the benefits of modalities that can provide more accessible diabetes self-management support not only has implications for rural patients who typically face barriers accessing in-person health care owing to long travel distances—these findings also support the value of encouraging SM use when in-person visits are not feasible. During the COVID-19 pandemic, VA facilities were directed to convert in-person to virtual care whenever clinically appropriate [43] and for rural patients in particular [44]. Use of SM can help maintain patient-provider communication and support disease self-management when patients cannot access in-person care. Emerging evidence suggests that disparities in rural patients' access to telemedicine, including video visits and portals, have persisted despite dramatic increases in adoption [45]. Our findings suggest that efforts to reduce these disparities are important not only to improve equity but also to support improved outcomes.

Limitations and Future Directions

This study has some limitations. For one, this sample purposely surveyed patients who were both recent and repeated users of patient portals; it does not speak to the potential benefit of SM in those who have never used portals. Those who responded to our study may, as a group, have had better self-management than the average patient with diabetes. Indeed, our sample scored higher on the DSMQ than other populations, though not outside the SD [35]. Similarly, as is common in many US Veteran studies, our sample size was mostly male, which limits the potential generalizability of these findings to females and non-Veterans.

The current analysis examined self-management as a composite score. Future research may examine the relationship between SM use and various self-management behaviors, and if certain self-management behaviors are more important in the relationship between SM use and $A_{1c}\%$TIC. Finally, another limitation is the cross-sectional and observational nature of the study. Our mediation model allows us to begin to think about the causal nature of these relationships. Future studies might benefit from interventional designs that examine changes to diabetes self-management and glycemic control after initiating SM use compared to a sample who have never used SM.

Conclusions

On average, patients with diabetes who live in rural areas are disproportionately affected by diabetes, in part owing to their limited access to health care. Among rural patients, greater use of SM was associated with better diabetes self-management, which was associated with better glycemic control. This was not observed among urban patients. Rural patients with diabetes may benefit significantly from using SM to support their diabetes self-management and diabetes-related outcomes. Encouraging patients to ask questions between visits, or reaching out to them directly via SM, are examples of light-touch interventions with potential to improve outcomes for millions of patients with diabetes who lack ready access to in-person care.

Conflicts of Interest

None declared

Multimedia Appendix 1
Supplementary sensitivity analysis.
[DOCX File , 18 KB - diabetes_v6i4e32320_app1.docx]

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Abbreviations

A_{1c}%TIC: percentage of time in control over the course of the year based on hemoglobin A_{1c} measurements

CDW: Corporate Data Warehouse

DSMQ: Diabetes Self-Management Questionnaire

HbA$_{1c}$: hemoglobin A_{1c}

MHV: My Health*e*Vet

RUCA: Rural-Urban Commuting Areas
SM: secure messaging
TIC: time in control
VA: Veterans Affairs
VHA: Veterans Health Administration

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Original Paper

Cocreation of Massive Open Online Courses to Improve Digital Health Literacy in Diabetes: Pilot Mixed Methods Study

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Abstract

Background: Self-management education is a fundamental aspect in the health care of people with diabetes to develop the necessary skills for the improvement of health outcomes. Patients are required to have the competencies to manage electronic information resources—that is, an appropriate level of digital health literacy. The European project IC-Health aimed to improve digital health literacy among people with diabetes through the cocreation of massive open online courses (MOOCs).

Objective: We report the preliminary results obtained in 3 participating countries in the IC-Health project (Italy, Spain, and Sweden) regarding (1) experience of the participants during the cocreation process of MOOCs, (2) perceived changes in their digital health literacy level after using MOOCs, and (3) a preliminary assessment of the acceptability of MOOCs.

Methods: The cocreation of the MOOCs included focus groups with adults and adolescents with diabetes and the creation of independent communities of practice for type 1 diabetes and type 2 diabetes participants aimed to co-design the MOOCs. Quantitative measures of the acceptability of MOOCs, experience in the cocreation process, and increase in digital health literacy (dimensions of finding, understanding, and appraisal) were assessed.

Results: A total of 28 participants with diabetes participated in focus groups. Adults and adolescents agreed that the internet is a secondary source of health-related information. A total of 149 participants comprised the diabetes communities of practice. A total of 9 MOOCs were developed. Acceptability of the MOOCs and the cocreation experience were positively valued. There was a significant improvement in digital health literacy in both adults and adolescents after using MOOCs ($P<.001$).

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Conclusions: Although the results presented on self-perceived digital health literacy are preliminary and exploratory, this pilot study suggests that IC-Health MOOCs represent a promising tool for the medical care of diabetes, being able to help reduce the limitations associated with low digital health literacy and other communication barriers in the diabetes population.

Introduction

Background

Diabetes is a chronic disease leading to severe morbidity, reduced quality of life, and anticipated mortality. According to the Diabetes Atlas of the International Diabetes Federation, more than 59 million adults aged 20 to 79 years in the European Union had diabetes in 2019 and it is estimated to reach 68 million in 2045 [1].

Self-management education is a fundamental aspect in the health care of people with diabetes to increase knowledge about their disease and develop the necessary skills to improve glycemic control and health outcomes [2]. Structured education programs have proven to be cost-effective to improve glycemic control and patient quality of life and reduce diabetes complications [3]. However, not all people with diabetes have access to these interventions due to financial barriers or limited offer by the health care system, among others [4,5].

These limitations in glucose control can be partly overcome through technological advances such as continuous glucose monitoring systems or insulin pumps. The daily use of these medical devices has improved the quality of life of people with diabetes [6] and requires some degree of health literacy [7,8] or digital health literacy [9,10]. The skills related to digital health literacy are to find, understand, appraise, and apply health information from electronic sources and apply the knowledge gained to addressing or solving a health problem [11]. Several studies have shown that internet-based diabetes education may improve patient knowledge and ability to access and interpret online health information, provide greater interaction with health care professionals, and promote better self-management of health conditions, healthier lifestyles, diabetes control, and quality of life [12-17]. Involvement in online peer support communities can be a beneficial adjunct to learning, serving as an option for ongoing diabetes peer support [18,19]. However, a barrier to the use of internet may be a lack of knowledge about how to find and interpret information online, since having access to technology is not necessarily associated with knowing how to use it [20,21].

Massive open online courses (MOOCs), a type of open educational resource [22], are innovative tools to improve education and practice, easily applicable to empower patients with chronic conditions to find quality, equitable, patient-centered education aimed at better health outcomes [23-25]. Cocreation is an option to enhance the relevance and usability of MOOCs by involving potential users and health care professionals, resulting in an effective strategy to design

possible solutions aimed at increasing self-efficacy and empowerment of patients [26-29].

The European Commission works on the development of specific health innovation initiatives aimed to empower patients and promote the adoption of eHealth across the European Union, as can be seen in some programs and plans [30].

In this regard, the European project IC-Health: Improving Digital Health Literacy in Europe aimed to improve the digital health literacy level of European people with diabetes and other population cohorts through the cocreation of MOOCs focusing on the essential digital health literacy skills [31].

Objectives

This study aimed to develop MOOCs designed to improve the digital health literacy level of people with type 1 diabetes (T1D) and type 2 diabetes (T2D) in 5 European countries (Spain, Belgium, Denmark, Italy, and Sweden) under the framework of the IC-Health project. In this paper, we present (1) the results of the focus groups run to explore the experience of people with diabetes in the use of the internet for health-related issues, as well as their needs and expectations, in order to inform the MOOCs' development; (2) the cocreation methodology applied and the developed MOOCs; and (3) a pilot assessment of participant experiences in the cocreation process, the acceptability of the MOOCs, and their effect on self-perceived digital health literacy.

Methods

Ethics

The partner organizations were responsible for processing the necessary procedures to request approval by the corresponding ethical committees to evaluate their organization, and they assured the compatibility of the research activities with national and European ethics requirements in order to protect the rights, safety, and well-being of participants involved. An internal ethical committee was created comprising representatives appointed by each project partner and identified among highly skilled professional experts in any of the following areas: public health, health care evaluation, health promotion, social research, engineering, development, or human rights. The presence of different national members ensured that any country-specific ethical requirements were considered throughout the project life. Partners required approvals from the internal ethical committee to perform cocreation activities for the project.

Study Design

A broader description of the design and methodology of the IC-Health project can be found in Perestelo-Pérez et al [32]. It

included a review of the literature, exploratory survey with T1D and T2D adults, results of the focus groups with adults and adolescents (aged 14 to 17 years) with diabetes, and formation of communities of practice aimed to co-design the MOOCs. The literature review and survey results were reported in the final project report [33,34]. In this paper, we report the results of the focus groups and formation of communities of practice.

Recruitment and Procedure

Participants were recruited from primary care centers, hospitals, and social networks following a snowball sampling approach [35]. There were no exclusion criteria. The confidentiality of patient personal data was guaranteed in accordance with the European Commission's guidelines.

Three focus groups were held in Spain and Italy between March and April 2017 following a semistructured guide to qualitatively explore the dimensions of digital health literacy and complement the information from the survey. All discussions were audiorecorded.

The cocreation process to develop the MOOCs was accomplished by creating communities of practice [36,37] independently by country and diabetes type. Each one comprised key stakeholders (people with T1D or T2D, endocrinologists, nurses, pediatric diabetologists, psychologists, and researchers) and was organized and coordinated by a project researcher through a closed Moodle learning management system platform (a screenshot of the platform is shown in Figure 1).

Figure 1. Screenshot of the platform for cocreation activities.
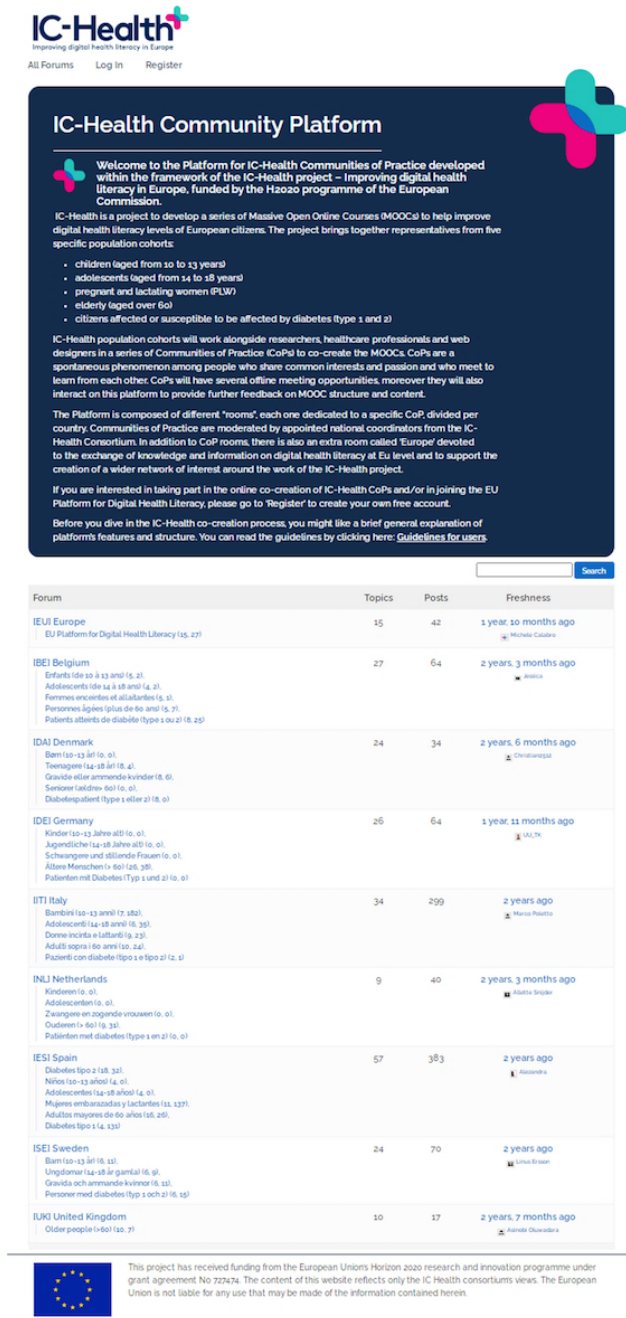
Within each community of practice, the cocreation process started with a face-to-face group session with the participants that lasted approximately 2 hours in each country. In these first sessions, the preliminary storyboard of each MOOC according to the dimensions of finding, understanding, appraisal, and applying health information was defined. Subsequently, participants continued to participate in the cocreation process through a web platform between October 2017 and April 2018. The community of practice coordinator shared the drafts developed for each skill weekly; requested feedback on the contents, format, and graphic materials; and promoted interaction between participants. Participant feedback on the content and design of each MOOC was considered for the pertinent modifications.

Finally, after the online participation, another round of face-to-face sessions was held. In these sessions, participants provided their final feedback on navigation, accessibility, content, and structure of the MOOCs, and quantitative measures were applied. Therefore, this pilot quantitative assessment was performed in the same sample that participated in the cocreation process. All sessions followed a semistructured guideline.

Quantitative Measures

The following questionnaires were administered either in face-to-face sessions and on the Moodle platform:

- Acceptability of the MOOCs was assessed through a 14-item questionnaire (developed specifically for this project and based in previous related studies [38]) that evaluated ease of navigation, clarity of the objectives and language, appropriateness of learning activities, and other characteristics of the MOOCs (Multimedia Appendix 1).
- Experience during the cocreation process was assessed by means of 3 self-developed items rated on a 4-point Likert scale from 0 (totally disagree) to 4 (totally agree): (1) "Being part of the cocreation process made the MOOC content more relevant to my needs," (2) "The cocreation process made me feel part of the project," and (3) "Taking part in the different workshops has improved my knowledge about digital health literacy. This has increased my ability to take charge of my health" Multimedia Appendix 2).

- Self-perceived digital health literacy was assessed before and after the MOOCs development. We used 5 items from the eHealth Literacy Scale [39], 2 items from the eHealth Impact Questionnaire [40], and one item from the Health Literacy Questionnaire [41]. Items assessed 3 main skills required in digital health literacy (finding, understanding, and appraising information on the internet; Multimedia Appendix 3).

Analysis

Qualitative Analysis

The focus groups were analyzed by means of a descriptive deductive content analysis [42]: (1) in-depth analysis of the audio-registration, (2) identification of relevant issues discussed, (3) codification of each relevant topic, (4) clustering of information obtained on each topic, (5) critical analysis and interpretation of information collected on each explored topic, (6) incorporation of the moderator and assistant observations, and (7) synthesis of results. The results of the focus groups were exploratory and informed the cocreation of semistructured guidelines in Spain and Italy.

Quantitative Analysis

Means and standard deviations were calculated for each item measuring acceptability, cocreation experience, and digital health literacy scales. Nonparametric analyses were used to compare results between countries (Mann-Whitney U test) in acceptability and experience items and within samples in digital health literacy (Wilcoxon signed-rank test) before and after the cocreation process.

Results

Focus Groups

A total of 8 Italian adolescents with T1D and 20 Spanish adults with T1D or T2D participated in the focus groups (Table 1).

The following main themes were identified: experiences, needs, expectations, and trust in the use of the internet as a source of information on health and illness issues (Table 2).

Table 1. Characteristics of the participants in focus groups (n=28).

Characteristics	Total diabetes participants (n=28)	Total T1D[a] participants (n=18)	Total T2D[b] participants (n=10)
Country, n (%)			
Spain (adults)	20 (71)	10 (56)	10 (100)
Italy (adolescents)	8 (29)	8 (44)	—[c]
Age range (years)			
Spain (adults)	22-75	22-54	35-75
Italy (adolescents)	14-17	14-17	—
Gender, n (%)			
Spain (adults)			
Female	11 (39)	5 (28)	6 (60)
Male	9 (32)	5 (28)	4 (40)
Italy (adolescents)			
Female	3 (11)	3 (17)	—
Male	5 (18)	5 (28)	—
Educations, n (%)			
Spain (adults)			
Primary education	1 (34)	1 (6)	—
Secondary school	3 (11)	—	3 (30)
Medium/high technical education	4 (14)	1 (6)	3 (30)
Undergraduate	5 (18)	2 (11)	3 (30)
University degree	7 (25)	6 (33)	1 (10)
Italy (adolescents)			
High school	8 (29)	8 (44)	8 (29)
Civil status, n (%)			
Spain (adults)			
Married/living with partner	7 (35)	4 (40)	3 (30)
Separated or divorced	5 (25)	1 (10)	4 (40)
Single	6 (30)	5 (50)	1 (10)
Widow	2 (10)	—	2 (20)
Employment status, n (%)			
Spain (adults)			
Employed	5 (25)	4 (40)	1 (10)
Unemployed	5 (25)	3 (30)	2 (20)
Retired	8 (40)	1 (10)	7 (70)
Student	2 (10)	2 (20)	—

[a]T1D: type 1 diabetes.

[b]T2D: type 2 diabetes.

[c]Not applicable.

Table 2. Themes and subthemes identified in the thematic analysis.

Themes	Subthemes	Example quote
Experience/general opinion using internet for health and illness issues	• Personal experiences • Level of satisfaction • Use of this information	• "I trust my doctor a lot, but I sometimes go into the internet to nose around." • "I read that a new resolutive treatment for diabetes was found but then going deeper in other websites I realized that the information was false." • "I used the web for a medical advice about diabetes (insulin question), but I didn't find the specific answer and I had to call the hospital."
Needs and expectations of the use of internet as source of information on health and illness issues	• Informational needs • Preferences relating display format	• "It would be very interesting internet forums, for example, that we are all from here, or wherever, if we could all have a forum to share our experiences and encourage each other." • "I prefer websites because they are easier to use, you don't need a smartphone, you don't have to download anything, and it doesn't take too much space in the memory of the device."
Trust on internet as source of information on health and illness issues	• Situations of NOT using • Why you trust information • Issues enhance or diminish level of trust	• "On the internet, you can find everything but then you have to ask your medical doctor, especially for big issues or emergency." • "On the internet a lot of things can be dumped. I think you can trust the government websites; they should hang those reliable pages." • "Social media, such as Facebook, tends to produce a lot of false information; eg, they often claim a permanent cure for diabetes."

The T2D group was older, which is related to the social distribution of this health problem. The T1D adult group was younger and used the internet more frequently. Adolescents with T1D used the internet every day. In general, all patients preferred images and videos with nontechnical language for better comprehension.

In the T2D group, internet use was variable. Almost all participants used the internet, but most of them stated they did not use it when related to health issues. Not all the participants were sure about how to establish trust in content found on the internet, and the internet was mainly considered a secondary health information source. We found 2 types of profiles of patients among the participants: those newly diagnosed patients who had very little information and those with a long-term diagnosis, more informed but with some myths and beliefs. Most of the participants demanded information about self-management in relation to eating (practical information about what to eat and how to find sugar level for different foods; see Multimedia Appendix 4 for illustrative quotes).

Most adults participants with T1D felt comfortable reading and using online health content and considered the internet a secondary source of information. Adults with T1D tended to seek practical information that helped them with everyday decision-making in their self-management. They demanded information on management of hypoglycemia, interaction between insulin intake and physical exercise and precise nutritional information (regarding food labels, ration calculation,

adjusting insulin intake, and the sensibility insulin factor). The main worry in the group was avoiding hypoglycemia and its consequences (Multimedia Appendix 4).

Adolescents with T1D used the internet for searching for health-related information. They agreed that the internet has never or hardly ever been the only or first source of health-related information. Most adolescents with diabetes said they use the internet but they face difficulties in establishing what is fake or reliable. Most participants reported that they would use the internet only for minor problems, immediate questions, to verify consequences of diabetes bad metabolic control, to understand therapies different from insulin and new types of insulin, to talk with other diabetic patients, and get updates about new technology for diabetes. For emergency and major problems or health questions, they would not use the web because of the overwhelming amount of information. Most participants expressed they would like information about how to recognize symptoms and diabetes complications that is tailored to personal needs (Multimedia Appendix 4).

Cocreation Process: Community of Practice and MOOCs Developed

A total of 214 people with diabetes were invited to participate in the communities of practice, of which 149 agreed to participate and attended the first face-to-face session; the diabetes cohort consisted of 39 Italian children and adolescents (aged 10 to 13 years) and 110 adults from Spain, Belgium, Denmark, and Sweden (Figure 2).

Figure 2. Flow of participants in the study. *Italian participants were children and adolescents (10-13 years).
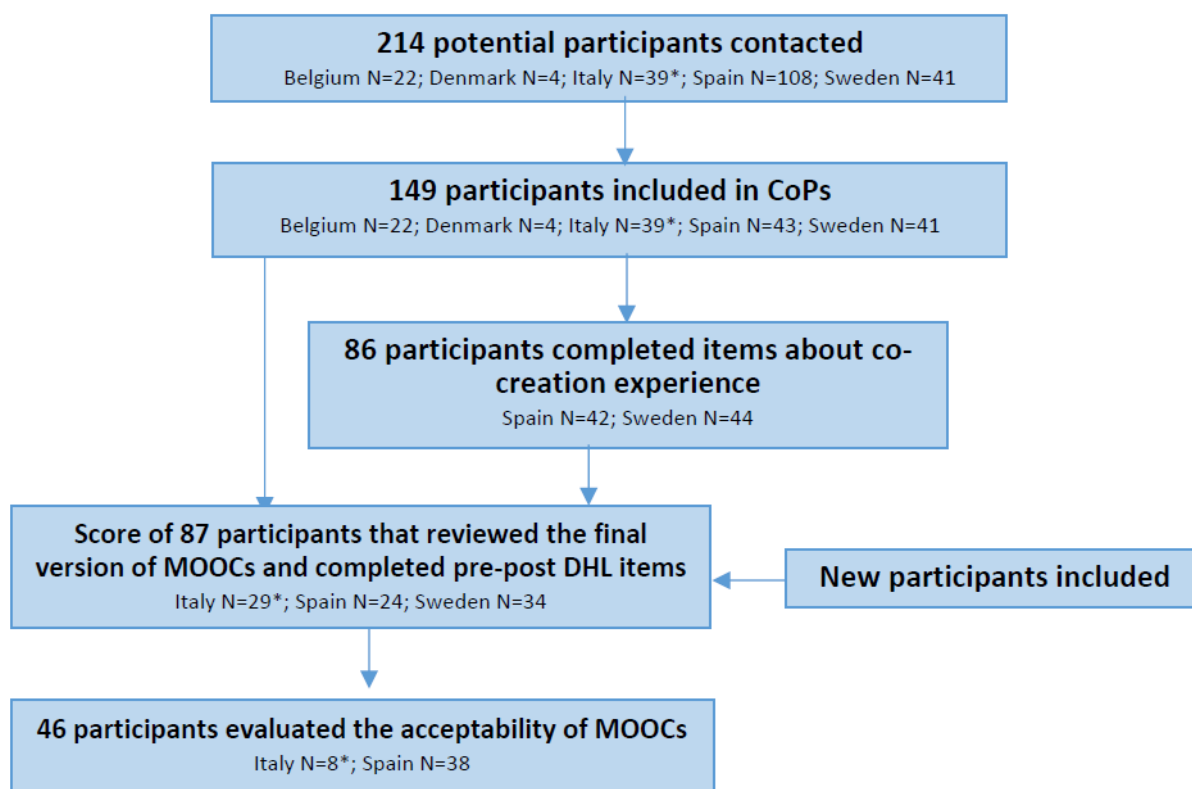
A total of 66.4% (73/110) of adult participants were female and 50.0% (55/110) had T2D. The most frequent age range was 40 to 59 years (58/110, 52.7%). Of the adult participants, 39.1% (43/110) had a high school diploma and 82.7% (91/110) used the internet daily. Of the participating children and adolescents, 67% (26/39) were female and 74.4% (29/39) used the internet once or twice a week.

In some cases with the T2D cohort and children and adolescents, the communities of practice coordinators taught basic digital skills before starting the actual project and cocreation. These participants had difficulty with computers in general and the communities of practice platform and Moodle registration specifically because they had not used laptops or computers frequently. As a result, they had more difficulties with basic actions, such as log-in or creating an account for the communities of practice platform or the MOOCs.

Italian children, adolescents, and their parents were more willing to participate in face-to-face meetings. They stated that sessions should have been organized closer in time, of longer duration, and less intensive in order to closely follow the discussions on MOOC development. We tried to motivate the younger participants asking them directly what they wanted to learn and how they wanted to be taught to then implement feedback.

A total of 9 self-administered MOOCs were developed on a Moodle platform (2 from Belgium, 1 from Denmark, 2 from Italy, 2 from Spain, and 2 from Sweden). Initially, the duration of each MOOC was estimated to be 15 minutes; at completion, however, MOOCs had an average duration of 60 to 90 minutes including materials and resources added by request of the participants. This supplementary material is not mandatory to

achieve an effective knowledge of each skill, but it will help users expand the information presented if necessary.

The structure and format of the materials in each MOOC were adapted to the interests of the diabetes participants in each country, but all of them comprised 4 compulsory topics referring to subskills of digital health literacy: find, understand, appraise, and apply. In addition to the compulsory units, including an introductory unit with an overview of the MOOC and an introduction to digital health literacy was strongly recommended to national coordinators.

Units included texts, videos, images and infographics, and links to documents and shared documents. Videos were relevant existing ones or ones recently produced by the national coordinators from feedback received in their communities of practice. Self-produced videos were developed using Animaker (Animaker Inc) or Powtoon (Powtoon Ltd) tools. In the case of images, communities of practice expressed they preferred images to be embedded in the MOOCs, and infographics were developed by national coordinators from the feedback of communities of practice.

Assessment questions were included while progressing through the courses and after each unit, and a postassessment was also included at the end of the MOOCs. Moreover, for some MOOCs certificates of attendance were issued when learners completed the course and answered the questions associated with the evaluation and impact assessment. MOOCs are accessible from anywhere, at any time, and for many participants, since no contact with the trainers is necessary and the activities are asynchronous.

An updated version of the Spanish MOOCs can be found on the website of the University of La Laguna [43] (Multimedia Appendix 5 and Multimedia Appendix 6).

Quantitative Outcomes

Acceptability of the MOOCs

Acceptability data were available for 46 participants (Multimedia Appendix 7). When totally agree and agree categories were combined, more than 90% of participants thought the language and objectives of the course were clear, contents were consistent with the objectives, learning activities were useful, and they would recommend the MOOC to other people.

A total of 89% (41/46) of participants stated that the duration of the course was appropriate and it had met their expectations

while 72% (33/46) stated that navigation was easy and 76% (35/46) said the examples provided were of high or very high quality.

The scores were similar for the Spanish and Italian subsamples, except for the quality of the examples, which was perceived as higher in the Spanish subsample (P<.001).

Experience During the Cocreation Process

Data were available for 86 participants. The percentage of Spanish participants who agreed or totally agreed was 76% for the 3 items, whereas in Sweden it was 91%, 100%, and 86%, respectively (Table 3). Mean differences between the two countries were significant for the 2 former items (P=.008 and P=.004, Mann-Whitney U test).

Table 3. Results on items about the experience of cocreation of the massive open online courses (n=86).

Question	Spain (n=42)		Sweden (n=44)	
	Agree/totally agree, n (%)	Mean (SD)	Agree/totally agree, n (%)	Mean (SD)
1. Because I was part of the cocreation process, the MOOC content felt more relevant to my needs.	36 (76)	2.98 (0.71)	40 (91)	3.36 (0.65)[a]
2. The cocreation process made me feel I was part of the project.	36 (76)	3.07 (0.86)	44 (100)	3.54 (0.50)[a]
3. Taking part in the different workshops has improved my knowledge about digital health literacy. This has increased my ability to take charge of my health.	36 (76)	3.14 (0.72)	38 (86)	3.23 (0.68)

[a]P<.01 for the mean difference between countries (Mann-Whitney U test). Score ranges: 0 to 5.

Digital Health Literacy Scores

Baseline data were available for 87 participants. Because of absence of postevaluation data, 25.6% (10/39) of Italian adolescents were eliminated from the analysis; their baseline scores were lower than completers in finding (P=.048), understanding (P=.04), and appraising (P=.07; not shown in Table 4). The remaining participants showed a significant increase in the understanding (z=0.58, P=.002) and appraising (z=0.30, P=.03) scales. Table 4 shows the prescores and postscores on the digital health literacy dimensions.

In the Spanish and Swedish samples, 43% (18/42) of Spanish adults and 23% (10/44) of Swedish adults (23%) were excluded from analyses due to the absence of baseline data; their postscores did not significantly differ from those of analyzed participants in any dimension. The Spanish sample significantly improved in finding (z=0.46, P=.03) and appraising (z=0.45, P=.04).

Finally, Swedish participants, who showed higher scores at baseline than the other 2 samples, significantly improved in 3 scales, with mean increases of 0.70 (finding, P=.002), 0.75 (understanding, P=.001), and 0.73 (appraising, P=.001).

Table 4. Pre-post differences (Wilcoxon signed-rank test) in digital health literacy (n=87)[a].

Digital health literacy skills	Italy (n=29)[b], mean (SD)			Spain (n=24), mean (SD)			Sweden (n=34), mean (SD)		
	Pre	Post	z (P value)	Pre	Post	z (P value)	Pre	Post	z (P value)
Finding	2.21 (0.75)	2.48 (0.93)	−1.09 (.28)	2.01 (0.86)	2.47 (0.44)	−2.24 (.03)	2.20 (0.88)	2.90 (0.76)	−3.10 (.002)
Understanding	2.07 (0.75)	2.65 (0.57)	−3.09 (.002)	2.14 (0.95)	2.44 (0.59)	−1.22 (.22)	2.45 (1.07)	3.20 (0.58)	−3.23 (.001)
Appraising	2.16 (0.69)	2.46 (0.55)	−2.24 (.03)	1.93 (1.02)	2.38 (0.54)	−2.03 (.04)	2.56 (0.95)	3.29 (0.62)	−3.23 (.001)

[a]Higher score is better (range 0-4); 10 Italian, 18 Spanish, and 10 Swedish participants were excluded due to the absence of baseline (Spain and Sweden) or postassessment (Italy) data.

[b]Adolescents.

Discussion

Principal Findings

This study has demonstrated the feasibility of developing an online resource to improve the digital health literacy of diabetes patients in a cocreation process with the target audience from the initial moments of the development process. The cocreation experience was positively valued by the participants; they felt part of the project and were willing to share ideas and discuss with their peers. Acceptability of the final MOOCs was good. Most of the participants would recommend the MOOC to other people, highlighting as positive aspects the clarity of the language, coherence between the contents and objectives, and usefulness of the learning activities. In the 3 subsamples in which self-perceived digital health literacy was assessed (Italy, Spain, Sweden), significant pre-post improvements were observed in the appraising information scale and at least 1 out of the other 2 dimensions (ie, finding and understanding). However, these quantitative results are preliminary and exploratory, and they must be interpreted cautiously, since evaluation of the effectiveness of the MOOCs was not the main objective of the project.

Usability and easily of navigation is an essential factor for any MOOC to be accepted by the users to whom it is addressed. In the subsamples assessed, this feature was poorly valued by 9% (4/46) of participants, whereas 20% (9/46) were not sure. We observed more difficulties in T2D patients, which is not surprising since this group includes more senior patients who are less familiar with the use of new technologies [44]. Apart from teaching them basic digital skills, we tried to promote their involvement by actively asking them for advice and suggestions during the MOOC development, trying to increase their motivation, awareness, and interest around digital health literacy topics [45].

Many participants wanted more face-to-face sessions, which are more difficult to organization than online sessions and require a well-designed schedule that accommodates job and school calendars so face-to-face meetings can be possible.

Two of the most important lessons for a successful cocreation process that can be drawn from our experiences are the communities of practice coordinator must have the necessary skills to motivate users to actively participate in the community and interventions directed to people with T2D must consider the previous digital literacy level of the participants, since many may be elderly. Overall, participants felt part of the project, and they were willing to share ideas and discuss them with their peers.

Strengths and Limitations

This study has several limitations. The focus groups were not originally part of the project and were held based on the subsequent initiative of the partners. Regarding the communities

of practice, the risk of selection bias is present, since participants were not randomly recruited and the participation rate was low in the larger sample (Spain). Therefore, it is possible that the sample was not representative in terms of motivation or digital health literacy. Future studies should assure that people with low literacy levels are included in the cocreation process and evaluation of the MOOCs to avoid widening the digital divide. The results of the pilot quantitative analyses are subjected to several limitations and must be interpreted with caution. Acceptability and the change in self-perceived literacy were not assessed in a sample independent of the cocreation process. The scale used for digital health literacy was short and not psychometrically validated. Furthermore, we have not evaluated objective performance on digital health literacy, which is necessary to demonstrate the utility of the MOOCs for improving diabetes knowledge and self-management.

Developing initiatives to promote self-management as a strategy to empower patients is a practice increasingly implemented around the world [46]. Digital-based interventions are designed to extend accessibility and improve attractiveness for people with a wide range of health literacy levels [47]. Comparison and integration of valid information found in patients' online searches with the information provided by their health care professionals can improve their knowledge and preferences related to treatment selection and use and decrease health risks due to poor understanding of online information or its reliability [48]. In the case of diabetes, although numerous interventions have been developed to improve health literacy and self-management, there is a large heterogeneity of intervention types and content and low completion rates, which produces mixed results [49-51]. The IC-Health project used a common methodology to develop a set of tools, in MOOC format, to promote digital health literacy of people with diabetes through materials accessible from anywhere, at any time, and for many participants, thus overcoming some barriers to the traditional education and training of this type of patients due to physical space limitations [52,53]. When cocreating MOOCs or any other e-learning content for people with diabetes, involvement of the target audience is recommended to maximize the likelihood that the final product is adapted to the needs and preferences of the end users [54-56].

Conclusions

The results of the IC-Health project in people with diabetes show that MOOCs could be an accepted and effective way to improve the digital health literacy of diabetes patients and empower them to optimize their self-management. The cocreation experience in the development of MOOCs was positive for most of the participants. This methodology could reduce the limitations associated with low digital health literacy and other communication barriers in this population. More studies focusing on assessing the effectiveness and impact of the MOOCs on self-perceived and objective digital health literacy and health status of diabetes people are necessary.

Acknowledgments

Authors' Contributions

LP, MP, and PS were responsible for project administration and funding acquisition. DA, ATC, BP, and JV contributed to the recruitment, development, and analysis of the focus groups. YA, AT, BP, JV, and MP contributed to the recruitment and coordination of communities of practice. YA, AR, LP, ATC, and AD were responsible for data analysis and writing the first draft of the manuscript. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Usability evaluation questionnaire.
[PDF File (Adobe PDF File), 93 KB - diabetes_v6i4e30603_app1.pdf]

Multimedia Appendix 2
Cocreation experience questionnaire.
[PDF File (Adobe PDF File), 96 KB - diabetes_v6i4e30603_app2.pdf]

Multimedia Appendix 3
Self-perceived digital health literacy questionnaire.
[PDF File (Adobe PDF File), 70 KB - diabetes_v6i4e30603_app3.pdf]

Multimedia Appendix 4
Illustrative quotes from focus groups.
[PDF File (Adobe PDF File), 126 KB - diabetes_v6i4e30603_app4.pdf]

Multimedia Appendix 5
Screenshot of updated version of the Spanish massive open online course: general appearance of the massive open online course for type 1 diabetes mellitus.
[PNG File , 332 KB - diabetes_v6i4e30603_app5.png]

Multimedia Appendix 6
Screenshot of updated version of the Spanish massive open online course: example of the content of the unit on appraisal of the massive open online course for type 2 diabetes mellitus.
[PNG File , 624 KB - diabetes_v6i4e30603_app6.png]

Multimedia Appendix 7
Acceptability of massive open online courses.
[DOCX File , 16 KB - diabetes_v6i4e30603_app7.docx]

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Abbreviations

MOOC: massive open online course
T1D: type 1 diabetes
T2D: type 2 diabetes

<u>Viewpoint</u>

Telemedicine via Continuous Remote Care: A Proactive, Patient-Centered Approach to Improve Clinical Outcomes

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Abstract

The COVID-19 pandemic has revolutionized health care for patients and providers alike. Telemedicine has moved from the periphery of our health care system to center stage more rapidly than anyone could have envisioned. Currently, virtual care has quite effectively replicated the traditional health system's care delivery model and reimbursement structure—a patient makes an appointment, then sees a physician (except with video or phone replacing in-office visits) who makes a care plan, and the patient and physician meet again at a later timepoint to assess progress. Replicating this episodic care paradigm virtually has been invaluable for delivering care swiftly during the COVID-19 pandemic; however, we can and should do more with the connectedness and convenience that telemedicine technology enables. Continuous remote care, with a data-driven, proactive outreach to patients, represents a decisive step forward in contrast to the currently available episodic, reactive, patient-initiated care. In the context of continuous remote care, patient biometric and symptom data (patient entered and connected data) are assimilated in real time by artificial intelligence–enabled clinical platforms to bring physicians' and other health care team members' attention to those patients who need intervention, whether this is via medication adjustments, acute care management, or lifestyle coaching. In this paper, we discuss how an innovative continuous remote care approach has improved outcomes in another deadly pandemic—type 2 diabetes mellitus.

KEYWORDS

Background

The COVID-19 pandemic has revolutionized health care for patients and providers alike. Telemedicine has moved from the periphery of our health care system to center stage more rapidly than anyone could have envisioned. Physicians and health care organizations alike have stepped up to the challenge of swiftly adapting their practices and organizations to virtual care. In the current setting, virtual care has quite effectively replicated the traditional health system's care delivery model and reimbursement structure, in that a patient first makes a medical appointment, then sees a physician (except with video or phone replacing in-office visits) who makes a care plan, and the patient and physician meet again weeks or months later to assess progress.

Replicating this episodic care paradigm virtually has been invaluable for delivering care swiftly during the COVID-19 pandemic; however, we can and should do more with the connectedness and convenience that telemedicine technology enables. Despite many advances in medicine, including the ever-growing options for connectivity, we have not realized the improvement in clinical outcomes as chronic diseases continue to be an unabated public health concern.

Continuous Remote Care

Overview

An option for a more patient-centered telemedicine experience is continuous remote care (CRC). This approach includes a data-driven, proactive outreach to patients, which represents a decisive step forward in contrast to the currently available episodic, reactive, patient-initiated care. In CRC, patient biometric and symptom data (ie, patient entered and connected data) are assimilated in real time by artificial intelligence–enabled clinical platforms to bring physicians' and other health care team members' attention to those patients who need intervention, whether this is via medication adjustments, acute care management, or lifestyle coaching. The care team can review hundreds of patients a day instead of just one or two dozen; proactively engage the patient to develop a care plan; and support patient empowerment, safety, and achievement of optimal health outcomes. As a result of the CRC model's connectedness, the care team can reassess progress in real time.

In this paper, we discuss how this innovative CRC approach has improved outcomes in another deadly pandemic—type 2 diabetes mellitus.

CRC for Type 2 Diabetes Mellitus

Patients with chronic diseases such as diabetes require ongoing, aggressive, team-based management to optimize health outcomes and ongoing support to ensure long-term adherence to their care plan. Patients with diabetes must make decisions many times a day related to their care, and for those on insulin and other diabetes medications, each decision can be quite complex. Furthermore, these decisions impact what will happen to the trajectory of their disease over time and may determine if they are destined to have a diabetes-related emergency and need to use emergency services at that time. This type of complex disease is an ideal fit for the CRC approach, as it requires more than the episodic care that our health care system has built upon in order to address the day-to-day, meal-to-meal needs of patients.

Advances in diabetes technology, such as blood sugar monitoring apps and continuous glucose meters, have already improved patient care [1,2]. However, provider advice based on data from these devices is generally delivered during traditional episodic visits. Asynchronous virtual feedback from a health coach or certified diabetes educator has been shown to add additional improvements in glucose control [3,4]. To date, the most significant improvements in glucose control have been seen when remote monitoring is tied to a physician-led care team, as our published results demonstrate [5].

Our CRC model was created to provide multifaceted, holistic patient support, ranging from medication adjustments to transformational lifestyle changes (Figure 1). Physicians are alerted by algorithmic prioritization to situations that may be a safety concern or where medications need to be adjusted based on incoming biomarkers, thereby allowing proactive outreach to patients. Health coaches operate in pods so that many specialists (eg, nurse practitioners, behavioral health providers, dieticians, and exercise physiologists) allow for specialized and personalized care for each individual by using the same prioritization system as physicians to guide lifestyle interventions. This high-touch care, including personalized nutrition advice, has allowed for medication de-escalation, often culminating in complete elimination of medication [5]. Moreover, integral to CRC are moderated peer-support groups and readily accessible patient resources that include education on many topics, such as recipe and menu planning, and behavior-focused content. This model has shown a retention and engagement rate of 74% at a 2-year timepoint [5].

Figure 1. Multifaceted holistic care offered by the continuous remote care model.
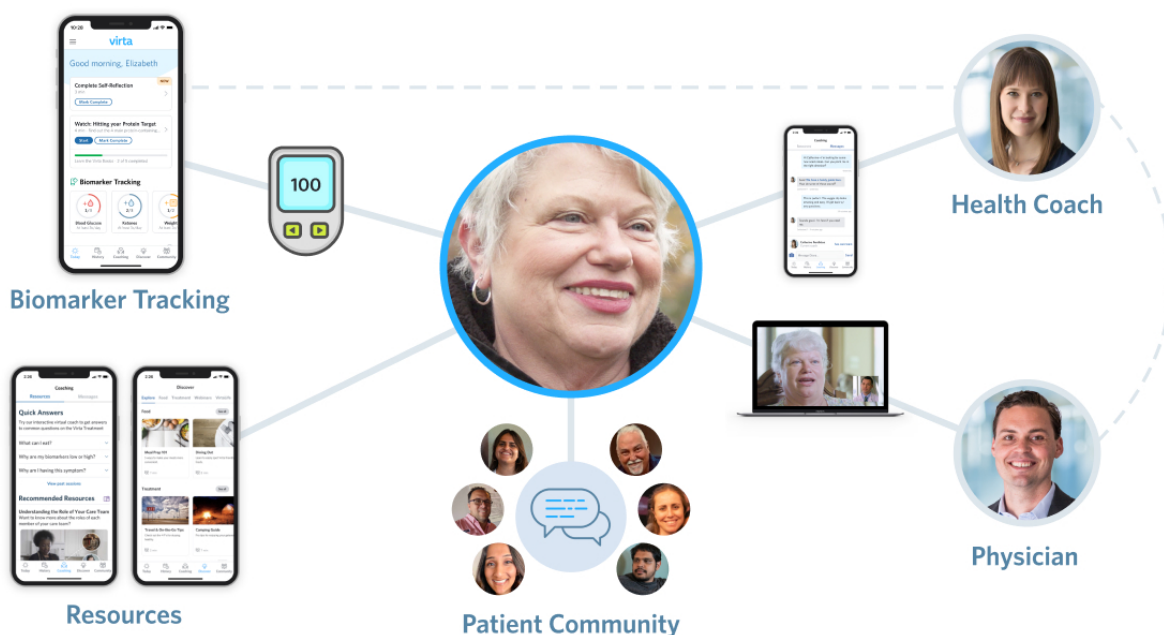
CRC for Other Chronic Diseases

Proactive outreach to patients based on incoming biomarker data has successfully been used for congestive heart failure (CHF) in many trials, with results demonstrating decreased hospitalization rates for CHF exacerbations and lower mortality [6,7]. This model can also track biomarkers for other chronic diseases, such as obesity and hypertension.

Barriers to Widespread Use

As CRC for diabetes and other chronic diseases continues to evolve, with increasing evidence for its efficacy increases and new indications for this care paradigm being established, the associated reimbursement models will need to evolve as well. Although CRC includes elements of evaluation and management episodes, as well as remote physiologic monitoring, its high frequency of asynchronous patient-provider interactions and the complexity of ongoing behavioral support are not readily captured under or even fully recognized by existing Current Procedural Terminology (CPT) codes. Therefore, development of CRC-specific CPT codes will incentivize adoption of this resource-intensive, but remarkably effective, care paradigm. A CRC paradigm also aligns with the essence and implementation of risk-based reimbursement, as utilized, for example, in Medicaid managed care plans. This would efficiently empower patients to achieve and maintain better health, thereby resulting in fewer costly episodic health services.

Although 90% of Americans now have access to the internet [8], the digital divide remains significant. Those without internet access are particularly vulnerable and are among the populations with the highest rate of diabetes incidence. Working toward universal connectivity and developing CRC programs that can be accessible even by patients with low technology literacy is essential if CRC is to promote real health equity.

Conclusions

A CRC paradigm, beyond merely providing increased convenience and lower cost of episodic telemedicine care, brings the opportunity for improved patient care and outcomes. A proactive, data-driven, team approach has already been demonstrated to be sustainably adopted by patients and to dramatically improve diabetes and CHF outcomes. This model may also improve outcomes across a wide range of chronic diseases, such as obesity and hypertension, among others, where treatment decisions should be made on incoming data quickly to engage patients and obtain the best health improvements. As we embrace this innovative care model and overcome barriers to its universal use, we can create a new era in which patients are not just the recipients of health care but also the agents and champions of good health.

Conflicts of Interest

SH is an employee of Virta Health with stock options and a member on the Scientific Advisory Board for Simply Good Food Company. DH is also an employee of Virta Health.

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Abbreviations

CHF: congestive heart failure

XSL•FO

RenderX

CPT: Current Procedural Terminology
CRC: continuous remote care

Review

Patient-Generated Data Analytics of Health Behaviors of People Living With Type 2 Diabetes: Scoping Review

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Abstract

Background: Complications due to type 2 diabetes (T2D) can be mitigated through proper self-management that can positively change health behaviors. Technological tools are available to help people living with, or at risk of developing, T2D to manage their condition, and such tools provide a large repository of patient-generated health data (PGHD). Analytics can provide insights into the health behaviors of people living with T2D.

Objective: The aim of this review is to investigate what can be learned about the health behaviors of those living with, or at risk of developing, T2D through analytics from PGHD.

Methods: A scoping review using the Arksey and O'Malley framework was conducted in which a comprehensive search of the literature was conducted by 2 reviewers. In all, 3 electronic databases (PubMed, IEEE Xplore, and ACM Digital Library) were searched using keywords associated with diabetes, behaviors, and analytics. Several rounds of screening using predetermined inclusion and exclusion criteria were conducted, after which studies were selected. Critical examination took place through a descriptive-analytical narrative method, and data extracted from the studies were classified into thematic categories. These categories reflect the findings of this study as per our objective.

Results: We identified 43 studies that met the inclusion criteria for this review. Although 70% (30/43) of the studies examined PGHD independently, 30% (13/43) combined PGHD with other data sources. Most of these studies used machine learning algorithms to perform their analysis. The themes identified through this review include predicting diabetes or obesity, deriving factors that contribute to diabetes or obesity, obtaining insights from social media or web-based forums, predicting glycemia, improving adherence and outcomes, analyzing sedentary behaviors, deriving behavior patterns, discovering clinical correlations from behaviors, and developing design principles.

Conclusions: The increased volume and availability of PGHD have the potential to derive analytical insights into the health behaviors of people living with T2D. From the literature, we determined that analytics can predict outcomes and identify granular behavior patterns from PGHD. This review determined the broad range of insights that can be examined through PGHD, which constitutes a unique source of data for these applications that would not be possible through the use of other data sources.

Introduction

Background

Diabetes is a serious metabolic condition in which the body experiences elevated blood glucose levels that can result in serious complications such as cardiovascular disease, kidney disease, stroke, eye disease, foot ulcers, nerve damage, and amputation. The World Health Organization has stated that high blood glucose levels are the third leading cause of premature mortality [1]. As of 2015, it is estimated that globally 415 million adults are living with diabetes, with 3.4 million in Canada; the latter number is expected to rise to 5 million, or 12.1% of the Canadian population, by 2025 [2]. Type 2 diabetes (T2D) is characterized by the body's resistance or insufficient production of insulin. Research suggests that the risks of further complications for people living with T2D can be mitigated through proper self-management [3]. The treatment protocol for proper management of T2D includes glycemic control, weight management, adequate nutrition, regular physical activity, sedentary behavior reduction, and medication adherence [4].

Technology-enabled tools may facilitate behavior change in people living with, or at risk of developing, T2D and help to manage their condition by delivering tailored feedback. Mobile health (mHealth) options through smartphones, mobile apps, wearable sensors, smartwatches, and additional devices that include Bluetooth-enabled blood glucose meters (BGMs), bodyweight scales, and commercial blood pressure monitors provide low-cost and accessible tools for self-management of diabetes [5]. These interventions have resulted in reductions of glycated hemoglobin of between 0.5% and 0.8% and an average weight loss of 2.4 kg [6,7]. Users of mHealth options for managing T2D reported higher satisfaction, better quality of life, self-efficacy, and potential for increased treatment adherence [7]. The emergence of web and mobile apps and internet-enabled sensory devices has resulted in the creation of a large repository of patient-generated health data (PGHD) [8,9]; in the context of health care, the sources of these data include sensors, social media posts, blogs, and smartphone activity [10]. In contrast to sources generated by clinicians, such as electronic medical records (EMRs), PGHD can provide a firsthand view of the behaviors of people living with, or at risk of developing, T2D because the data are generated directly from the consumer as well. These sources could include data from mHealth apps such as smartphone apps, from Bluetooth-enabled medical devices such as BGMs, or from social media platforms such as Twitter.

Advanced Analytical Techniques

Large volumes of data, or *big data*, can provide information through analytics, which is defined as the process of systematically using data to derive insights by using applied analytical disciplines to facilitate decision-making [11]. Traditionally, analytical insights were derived from statistical models. However, with the emergence of big data, machine learning (ML) and artificial intelligence (AI) have come to the fore as advanced analytical techniques in which computers automatically extract patterns from data [9,12]. Raghupathi and Raghupathi [10] express that "explosions" of data volumes from the aforementioned data sources have the ability to "improve care, save lives, and lower costs" [10], with PGHD from diabetes management tools being no exception. In particular, the benefit of PGHD from diabetes management tools is that there is opportunity to use analytics to derive insights into the health behaviors of people living with T2D because these data are generated directly from the consumer, with greater frequency and context, and not solely from the perspective of an infrequent observer such as a clinician. Health behaviors include techniques for self-management of T2D that encompass proper glycemic control, eating a healthy diet, increasing physical activity, reducing sedentary time, and taking prescribed medications. Analytics can describe current health behaviors of people living with T2D and make predictions about health outcomes and prescribe treatment recommendations based on these behaviors. The aim of this review is to consolidate the current literature on what has already been learned from analytics from PGHD of the health behaviors of people living with, or at risk of developing, T2D.

Methods

Scoping Review Framework

This review followed the scoping review framework of Arksey and O'Malley [13] using the following steps: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) charting the data, and (5) summarizing and reporting the results [14]. This scoping review methodology was chosen to identify the scope of research surrounding analytics of health behaviors gathered through PGHD from people living with, or at risk of developing T2D, and to map concepts obtained from the literature [15].

Research Question

Although data from EMRs or administrative sources can provide insights into clinical outcomes, they are obtained from the perspective of health care providers or administrators. Data that are obtained directly from the consumer can provide descriptive analytical insights into their health behaviors and predictive and prescriptive insights from these behaviors. This led to developing the following research question:

> *What is known in the current literature about analytical insights about health behaviors that have been derived from PGHD from people living with, or at risk of developing, T2D?*

Search Strategy

Searches were conducted in July 2020 through 3 databases, PubMed, IEEE Xplore, and ACM Digital Library, using the search terms diabetes, behaviors, and analytics. Related

keywords were refined as described in Textbox 1. Search terms were limited to *Title* and *Abstract* for studies in PubMed and *Abstract* for studies in IEEE Xplore and ACM Digital Library because there is no option to search for *Title* and *Abstract* in these 2 databases. The years of publication were limited to 2010-2020. Using the keywords identified, 2 reviewers (MSN and AB) conducted searches through the 3 databases and identified relevant studies using the inclusion and exclusion criteria. For review articles and studies included in the data charting phase, reference lists were scanned, and additional studies that were not found through the initial search were extracted. Studies that were not complete, those whose full text was not available, and those that were not published in English were not included.

Textbox 1. Search terms for the scoping review.

Search terms

- *Diabetes* AND (*Behav** OR *Coach**) AND (*Artificial Intelligence* OR *Big Data* OR *Machine Learning* OR *Analytics* OR *Decision Support* OR *Knowledge Engineer** OR *Intelligent Retriev** OR *Expert System** OR *Business Intell**)

Study Selection

Following the Arksey and O'Malley framework [13], articles were reviewed in 3 iterations. In the first iteration, abstracts were scanned and selected using the eligibility criteria (see *Inclusion Criteria* and *Exclusion Criteria* sections). In the second iteration, the full text was scanned using the same eligibility criteria, after which articles were selected. In the final iteration, data were extracted and charted, and studies were excluded if they did not meet the eligibility criteria.

For the purposes of this review, PGHD are defined as data that were generated directly from the patient through devices that are already available for consumer use. These would include data inputted directly by patients through mobile apps; data collected passively through wearable devices such as smartwatches or accelerometers as well as data from BGMs, continuous glucose monitors (CGMs), or insulin pumps; data obtained from social media platforms such as Reddit or Twitter; or data obtained from patient surveys or questionnaires. Although some of these studies integrated PGHD with other data sources such as EMRs, administrative health data, or census data, all included studies must have included at least one source of PGHD.

Eligibility was determined using the inclusion and exclusion criteria listed below. For an article to be included, it must have met all inclusion criteria and not have met any exclusion criteria.

Inclusion Criteria

The inclusion criteria are:

1. Primary intervention driven by an analytical method AND
2. Target population includes people living with, or at risk of developing, T2D (eg, people living with obesity) AND
3. Study objective primarily focuses on health behaviors AND
4. Study must include at least one source of PGHD

Exclusion Criteria

The exclusion criteria are:

1. Technologies that are not generally available at the consumer level (ie, prototype or investigational devices) OR
2. Theoretical models that have not been applied on actual data OR
3. Studies that have not been completed OR
4. Studies not published in English OR
5. Review articles (reference lists of review articles were scanned and articles were directly extracted) OR
6. Commentary and gray literature (ie, letters, commentary, editorials, blogs, and news articles)

Charting and Extracting Data

Articles meeting the inclusion criteria were examined and critically evaluated using the descriptive analytical method outlined by Arksey and O'Malley [13]. MSN created data parameters to guide extraction, and these parameters included year of publication, study goals, source of study data, study type, analytical method (ie, algorithms used on data), analytics type (ie, descriptive, predictive, or prescriptive), and main findings. Study goals were directly extracted and quoted from the article when available, and the remaining data parameters were interpreted through analysis from examining the article.

Summarizing and Reporting Results

The descriptive data were examined manually by MSN, and themes were identified and given numerical codes. These themes were categorized and organized into thematic groups to summarize the studies by their main findings. Doing this enabled us to present a narrative to answer our research question.

Results

Overview

A total of 432 articles were identified from 3 databases and reference list searches. Of these 432 articles, 36 (8.3%) were duplicates and were subsequently removed. The abstracts and full texts of the remaining 396 articles were screened by MSN and AB, and 83 (20.9%) were included for data extraction. Finally, after close examination from data extraction by MSN, of the 83 articles, 43 (52%) were included as part of this scoping review. Figure 1 summarizes the process.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart: systematic study selection.
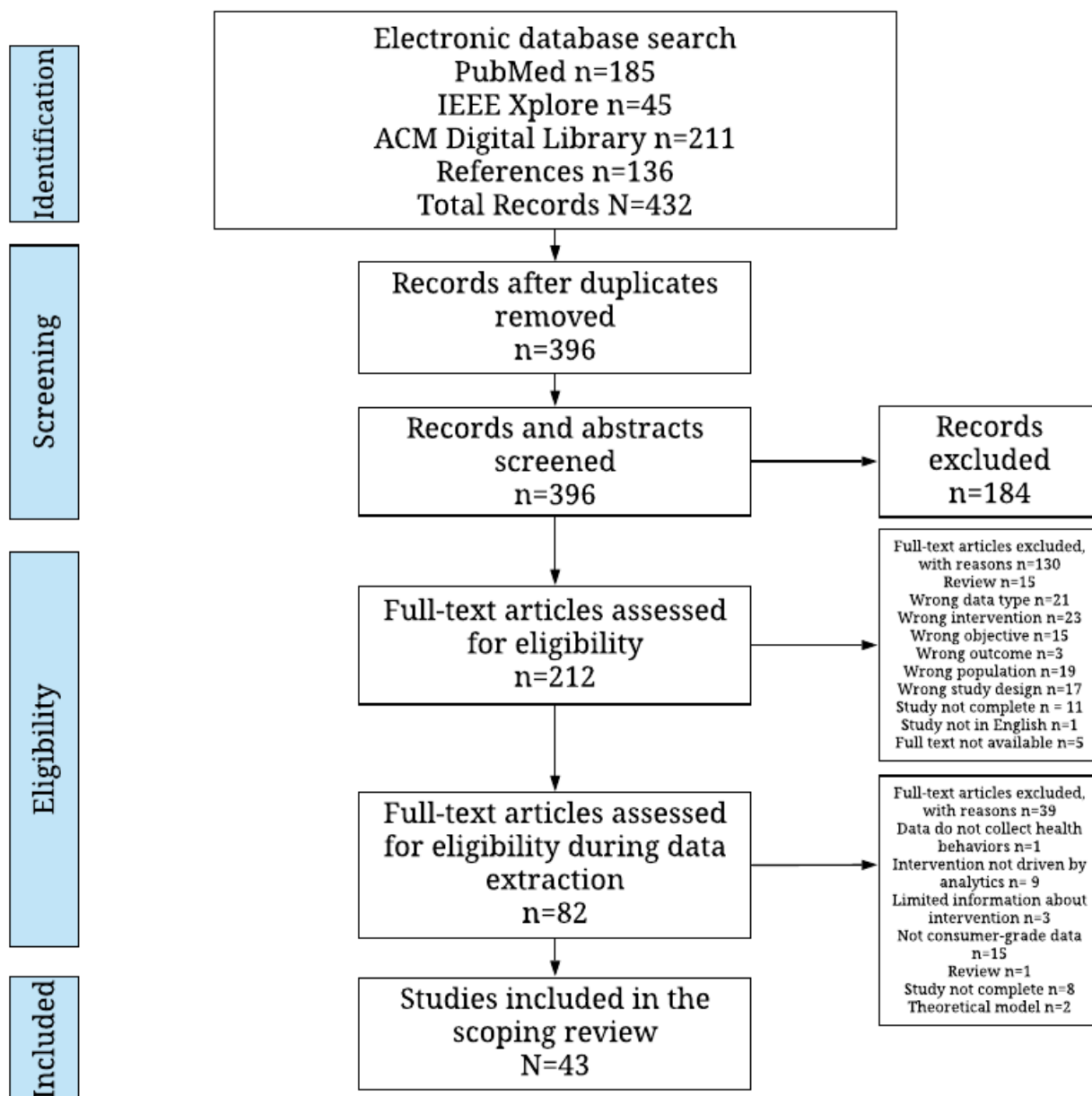
Study Characteristics

A total of 43 studies published from 2012 to 2020 were included in this review. With respect to study design, of the 43 studies, 18 (42%) incorporated a cross-sectional study, 12 (28%) incorporated an analytical framework or algorithm, 10 (23%) incorporated a comparative study, 2 (5%) incorporated a randomized controlled trial, 1 (2%) was a cohort study, 1 (2%) was a longitudinal study, and 1 (2%) was a mixed methods study.

Of the 43 studies, 30 (70%) examined only PGHD, whereas 13 (30%) combined PGHD with another source. Sources of PGHD include surveys and interviews (14/43, 33%); activity sensors (12/43, 28%); social media and forums (9/43, 21%); mHealth apps (6/43, 14%); CGMs, BGMs, and insulin pumps (3/43, 7%); self-reported data (3/43, 7%); open data sets (2/43, 5%); and web applications (1/43, 2%). The other sources of data that were not consumer generated included demographic data (5/43, 12%),

external knowledge or external databases (4/43, 9%), EMRs and clinical data (3/43, 7%), laboratory data (2/43, 5%), and administrative data (1/43, 2%).

Of the analytic types examined through the data sources, of the 43 studies, 19 (44%) used descriptive analytics, 24 (56%) used predictive analytics, and 5 (12%) used prescriptive analytics. Most of the studies used AI or ML algorithms for data analysis; 93% (40/43) used an AI-based algorithm alone or in combination with a traditional statistical method, whereas only 7% (3/43) used traditional statistical methods.

Findings From Thematic Analysis

The findings from this review suggest a broad range of themes pertaining to analytical insights through PGHD from people living with, or at risk of developing, T2D and are summarized in Multimedia Appendix 1 [16-58]. A total of 9 themes are classified into 4 categories as follows:

1. Forecasting clinical correlations and outcomes
   - Predicting diabetes and obesity (10/43, 23%)
   - Predicting glycemia (6/43, 14%)
   - Discovering clinical correlations from behaviors (3/43, 7%)

2. Understanding patient behaviors
   - Deriving factors that contribute to diabetes and obesity (8/43, 19%)
   - Obtaining insights from social media and web-based forums (7/43, 16%)
   - Analyzing sedentary behaviors (5/43, 12%)
   - Deriving behavior patterns (4/43, 9%)

3. Facilitating treatment Interventions
   - Improving adherence and outcomes (5/43, 12%)

4. Improving technology
   - Developing design principles (3/43, 7%)

Forecasting Clinical Outcomes

Overview

Analytics have the ability to forecast patient outcomes using a combination of descriptive and predictive analytics. Predictive analytics can predict adverse events before they occur, making it possible to prevent them from occurring, and descriptive analytics can describe current patterns that, in turn, can forecast clinical likelihoods. This review found that the prevalent themes in this category are predicting diabetes and obesity, predicting glycemia, and discovering clinical correlations from behaviors.

Predicting Diabetes and Obesity

The most prevalent theme in this review was using PGHD to predict the likelihood of diabetes or obesity through PGHD [16-25] from health behaviors. Considering that 80%-90% of the people living with T2D are overweight or obese [59,60], the risk of obesity was considered as a precursor condition to developing T2D.

Of these 10 studies, 9 (90%) used survey or questionnaire data to make these predictions; of these 9 studies, 7 (78%) were comparative studies in which different ML algorithms were compared for accuracy in predicting obesity and diabetes. Meng et al [16] and Abdullah et al [19] found that performing decision tree algorithms on survey and questionnaire data was the most successful in predicting childhood obesity with an accuracy of 82.63% and diabetes with an accuracy of 77.87%, respectively. Choi et al [17] and Han et al [18] found support vector machine (SVM) models on data from national health and nutrition surveys conducted in Korea and China to be the most accurate at predicting diabetes risk, with an area under the receiver operating characteristic curve value of 0.731 and an accuracy of 89.6%, respectively. However, the model presented by Han et al [18] integrates SVM with random forest (RF) because they had more success with the integrated approach than by using SVM alone [18]. Other studies suggested that logical regression analysis, naive Bayes, gradient boosting, RF with AdaBoost, and recurrent neural network were accurate in predicting obesity or diabetes through survey data, EMR data, and activity data

from wearables, with accuracies ranging from 72% to 99% [20,22-25].

Predicting Glycemia

From the studies identified, blood glucose levels could be predicted through information about food intake, exercise, medications, insulin, sleep, and blood glucose readings entered through web applications, mobile apps, smartphone activity sensors, or BGMs [26-29]. These studies showed promising results, with Hidalgo et al [26] predicting hypoglycemia with 79%-100% accuracy and hyperglycemia with 74%-97% accuracy, Gu et al [27] predicting blood glucose levels with accuracy of 84.14%, and Faruqui et al [29] accurately predicting next-day blood glucose levels with a Clarke Error Grid and a range of −10% to 10% of actual values. Heuschkel and Kauschke [30] used data from CGMs and insulin pumps as well as smartphone movements and heartrate sensors to predict glycemia and found that their algorithm performed slightly better than commercial insulin pumps (mean absolute error 8.74 for the model during 15-minute intervals vs mean absolute error of 10.10 with the insulin pump) [30]. However, this model was still unable to detect crisis situations. Machado [28], however, developed a framework to detect glycemic crisis situations from mobile app data using rule-based logic. Finally, Namayanja and Janeja [31] examined the University of California, Irvine, Diabetes Data Set to derive clusters of behavior patterns correlating to insulin dosage and blood glucose levels to determine at which specific time periods people living with T2D had more imminent needs.

Discovering Clinical Correlations From Behaviors

Examining PGHD provides the opportunity to examine clinical correlations from the health behaviors of people living with T2D. In the study by Chen et al [32], it was found that strong social connections increased physical activity, with Fitbit data from participants seeing an increase of average daily step count from 6332 to 6631 after the establishment of a strong social connection. This study demonstrated through analysis of PGHD from patients living with diabetes that a positive correlation exists between strong social connections and physical activity level. Another study that used Fitbit data was by Weatherall et al [33], who used Fitbit data combined with patient-reported outcomes to examine the correlation of patient outcomes with physical activity and sleep. They found a positive correlation of better patient outcomes with increased physical activity and sleep that was captured by Fitbit data. Finally, Sarda et al [34] examined depressive characteristics of people living with T2D by examining smartphone activity. They found among a sample of people living with diabetes that lower smartphone activity and decreased social contacts correlated with increased symptoms of depression. All these studies demonstrate that PGHD offer a unique opportunity to uncover correlations between health behaviors and clinical outcomes by analyzing passive activity through device use; both Chen et al [32] and Weatherall et al [33] used passive data collected through Fitbit to discover their findings, whereas Sarda et al [34] used data collected through passive smartphone activity.

Understanding Patient Behaviors

Overview

With the ability to collect large volumes of data both actively and passively, analytics provide clinicians with a more detailed account of the health behaviors of patients. Clinicians can then understand the behavior patterns of patients and the factors that affect their clinical outcomes.

Deriving Factors That Contribute to Diabetes and Obesity

This review found that through PGHD it was possible to derive the factors responsible for obesity or diabetes [21,23,25,35-39]. Height, weight, BMI, and weight loss were anthropometric measurements that correlated to the incidence of diabetes and obesity [21,23,25,37,39], and age was a demographic variable that was also predictive of diabetes and obesity [23,37]. Diet and sleep were lifestyle behaviors contributing to diabetes and obesity [23,35,37,38], with Xie et al [38] suggesting that sleeping for 9 hours or more per day increases the risk of developing diabetes. Data sources from these studies included not only questionnaires, but also more passive sources, which included CGMs and sensors as well as social media discussions.

Obtaining Insights From Social Media and Web-Based Forums

Social media and web-based forums provide platforms for people living with T2D to discuss their condition and related information among their peers [40]. The themes that emerged through web-based discussions include diet, food, symptoms, research, recipes, and news [35,37,40,41]. All studies under this theme used social media data as their data source. Abbar et al [35] and Griffis [41] found that tweets posted on Twitter about unhealthy foods correlate to geographical areas with higher incidences of obesity and diabetes. Sentiment analysis of social media posts suggested a negative correlation of positive emotions and blood glucose levels for people living with diabetes [42] and a correlation of negative emotions to higher weight loss [39]. Finally, social media connections have been shown to influence behaviors that lead to obesity; Wilder et al [43] created an algorithm in which participants updated their behavior under the influence of the people around them, averting 230 cases of obesity.

Analyzing of Sedentary Behaviors

Activity sensors provided a source of PGHD that could be analyzed to determine sedentary behaviors (time spent by the user being stationary while awake). Reducing sedentary behaviors is considered to be a positive health behavior in the treatment of T2D. Li et al [44] found that the rotating forest algorithm was the most successful at predicting sedentary behaviors through sensors, with an accuracy of 73%. He and Agu [45] found that people's future sedentary behaviors can be predicted by historic sedentary behaviors in previous 6-hour windows, with patterns being repeated daily and weekly, and subsequently, in a later study, they found that the rhythms of sedentary behavior tend to be cyclical, as opposed to linear [46]. Xiao et al [47] developed a framework using the demographic feature hidden Markov model to predict the trajectory of latent states using synthetic and sensor data. Early prediction of sedentary behaviors can potentially alert the user to move about and reduce stationary time.

Activity sensors that detect sedentary behaviors can also find clinical correlations from stationary patterns. Chang et al [48] found that longer sitting time was associated deleteriously with higher fasting insulin and triglyceride concentrations, insulin resistance, and increased BMI, and waist circumference among female participants, with the correlation between mean sitting bout duration and fasting blood glucose concentration being significantly stronger among Hispanic women than among non-Hispanic women.

All these studies used data from some form of activity sensor and demonstrated the unique perspective provided by PGHD through activity sensors: the ability to monitor the daily physical movements of users and provide an accurate measurement of sedentary behaviors and subsequently reduce them, if necessary, as a means of treating T2D.

Deriving Behavior Patterns

Large volumes of PGHD can help to detect different combinations of health behavior patterns of people living with T2D, which may not necessarily be captured through other data sources. Exploring behavior patterns can potentially unveil correlations among different health behaviors and can better advise users to make necessary changes. In the study by Machado et al [28], a mobile app was developed to allow users to record their meals, exercise sessions, and blood glucose levels, and a rule-based system would advise users about crisis situations. Namayanja and Janeja [31] captured granular behavior patterns correlating to blood glucose level and insulin dosage through k-means clustering, which was more accurate than statistical analysis. Tirunagari et al [49] further captured behavior patterns using self-organizing maps and found that those who took correct insulin dosages took them at the right time, those who ate on time ate the correct portions, and those who regularly checked their blood glucose levels carried snacks or took correct insulin dosages. Finally, Seixas et al [50] examined behavior patterns to investigate diabetes prevalence by race. They found that physical activity with low stress, adequate sleep, and average body weight reduced the diabetes risk among Black people. These studies used some form of survey and questionnaire data to derive these patterns. Analytics from PGHD have the ability to recognize patterns of health behaviors and infer correlations as a result of these patterns.

Facilitating Treatment Interventions

Overview

Technological tools to manage T2D have the ability to help people manage their treatment by improving adherence to behavior changes, alerting users about predicted adverse events, and prescribing recommendations for behavior change.

Improving Adherence and Outcomes

Analytics from PGHD can be used to improve adherence to treatment as well as overall outcomes for people living with T2D [28,51-54]. Prescriptive interventions that advise users and personalize messages have been shown to improve

adherence to treatment interventions [51,54]. In Feller et al [54], visual analytics and hierarchal clustering determined that users assigned to use a web- and mobile-based diabetes app displayed 50% more use than those who used static logbooks. Of the 43 studies, 2 (5%) were frameworks with intentions to improve user outcomes: Nag et al [52] devised personalized meal recommendations using nutritional and restaurant databases, with findings validated by a dietitian, and Machado et al [28] analyzed behavior patterns in regard to nutrition management, exercise, and glycemic control and used rule-based logic to advise users about potential crisis situations. All studies used a form of self-reported data through an app through nutrition logs, blood glucose readings, and activity sensors.

Improving Technology

Overview

As technologies are used and tested, newer technologies have the opportunity to improve on previous generations by analyzing feedback and results from users. In the next section, we discuss studies that used PGHD to create frameworks for new technologies.

Developing Design Principles

The development of frameworks using PGHD and close examinations of user feedback have given insight into general design principles of creating a technical intervention to help people living with T2D to manage their condition. Al-Ramahi et al [55] examined user reviews of diabetes management mobile apps on the iTunes store and determined that the most important design principles were "effort expectancy," "self-monitoring," "informative presentation," "communication with doctors," and "integration with information systems." Other critical design principles were "integration with medical devices," "customization," and "technical support" [55]. Fong et al [56] created a framework for a clinical decision support system for diabetes therapy and found that a system needs to (1) be able to handle live streams, (2) have a short time delay, and (3) have accurate and consistent performance. Finally, Albers et al [57] created a system that generated personalized blood glucose–level forecasts that had the following attributes: (1) estimated data in real time according to metrics; (2) forecast in line with the opinions of certified diabetes educators; (3) personalized the model to the individual; (4) integrated with model selection machinery and chose the best model; (5) performed well, given realistic data; (6) produced accurate output, and (7) averaged in real time to produce accurate forecasts.

Discussion

Principal Findings

The goal of this review is to understand what we can learn from analytics from PGHD about the health behaviors of people living with, or at risk of developing, T2D. Through examination of literature, a broad range of themes was identified, pertaining to analysis performed on consumer-generated sources either independently or combined with another source. Most of the studies used ML algorithms to perform their analysis, speaking to the complexity of these data sets. These algorithms included k-means clustering, neural networks, decision trees, SVMs, and

RF. PGHD is well suited for behavior insights in that the data can be collected far more frequently and they provide greater context than the coarse observations obtained during clinic visits and from static laboratory results.

The most prevalent theme from this review suggests that analysis of PGHD has the potential to detect undiagnosed diabetes or obesity or predict risk of developing diabetes or obesity [16-25]. Detection of T2D in the early stages or before onset can inform users of their risks and allow them to make necessary behavior changes to mitigate the risk of progression of the disease or further complications. Furthermore, models built to assess risk and manage T2D can be applied to other chronic diseases [56]. However, from our review, predicting risk requires structured data from questionnaires or surveys.

In addition to predicting the likelihood of disease, PGHD from people living with diabetes could also predict glycemic events [21,26-28,30,31]. However, this type of prediction requires commercial BGMs or CGMs in which the data are entered into an app either manually or automatically. People living with T2D are encouraged to frequently self-monitor blood glucose levels to obtain feedback on the healthy behavior changes already made, allowing treatments to be adjusted if necessary [61]. Being able to predict glycemic events adds further feedback about treatment regimens in relation to glycemic control, allowing patients and providers to adjust care plans accordingly.

Another significant theme discovered through this review was the identification of factors that are characteristic of diabetes and obesity through PGHD from sources that include a combination of questionnaires or surveys, social media activity, and activity sensors [21,23,25,35-39]. It was specifically found through this review that diet and sleep quality were health behaviors that were contributing factors with regard to diabetes and obesity [23,26,37,38]. Furthermore, analysis of large data sets through PGHD was able to detect patterns or clusters of different health behaviors that are characteristic of people living with diabetes; the sources included surveys and apps [28,31,50]. Finally, PGHD regarding health behaviors can provide insights into new clinical findings related to diabetes [32-34]. From our review, these insights were obtained by analyzing passive activity collected from devices. Analysis of PGHD can provide new insights into the disease and the behaviors of people living with it, and further research may benefit by examining the intersectionality of behavioral clusters and patient outcomes.

Activity sensors served as another data source, passively collecting data about physical activity and sedentary behaviors. Whereas exercise is an important treatment for managing T2D, sedentary behaviors while awake are associated with premature mortality, increased BMI, increased glycated hemoglobin levels, increased adiposity, and hyperglycemia [57]. Even with regular moderate to vigorous physical activity, adverse health outcomes are associated with prolonged periods of sedentary time, which should be considered a separate behavior from physical activity, and people living with T2D should follow some exercise regimen while reducing time spent on sedentary behaviors [62]. Through this review, it was found that PGHD from activity sensors could detect patterns of sitting behaviors and find

increased insulin resistance and higher triglyceride concentrations with increased sitting behaviors [28,44-48]. Further research may be necessary to examine the correlation of physical activity with sedentary behaviors in relation to the glycemic outcomes of people living with T2D.

Social media provided another data source to examine how people living with T2D manage their condition [35,37,39-41]. Social media sites not only provide a platform for people living with T2D to discuss their disease and share information, but also provide epidemiological insights into geographical correlations of the disease [35,41] as well as microinsights into the emotional status of people living with obesity or diabetes [39,42]. Further research may be necessary to examine a longitudinal picture of disease progression through social media analysis.

As found by Kitsiou et al [6] and Wang et al [7], mHealth interventions show promise for improving outcomes and increasing treatment adherence for people living with T2D. Our review expands on these findings by measuring adherence and outcome through analytics from PGHD [28,51-54]. Although prescriptive interventions that personalize messages have been shown to increase adherence [51,53], digital tracking tools were also shown to have increased adherence to treatment as opposed to standard treatment through logbooks [54]. These findings suggest that PGHD can provide granular insights into adherence to treatments and assess which treatment interventions are likely to increase adherence. Further research may be necessary to examine how certain interventions correlate to adherence.

Diabetes management and fitness technologies, as well as the use of social media, clearly constitute a rich data set for behavioral insights. Their frequent use, and in some cases continuous acquisition of detailed, relevant, and contextual data, gives unprecedented ability to develop applications for prediction, prognosis, and self-management insight. This provides a glimpse of the potential of using PGHD for other chronic conditions that lend themselves to similar frequent acquisition of quantitative data, such as cardiac conditions. Other conditions such as respiratory disease, mental health, and chronic pain are more elusive in this respect because of their qualitative mode of characterizing the condition. Future innovations should look to the advances made in diabetes management with respect to PGHD to consider these conditions.

Limitations

This detailed review was conducted by only 1 reviewer, with a second reviewer contributing to the selection of studies and the remaining authors providing revision suggestions and commentary to the final draft of the paper. As all these studies contained PGHD, the accuracy of the data is limited to what was reported by the patients or what was passively collected through external devices. Furthermore, because some studies contained PGHD sources combined with other sources, some of the findings are not completely representative of PGHD. Moreover, the studies may not necessarily consider real-life use patterns because they may have been conducted in controlled settings. In addition, the scope of this study could not determine the efficacy of these approaches when implemented practically. Finally, the inclusion and exclusion criteria were developed by the authors based on their best knowledge of the subject, and articles were selected if the 2 reviewers (MSN and AB) believed that the articles met these criteria. Quality was assessed against the authors' current knowledge of the topic, and they excluded articles if they believed that the articles contained information that contradicted their current knowledge.

Conclusions

The emergence of technology-enabled tools that support individuals to manage their diabetes has resulted in the creation of a repository of PGHD to use ML algorithms to gather analytical insights into the health behaviors of people living with T2D, which otherwise cannot be gathered through other data sources. This review identified that analytics from PGHD have the potential to predict disease and outcomes, identify factors contributing to disease, investigate behavior patterns, discover new clinical findings, and improve adherence to treatments. Further research may benefit from examining the intersectionality of these concepts to create cohesive treatment plans for managing T2D.

Authors' Contributions

MSN and AB reviewed and screened the articles. MSN analyzed the extracted text. MSN drafted the manuscript for all authors to comment on and revise. All authors approved the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Charting of scoping review studies.
[DOCX File , 41 KB - diabetes_v6i4e29027_app1.docx]

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Abbreviations

AI: artificial intelligence
BGM: blood glucose meter
CGM: continuous glucose monitor
EMR: electronic medical record
mHealth: mobile health
ML: machine learning
PGHD: patient-generated health data
RF: random forest
SVM: support vector machine
T2D: type 2 diabetes

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<u>Original Paper</u>

Mapping Individual Differences on the Internet: Case Study of the Type 1 Diabetes Community

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Abstract

Background: Social media platforms, such as Twitter, are increasingly popular among communities of people with chronic conditions, including those with type 1 diabetes (T1D). There is some evidence that social media confers emotional and health-related benefits to people with T1D, including emotional support and practical information regarding health maintenance. Research on social media has primarily relied on self-reports of web-based behavior and qualitative assessment of web-based content, which can be expensive and time-consuming. Meanwhile, recent advances in natural language processing have allowed for large-scale assessment of social media behavior.

Objective: This study attempts to document the major themes of Twitter posts using a natural language processing method to identify topics of interest in the T1D web-based community. We also seek to map social relations on Twitter as they relate to these topics of interest, to determine whether Twitter users in the T1D community post in "echo chambers," which reflect their own topics back to them, or whether users typically see a mix of topics on the internet.

Methods: Through Twitter scraping, we gathered a data set of 691,691 tweets from 8557 accounts, spanning a date range from 2008 to 2020, which includes people with T1D, their caregivers, health practitioners, and advocates. Tweet content was analyzed for sentiment and topic, using Latent Dirichlet Allocation. We used social network analysis to examine the degree to which identified topics are siloed within specific groups or disseminated through the broader T1D web-based community.

Results: Tweets were, on average, positive in sentiment. Through topic modeling, we identified 6 broad-bandwidth topics, ranging from clinical to advocacy to daily management to emotional health, which can inform researchers and practitioners interested in the needs of people with T1D. These analyses also replicate prior work using machine learning methods to map social behavior on the internet. We extend these results through social network analysis, indicating that users are likely to see a mix of these topics discussed by the accounts they follow.

Conclusions: Twitter communities are sources of information for people with T1D and members related to that community. Topics identified reveal key concerns of the T1D community and may be useful to practitioners and researchers alike. The methods used are efficient (low cost) while providing researchers with enormous amounts of data. We provide code to facilitate the use of these methods with other populations.

KEYWORDS

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Introduction

Background

Social media platforms, such as Twitter, are increasingly popular among communities of people with chronic conditions, including those with type 1 diabetes (T1D) [1]. These platforms potentially have an outsized impact on the daily experiences of people with diabetes, as they provide new opportunities for seeking support, which appears to be a key factor in therapy adherence [2]. Twitter and other platforms also potentially provide instrumental support to people with diabetes and their caregivers through the spread of information regarding new medical treatments or policies (eg, health care). A major challenge to studying the role of social media for people with diabetes is the efficient analysis of content; participants in web-based communities amount to tens of thousands of users, generating millions of posts. This study attempts to document the major themes of Twitter posts using a natural language processing method to identify topics of interest in the T1D web-based community. While this study focuses on people with T1D, we believe similar methods can be employed to explore other health communities on the internet.

Social Media Benefits People With Diabetes

Prior work documenting the role of social media platforms—including Facebook, Instagram, Reddit, YouTube, Tumblr, and Twitter, as well as community-specific message boards—concludes that social media is mostly beneficial for people with diabetes. This conclusion is primarily based on evidence that the topics of social media posts by the TID community are largely positive and revolve around improving mental health related to diabetes, providing social support, and sharing practical information [3-6]. For example, qualitative analysis of various social media platforms found that posts included themes of humor, pride, and community-building, as well as discussing diabetes-related technology and sharing practical tips [3]. When asked directly, people with diabetes confirm these themes by reporting that web-based communities provide social support, help them feel empowered, and teach practical knowledge for managing diabetes [4,5]. Importantly, concerns about the role of social media platforms in spreading misinformation or negatively impacting self-esteem among young people with diabetes [7] appear to be largely unfounded, as recent synthesis suggests relatively few negative consequences for this community [6].

Subjective impressions about the potential utility of social media are supported by the association of social media with objective indices of health [8,9]. Those who sought health information on the internet were better at testing their blood glucose regularly, taking proper action for hyperglycemia, and adopting nonpharmacological management [8], and bloggers report improved blood glucose levels [9]. In addition to providing emotional support and diabetes-specific health literacy, "diabetes online communities" (DOCs) appear to provide relevant information about navigating health systems [10]. Much of the benefits of DOCs are experienced by not only people with diabetes but also their caregivers [6,11]. It is important to note,

however, that these studies rely on observational data; therefore, the causal effect of social media is unknown.

DOCs serve as major sources of advocacy for diabetes communities [7]. In one case, a qualitative assessment of web-based communities suggested that aging individuals are concerned about the limited access to treatment, inability to provide self-care, and health care provider capacity to support aging [12]; the use of web-based platforms brings awareness to these issues and generates the potential for action. For example, Omer [13] documents the "#WeAreNotWaiting" case in which DOCs raised awareness of inaccuracies in glucose monitors, culminating in a web-based chat between patients and the Food and Drug Administration and an in-person meeting to work on these issues.

Finally, social media platforms may benefit people with diabetes by facilitating access to information regarding diabetes. Information may be shared, for example, by health care providers who use social media as a public relations tool [14], to provide advertising services. By sharing information on the internet, health care providers and health researchers have the potential to reduce systematic barriers to accessing new information. In one instance, assessment of social media use around medical conferences suggested that even when only a small proportion of attendees use social media, the information presented at the conference can be widely disseminated to those unable to attend [15,16].

Scaling Up Social Media Research for Diabetes Communities

As social media websites have gained popularity, the amount of information generated on these sites has increased exponentially. This is a boon to diabetes researchers and presents a methodological challenge: commonly used methods of qualitative data analysis have limited utility in the realm of social media research.

Empirical or data-driven methods of measuring and analyzing social media use can orient research on diabetes communities in several key directions. First, these methods are scalable to large samples of participants. Data-driven approaches forgo the need for interviewers and coders, thus allowing researchers to potentially analyze tens of thousands of participants and millions of posts. Large sample sizes are essential to capturing rare but impactful experiences, which may remain undocumented to this point. For example, while research on DOCs to date has concluded that these communities are supportive and inclusive, it may be that a small subset of individuals experience exclusion or bullying on the internet. Small samples may not capture these individuals, or only include a few of them, thus failing to identify these experiences. In addition, large data sets allow researchers to explore the role of social media in the experiences of caregivers, clinicians, policy advocates, and others invested in the diabetes community and interactions within and across roles.

Second, data-driven methods allow rapid assessment of events or changes, preparing researchers and clinicians for faster response. For example, the political debates around universal health care or changes in national health insurance coverage are

important concerns to people with diabetes, as these changes often impact the price and availability of insulin and glucose-monitoring technologies (eg, the #WeAreNotWaiting advocacy and awareness campaign [13]). Researchers can analyze the response to such debates in real-time using models which take a data-driven approach.

Identifying Topics of Discussion

A challenge with data-driven approaches to analyze large data sets is that many techniques work in a "black box," obscuring relationships between variables and making the interpretation of statistical models difficult or impossible. For example, many machine learning models that are used to assess large pools of data primarily prioritize out-of-sample prediction rather than interpretable synthesis [17]. Recent advances in linguistic analyses pave the way for empirical analyses of web-based behavior and allow for the synthesis of web-based behavior, thus leveraging large data sets while maintaining focus on descriptive models, rather than predictive models.

Latent Dirichlet Allocation (LDA) [18,19] is one such method for summarizing web-based behavior. LDA is a topic modeling technique that seeks to identify underlying themes that can be used to classify text in a document (eg, a user's set of tweets). This analysis attempts to uncover a hidden process without input or assumptions from researchers as to the primary themes of the documents. Importantly, LDA allows for mixed membership or for a single document to contain 2 or more topics. LDA analysis has already been successfully applied to social media: tweet (Twitter posts) topics are associated with county-level obesity rates [20] and predict individuals' risk of developing chronic health conditions [21].

Other machine learning–type methods have also been used to analyze web-based behavior. Relevant to this study, Ahne et al [22] identified tweets related to diabetes through the use of keywords and hashtags and summarized the topics therein using *k*-means clustering. They identified a set of 30 topics, several of which were variations on concerns regarding insulin pricing and availability. These results are promising, in that the majority of topics identified were easily understood by researchers and clearly connected to major concerns of people with T1D. However, inclusion of only diabetes-related tweets—rather than all tweets by people with T1D—potentially omits important experiences by these communities. Moreover, it is unclear how these topics are transmitted within DOCs. For example, is insulin pricing a topic discussed in detail by a subset of accounts or disseminated broadly throughout the community? With these questions in mind, we turn to the current study.

The Current Study

This study seeks to empirically assess the use of Twitter by the T1D community, including persons with diabetes, caregivers, medical professionals, advocates, and policy makers. We aim to address 3 primary research questions: (1) what is the overall sentiment of social media posts? (2) What are the major topics of discussion on the internet? (3) How is the social network of Twitter users organized around topics of discussion?

Of note, similar analyses of Twitter use by people with (all types of) diabetes were conducted recently by Ahne et al [22]. While our study is both conceptually and analytically similar to that of Ahne et al [22], we expand on the methodology and research questions in two ways: first, data collection was driven by the goal of including members of the type 1 DOC, rather than tweets covering a specific topic. This allows us to generate a more holistic view of these users' lives and concerns. Second, by including network analyses, we can investigate how topics are being shared within DOCs, whether users are exposed to a large number of topics or a narrow subset, and to what extent there is a single large DOC or many smaller ones on Twitter.

Methods

Sample and Data Collection

To begin identifying tweets in the T1D community, we used the following hashtags: #t1d, #t1dlookslikeme, #brokenpancreas, #type1kid, #typeonetypenone, #diabadass, #type1warrior, #beyondtype1, #insulindependent, #typeonestrong, #dexcom, and #GBdoc. This list was generated through discussion with Twitter users within the T1D community and an informal survey of tweets. We avoided using more generic hashtags such as #diabetes, which may also include tweets from those in the type 2 diabetes community, which were not the focus of this study. Using the Rtweet package (version 0.7.0) [23] in R, we pulled 1500 tweets containing these hashtags over the prior week (December 28, 2019, to January 3, 2020). These tweets represent a mixture of the most recent tweets and the most popular tweets during that 1-week period.

In this initial pull, we gathered 915 unique Twitter accounts. In line with our goal to include all tweets from T1D community members, not just tweets about T1D, we pulled the 100 most recent tweets (including retweets and replies) from each of these accounts. Additionally, to make sure that the accounts we pulled were accounts with T1D as a recurring topic of tweets, we included only accounts with at least 3 separate tweets containing at least 1 of the T1D hashtags (481 accounts and 42,062 tweets). Finally, we recognize that not all people with T1D will have tweeted about their diagnoses within the past week. However, these individuals are more likely to follow accounts that include frequent posts about T1D. Therefore, we attempt to capture more members of the T1D web-based community by pulling the Twitter followers of the accounts in our data (up to 5000 followers for each account). For each of these followers, we pulled 100 of their most recent tweets. We again included only those accounts where there were 3 separate tweets containing any of our selected T1D hashtags, to restrict the accounts included to those in the T1D community. Finally, for consistency in our natural language processing results, we included only those tweets written in English. Our final analysis sample consisted of 691,691 tweets from 8557 accounts (Figure 1).

Tweets used in this analysis spanned a date range of April 4, 2008, to January 15, 2020. Just over half (54%) of the tweets in our sample occurred after January 2019, within approximately 1 year of our data collection date, and 69% of tweets occurred within 2 years of our collection date.

Figure 1. Tweet collection procedure. T1D: type 1 diabetes.
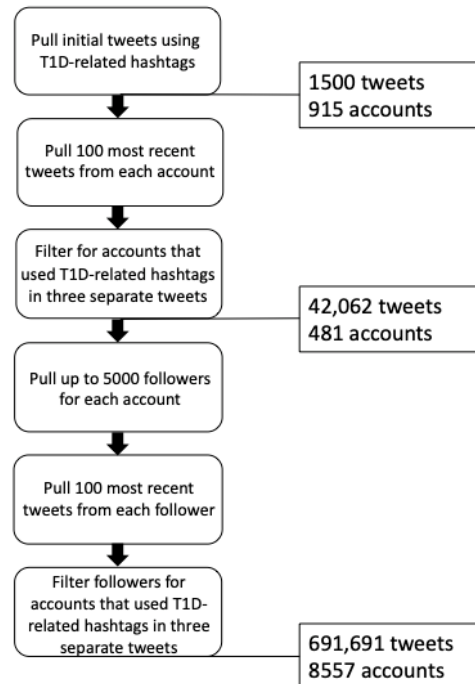
Data Analyses

Prior to analyzing our tweets, URLs were removed from our sample of tweets as well as greater-than signs (>), less-than signs (<), ampersands (&), and the letters "RT," which denote the classic version of the retweet. These characters were removed because they do not contribute to the sentiment of a tweet and are often not handled well by language processing methods [24]. Finally, we removed the set of hashtags initially used to search for and identify T1D tweets as they are oversampled in our set of tweets.

To address our first research question (ie, "What is the overall sentiment of social media posts?"), we analyzed our tweet sample using sentiment analysis. This approach, also known as opinion mining, is used to determine whether a given text is positive, negative, or neutral. For this study, we are interested in, on average, how positive or negative a user's set of tweets is. We can accomplish this using the Noncommercial Research (NRC) sentiment lexicon [25], a sentiment dictionary designed for and validated with tweets; this includes a large set of words where each word has been assigned a score for positive/negative sentiment (ranging from –6.93 to 7.53). This set of words is then compared to the words in a user's tweets, giving us an average sentiment for each user. Finally, we are able to take an average of sentiment across all our users to get a sense of overall sentiment in our T1D web-based community.

Next, we answered our second research question (ie, "What are the major topics of discussion on the internet?") using the natural language processing technique of LDA [18], an unsupervised machine learning algorithm that identifies latent topic information among large document collections. Unlike other topic modeling methods, LDA does not focus on the frequency of words but rather assumes that a topic is made up of a probability distribution of words. A topic is a list of words. Each word is assigned a probability value for each topic, which

represents the likelihood that the word would be used in a document containing that topic. LDA assigns to each document latent topics together with a probability value that each topic contributes to the overall document. In this case, a document refers to a user's 100 most recent tweets.

Similar to other data reduction methods (eg, factor analysis), researchers must choose the number of latent topics to fit. We used both perplexity (a quantitative index) and subjective interpretability to decide how many topics to fit. *Perplexity* measures how poorly a probability model predicts a sample. More specifically, the normalized log-likelihood of a held-out test set of data is used to determine how "surprising" the test set is, considering the model. We fit many LDA models, each for a different number of topics (Figure 2) and calculated the perplexity score for each. Per usual, an LDA solution with more topics results in lower perplexity, which indicates superior prediction in our model. While lower perplexity is desirable, interpretability of the latent topics is also important. While a 30-topic model appears ideal in terms of predictive utility, this large number of topics was difficult to interpret (Multimedia Appendix 1 shows the 30-topic model). We instead chose 6 topics as our final model, which appeared to be a sort of elbow in our perplexity chart and showed generally interpretable topics. For sensitivity analyses, we fit LDA models with 5, 7, and 8 topics, and the latent topic categories appeared very similar.

For our third and final research question (ie, "How is the social network of Twitter users organized around topics of discussion?"), we used social network analysis [26]. Here, we mapped a network of the top followed accounts in our tweet sample, connecting accounts on the basis of whether one follows the other. We colored nodes (accounts) on the basis of the dominant topic in their tweets. Unlike the previous 2 analyses, this method is a more qualitative representation of data. Interpretation of a graphical display of the social network—in which individual Twitter users, or "nodes"—are color-coded

in accordance with their most common topic is somewhat subjective. Similar methods have been used in other research to map comments related to Japanese and Korean public diplomacy organizations [27], as well as contributions of websites related to the food safety movement in the United States [28]. Together, these methods provide an insight into how the community connects and interacts.

All analyses were preregistered on the Open Science Framework [29]. Twitter prohibits the sharing of tweet content, but we are allowed to share tweet IDs and user IDs for the tweets analyzed here. That data file, as well as all R code for these analyses, can be found on the Open Science Framework [30]. Interested researchers can use these data to identify the tweet content using the Twitter application programming interface.

Figure 2. Perplexity by the number of topics in Latent Dirichlet Allocation models. LDA: Latent Dirichlet Allocation.
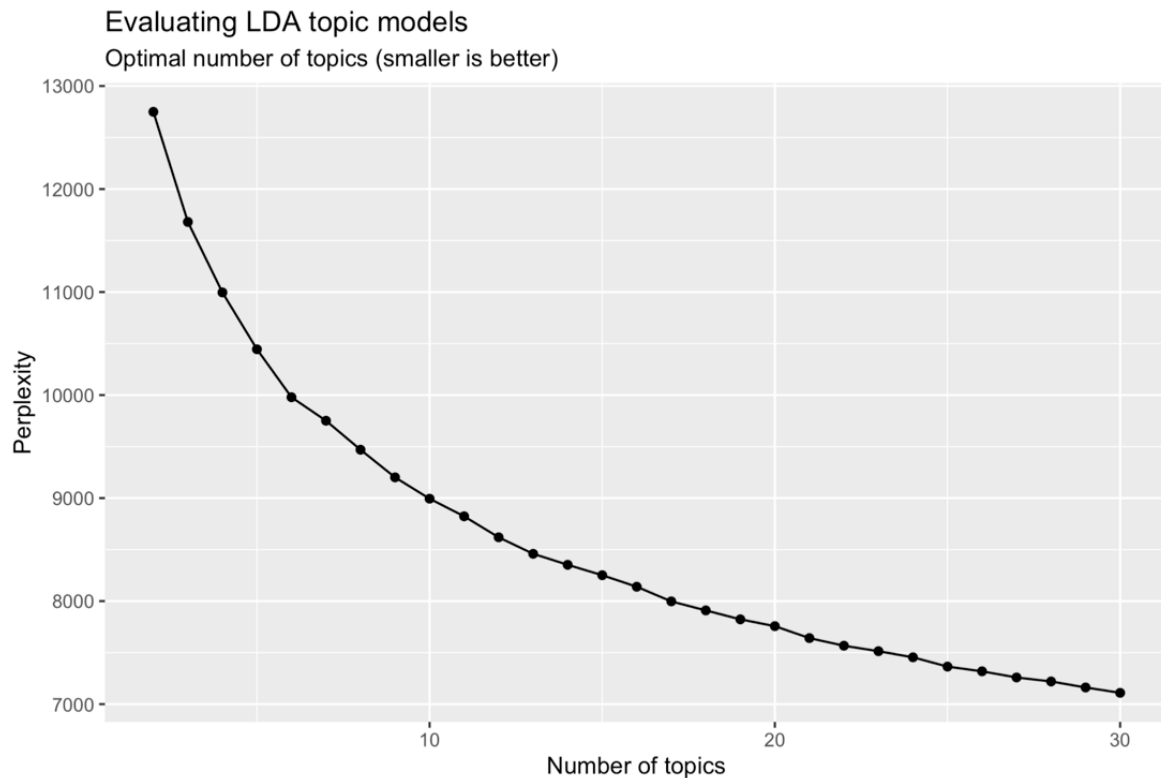
Results

What is the Overall Sentiment of Social Media Posts?

The NRC sentiment lexicon [25] was used to answer our first question regarding the overall sentiment in our sample of Twitter posts. The sentiment score of a user is the average of the sentiment score of their words across all tweets. As such, user sentiment is independent of the number of times the post or the length of their posts. User sentiment ranged from –2.03 to 1.64, with an average score of 0.052 (Cohen d=0.32), indicating an overall slightly positive sentiment of user tweets (Figure 3). Within our sample, 64% of users had a sentiment that was greater than zero, indicating that the sentiment of their tweets was more often positive than negative.

Figure 3. Distribution of sentiment for our type 1 diabetes tweet sample.
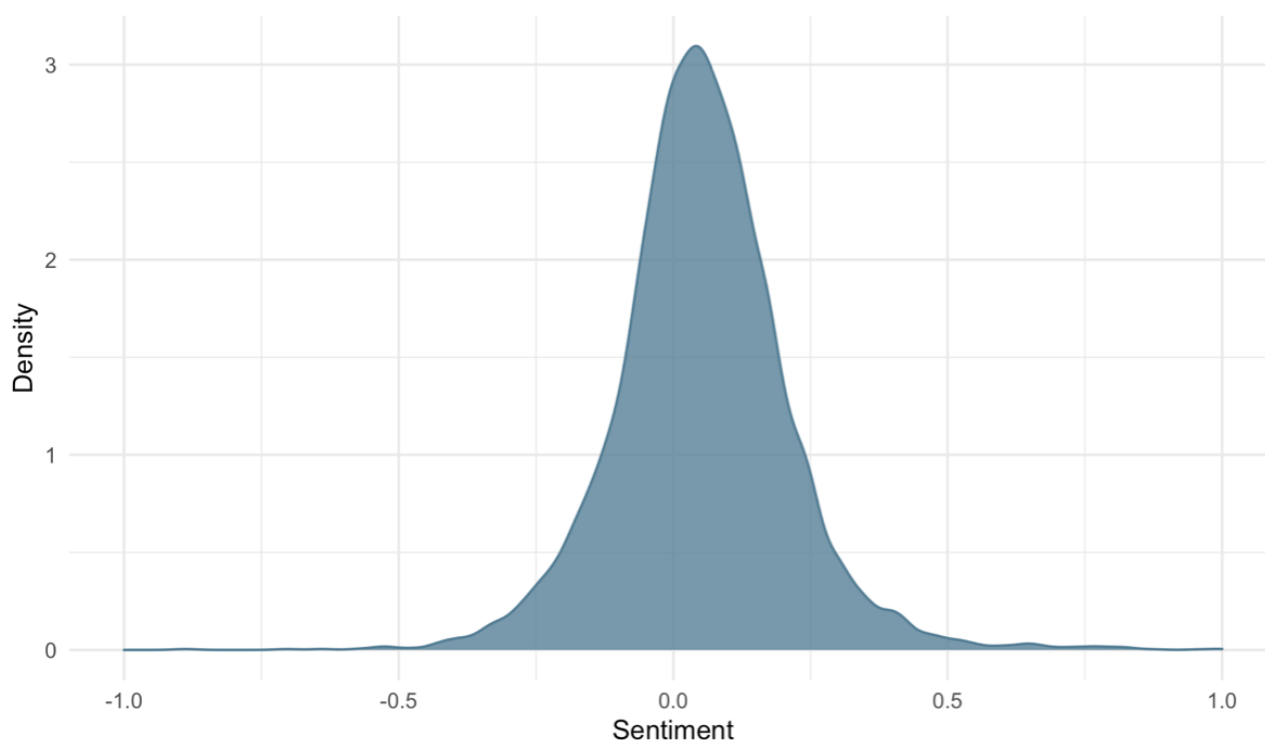
What are the Major Topics of Discussion on the Internet?

Prior to running the LDA analysis, we first looked at the most popular words in our sample (Figure 4). Top words included very explicit indicators of diabetes and related management tools including diabetes, #diabetes, and insulin. While these words are not surprising to see, they serve as an indicator that our method of pulling tweets accessed the community we were targeting. Additionally, we noted a strong theme of encouragement with popular words of love, support, and care.

Next, we extracted 6 topics using the LDA approach. To ensure sufficient document length, we aggregated tweets within accounts to create a single document. This allows us to characterize the content generated by each user, but we are unable to disaggregate these results to individual tweets. After extracting topics, we examined the words most likely to appear in each topic using a comparison cloud (Figure 5). Thereafter, we examined tweets from users, which had the highest probability of being assigned that topic to gain context for the most likely words and help generate descriptions for each topic. Topic 1 was centered around the *insulin price crisis*, which refers to the drastic increase in insulin prices since the 1990s and the call for access to affordable insulin as a human right. This topic additionally references Donald Trump and his involvement with this movement. The *insulin price crisis* accounted for approximately 19% of words across all tweets. The second topic is about T1D *clinical research* including reference to studies, risk, patients, and treatment. This is focused on new developments in the clinical trials area of research, and accounted for 14% of words. Topic 3 addressed *daily management of T1D* and featured tools including a pump as

well as eating-related words including "sugar" and "carb." This topic was the most prevalent, accounting for 23% of words. The fourth topic in our model highlighted *technology advancements* using words including "loop," referring to the concept of a closed-loop system or "artificial pancreas." This method of T1D blood sugar regulation combines a continuous glucose monitor and an insulin pump to manage insulin delivery with minimal interaction required from the patient. This topic also heavily utilized the hashtag #wearenotwaiting, referencing a movement of those in the T1D community who are taking technology development into their own hand with new apps and cloud-based solutions that utilize patient health data to inform blood sugar management. However, this topic was also among the least prevalent, accounting for only 13% of words. Topic 5 encompasses the many *awareness organizations* that utilize Twitter to educate the public about T1D and related fundraising events. This topic accounted for 13% of words tweeted. Finally, the sixth topic seems to encompass *positive emotions* with words including "love" and "happy" as well as life outside of T1D using words such as "watch," "run," "game," "home," and "weekend," and this topic accounted for 18% of words. This topic is notable, especially given the goal of studying all tweets from the T1D community and not only those tweets specifically about diabetes. Taken together, these topics give us a broad view of the key topics discussed on the internet in the T1D community (Table 1). We looked at the relationship among our 6 topics by correlating the probability of a user's tweets being in a given topic. Correlations, were negative, ranging from –0.12 to –0.26. Low magnitude suggests that topics are relatively distinct (ie, not highly associated), but also that as accounts include more content related to one topic, they are less likely to include content related to the others.

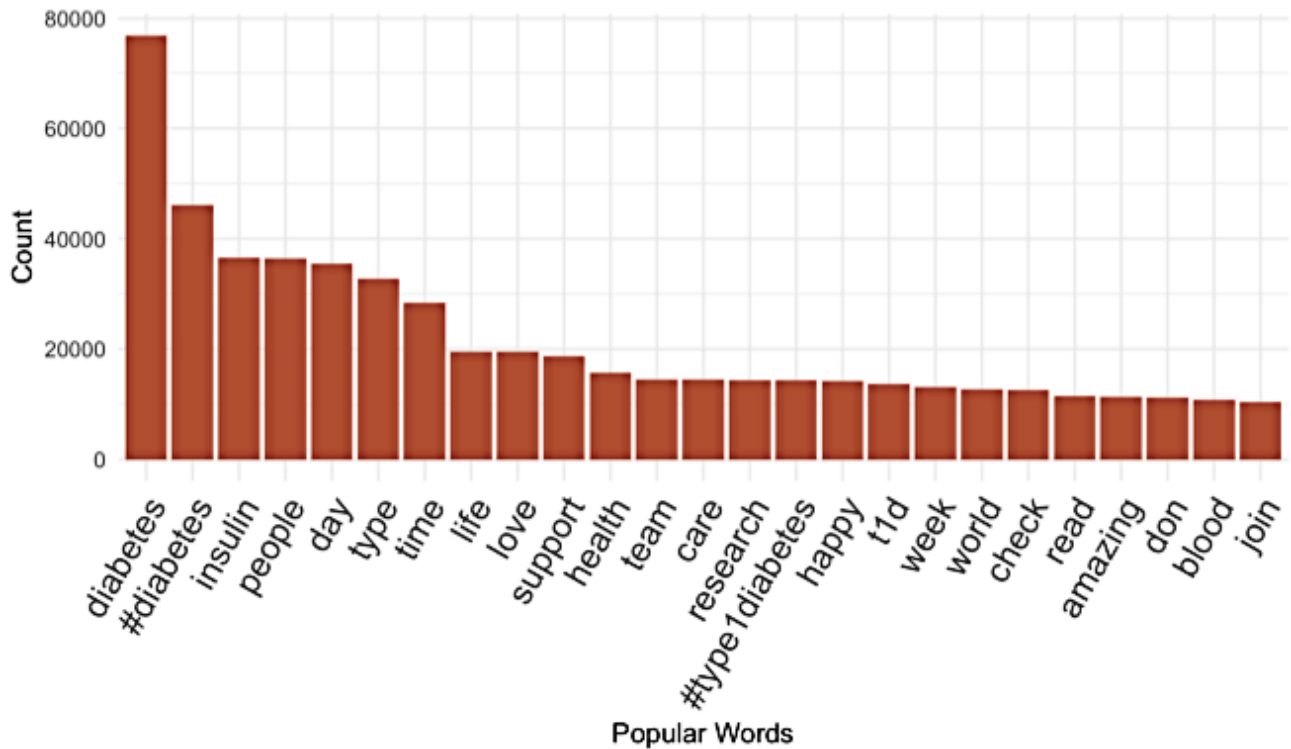**Figure 4.** Most popular words in our type 1 diabetes tweet sample.

Figure 5. Comparison cloud of the most likely words to appear in each topic of our 6-topic Latent Dirichlet Allocation model.
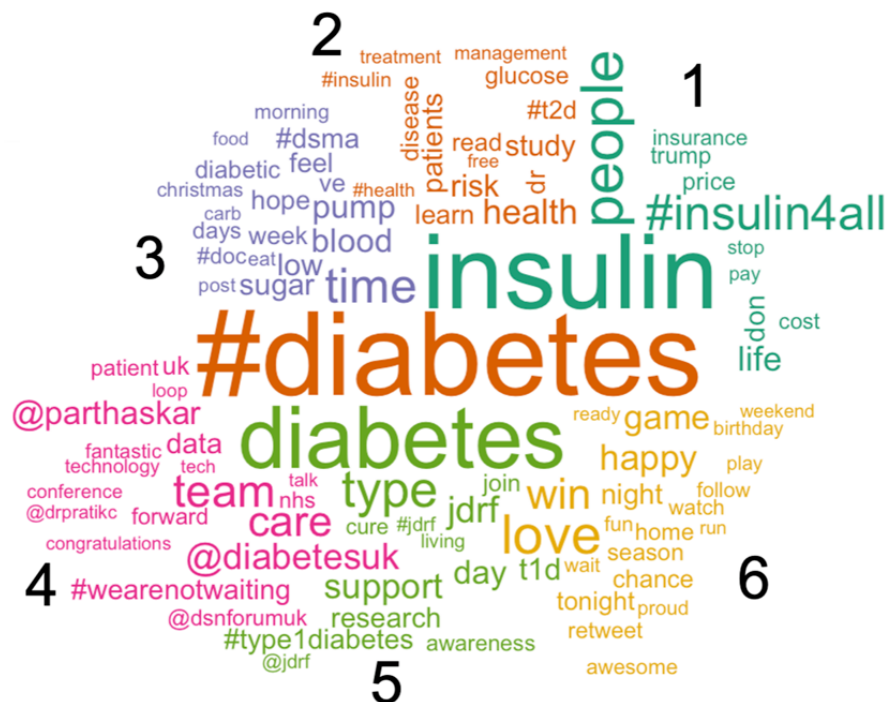
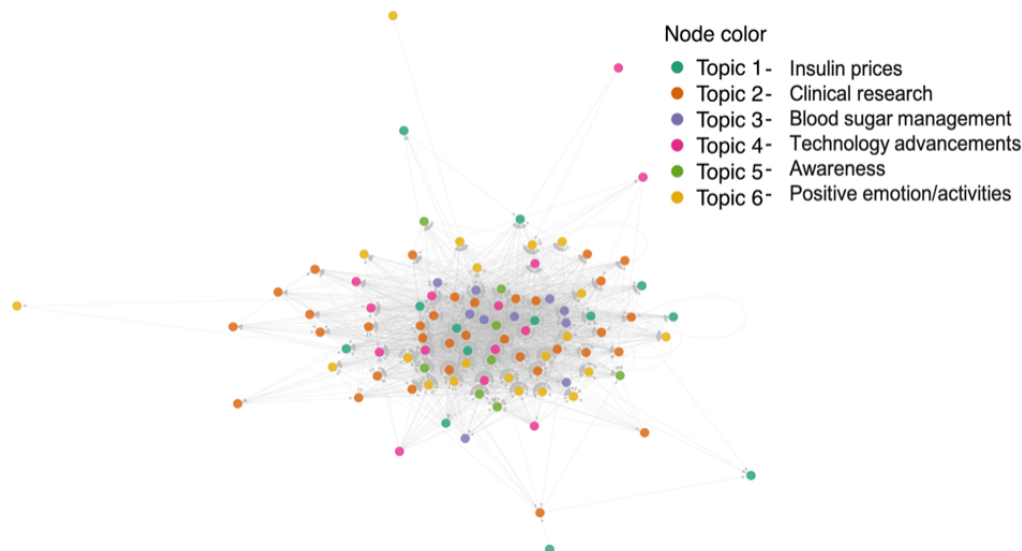**Table 1.** Example tweet for each latent topic.

Latent topic	Example tweet
Insulin price crisis	"It's not my fault that insulin costs so much. I'm doing my part as a citizen, I'm working. I have these benefits. I can get my teeth cleaned, my eyes checked, but I can't get the medicine that keeps me and my sister alive. #insulin4all"
Clinical research	"@WNDU reports on @T1D_TrialNet's groundbreaking study that showed an immunotherapy drug delayed a #type1diabetes diagnosis by two years. #immunotherapy"
Daily management of T1D	"My Monday and Tuesday blood sugars were BEAUTIFUL Today my blood sugars were garbage bc I should have changed my site earlier And I'm okay with that. Here's your reminder to pat yourself on the back for the good days, and learn from your mistakes on the bad ones!"
Technology advancement	"Managing my sons bs while he sleeps in the USA while on the Amalfi coast! I'm #forevergrateful to you all @NightscoutFound @WeAreNotWaiting #wearenotwaiting #tripofalifetime #sohardtoleavehim"
Awareness organizations	"Walk with us to turn Type One into Type None. By donating or registering today, you will help JDRF create a world without Type 1 Diabetes (T1D)"
Positive emotions	"Had such a great and full weekend. Went for a drive to the Gold Coast after training on Saturday and ate some great vegan food from Govindas then went for a long walk on the beach to reflect on the past week"

How is the Social Network of Twitter Users Organized Around Topics of Discussion?

To address how the social network of Twitter users organized around topics of discussion, we used social network analysis (Figure 6). While it would be ideal to complete this analysis with all 8557 participants in our sample, this would not be feasible with the personal computing power available to us. Instead, we narrowed our sample to the 100 accounts with the most followers. This provided us with a sample of highly influential accounts within the T1D web-based community for assessment. These accounts ranged from having 7202 followers to 278,180 followers and spanned a wide range of identities including research or awareness organizations, public figures including actors or singers, blog- or community-focused accounts, and doctors. In our social network analysis, each node represented a Twitter account, and each edge represented a follow. The color of each node represents the dominant topic of each account in correspondence with the 6-topic LDA model described above. The dominant topic was determined by selecting the topic with the largest per-document-per-topic probability; that is, the probability of each topic within each account's set of tweets.

Figure 6. Social network analysis of the top 100 most followed accounts in our type 1 diabetes tweet sample. Nodes represent Twitter accounts and edges represent follows. The color of each node represents the dominant topic of each account in correspondence with the 6-topic LDA model.

Node color
- Topic 1 - Insulin prices
- Topic 2 - Clinical research
- Topic 3 - Blood sugar management
- Topic 4 - Technology advancements
- Topic 5 - Awareness
- Topic 6 - Positive emotion/activities

Our analysis showed that there is a considerable amount of intermingling among dominant topics in our group of influential Twitter accounts. One possibility is that we would see distinct clusters of colors in our analysis, indicating that groups were primarily following accounts that had the same dominant topic as their own account. Instead, we see considerable overlap in dominant colors across our network of accounts. This indicates that influential accounts in the T1D web-based community see a wide range of topics on their Twitter feed rather than just the topic that dominates their tweets. It was observed that there is a cluster of topic 2 (*clinical research*), which accounts at the center of our network, indicating that these accounts are the most followed within the T1D community. Accounts with *positive emotions* as their dominant topic rarely appear at the center of our network. While these accounts do appear to follow other accounts in the network, they appear to be somewhat less

integrated. This may be an indication that, while they may be members to the T1D web-based community, TID may not be central to their web-based identity. Accounts primarily tweeting about *insulin prices* also tended to hang around the edge of our network, and those accounts were followed by very few others within our network. The insulin price crisis affects those beyond the T1D community and is also frequently discussed by politicians or those who work in policy- or insurance-related fields. Finally, we observed that within our sample of 100 top followed accounts, *clinical research* was the most common dominant topic (34 accounts). This was followed by *positive emotions* (21), *technology advancement* (14), *insulin price* (13), *daily management of T1D* (10), and finally *organization* (8). In contrast, management of T1D was the most popular topic in our full sample of 8557 accounts.

Discussion

Principal Findings

The current study examined the tweets and network structure of accounts within the T1D Twitter community, demonstrating the feasibility of latent topic modeling as a tool to analyze the use of social media by this and other communities. We identified several broad-bandwidth topics, ranging from clinical to advocacy to daily management to emotional health, which can inform researchers and practitioners interested in the needs of people with T1D. Moreover, network analysis suggests that users are likely to see a mix of these topics discussed by accounts they follow.

Importantly, these findings converge with prior conclusions regarding web-based engagement, such as those web-based communities serving as sources of positive emotion [3], providing practical support [3-5], advocating for needed health care reforms [12,13], and disseminating results from clinical research [15,16]. Compared to prior work, however, these analyses incorporated a very large number of users and made use of algorithmic methods to categorize web-based messages. Despite using different methodology to select tweets for inclusion and for identifying major topics of interest, we replicate recent work by Ahne et al [22], who reported that a major concern of the Twitter DOC is insulin pricing. We also recovered several other major topics, such as diabetes awareness and support, and our *positive emotions* topic may correspond to "enjoying the exchange in the diabetes online community" [22], although the content of the positive tweets in our data appeared more tangential to diabetes. However, a major divergence between these projects was the choice of number of topics to extract and evaluate (6 in ours, compared to 30). A greater number of topics provides the benefit of specificity and nuance, although there is also greater susceptibility to trends, niche topics, and coincidences. For example, Ahne et al [22] found among their 30 topics a discussion of the pop star Nick Jonas (who has been diagnosed with T1D) and advertisements for a makeup product called Bloodsugar. It is unclear as to whether topics such as these are irrelevant to the research goals of psychologists and clinicians or whether they represent sources of advocacy and normalization. Judgement may be made depending on the specific topics extracted and the goals of a particular analysis. Certainly, niche and trend topics inform the understanding of cultural influences and inner lives of people with diabetes, but they may have limited predictive power for broad outcomes. Speaking more broadly, fewer numbers of topics may be more generalizable and easier to track over time, although they lose specificity. Differing numbers of topics are likely useful for different research questions. For example, future research might include pairing Twitter information with real-world outcomes (eg, HbA1c levels) to identify the topics that predict changes in health status.

We believe the current research demonstrates the utility of the LDA method for utilizing social media data in studies on type I diabetes and for patients with chronic illnesses more broadly. Indeed, these analyses could be easily applied to other communities by simply changing the initial key words and hashtag search. Through open-source software, we were able to analyze nearly 700,000 tweets from more than 8000 accounts. Given the feasibility of these analyses, we anticipate they could be used for a number of purposes. Simple adaptations of our code will allow for the study of other communities of people with chronic conditions (eg, cancer survivors or autoimmune conditions). Alternatively, linking Twitter with other forms of data collection (eg, self-report or biological assessments) can be used to study the association between social media engagement and real-world outcomes.

Limitations

However, these methods are not without their limitations. In contrast to more recently developed natural language processing methods, LDA is not based on word embeddings and does not take sentence structure into account as it assumes that words are exchangeable. It also cannot be argued that Twitter users are representative of the United States or world populations, nor do we expect them to be representative of all people with T1D. We expect to have undersampled older adults [31] and communities with limited or unreliable internet access, and there are expected issues with sampling related to geography and race/ethnicity [32]. Notably, however, Black people may be more highly represented on Twitter (compared to other ethnic groups) [33], creating an advantage to using this platform in that researchers can reach populations typically underserved. More specific to this population, our method of selecting participants in the study on the basis of the content of their most recent 100 tweets will not capture Twitter users who choose not to disclose their T1D status on the internet. This exclusion is arguably not relevant to the research question, "What is the focus and network structure of diabetes online communities?" as these users would not participate in these communities.

Conclusions

In sum, the current study contributes to a growing literature of examining the use of social media by people with chronic conditions; in this case, T1D. These findings show that health researchers can leverage the vast amount of data available on Twitter (and potentially other platforms) to efficiently understand major concerns of these populations. Moreover, these findings support prior work showing that people with chronic conditions may use social media to access practical information and social support.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Comparison clouds of the most likely words to appear in the 30-topic Latent Dirichlet Allocation model.

[DOCX File , 2806 KB - diabetes_v6i4e30756_app1.docx]

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Abbreviations

DOC: diabetes online community
LDA: Latent Dirichlet Allocation
NRC: Noncommercial Research
T1D: type 1 diabetes

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<u>Original Paper</u>

Augmenting Traditional Support Groups for Adolescents With Type 1 Diabetes Using Instagram: Mixed Methods Feasibility Study

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Abstract

Background: In-person support groups have been shown to benefit adolescents with type 1 diabetes (T1D) by helping to decrease perceived diabetes burden and improving knowledge related to chronic disease management. However, barriers exist to participation in traditional support groups, including the timing and location of meetings and resources needed to attend. Adolescents are increasingly utilizing online support groups, which may provide solutions to some of the challenges faced when implementing in-person support groups.

Objective: The purpose of this study was to assess the feasibility and acceptability of a hybrid support group model where traditional in-person support groups were augmented with Instagram participation between monthly support group sessions for adolescents with T1D.

Methods: Participants (13-18 years old with T1D for ≥6 months) were asked to post photos each week for 3 months based on predetermined topics related to diabetes management. At the end of each month, participants attended an in-person support group to discuss their photos using the Photovoice method. Feasibility was assessed through enrollment and retention, number of Instagram posts, poststudy questionnaire, and a template analysis of the focus groups.

Results: Of 24 eligible participants, 16 (67%) enrolled in the study, with 3 dropping out prior to support group participation. The number of photos posted over 3 months ranged from 14 to 41. Among the 11 participants who completed a follow-up questionnaire, the majority of participants (6/11, 55%) reported that they very much enjoyed participating in the hybrid support group, and more than three-quarters (9/11, 82%) of participants reported that they "related to the photos posted." Over half of participants (8/11, 73%) reported "learning something new from the photos posted," which arose from sharing knowledge and experiences related to navigating the common challenges of diabetes management. Additionally, the use of Instagram posts helped facilitate peer discussions during the in-person support groups.

Conclusions: The novel combination of using Instagram to augment traditional in-person support groups was feasible and acceptable to adolescents with T1D. The overall satisfaction with the hybrid support group model, combined with the observed engagement with peers between support group sessions over social media, suggests that a hybrid support group model may have the potential to provide more pronounced benefits to adolescents than in-person meetings alone. Future research should investigate the use of social media as part of the support group model and examine the potential improvement of self-esteem, benefit-finding, and social support using validated tools in adolescents with diabetes.

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Introduction

Adolescents with type 1 diabetes (T1D) struggle with difficult and complex treatment plans to maintain adequate glycemic control. Heightened concerns about social context and peers, the premature shift in responsibility for management from parent to adolescent, fatigue from daily diabetes care (ie, diabetes burnout), and incomplete knowledge and understanding of treatment regimens and future health risks have been cited as barriers to diabetes care in this age group [1,2]. As a result, only a small proportion of adolescents with T1D meet targets for glycemic control [3], placing them at higher risk for long-term microvascular and macrovascular complications [4,5].

Although pubertal factors may partly contribute to poor glycemic control in adolescence, psychosocial factors consistently demonstrate meaningful associations with glycemic outcomes [6,7]. Youth with diabetes have a greater incidence of depression and psychological distress compared to their healthy peers [8]. Depression and distress have been associated with worse glycemic control, more complications, higher health care costs, and increased frequency of adverse events [9]. The high rates of distress and depression coupled with poor outcomes in adolescents with T1D highlight the need for age-specific preventative interventions.

Previous studies have shown that adolescents with T1D who participate in support groups have significantly less perceived diabetes burden and more knowledge of the disease [10-12]. Moreover, support groups that provide adolescents with T1D with coping skills training and peer support lead to improved adjustment and metabolic control [13,14]. However, there are often difficulties implementing and maintaining these types of traditional support groups due to location, possible interference with school demands, and resources needed to attend [15,16].

Today, it is common for youth to look to online communities and social media for support and guidance [17,18]. Indeed, online support groups provide an opportunity to overcome some of the limitations related to traditional in-person support groups, particularly related to resources and engagement issues [19,20]. Therefore, this study aimed to explore the feasibility and acceptability of augmenting traditional in-person support groups with Instagram support between monthly support group sessions for adolescents with T1D.

Methods

Participants

Eligible participants were 13 to 18 years old with a diagnosis of T1D for at least 6 months from existing clinic patients at Seattle Children's Hospital (SCH). Participants were required to be English-speaking and have personal access to Instagram, a popular social networking photo application, through their smartphone. At the time of the study, Instagram was available on Android (version 2.2 or above) or Apple iOS devices (version 4.2.1 or above) with a camera attached (iPhone 3GS or above; iPod Touch with an internet connection, 3rd and 4th generations). We excluded any adolescents with a major psychological or psychiatric disorder based on social work notes from the previous year.

The protocol was approved by the Seattle Children's Research Institute Institutional Review Board, and voluntary informed written assent and consent were obtained from each participant and their caregiver (for those <18 years old). A total of 16 adolescents agreed to participate in the study.

Study Protocol

At the first visit, after informed assent and consent were obtained, the participant was given basic training on using and sharing content on Instagram. This training included instructions and tips on downloading the application onto the participant's phone, adjusting privacy settings on Instagram, sharing photos, interacting with others through the app, and allowing the study team to follow their account. Real names were not required to be used for privacy purposes. Current Instagram users were given the option of using their account or setting up a new one for the study, with privacy considerations discussed in each case. Participants were encouraged to "follow and friend" their cohort members, but this was not required. The study staff had their own Instagram account, and the participants were required to allow this account to "follow" the user.

Participants were placed into one of two cohorts. Placement into each cohort was determined solely by time of consent: the first half enrollees were assigned to the first cohort, and the second half were assigned to the second cohort. The intervention consisted of two main components. The first was sharing photos with their cohort on Instagram either through their general Instagram feed or through "direct messaging." All participants were provided the list of the other cohort members' Instagram names during the first week. Topics of photos were suggested each week to aid participation (Textbox 1). These topics were generated from previous work in this area [21]. When posting photos, participants were encouraged to caption their photo and use the study-specific hashtag to ease the identification of photos related to this project.

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Textbox 1. Suggested Instagram photo feed topics.

Month #1

- Week 1: What I eat

- Week 2: How I stay active

- Week 3: What I find funny

- Week 4: Free choice

Month #2

- Week 1: Struggles and challenges

- Week 2: What makes me happy

- Week 3: How I cope

- Week 4: The truth about diabetes

Month #3

- Week 1 How others view my diabetes

- Week 2: What I can teach others

- Week 3: What I have learned

- Week 4: Free choice

A monthly support group meeting was scheduled at the end of each month.

The second component of the intervention was participation in an in-person support group at the end of each month. Support groups were conducted using the Photovoice method, a community-based participatory research method in which participants take photos about a community issue and then discuss the photos in a group setting where they can reflect on these experiences and issues and feel empowered to make changes [22,23]. The Photovoice method has been shown to improve meaning-making, life satisfaction, and empowerment in many diverse populations and has also been shown to provide psychosocial support for various adolescent communities [24-26].

Support groups were held in approximately 1-hour sessions at SCH by cohort during an evening or weekend every 4th week of the intervention. In preparation for the discussion, study staff printed photos posted that month. A study staff member trained in facilitating support groups used the SHOWeD approach to guide the group sessions. The SHOWeD method focuses on five questions: (a) what do you see here, (b) what is happening here, (c) how does this relate to our lives, (d) why does this issue exist, and (e) what can we do about it [22]? Discussion tactics included pile sorting, categorization of topics, and other techniques garnered from traditional Photovoice methodology [27]. Feedback about comfort and satisfaction with the intervention was also discussed. Support groups were recorded and transcribed for the template analysis. At the end of the study, participants were asked to complete a follow-up questionnaire that assessed the acceptability of the intervention. Participants were given a US $20 gift card for each group attended and a US $10 gift card if all follow-up surveys were completed.

Feasibility Measures

Acceptability

Acceptability was assessed through enrollment and retention rates and survey questions evaluating the acceptability of the intervention. These questions included overall satisfaction of the intervention, how interesting the photos were that were shared with listed options ("very interesting," "interesting," "mildly interesting," and "not at all interesting"), whether they could relate to the photos they saw, whether they learned anything from the photos shared, and their comfort with posting and privacy issues. In addition, participants were given room to give comments and suggestions and to expand on their responses.

Implementation

Implementation was evaluated by examining support group attendance and the actual use of Instagram during the intervention, including the number of posts and likes by study participants. In addition, a template analysis of the support groups was carried out [28]. For the template analysis, support groups were digitally recorded, transcribed verbatim, and reviewed by investigators to ensure data integrity. A hierarchically organized codebook was developed a priori based on the feasibility domains of acceptability and implementation. Support group transcripts were coded by 2 team members using the final version of the codebook and Excel (2019; Microsoft Corporation). Coders were blind to each other's coding, and all differences were resolved by discussion with a third team member until 100% agreement was reached. During synthesis, coded excerpts were summarized into theme domains related to feasibility with associated quotes. In addition, Instagram posts related to themes were identified.

Results

Acceptability

Adolescents in this study provided insights into the potential acceptability for the hybrid support group model. Participants also expressed to what extent the intervention was suitable and satisfying to recipients.

Rates of Enrollment and Retention

We approached 24 English-speaking, 13 to 18-year-old patients with T1D for at least 6 months to participate in this study. Of the 24, 16 (67%) enrolled (Table 1). Reasons shared for not enrolling included no personal access to Instagram (4/24, 17%), no interest (2/24, 8%), and being too busy (2/24, 8%). All 16 enrolled participants reported using Instagram prior to enrollment, and they were divided into two equal cohorts (8 participants each), of whom 2 (13%) elected to create new Instagram accounts for study participation. Of the 16 who enrolled, 3 (19%) participants from the second cohort dropped out after enrollment but prior to participation. Among the remaining participants, 85% (11/13) that engaged in at least one support group completed the acceptability questionnaire at the end of study participation.

Table 1. Demographic and clinical characteristics for enrolled adolescent participants (n=16).

Characteristics		Value
Age (years), mean (SD)		15.3 (2.3)
Gender, n (%)		
	Female	9 (56.25)
	Male	5 (31.25)
	Prefer not to answer	2 (12.50)
Race/ethnicity, n (%)		
	Non-Hispanic White	10 (62.50)
	Other	4 (25.00)
	Prefer not to answer	2 (12.50)
Health insurance, n (%)		
	Private	9 (56.25)
	Public	3 (18.75)
	Not sure or prefer not to answer	4 (25.00)
Baseline HbA$_{1c}$ (%), mean (SD)		9.2 (2.3)
Diabetes duration (years), mean (SD)		5.3 (4.4)

Satisfaction

Of participants that completed the acceptability questionnaire, 55% (6/11) reported that they "very much enjoyed" participating, 45% (5/11) reported that "it was OK," and none stated that they "thought they would enjoy it more" or "did not like it at all." When asked how they would rate the suggested topics, one participant rated the topics "very interesting," while all others rated them "interesting." No one endorsed "mildly" or "not at all" interesting.

For the majority of participants, the ability to reflect and relate to photos from other adolescents with T1D was a major draw to engage in the in-person support groups. Most participants reported that the ability to learn from others and not feel alone in navigating the daily diabetes self-care challenges was a key reason they enjoyed posting and participating in the support groups.

> *Just feeling like you're not the only one going through it…and that you can still lead like a normal life and still have diabetes. Plus, [seeing] other people also going through the struggles so you aren't there alone.*

Some also touched on how they found the hybrid support group model more empowering than other group settings they had participated in, such as diabetes camps.

> *I've only had [T1D] for 2 years, so I feel like it was more helpful for me. Some of the posts and the pictures were [about] things that I didn't really know because I don't really usually talk to other people about [my] diabetes. Because I think going to [diabetes] camps, like they say they're supposed to make you feel better but whenever I try to talk, it just makes me feel worse.*

Implementation

Participants also shared their views on the successful execution of using Instagram as a modified application of Photovoice and support group participation. Specifically, adolescents offered insights into the extent, likelihood, and manner in which the hybrid support group model can be fully implemented as planned and proposed.

Support Group Participation

Attendance rate of support groups varied over 3 months. In the first cohort (8 participants), 75% (6/8) participated in the first support group, 63% (5/8) in the second, and 38% (3/8) in the final support group. In the second cohort (5 participants), 60% (3/5) participated in the first support group, 100% (5/5) in the second, and 80% (4/5) in the final support group. Many participants shared how they felt the support groups were really beneficial in augmenting the self-reflection and discussion of photos on Instagram.

> [The support groups] were really beneficial to, like, see other people's views and stuff about it. For me, I didn't really look at other people's pictures when they were posting, I just thought about mine and then moved on because I had other things to do.

Participants also shared that the in-person support group helped them connect more effectively with group members online, as they knew who they were interacting with on Instagram.

> I think that [meeting participants in the support groups] pushed me to post more…I know like the people and their faces so I'll be, 'Oh, I know that person kind of, like I've seen her.'

> I liked being able to put the posts with the people. Because like seeing your posts I didn't get a ton out of your personalities but then coming here I was able to meet people.

Using Instagram as a Modified Application of Photovoice

Participation by week is represented in Figure 1. The linear trend line shows an average upward trend in the number of posts throughout the study. Between both cohorts, the number of photos posted ranged from 14 to 41, with the highest participation charted for the first "free choice" (no suggested theme), "how I cope," and "what I can teach others" topics. The lowest number of posts were seen with the suggested topics of "what I eat," "struggles and challenges," and the "free choice" topic suggested the second time.

Figure 1. Number of Instagram posts between support groups.
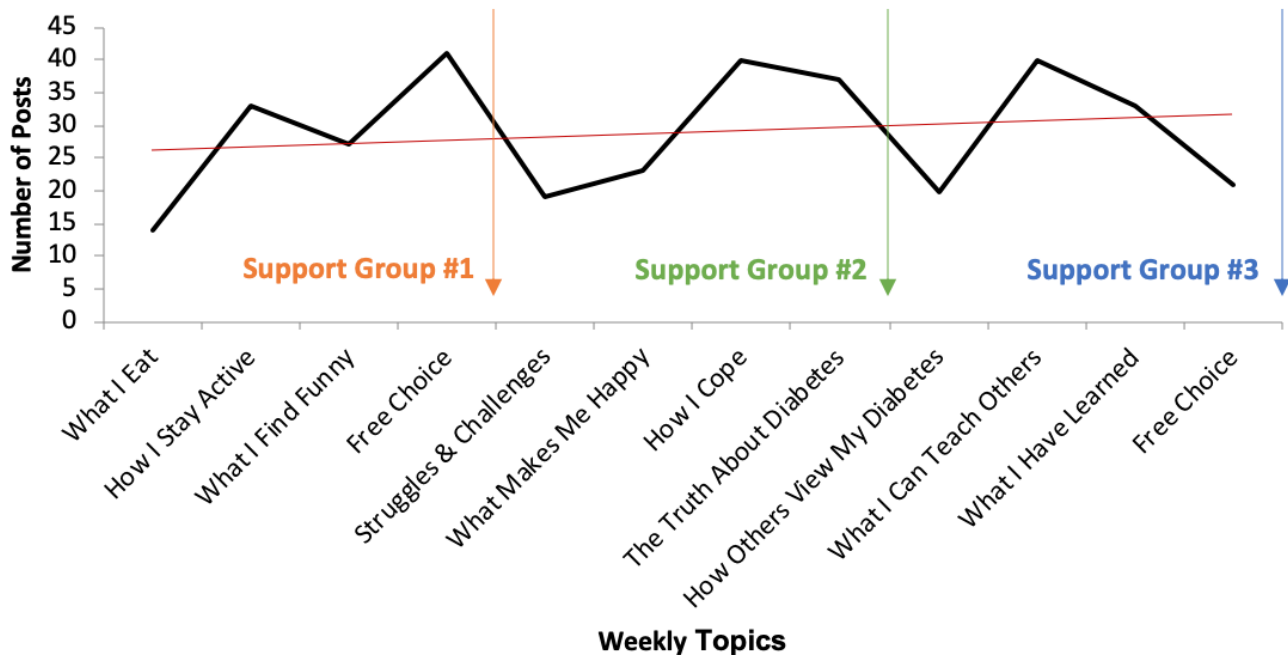
The majority of respondents (7/11, 64%) reported their cohort members' photos as "very interesting." The remaining participants described their cohort members' photos as either "interesting" or "mildly interesting." No participants marked "not interesting." In addition, 82% (9/11) of participants reported "relating to the Instagram posts" (Figure 2).

Figure 2. Example post of a participant "relating to the Instagram post" at a support group.
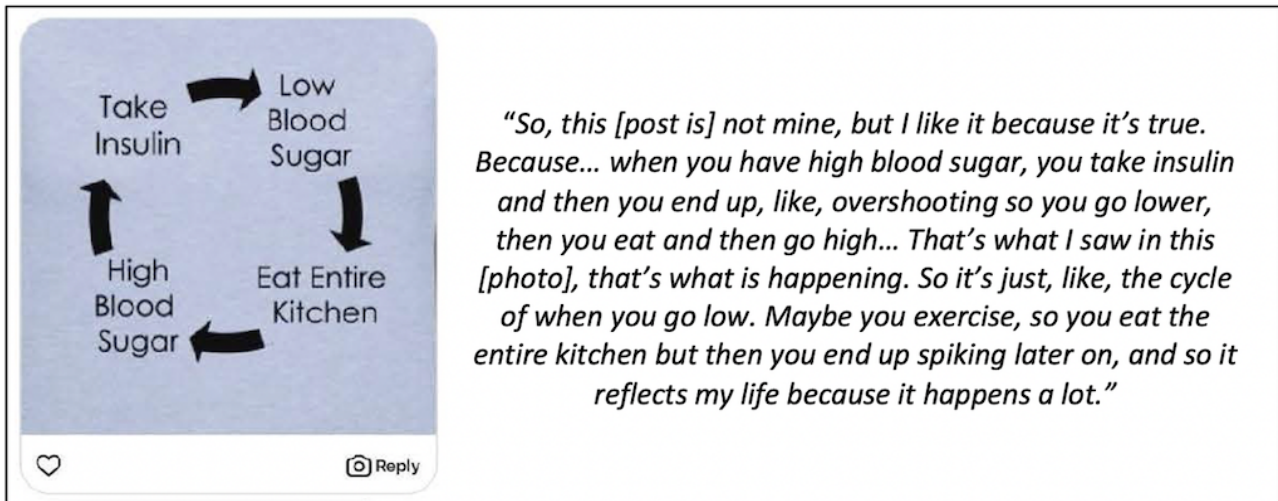
Moreover, 73% (8/11) reported "learning something new from the photos posted" (Figure 3). When asked to expand on what they learned, participants indicated posts that included suggestions on how to make healthy snacks, how to think about the impact of different types of food on glycemic control, and how other youths with T1D experience similar struggles with diabetes management were particularly helpful.

Figure 3. Example post of a participant "learning something new from the photos posted" at a support group.
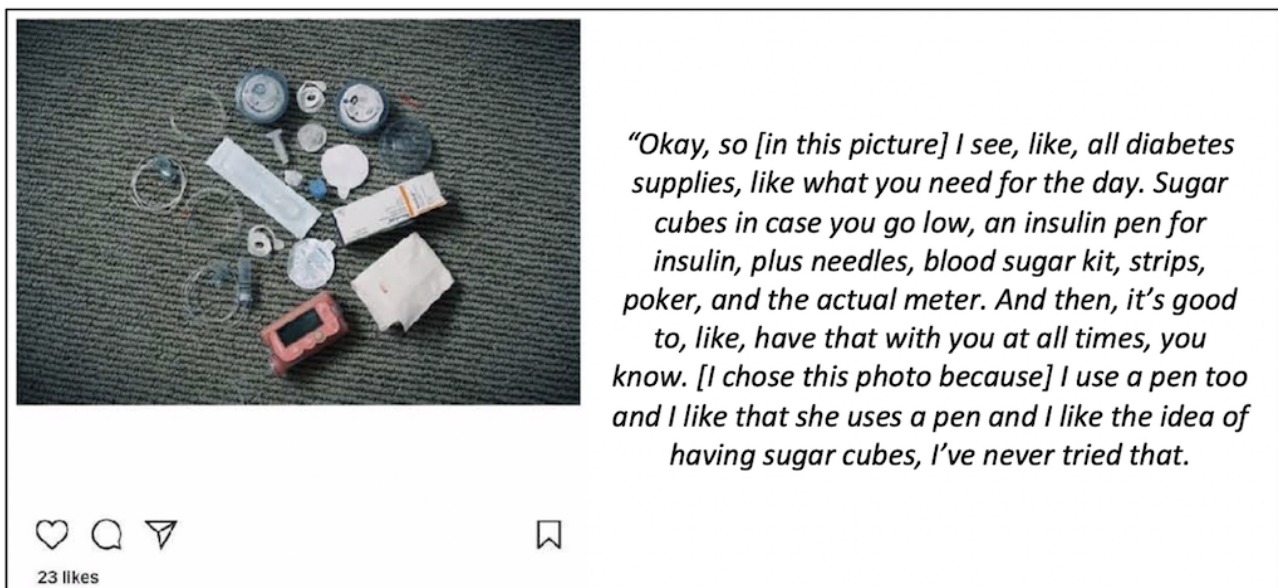
In addition to posting photos, most Instagram posts by participants included text captions, which routinely provided context for the photos posted. Captions accompanying the posts provided the participants with the ability to share personal stories and experiences about particular issues. Posts with captions facilitated peer discussions during the in-person support groups (Figure 4).

Figure 4. Example post with text caption facilitating peer discussions at a support group.
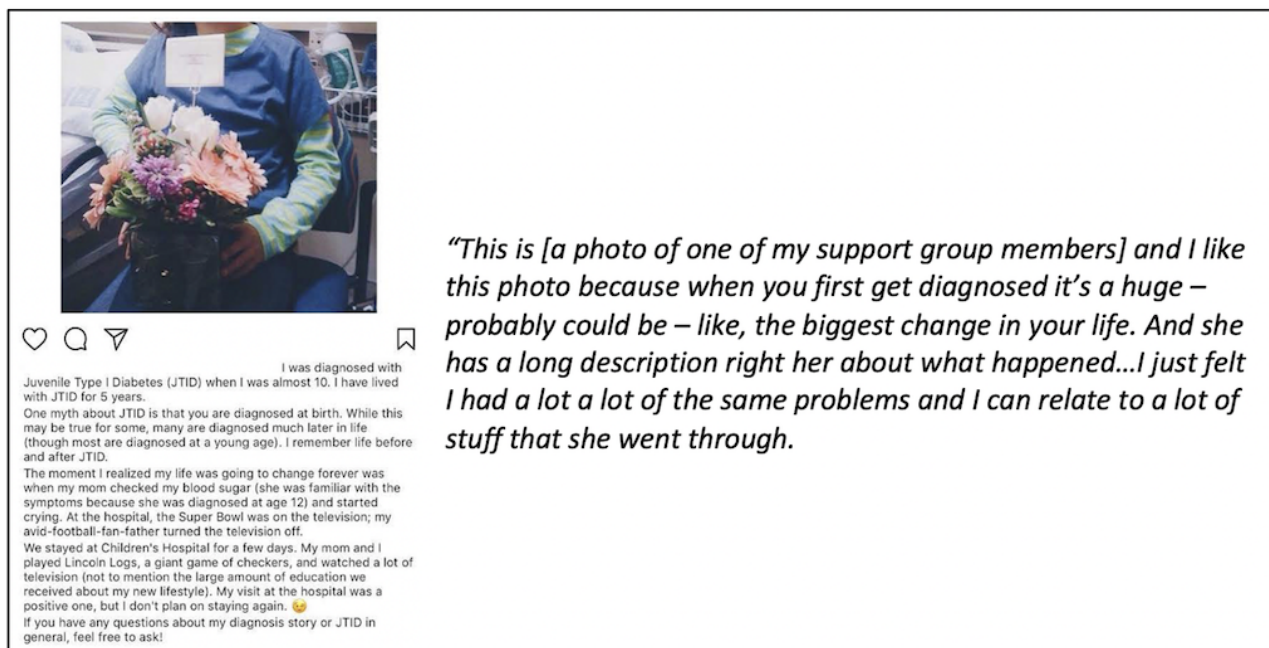
None of the participants who completed a follow-up survey reported any privacy concerns before the study, during participation, or after the study.

Discussion

Principal Results

We found that the novel combination of using Instagram to augment traditional in-person support groups was feasible and acceptable to adolescents with T1D. Participants posted Instagram photos consistently between support group visits and found other members' photos interesting and relatable. Although in-person support group attendance varied over 3 months and between cohorts, no participants reported dissatisfaction with the hybrid support group intervention. Given the need for increased support for adolescents with T1D and the overall feasibility and acceptability of this intervention, combining traditional in-person support groups with online support group options through social media use could be a means to increase engagement in psychosocial support outside of the clinic setting.

Our study enrollment rate for this feasibility study was comparable to traditional in-person support groups for adolescents [29,30]. Additionally, participants' attendance and satisfaction were similar to our previous study in which we assessed the feasibility and acceptability of using Instagram to implement the Photovoice method to share diabetes-related information [21]. By offering the social media component between support groups, participants were given increased opportunities to engage in photo-sharing and discussions of weekly topics than what is offered in traditional Photovoice projects.

The overall satisfaction with the hybrid support group model also highlights the potential for more pronounced benefits using the Photovoice method than what is currently seen from in-person support groups alone. Given that a higher level of emotional support from peers is predictive of less

diabetes-related distress [12], strategies to promote positive peer interactions are needed. Photovoice, rooted in core community-based participatory research principles, stresses empowerment and emphasizes individual and community strengths, colearning, and community capacity building [31]. Our findings demonstrate that adolescents benefited from self-reflection and discussion of photos in the support group sessions using the SHOWeD questioning technique. In addition, the finding that a majority of participants reported learning new approaches to support diabetes self-care and management reinforces the value of support groups in promoting peer education.

In our study, participants remained engaged in the support group topics even outside of in-person sessions. Support groups have been shown to increase self-care behaviors and decrease the perception of diabetes-related burden in young adults with T1D [11]. However, these benefits are difficult to sustain if the educational and psychosocial elements provided from involvement with support groups are not continuously reinforced [32]. The addition of social media with in-person support groups, as shown in our study, could be a means to facilitate reinforcement between support group sessions. While in-person support group sessions are held at set times, which members may or may not be able to attend depending on their schedule, social media can be accessed at any time of the day and for any number of times depending on the user's needs.

Of additional interest, some participants shared that connecting with Instagram community members in person motivated them to engage more online after support group participation. Patients with diabetes are increasingly looking to online communities on the internet for clinical information and to provide and receive support [33]. While utilized by many, the helpfulness of online support groups varies depending on the media platform, intervention style, and target population, and its effectiveness has yet to be accurately identified [34,35]. Furthermore, the authenticity of online group members and the

information that they share may not always be trustworthy [36]. The hybrid support group model used in this study could address some of these concerns by allowing participants the opportunity to verify that the Instagram profiles are for the same individuals they met in their support group sessions.

Limitations

While this study provides insight into the acceptability and feasibility of a hybrid support group model, it has limitations. The first is the small sample size due to the pilot nature of the study, which limits generalizability. The second limitation is that we may not have fully replicated a typical Instagram social media environment for the 2 participants that elected to create a separate Instagram account for the study. Those who created a separate account might not have had as much engagement in their study-specific account, likely due to the inconvenience of switching between their personal account, where perhaps most of their consistent social media engagement is, and their new study account to meet the weekly posting suggestions. Third, we were unable to capture participant interaction that could have been taking place via direct messaging or other social media platforms that may have provided additional insight into participant engagement between monthly support groups. Finally, given that the majority of our participants used their primary Instagram account for study participation, it is possible that some participants self-censored the content of their diabetes posts since it was viewable by their other nonstudy Instagram followers. However, the potential utility of the hybrid support group model would remain, given that the majority of participants posted reliably and engaged with support group peers despite having nonstudy participants also view their social media content.

Conclusions

Adolescents with T1D often struggle with managing their disease, and as a result, they may look online or offline for the psychosocial support they need. Traditional in-person support groups provide many benefits, but some barriers prevent many youths from engaging. Online support groups are easily accessible for many adolescents and offer them the ability to connect with and learn from others that they may not have otherwise been able to; however, the authenticity of their online peers may not always be trustworthy. Our study demonstrated that a hybrid combination of in-person and online support groups is feasible and acceptable, offering the potential for increasing social support and optimizing diabetes outcomes in young adults with T1D. Future studies should focus on examining the amount of in-person versus online support required to support adolescents with T1D, along with the efficacy of this hybrid support group model, including its impact on diabetes outcomes and self-esteem, benefit-finding, and social support using validated tools in adolescents with diabetes.

Conflicts of Interest

None declared.

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Abbreviations

T1D: type 1 diabetes
SCH: Seattle Children's Hospital
NIH: National Institutes of Health

Original Paper

The Significance of Alliance Networks in Research and Development of Digital Health Products for Diabetes: Observational Study

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Abstract

Background: Digital health has been advancing owing to technological progress by means of smart devices and artificial intelligence, among other developments. In the field of diabetes especially, there are many active use cases of digital technology supporting the treatment of diabetes and improving lifestyle. In the innovation ecosystem, new alliance networks are formed not only by medical device companies and pharmaceutical companies, but also by information and communications technology companies and start-ups. While understanding and utilizing the network structure is important to increase the competitive advantage of companies, there is a lack of previous research describing the structure of alliance networks and the factors that lead to their formation in digital health.

Objective: The aim of this study was to explore the significance of alliance networks, focusing on digital health for diabetes, in effectively implementing processes, from the research and development of products or services to their launch and market penetration.

Methods: First, we listed the companies and contracts related to digital health for diabetes, visualized the change in the number of companies and the connections between companies in each industry, and analyzed the overview of the network. Second, we calculated the degree, betweenness centrality, and eigenvector centrality of each company in each year. Next, we analyzed the relationship between network centrality and market competitiveness by using annual sales as a parameter of company competitiveness. We also compared the network centrality of each company by industry or headquarters location (or both) and analyzed the characteristics of companies with higher centrality. Finally, we analyzed the relationship between network centrality and the number of products certified or approved by the US Food and Drug Administration.

Results: We found the degree centrality of companies was correlated with an increase in their sales. The betweenness and eigenvector centralities of medical devices companies located in the United States were significantly higher than those outside the United States ($P=.04$ and $.005$, respectively). Finally, the degree, betweenness, and eigenvector centralities were correlated with an increase in the number of Class III, but not of Class I nor II, medical device products.

Conclusions: These findings give rise to new insights into industry ecosystem for digital health and its requirement and expect a contribution to research and development practices in the field of digital health.

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Introduction

Background

According to the US Food and Drug Administration (FDA), the scope of digital health covers categories such as mobile health (mHealth), health information technology, wearable devices, telehealth and telemedicine, and personalized medicine [1]. Digital health involves the use of sensors, software, connectivity, and computing platforms. These technologies have been used across a range of medical applications and wellness applications; in medical applications, they can be used as medical products themselves or separately added to medical products. They can also be used for research and development of medical products [1]. Digital health aims to reduce inefficiencies in health care services and costs, improve access to health care services and their quality, and promote personalized medicine. Digital tools are expected to aid disease prevention, early diagnosis, and appropriate management of chronic diseases, along with providing opportunities to improve health care outcomes and increase efficiency by enabling patients to access their own data, gain a holistic view of their health status, and take control of their own health.

Another expected utility of digital health is lean innovation or increased cost efficiency. Currently, health care costs are increasing in developed countries, accounting for more than 10% of gross domestic product; reducing health care costs has been a major issue. In addition, the number of patients with chronic diseases such as diabetes is expected to increase due to accelerated aging of the population, which would further increase health care costs [2]. Furthermore, in emerging countries, there is a lack of medical and health care services, and digital health is expected to be a solution to this problem.

The use of digital health is increasing with regard to diabetes mellitus. Diabetes is a chronic disease characterized by elevated levels of blood glucose, which causes serious damage to the heart, blood vessels, eyes, kidneys, and nerves. The treatment and management of diabetes differs from those of other diseases in that it requires medical devices such as syringes, insulin pens, insulin pumps, for drug administration; blood glucose monitoring devices such as continuous glucose monitoring and flash glucose monitoring for disease management; and lifestyle guidance such as diet and exercise, which can be managed by the use of mobile apps [3]. In the digital health for diabetes space, in addition to the existing health care companies, such as medical device companies and pharmaceutical companies, new players, such as app service providers and data management solution providers, are being engaged, according to research2guidance [4]. However, the relationships among companies, that is, what roles each plays and how each partner contributes to digital health, are not very well understood.

Understanding alliance networks among companies is critical for predicting future developments in digital health. The goal is to integrate digital technology with, and not make it a substitute for, health care providers. To realize this, existing electronic medical records and treatment and management methods need to be integrated with digital data, and systems need to be built so that hardware can be interoperable. Digital therapy platforms are expected to play a central role in supporting diabetes treatment and self-management through embedded algorithms [5]. As part of the new system, existing health care companies, including medical device companies, will need to partner with companies that own digital therapy platforms, or simply technology companies, and form a network centered on technology companies.

In our previous research, we focused on the research about technology companies with high network centralities in the alliance network about digital health for diabetes, and characterized them into 3 business models: (1) intermediary model, (2) substitute model, and (3) direct-to-consumer model [6]. As the next step, in this research, we provide an overview of the structure of the alliance network and its time change, and factors that lead to their formation in digital health for diabetes.

Research Objectives and Hypothesis

The significance and utility of alliance networks have been discussed in many previous studies. Companies can form alliances according to their strategic intentions and actions, and benefit from access to and exchange of information through their networks [7]. It has been pointed out that alliance networks can promote information diffusion, innovation, and learning in companies [8,9], and that they can change the flow of information and knowledge and affect the competitive advantage of companies [10]. Therefore, companies located at the center of an alliance network can disseminate information and knowledge, and act as a gateway for information exchange, making a bigger impact as compared with other firms in the network. Some studies have also linked firm performance to network centrality, noting that the formation of new networks facilitates collective knowledge sharing and exploratory learning in new technological domains [9,11].

Previous research studies have shown that facilitating learning in alliance networks is important in new technology domains, and that being centrally located in such networks can lead to increased competitive advantage for companies [7-12]. In drug development including antibody, cell therapy, gene therapy, and personalized medicine, increase of external collaborations has been observed [13]. Wherever new technologies are used in digital health, it is assumed that alliance networks are built, and that learning and performance are improved through them. In this study, we examined the relationship between network centrality and competitiveness by using the increase in total annual sales as a parameter to show an increase in competitiveness.

> *Hypothesis 1: The more central a company is in an alliance network, the more competitive it is in the market.*

Regarding the use of digital health for diabetes, Kerr et al [5] predicted a future ecosystem in which digital therapeutic platforms are at the center. While technology companies are capable of platform-based horizontal specialization, pharmaceutical and medical device companies need vertical integration because their products are approved individually [14]. Considering the above, it is assumed that a network

centered on technology companies is being formed in the digital health of diabetes.

In addition to the attributes of the companies being important in digital health, their geographic location may also be consequential, because many US companies have a significant presence. The number of guidelines on digital health issued by the regulatory authorities in each region from 2005 to 2020 was 21 from the FDA, 1 from the European Medicines Agency (EMA), and 0 from the Japan Pharmaceuticals and Medical Devices Agency (PMDA) as of October 2020 [15,16]. This suggests that the United States may be the country most likely to develop and launch products related to digital health. In today's globalized world, any company from any country can develop a product in the United States. However, because it could be thought that geographical proximity to the FDA would be advantageous in negotiations with the FDA, and it was assumed that companies headquartered in the United States would likely be better positioned in the alliance network, we hypothesized the following.

Hypothesis 2: Companies with high network centrality are characterized as technology companies and companies headquartered in the United States.

Finally, we examined the relationship between network centrality and the profile of the digital health products and services that these companies are engaged in. Digital health is characterized by its ability to handle big data. Medical devices can be broadly classified into those that are used only when necessary and those that are worn at all times, such as wearable devices, the former being classified as Class II medical devices, and the latter as Class III. In the digital health sector, Class III medical devices are thought to be used because they can obtain a large amount of data 24/7 by connecting to wearable devices.

While it has been reported that about 21% of users abandon mobile apps after one use, with retention of users being a challenge [5], when an app is connected to a wearable device, data transfer and other activities are performed passively, even if the user does not actively use the app. Therefore, for continuous data collection, products accompanied by wearable devices are likely to become more mainstream as compared with mobile apps alone. Here, a product with a mobile app falls under Class II, while a product connected to a wearable device falls under Class III. Considering the above, it is assumed that Class III products are likely to be the main battleground for leading companies.

Hypothesis 3: Companies with high network centrality are more likely to have Class III products as compared to those with Class I and II products.

Methods

We used the data set which we made in the previous research [6]. We listed 57 companies that were engaged in diabetes digital health based on public information [4,17,18]. Next, we listed their alliance partnerships in diabetes digital health from their press releases. The partnerships we listed covers not only simple contracts such as collaboration agreement, financial agreement, commercial agreement, and patent license agreement, but also joint venture, merger and acquisition, and Precertification (Pre-Cert) Pilot Program by the FDA as one of the styles of partnership. New companies that appeared as partners were added to the list, and the listings of partnerships of these companies were repeated in the same way until no new companies appeared. As a result, 231 companies and 331 contracts were listed [6]. We listed information from Crunchbase [19] for company name, year of establishment, country of headquarters, company website link, and Bloomberg [20] for sector and industry affiliation. The sector and industry information were taken directly from Bloomberg [20]. The listing included contracts that were released until August 13, 2020 [6].

For the number of FDA approvals, we used the Premarket Approval (PMA) database for Class III [21] and the 510(k) database for Classes I and II [22]. The number of FDA approvals of medical devices related to diabetes from 2005 to 2020 by the company was listed.

For network analysis, we used the open software package Gephi 0.9.2 [23], with the companies collected as nodes and the contracts collected used as edges. Thereafter, for each company, we calculated and extracted the degree, betweenness centrality, and eigenvector centrality as network parameters from 2011 to 2020 using Gephi 0.9.2. The definitions of the 3 network parameters were as follows: the degree, the number of edges connected to the node; the betweenness centrality, the number of times a node lies on the shortest path between other nodes; and the eigenvector centrality, the node's influence based on the number of links it has to other nodes in a network.

Results

Number of Players and Contracts in Digital Health for Diabetes

The number of companies and the number of contracts related to diabetes digital health at each point in time from 2011 to 2020 (until August 13, 2020) are shown in Figure 1. The number of companies and contracts are found to have increased slightly from 2011 to 2014, rapidly after 2015, and reached 228 and 325 in 2020, respectively.

Figure 1. Number of companies and contracts in the diabetes alliance network (year 2011-2020). Each bar represents the number of companies within the scope, while the line represents the number of contracts over time.
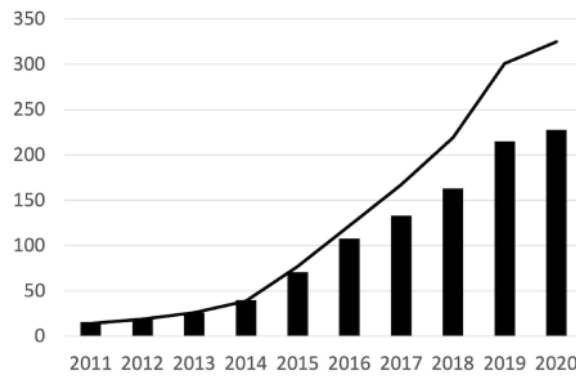

Network Structure and Components Over Time

To observe the changes in the connections between players in the alliance network for diabetes digital health, we drew the networks in 2011, 2015, and 2020, using node as the player, edge as the contract, and color coding by the sector to which the player belongs (Figure 2). The alliance network in 2011 was drawn as a representative of the embryonic phase of digital health, in 2015 as the start of growth phase, and in 2020 as the latest.

Figure 2. Changes in the alliance network for digital health in diabetes. Network in (A) 2011, (B) 2015, (C) 2020. Each label represents the centered company name(s) in a cluster.
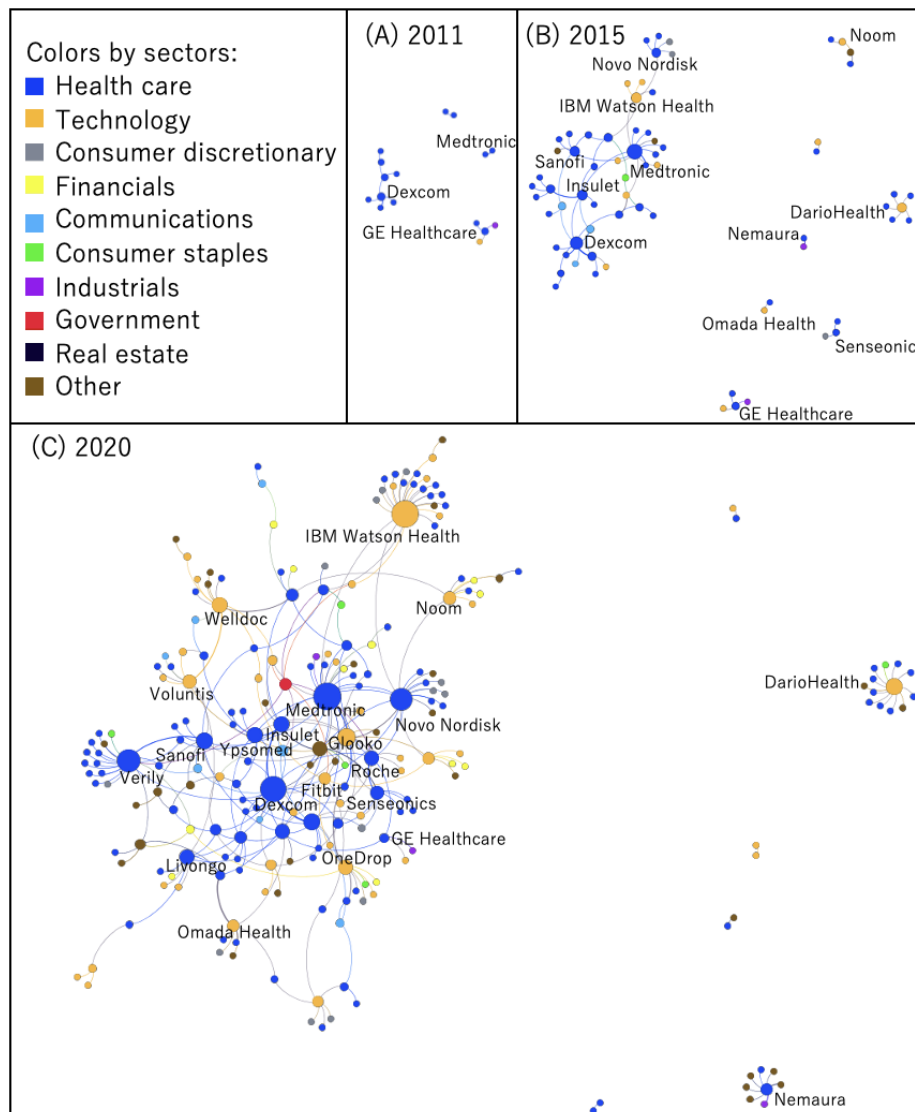
In 2011, contracts were mainly made by health care companies (medical equipment and devices, and biotech and pharma). In 2015, the number of technology companies increased and they started to connect to health care companies, including health care facilities; some communications companies (eg, Google, Tidepool) entered the network and connected to health care companies. In 2020, the number of technology companies increased further; companies from various sectors, including consumer discretionary services (mainly universities), entered the network, and health care and technology companies worked as hubs in this network.

Relationship Between Network Centrality and Companies' Total Annual Sales

To investigate the relationship between network centrality and the total annual sales of the companies (hypothesis 1), we selected 16 companies with a degree higher than 4 in 2020, and annual reports published from 2011 to 2020. Of the 16 companies, 7 were medical devices companies, 7 were pharmaceutical companies, and 2 were technology companies. We then examined the relationship between the degree and annual gross sales ratio, and only the degree was correlated with the sales ratio (r=0.188, *P*<.03; Figure 3).

Figure 3. Scatter plot of network centrality and annual growth in sales.
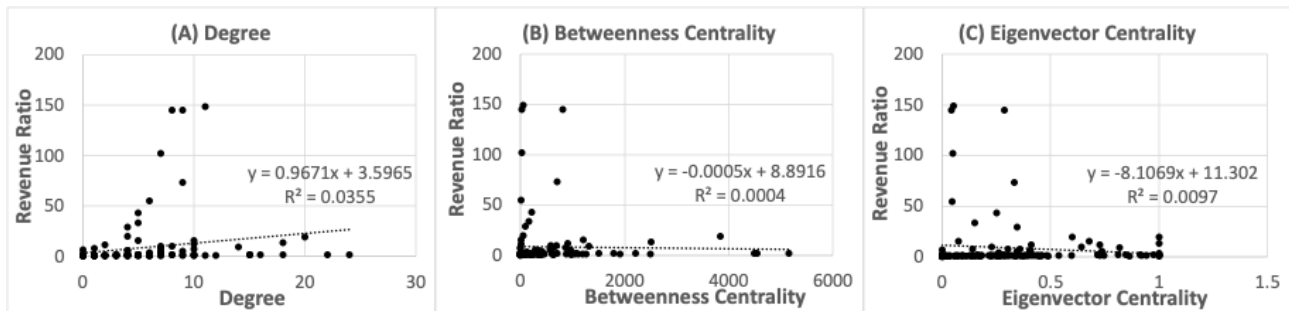
We then examined the relationship between the degree and sales, focusing only on medical devices and pharmaceutical companies. As for the medical equipment and devices, and biotech and pharma companies, 5 out of 7 showed a positive and significant correlation (Figure 4, Table 1).

Based on these results, an increase in sales for centered companies was confirmed for degree centrality. At the individual company level, 5 of the 7 medical equipment and devices, and biotech and pharma companies showed a positive and significant correlation. Therefore, hypothesis 1 was confirmed for degree centrality and selected company cases in medical equipment and devices and biotech and pharma sectors.

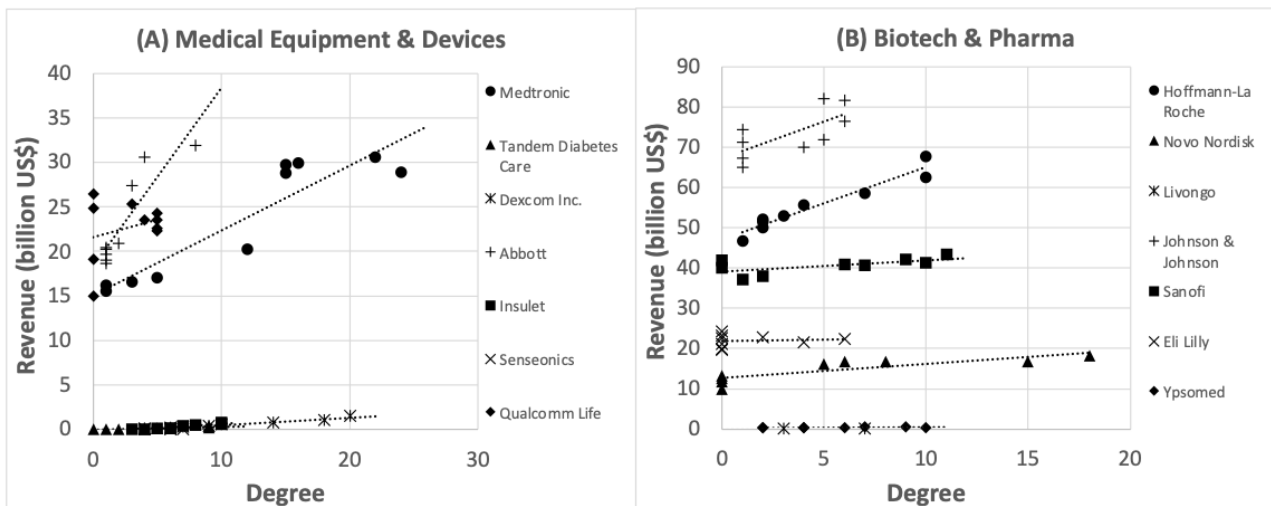**Figure 4.** Scatter plot of degree and annual sales.

**Table 1.** *t* test of relationship between degree and annual sales in each company.

Sector and companies	n	r	*t* value (*df*)	*P* value
Medical equipment and device				
Medtronic	10	0.920	6.66 (8)	<.001
Tandem Diabetes Care	9	0.888	5.10 (7)	.001
Dexcom Inc.	9	0.981	13.4 (7)	<.001
Abbott	9	0.904	5.59 (7)	<.001
Insulet	9	0.927	6.56 (7)	<.001
Senseonics	3	0.932	2.56 (1)	.24
Qualcomm Life	10	0.283	0.835 (8)	.43
Biotech and Pharma				
Hoffmann-La Roche	9	0.965	9.72 (7)	<.001
Novo Nordisk	9	0.842	4.12 (7)	.004
Johnson & Johnson	9	0.706	2.64 (7)	.03
Ypsomed	8	0.857	4.07 (6)	.006
Sanofi	9	0.631	2.15 (7)	.07
Eli Lilly	9	0.0856	0.227 (7)	.83
Livongo	2	NA[a]	NA[a]	NA[a]

[a]NA: not applicable.

Characteristics of Companies With High Network Centricity

Companies in the network in 2020 were classified into medical device companies, health care facilities, pharmaceutical companies, and technology companies, and their network parameters were compared (Figure 5). It was confirmed that technology companies were significantly higher than health care facilities in terms of degree, betweenness centrality, and others in all indicators (*P*<.001 and .001 for degree and betweenness centrality, respectively). It was also confirmed that technology companies were not significantly different from medical device companies or pharmaceutical companies in these indicators (*P*<.001 for degree and betweenness, and *P*=.03 for eigenvector centrality, respectively). These results suggest that technology companies are located at the center of the alliance network as well as medical device companies and pharmaceutical companies.

Figure 5. Comparison of network parameters by industry. *P*<.05, n.s.: not significant.
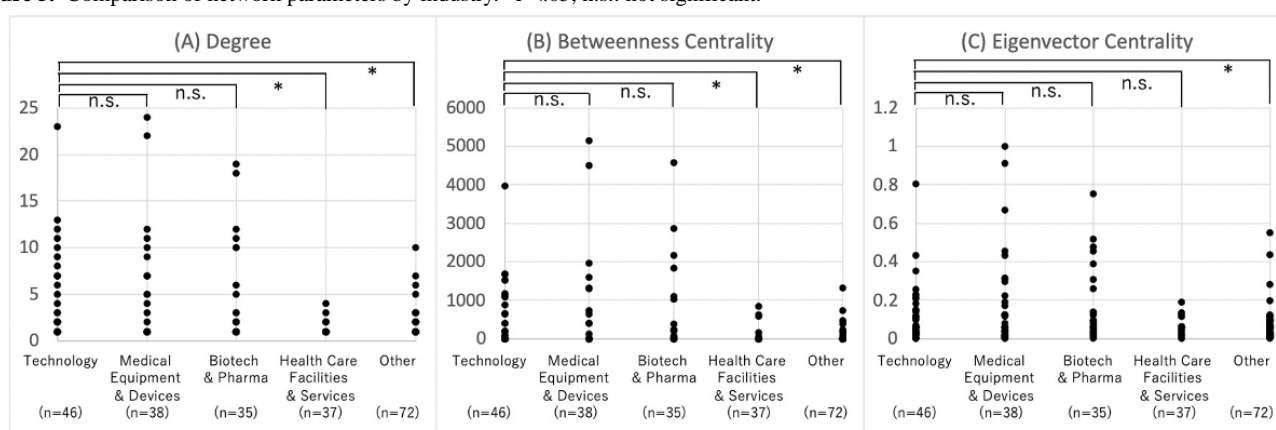
Next, we focused on regional and industry classifications and categorized companies according to the location of their operational headquarters in 2020 into the United States and other countries (Figure 6). No significant differences in degree, betweenness centrality, and eigenvector centrality were found between companies in the United States and other countries, except for the betweenness (*P*=.035) and eigenvector centrality (*P*=.005) of medical equipment and device companies.

Figure 6. Comparison of network parameters by industry and region. *P<.05, n.s.: not significant.
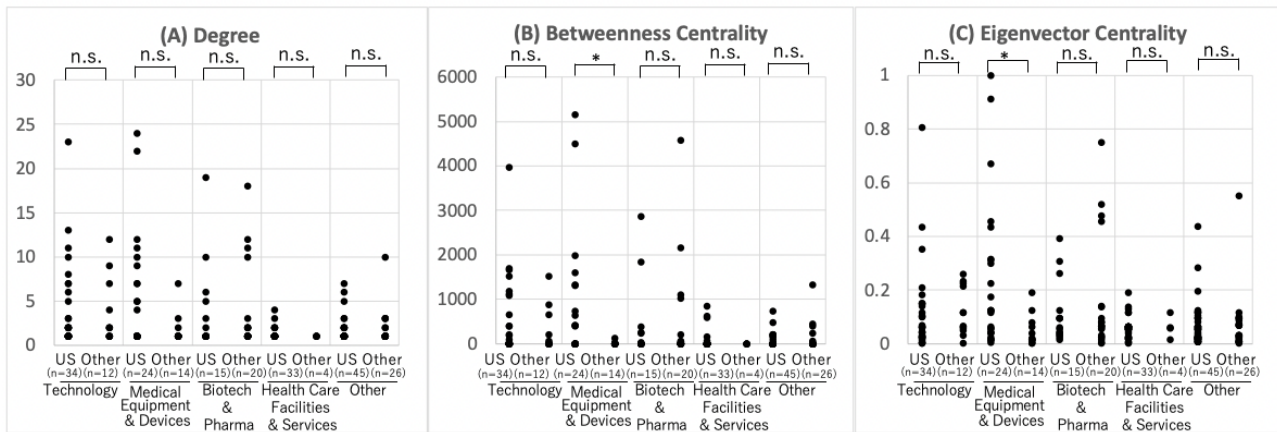
From these results for hypothesis 2, we confirmed that technology companies have high network centrality, as do medical devices and pharmaceutical companies, and, in particular, medical device companies based in the United States.

Relationship Between Network Centrality and the Number of FDA-Approved Products of a Company

To confirm the relationship between network centrality and the number of products of a company (hypothesis 3), we examined the number of FDA approvals for diabetes-related medical devices (Class I, II, and III) from 2005 to 2020 and the number of FDA approvals by company. In PMA, 17 products (6 companies) were approved for diabetes. We could use all 6 companies for our analysis because all had at least one degree in the network. In 510(k), 568 products (148 companies) were

cleared for diabetes. For simplicity, we selected 32 companies whose cumulative number of approvals was more than 3 in the timeframe from 2005 to 2020. Next, we selected companies with a degree of at least one in the network, after which 7 out of 32 companies remained.

There was a relationship between network centralities (ie, degree, betweenness centrality, and eigenvector centrality) and the cumulative number of FDA approvals, as PMA showed a significant correlation ($P=3.33\times10^{-12}$, 4.27×10^{-10}, and 2.40×10^{-6}, respectively), whereas there was no correlation found for 510(k) (Figure 7). These results suggest that companies with high network centrality are more likely to have Class III products as compared to those with Class I and II products.

Figure 7. Scatter plot of network centrality and the number of 501(k) products or PMA products. PMA: premarket approval.
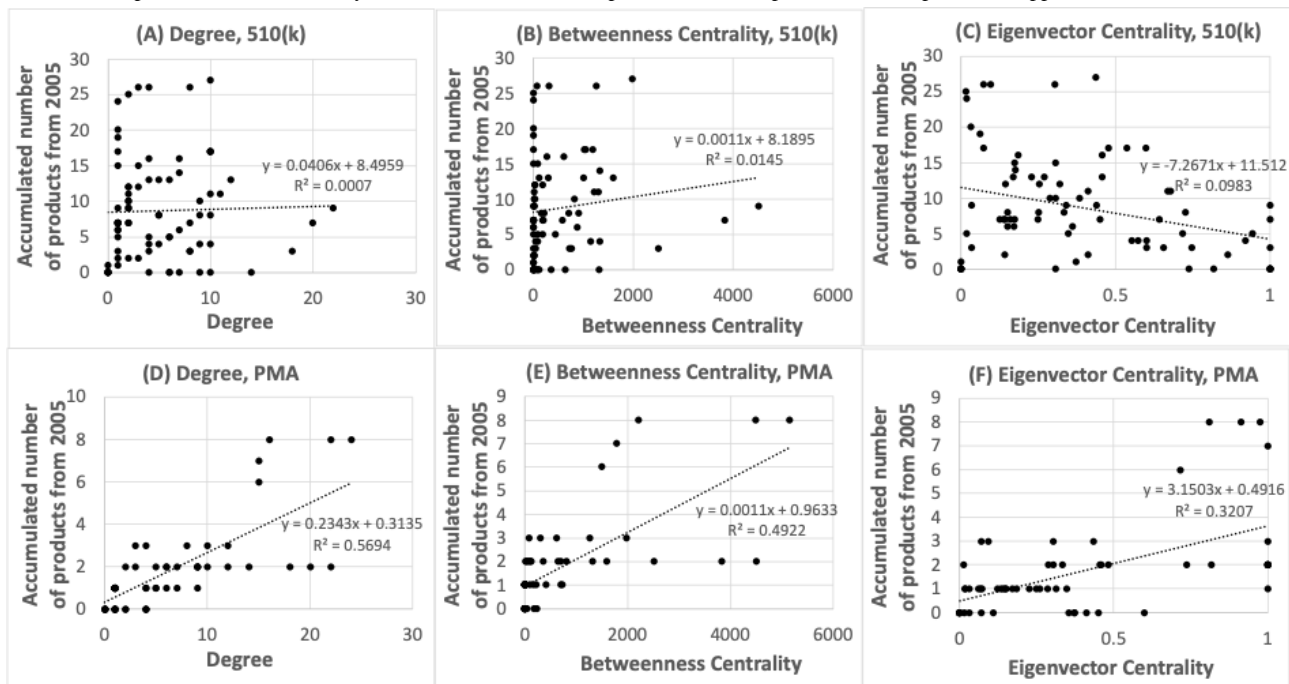
Discussion

Principal Findings

This paper is the first to highlight the importance of studying the business strategies of distinctive companies by focusing on network centrality and aims to contribute to the creation of innovative digital health products and services. The structure of the alliance network and its time change, and factors that lead to their formation in digital health for diabetes were observed.

It was confirmed that the higher the degree of a company's alliance network, the greater the increase in sales of the company. One reason for this is the possibility that the degree increases with an increase in sales; in general, as the size of a company increases, its presence increases, and it becomes easier to invest in the next business, thus expanding the opportunities for alliances with other firms. The other is the possibility that an increase in the degree of new alliances leads to the development and sale of new products and services, which in turn increase total annual sales.

In the alliance network, technology companies were located at the center of the alliance network as well as medical device companies and pharmaceutical companies. In terms of regions,

medical device companies in the United States showed higher betweenness and eigenvector centrality than the companies in other countries. This indicates that medical device companies in the United States are more connected to firms with high network centrality as compared with those in other countries. As mentioned in the "Introduction" section, the reason for this may be the geographical proximity to the FDA, which promotes digital health through the issuance of guidelines.

Furthermore, companies with higher network centralities have a higher number of Class III FDA-approved products. This can be attributed to 2 possible causal relationships: (1) new alliances may have enabled a firm to gain the ability to develop Class III products, or (2) the possession of new Class III products may have led to new alliances, or both. Product-based case studies and time-series analyses are necessary to elucidate this mechanism.

A schematic diagram of the ecosystem transition from 2011 to 2020 is shown in Figure 8. In the observed evolution of the alliance networks for digital health in diabetes, the key actors used to be incumbent companies in 2011, and a diverse range of companies participated, creating an ecosystem different from that of the traditional health care industry. In particular, the presence of technology companies is growing and has the potential to drive paradigmatic innovation in digital health.

Figure 8. Overview of industry ecosystems and historical change.
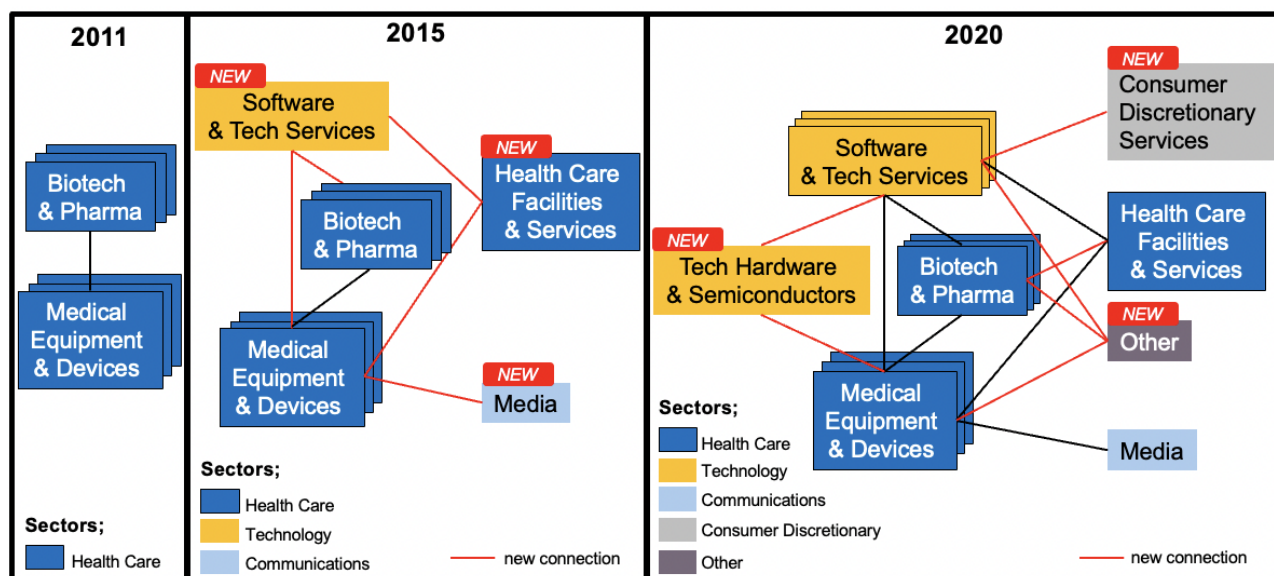
Limitations

First, this study focused on diabetes. Because digital technologies are used in the treatment and management of diabetes, we used the case study of digital health for diabetes. The findings of this study might be limited to the field of diabetes, and a more detailed study is needed to elucidate the innovation mechanism behind it. For example, there might be a different feature in the digital health for psychiatry (eg, a digital biomarker to assess the efficacy in patients).

Second, the contracts and companies which are listed for this study are limited to information that was publicly available in the press releases of the companies by August 13, 2020. Because

the contracts about digital health are increasing drastically in recent years and digital health was accelerated due to the COVID-19 pandemic in 2020, the findings in this study might be just a snapshot until August 13, 2020.

And finally, a cluster analysis in the alliance network was not implemented. In this study, the overall picture of the Diabetes Alliance Network was analyzed. By contrast, as 14 clusters have been identified in the network as of 2020, new insights may be gained by conducting cluster analysis. For example, it may be possible to classify clusters as some aiming at personalized diabetes care and some aiming at diabetes prevention, and each cluster may have its own unique characteristics.

Comparison With Prior Work

To our knowledge, this is the first study to highlight the importance of studying the business strategies of distinctive companies by focusing on network centrality and aims to contribute to the creation of innovative digital health products and services.

This paper is aligned with the past literature which showed that facilitating learning in alliance networks is important in new technology domains, and that being centrally located in such networks can lead to increased competitive advantage for companies [7-12]. In this study, the alliance network is growing in digital health for diabetes, and it was confirmed that the higher the degree of a company's alliance network, the greater the increase in sales of the company.

In our previous research, we listed the technology companies with high network centralities in the alliance network about digital health for diabetes, and characterized them into 3 business models: (1) intermediary model, (2) substitute model, and (3) direct-to-consumer model [6]. The study focused on the technology companies. By contrast, this study, for the first time, presents an overview of the structure of the alliance network and its time change, and factors that lead to its formation in digital health for diabetes.

Conclusions

In this study, we focused on digital health for diabetes and analyzed the structural search of alliance networks and the factors affecting their structure formation. We found that the degree in the alliance network was correlated with the growth rate of sales, whereas the betweenness and eigenvector centralities were not, suggesting that the network centrality may not affect the companies' sales. In addition, medical device companies in the United States had a higher betweenness and eigenvector centrality than those of others, implying the contribution of closer proximity to the FDA that had been proactively establishing related guidelines and encouraging new entrants to digital health. Furthermore, network centralities were correlated with an increase in the number of Class III products but not of Class I nor II products, suggesting that currently, the higher network centrality may matter to products with potentially higher risks.

This is the first study to highlight the importance of studying the business strategies of distinctive companies by focusing on network centrality and aims to contribute to the creation of innovative digital health products and services.

Conflicts of Interest

SK is an employee of Chugai Pharmaceutical Co, Ltd.

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Abbreviations

EMA: European Medicines Agency
FDA: Food and Drug Administration
mHealth: mobile Health
PMA: premarket approval
PMDA: Pharmaceuticals and Medical Devices Agency

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