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Systematic Review

Effectiveness of Mobile App-Based Interventions to Support Diabetes Self-Management: A Systematic Review

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ABSTRACT

Introduction: Diabetes is a major health problem worldwide due to its rapidly growing prevalence and high disease burden. Nowadays, the evolution of mobile technology provides a large number of health-related mobile applications (apps) mainly focusing on the self-management of diabetes. The aim of this paper is to systematically review the effectiveness of mobile app-based self-management interventions on clinical and/or psychological outcomes in patients with type 1 and type 2 diabetes.

Methods: A systematic search of four databases (Scopus, Medline, CINAHL, and Proquest) was conducted using the terms "diabetes" AND "self-management" AND "mobile applications" OR "mobile based" OR "smartphone". Studies published in English from 2016 to 2020 were considered. Only randomized controlled trials (RCTs) for patients with type 1 and type 2 diabetes that reported any of the study outcomes were included. Using our search strategies, we identified 4339 articles. After removing duplicate studies, a total of 12 articles met the inclusion and exclusion criteria included in the review.

Results: The majority measured self-monitoring of blood glucose monitoring frequency, glycated hemoglobin (HbA1c) and/or psychological or cognitive outcomes. The most positive findings were associated with mobile app-based health interventions as a behavioral outcome, with some benefits found for clinical and/or psychological diabetes self-management outcomes for patients with type 1 and type 2 diabetes mellitus.

Conclusion: Therefore, more research with larger and longer studies to develop the ideal mobile-app based self-management tool for diabetes is needed.

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INTRODUCTION

Diabetes mellitus (DM) is a major health problem worldwide due to its rapidly growing prevalence and high disease burden (Binte et al., 2019). Worldwide, diabetes mellitus has been diagnosed in 415 million people. According to the International Diabetes Federation (IDF), by 2045 this number will rise to 629 million (International Diabetes Federation, 2019). The prevalence of DM has resulted in a substantial financial burden on medical systems, families, and societies (Chao et al., 2019). Currently, in the United States, only 50% of diabetes patients are achieving the recommended target glycosylated hemoglobin (A1c, %) level of 7% or below (Casagrande et al., 2013). Uncontrolled diabetes leads to deleterious complications, such as retinopathy, neuropathy, and nephropathy(Fox et al., 2004). Its complications are a global health emergency. Annual global health expenditure on diabetes is estimated at around USD 760 billion. It is projected to reach USD 825 billion by 2030 and increase to USD 845 billion by 2045 (International Diabetes Federation, 2019). Furthermore, the WHO projects that diabetes will be the seventh leading cause of death in 2030 (Mathers & Loncar, 2006).

As the prevalence of type 1 and type 2 diabetes continues to rise worldwide, more individuals and families are living with the challenge of integrating an exhausting, complex, and long term regimen into their lives to control their progressive illness and prevent diabetes complications (Gonzalez et al., 2016). Indeed, the management of diabetes mellitus is challenging for both patients and clinicians. To successfully self-manage, diabetes patients must have high levels of health literacy and numeracy. Clinicians often advocate lifestyle change including diet, exercise, interpreting blood glucose trends, adjusting medication doses within brief clinic visits and sometimes engaging with patients who may have a limited understanding of their condition or treatment plan (Shan et al., 2019).

Long-term medication use and lifestyle changes are necessary for the successful management of both type 1 and type 2 DM (Gonzalez et al., 2016). The diverse lifestyle changes requirements for the self-management of diabetes including regular medication taking, self- monitoring of blood glucose (SMBG), changes in diet and physical activity, foot self-care, and visits with health care providers are detailed elsewhere in this issue (Gonzalez et al., 2016). Traditionally, self-management support for diabetic patients comprised face-to-face patient education using printed materials, demonstrations or videos (Binte et al., 2019). Therefore, effective tools to support patients in their self-management to enhance the quality of life and help to reduce complications are needed.

The rise of mobile-based applications (apps) over the past decade has led to increasing interest in using this technology to assist patients or clinicians in chronic disease management such as diabetes mellitus. Diabetes mobile-based applications as an emerging set of technologies are a promising tool for self-management. This technology combines the functions of the mobile phone, wireless network for data transmission, and sometimes HCPs for providing feedback (Hou et al., 2016). Accordingly, the American Diabetes Association (ADA) has stated that mobile apps may be a useful element of effective lifestyle modification to prevent diabetes (American Diabetes Association, 2017).

The purpose of diabetes apps is increasing the patient's self-management skills by storing personal data, such as glucose, hemoglobin A1c or glycated hemoglobin (HbA1c), blood pressure, body weight etc., and facilitating them in making treatment decisions by utilizing pre-stored validated algorithms (Doupis et al., 2020). Most of them provide services such as glucose and meal tracker, insulin calculator, planned physical activity, and health education presented in the form of diaries, pictures, videos or animations (Doupis et al., 2020; Veazie et al., n.d.). Some applications have facilitated real-time communication between a healthcare professional and the patient (Diabetes Diary (Skrøvseth et al., 2015), Diabetes Interactive Diary (Rossi et al., 2013), D-Partner (Doupis et al., 2020), Diabeo (Jeandidier et al., 2018), Diabetes Pal (Bee et al., 2016b), and BlueStar (Agarwal et al., 2019)). However, most of them have not been approved by the US Food and Drug Administration (FDA) or other corresponding regulatory authorities and BlueStar was the first mobile app-based in the USA to be given FDA approval as a mobile prescription therapy (Doupis et al., 2020).

There was current uncertainty on the clinical and psychological effectiveness of diabetes apps and limited research on the mechanisms of patient engagement, including use by specific populations. Previous studies have shown that the use of diabetes applications is currently limited because they fail to assess patient engagement among older adults with diabetes (Quinn et al., 2015). So, the aim of this paper is to systematically review the effectiveness of mobile app-based self-management interventions on clinical and/or psychological outcomes in patients with type 1 and type 2 diabetes.

MATERIALS AND METHODS

Data Sources and Search Strategy

The PRISMA statement and checklist was followed. Five databases were used in the searching process: Scopus, Medline, CINAHL, and Proquest for studies published between 1 January 2016 and 1 January 2020. The terms "Diabetes mellitus" AND "self-management" AND "mobile applications" OR "mobile based" OR "smartphone" were used during the search.

Inclusion and Exclusion Criteria

We included studies that were randomized controlled trials (RCTs) and that met the following inclusion criteria. 1) Study participants were patients who were age 14 years and above with a confirmed diagnosis of type 1 and type 2 diabetes mellitus. 2) Studies evaluated the effectiveness of the mobile app-based self-management interventions. 3) Studies separated participants into at least one group receiving mobile app-based self-management interventions and one group receiving usual care. 4) Studies that investigated at least one of the following outcomes: self-efficacy, self-care activities, health-related quality of life and/or clinical outcomes, such as glycated hemoglobin (HbA1c), fasting blood glucose, body mass index (BMI), and blood pressure. We excluded studies wherethe participants were pregnant women who required different therapeutic strategies. We also excluded studies that used qualitative data as an outcome measure, were not written in English, and did not use mobile app-based technology for diabetes self-management purposes.

Study Selection

The results of the systematic searches were imported into a reference manager, Mendeley software. Duplicates were removed using the software and manual. Then, we independently screened the titles and abstracts of the studies and categorized them into

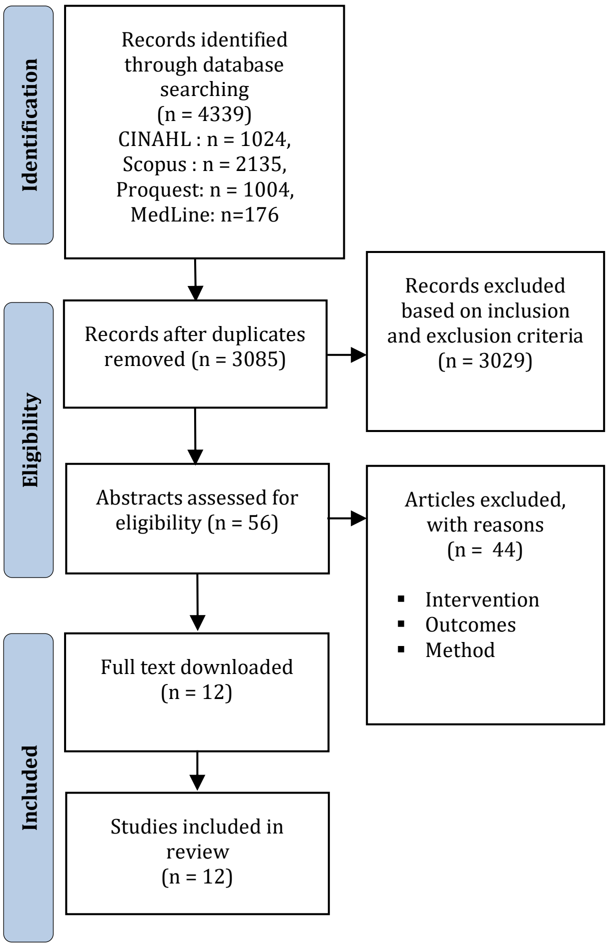

Figure 1. PRISMA flowchart of included studies.

those that meet, potentially meet or do not meet the eligibility criteria. Studies with titles and abstracts deemed irrelevant and that did not meet the eligibility criteria were thus removed. The full texts of those that met or could potentially meet the eligibility criteria were retrieved.

Risk of Bias Assessment

The quality of the studies in this review was analyzed by reviewers. The risk of bias was assessed using the Cochrane risk of bias tool for randomized controlled trial (Cochrane, 2016). We used a study's overall risk of bias as a determinant measure for three quality categories: low risk of bias meant a study was likely high quality, a moderate risk of bias meant a study was likely moderate quality, and a high risk of bias meant a study was likely low quality.

RESULTS

These studies examined only type 1 diabetes, only type 2 diabetes or both type 1 and type 2 diabetes. The main characteristics of the 12 studies identified in this systematic review are summarized in Table 1.

Study and participant characteristics

We identified two studies from the twelve evaluating mobile applications only for type 1 diabetes mellitus (Agarwal et al., 2019; Garg et al., 2017), eight studies evaluating mobile applications only for type 2 diabetes mellitus (Agarwal et al., 2019; Anzaldo-Campos et al., 2016; Bee et al., 2016b; Boels et al., 2019; Chao et al., 2019; Dugas et al., 2018; Franc et al., 2019; Kusnanto et al., 2019), two evaluating mobile applications for both type 1 and type 2 (Gunawardena et al., 2019; L. Zhang et al., 2019). The size of the study ranged from 29 to 330 participants. Participants ranged in mean age from 14 to 80 years old and had had diabetes for an average of no more than 3 years. Average of baseline HbA1c more than 7.0 was measured with laboratorium standard method or a single automated glycohemoglobin analyzer then the result was recorded in the application. Study length and length of time that participants used the apps and also an evaluation of the interventions ranged from 3 to 12 months. For most studies, the intervention group used the app with additional support from a clinician doctor or nurse diabetes educator. The control group typically received usual care, standard education, or use of a paper diary and the comparison group (intervention group) used diabetes mobile-based apps.

Risk of Bias

Of the 12 RCT studies, nine were found to have low to moderate risk of bias (Agarwal et al., 2019; Anzaldo-Campos et al., 2016; Boels et al., 2019; Castensøe-Seidenfaden et al., 2018; Chao et al., 2019; Dugas et al., 2018; Gunawardena et al., 2019; Kusnanto et al., 2019; L. Zhang et al., 2019), and 3 had a high risk of bias (Bee et al., 2016a; Garg et al., 2017; Jeandidier et al., 2018)

Features

Common features of apps for diabetes management included the ability to track health data such as blood glucose, diet programs, prescriptions, and exercise, patient feedback such as reminders to take medication or measure blood glucose, and diabetes education such as foot care.

Impact on HbA1c

All studies assessed changes in HbA1c as the main outcome of interest and showed a reduction on HbA1c level but five studies were not statistically significant (Agarwal et al., 2019; Bee et al., 2016b; Boels et al., 2019; Chao et al., 2019; Dugas et al., 2018). DiaSocial app has no significant statistic in lowering HbA1c between-group comparison (Dugas et al., 2018).

Impact on lipid or total cholesterol

Two studies assessed the impact of diabetes application on lipid or total cholesterol (Anzaldo-Campos et al., 2016; L. Zhang et al., 2019). Those studies had better control of HDL or LDL level at month 3 and 6 (all $p<.05$) but no significant differences were observed (all $p>.05$).

Table 1. General characteristic of selected studies (n=12)

Category	n	%
Year of publishing		
2016	2	16.6
2017	1	8.3
2018	2	16.6
2019	7	58.3
Type of DM		
T1DM	2	16.6
T2DM	8	66.6
T1DM and T2DM	2	16.6
Participants Age		
Adolecense	4	33.4
Adult	8	66.6

**DM: Diabetes mellitus: T1DM: Type 1 Diabetes mellitus: T2DM: Typ2 2 Diabetes mellitus*

Impact on body mass index

Three studies assessed the impact of diabetes application on body mass index (BMI) (Anzaldo-Campos et al., 2016; Boels et al., 2019; L. Zhang et al., 2019). No significant differences were founded for BMI in all those studies in this review (all p>.05).

Impact on hypoglycemia event

Three studies assessed the impact of diabetes application on hypoglycaemia events (Bee et al., 2016b; Boels et al., 2019; Castensøe-Seidenfaden et al., 2018). The hypoglycemic event was marginally lower in the intervention group, but this difference was also not statistically significant and no severe hypoglycemia was reported.

Impact on psychological aspects

We identified four studies from twelve that assessed psychological aspects such as self-efficacy, depression, quality of life, knowledge, and adherence (Agarwal et al., 2019; Anzaldo-Campos et al., 2016; Chao et al., 2019; Kusnanto et al., 2019). The impact of self-efficacy has increased through the use of DM-calendar apps and there was improved behavior of good self-management referred from National Standards Diabetes Self-Management Education (DSME) (Funnell et al., 2010; Kusnanto et al., 2019). A significant interaction effect was also observed for diabetes knowledge but not for any of the other self-reported outcomes: self-efficacy, depression, lifestyle, and quality of life (all P values >0.05) (Anzaldo-Campos et al., 2016). But other studies stated that the results of the case group was better than those of the control group, especially those for knowledge score (P=.05) (Chao et al., 2019). Participants at a high risk indicated a high motivation to change and to achieve high scores in the self-care knowledge assessment.

DISCUSSION

Our findings suggest the significant glycated haemoglobin (HbA1C) reduction associated with SGM was probably due to the app's ability to continuously engage the participants in the dietary and exercise advice given by diabetes educators (Castensøe-Seidenfaden et al., 2018; Franc et al., 2019; L. Zhang et al., 2019). Patient engagement with technology, educational content and self-care behaviors influence outcomes of mobile app-based interventions. People living with diabetes are more likely to check their mobile phones or smartphones more than once a day (Gunawardena et al., 2019). This allows the mobile app to maintain the attention of an individual while managing symptoms of their illness to prevent further adverse outcomes or complications associated with diabetes such as retinopathy, neuropathy, nephropathy, foot ulcers, and other morbid conditions such as cardiovascular disease, chronic kidney disease, functional and cognitive decline, and even mortality. Another reason for this may be that patients generally show interest or enthusiasm toward treatment through mobile app advances that ease the burden imposed by traditional strategies to manage diabetic symptoms and complications. We believe this might be the driving reason for a more prominent effect of apps on A1C levels after 3 months of the trial.

In the other point of view, clinicians often direct patients to attend in-person diabetes self-management classes, which may be burdensome and this may be partly responsible for the low attendance rates (National Center for Chronic Disease Prevention and Health Promotion, 2015). Mobile-based application interventions for education and self-management generally provide holistic content, are targeted towards patients with type 1 or type 2 diabetes, and are informed by behavioral change theories (Orsama et al., 2013), such as the Information-Motivation-Behavioral Skills Model, social cognitive theory (Arora et al., 2014), motivational interviewing (Block et al., 2015) or the theory of planned behavior (Holmen et al., 2014). Patients are encouraged to monitor glucose, diet, insulin dosages, and exercise regularly, and this data can be used to adjust feedback messages sent through the application (Y. Zhang et al., 2018). The content of the messages includes diabetes education, health promotion, motivational messages, reminders for medications and, self-monitoring blood glucose, or specific behavioral changes to implement, which are

Table 2. Summary of selected studies

Author	Type of DM	Design	Sample	Variable	Result
(Anzaldo-Campos et al., 2016)	T2DM	Randomized controlled trial	301 participants were enrolled in the study and were allocated randomly: - 99 to Project Dulce-only (PD) - 102 to Project Dulce Technology Enhanced With Mobile Tools (PD-TE), - 100 to standart care/control group (CG)	Clinical: 1. Glycated haemoglobin (HbA1c) 2. Total cholesterol, low-density lipoprotein cholesterol (LDL-c), high-density lipoprotein cholesterol (HDL-c), triglycerides 3. Systolic blood pressure (SBP) 4. Diastolic blood pressure (DBP) 5. Body mass index (BMI) Self-reported: 1. Self-efficacy 2. Depression 3. Lifestyle 4. quality of life 5. diabetes knowledge	HbA1c reductions from baseline to month 10 were significantly greater in intervention groups. Significant improvement in diabetes knowledge when compared with control. No statistically significant differences were detected between PD and PD-TE on these indicators. Several within-group improvements were observed on other clinical and self-report indicators but did not vary significantly across groups.
(Gunawardena et al., 2019)	T1DM and T2DM	Randomized clinical trial	67 participants were randomized: - Smart Glucose Manager SGM (n = 27) - Control group (n = 25).	Glycated hemoglobin (HbA1C)	At the 6-month follow up, the SGM group had significant lower A1c levels than the control group. For both groups, A1c values decreased from baseline to the 3 months. From 3 months to 6 months, the SGM group showed further improvement of A1c, whereas the control group did not. A1c improvement was positively correlated with SGM usage.
(Dugas et al., 2018)	T2DM	Randomized control trial	29 participants were randomized: - usual care group (*n* = 5) - intervention group (*n* = 24)	1. Glycated hemoglobin (HbA1C) 2. Adherence	There were no differences in adherence levels across treatment conditions. Between group comparisons detected no significant effects on HbA1C change over time.
(Boels et al., 2019)	T2DM	Open two-arm multicenter parallel randomized controlled superiority trial	330 participants were randomized: - Intervention group (n=115) - Control group (n=115)	1. HbA1c 2. Hypoglycemic event 3. Body mass index 4. Glycemic variability 5. Dietary habits 6. Quality of life.	HbA1c level was slightly lower in the intervention group in both the unadjusted and the adjusted analysis, but this difference was not statistically significant. There was no effect on secondary outcomes included dietary habits and quality of life. No adverse events were reported.

Author	Type of DM	Design	Sample	Variable	Result
(L. Zhang et al., 2019)	T1DM and T2DM	prospective randomized controlled trial	276 participants were randomized: - control group (group A) (n=78) - app self-management group (group B) (n=78) - app interactive management group (group C) (n=78)	1. HbA1c 2. Fasting plasma glucose (FPG) 3. body weight 4. lipid	At months 3 and 6, all 3 groups showed significant decreases in HbA1c levels. Patients in the app interactive management group had a significantly lower HbA1clevel than those in the app self-management group at 6 months.
(Franc et al., 2019)	T2DM	randomized controlled trial	191 participants were randomized: - group 1 (standard care, n = 63) - group 2 (G2, interactive voice response system, n = 64) - group 3 (G3, Diabeo-BI app software, n = 64).	1. HbA1c levels 2. fasting blood glucose (FBG)	HbA1c levels decreased significantly more in patients from the intervention than in the control. HbA1c decreases from baseline were also significantly higher in G2 and G3 compared with the control. The glycaemic control target (HbA1c < 7.0%) was achieved in twice as many patients as in the control.
(Chao et al., 2019)	T2DM	Randomized controlled trials	121 participants were stratified randomized: - Case-group patients participated (n=62) - Control-group patients (n=59)	1. HbA1c 2. Self-knowledge 3. Self-care	The associated clinical outcomes in the case group with the mobile-based intervention were slightly better than in the control group. In addition, 86% (42/49) of the participants improved their health knowledge through the mobile-based app and information and communications technology.
(Garg et al., 2017)	T1DM	Randomized controled trial	100 participants were stratified randomized: - control group (n=50) - intervention grup (n=50)	1. A1C 2. Complete metabolic panel 3. Complete cell counts	There was a decrease in A1c among both the control and intervention groups at 3 months, although the amount of change in A1c was not different between groups. However, at 6 months, there was a significant decrease in A1c from baseline only in the intervention group.
(Kusnanto et al., 2019)	T2DM	randomized controlled trial	30 participants were randomized: - Control group (n=15) - Intervention group (n=15)	1. Self-efficacy 2. HbA1c	Education with DM-calendar media has increased the perception of self-efficacy and improved the behavior of good self-management that can be seen from changes in controlled HbA1c level, lipid profile and insulin.
(Agarwal et al., 2019)	T2DM	Multicenter Pragmatic Randomized Controlled Trial	240 participants were randomized: - immediate treatment group (ITG) (n=110)	1. HbA1c 2. Patient self-management 3. experience of care	The results of an analysis of covariance controlling for baseline HbA1c levels did not show evidence of intervention impact on HbA1c levels at 3 months. Similarly, there was no

Author	Type of DM	Design	Sample	Variable	Result
			- control group (n=113)	4. self-reported health utilization	intervention effect on secondary outcomes measuring diabetes self-efficacy, quality of life, and health care utilization behaviors.
(Castensøe-Seidenfaden et al., 2018)	T1DM	Randomized Controlled Trial	151 Participants were randomized: - intervention group (n=76) - control (n=75)	1. HbA1c 2. Hypoglycemia 3. Hospitalizations	At 12 months, HbA1c was significantly higher in the intervention group. The apps did not improve HbA1c, but it may be a useful tool for complementing self-management in young people with T1DM. This finding did not occur when comparing app users with nonusers. Most young people and half of the parents reported that the apps helped them.
(Bee et al., 2016b)	T2DM	A Pilot Randomized Controlled Trial	66 participants were randomized: - intervention group (n =33) - control group (n=33)	1. fasting plasma glucose 2. HbA1c 3. Hypoglycemia	Reductions from baseline were numerically greater in the intervention group at allthree follow-ups, mean reduction of HbA1c from baseline was numerically greater in the intervention group than the control group with no significant difference between groups.

usually sent automatically according to an algorithm (Schramm, 2018; Shan et al., 2019).

Previous studies showed that performance expectancy had the strongest direct effect on behavioral intention (Y. Zhang et al., 2019). Furthermore, novel mobile apps should aim to initiate behavioral changes and treatment adjustments in a positive way for both clinical and psychological outcomes, considering that diabetes is a chronic and complicated disease in which glycemic management alone may not be enough to improve health outcomes (Modzelewski et al., 2018). Other evidence indicates that the use of some mobile apps with additional support from a healthcare provider or study staff may be useful in improving short-term outcomes, especially HbA1c, compared with controls for both type 1 and type 2 diabetes (Veazie et al., n.d.). This study suggests that mobile apps have the potential to improve diabetes self-management skills in patients with diabetes mellitus both type 1 or type 2. But, there is limited evidence that the use of apps improves other important outcomes such as quality of life, depression, blood pressure, weight, or body mass index (BMI) (Holmen et al., 2014), (Pramanik et al., 2019).

Emerging evidence shows that mobile apps provide benefits for diabetes treatment after an average of 3 months. Similar with we have found in this review, previous studies by Osborn et al. found that both type 1 and type 2 diabetes patients reported a mean A1C reduction over 4 months using an app called One Drop (Osborn et al., 2017). However, this reduction was detected not in a randomized trial design but an observational setting. In addition, diabetes-related complications such as neuropathy, retinopathy, or hypertension were not measured, so we could not determine if the use of the apps reduced their incidence or severity and also assess what components of the mobile-apps based were most associated with long-term compliance to the management of diabetes. So, further research must explore many aspects that have not been reviewed in previous studies both clinical and psychological output.

CONCLUSION

Most of the reviewed mobile-app-based diabetes management tools have been shown to positively effect outcomes, including HbA1c levels, hypoglycemia rates, cholesterol level, self-efficacy, quality of life, diabetes knowledge and more. Giving that, now the need for individualized or self-care management for patients with diabetes is more evident than ever.

The development and evaluation of more comprehensive mobile apps that allow logging of glucose readings, calculation of carbohydrates and insulin doses, incorporate reminders for medication, support education to prevent complications, and provide feedback are warranted and should incorporate both patient and clinician feedback on lifestyle or workflow integration, respectively, as well as usability and content. Thus, further long-term, multicenter studies are necessary to prove the long-term impact of the available applications today, while continuing efforts should target the development of the ideal mobile-app based self-management tool for diabetes. Hence, guidelines from scientific organizations and authorities in the field of mobile health are also necessary to successfully carry on the programs.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

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