Original Article

The Impact of mHealth Apps in the Self-Management of Diabetes Mellitus type 2: A Systematic Review

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Abstract
Introduction: Self-management in type 2 diabetes mellitus is crucial for reducing costs, improving patient empowerment and participation in treatment, while maintaining their well-being and quality of life. mHealth apps have the potential to support self-management of T2DM patients and improve their outcomes. Most studies investigate the effect of mHealth on the self-management of T2DM by measuring HbA1c levels as the main outcome.
Aim: This systematic review aimed to investigate the effectiveness of mHealth apps in the self-management of T2DM and their impact on patient outcomes. **Methodology:** The Pubmed and Scopus bibliographic databases were searched for relevant RCts. Target population was patients with T2DM.Eligibility criteria for interventions included intervention with the use of mHealth Apps for T2DM Self – Management. The primary expected outcome was changes in HbA1c levels or blood glucose levels, while the secondary outcome was an increase in physical activity.
Results: A total of eleven trials were identified and analyzed. Six RCTs examined the use of mHealth apps in T2DM self-management, while five RCTs focused on the use of text-message-based mHealth apps. In six trials (N=893), mobile app-assisted self-care interventions were not associated with significant reductions in HbA1c levels. In six RCTs, a significant reduction in HbA1c levels was observed in both control and intervention groups. Three RCTs yielded mixed results regarding the correlation between mHealth apps and physical activity. Furthermore, three RCTs demonstrated reductions in HbA1c levels when the app was combined with interactive online management, providing personalized, bidirectional feedback from physicians.
Conclusion: The association between HbA1c reduction and the use of mHealth apps in T2DM remains unclear. However, mobile health (mHealth) tools have shown promise in enhancing diabetes management through diverse interventions.

Keywords: mHealth App, Diabetes Mellitus type 2, Self-Management, HbAc1

Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia (Goyal & Jialal, 2023). According to The International Diabetes Federation Atlas (2021), approximately 10.5% of the adult population (aged 20-79 years) has diabetes, and nearly half of them are unaware of their condition. Projections by the IDF indicate that by 2045, approximately 783 million adults, or 1 in 8, will be living with diabetes, representing a 46% increase. Type 2 diabetes (T2DM) accounts for over 90% of diabetes cases and is influenced by socio-economic, demographic, environmental, and genetic factors(International Diabetes Federation. IDF Diabetes Atlas, 10th ed. Brussels, 2021). While T2DM was traditionally associated with individuals aged 45 and above, it is now increasingly prevalent among children, adolescents, and younger adults due to the rise in obesity rates, sedentary lifestyles, and diets high in calories (Goyal & Jialal, 2023).

As healthy behaviors have an impact on disease outcomes, approaches to support and sustain diabetes self-management are vital (Young et al., 2020). Self-management in type 2 diabetes mellitus is central to reducing costs, improving patient empowerment and participation in treatment without reducing patients' well-being and quality of life (Isaksson et al., 2015). The term self-management is generally used to describe the active involvement of patients in their medical treatment (Sherifali et al., 2013). From the patient's perspective, self-management has been described as, learning from one's own reactions to illness and treatment through experiences of daily life, restructuring one's identity and through exploring one's personal limitations (Kralik et al., 2004). Cultural aspects of self-management and gender norms could imply such limitations. A study by Svennigsson et al. (2011) reported differences in quality of life between men and women after diagnosis of the disease, where it appeared that women experienced more limitations and saw the disease as more unbearable and more difficult to cope with than men. Self-management for patients with TDM2 involves taking responsibility for achieving normal blood glucose levels, implementing a healthy diet, exercising and taking prescribed medications correctly. However, these are situations that may need further support.In some geographical areas where access to healthcare may be limited (e.g. rural areas) support from family members becomes important it is suggested that not only newly diagnosed people with DM2, but all should be offered group-focused support, enhancing patient empowerment (Isaksson et al., 2015).

According to the N.I.C.E (National Institute for Health and Care Excellence., 2019) the objectives of diabetes self-management education programs are categorized into four areas.

1. Improving knowledge, health beliefs and lifestyle changes (healthy eating, weight management, physical activity, stress management and smoking cessation).

2. Improvement in clinical and psychosocial patient outcomes, for example: body weight, HbA1c levels, lipid levels, smoking and psychosocial changes such as quality of life and depression levels.

3. Improvement in physical activity levels

4. Reducing the need for, and possibly better targeting of, medications and other items such as capillary glucose monitoring strips.

The term mHealth, short for mobile health, refers to the use of mobile devices, such as smartphones and tablets, for healthcare purposes. An mHealth app is a mobile application designed to provide health-related services, information, or tools to users (Bene et al., 2019). Mobile health (mHealth) solutions, which include mobile applications (apps), have been rapidly gaining popularity in the management of chronic diseases and have further created opportunities and potential to enhance the ability of T2DM patients for self-management (Bene et al., 2019). Recent mHealth interventions directed at patients with T2DM have different goals and features, including insulin management apps, portable blood glucose meters, automated text messages, health diaries and virtual health guidance (Shan et al., 2019). Short message service (SMS) texts have also shown promise as a low-cost intervention

(Farmer et al., 2021). A system that combines technology and web-based coaching can help treat chronic conditions such as diabetes. However, the effectiveness of apps in mobile health (mHealth) interventions is inconclusive and unclear due to heterogeneous interventions and varying follow-up durations (Owolabi et al., 2019). Many studies investigate the effect of mHelath on the self-management of T2DM by measuring HbA1c levels as the main outcome. A systematic review was conducted to investigate the effectiveness of mHealth apps in self-management of T2DM in improving patient outcomes.

Methodology: The PICO tool (Population, Intervention, Comparison and Outcomes) was used to identify components and terms of the search algorithm (*Table 1*). Using the PICO headings, the research question was formulated as follows: "In patients with Type 2 Diabetes Mellitus, does the use of mHealth Apps for T2DM Self-Management, compared to those receiving usual care, lead to improvements in one or more of the following outcomes: Blood Glucose levels, HbA1c levels or Physical Activity?"

Design: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was used as the basis for conducting and reporting this systematic review (Moher et al., 2009).

Table 1: Search categories and PICO Headings

Search categories	PICO Headings
Patients with Diabetes Mellitus 2	**P**opulation
mHealth Apps Self-Management Support	**I**ntervention
Standard Self-Management Support	**C**omparison
Improvement in HbAc1, blood glucose levels or Physical Activity	**O**utcome

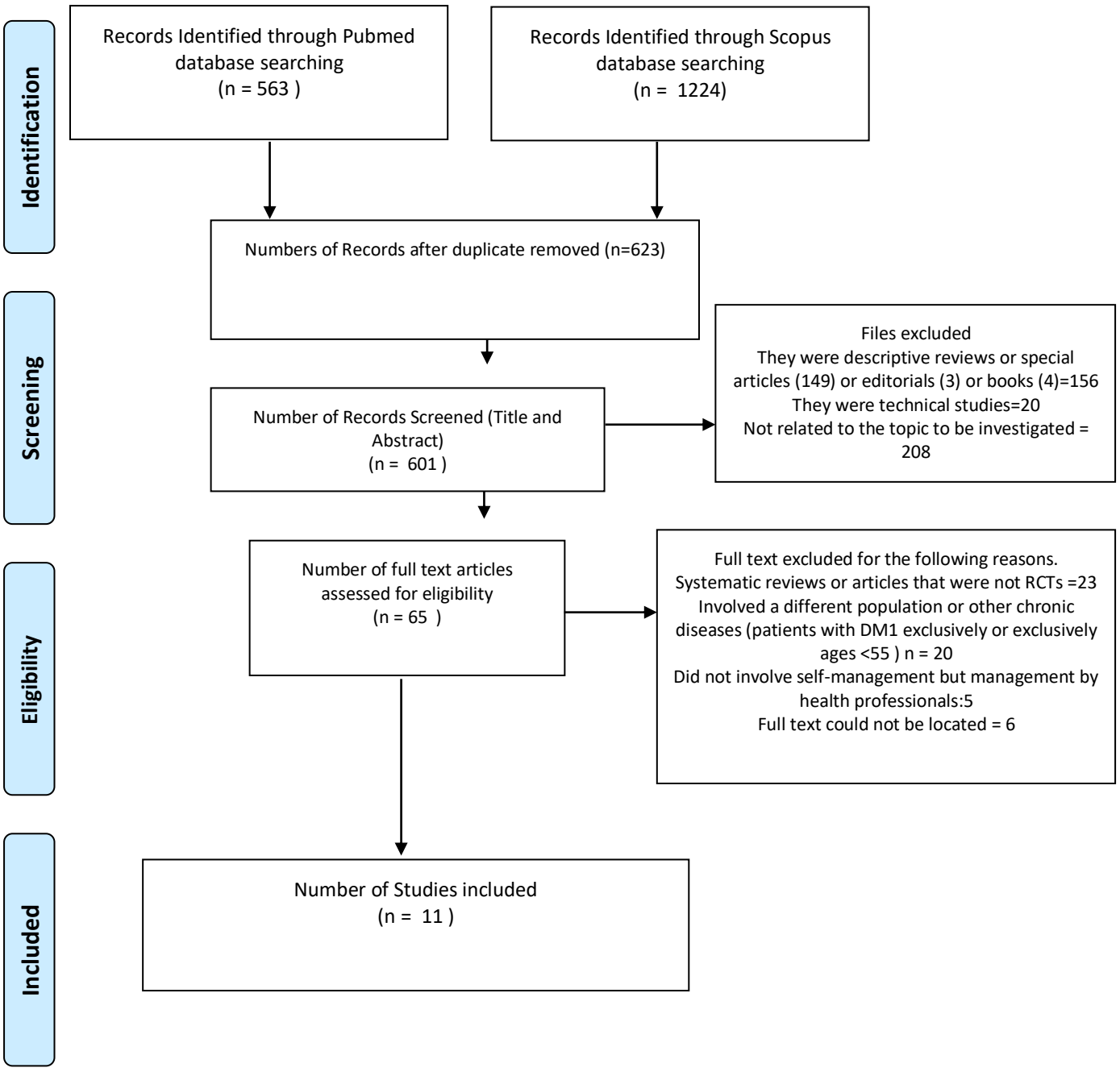
Inclusion and exclusion criteria: Only Randomized Controlled Trials were included of the last 10 years. Target population was patients with Diabetes Mellitus 2 with poorly controlled or non-controlled diabetes aged 18 and above. Eligibility criteria for interventions included intervention with the use of mHealth Apps for T2DM Self – Management in a group of Patients with Diabetes Mellitus 2 and compare it with a group of patients that received usual care. The outcome measures of the included studies focused on at least one of the following measurable outcomes: HbA1c levels, Blood Glucose levels, or Physical Activity. Only studies written in the English language with full-text availability were included. Studies where mHealth apps were used solely by health professionals and not by the patients themselves were excluded from the analysis.

Search strategy: The Pubmed and Scopus bibliographic databases were searched for relevant studies. The keywords used were: patients (self-management OR care) AND (diabetes) AND (app OR mHealth OR Digital Health) in the last 10 years . The Prisma Statement flowchart was used to evaluate the information through the different phases of a systematic review (Moher et al., 2009).

Search Outcomes: The initial search across the two databases resulted in a total of 1787 publications. Upon reviewing the titles and abstracts of these publications for content and relevance to the review's objectives, 65 publications were deemed suitable and their full texts were obtained. However, after

conducting a thorough examination of the full texts, 54 publications were excluded, as illustrated in Diagram 1. Ultimately, 11 publications were selected and retained for inclusion in this systematic review.

Diagram1. Flow of information through the different phases of the systematic review.PRISMA Flow Diagram.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Quality appraisal: A quality appraisal of publications included in this review was undertaken using CASP Randomised Controlled Trial Standard Checklist which is not a scoring system but it is mostly an appraisal tool (Critical Appraisal Skills Programme (CASP) Randomised Controlled Trial, 2020). The CASP appraisal tool checks 4 major sectors: Is the basic study design valid for a randomised controlled trial? (Section A) Was the study methodologically sound? ((Section B) What are the results? (Section C) Will the results help locally? (Section D). RCts were appraised separately based on 11 CASP questions that checked the previous sections (0 for no/can't tell and 1 for yes) with scores of 8–11 considered to reflect high quality, 5–7 moderate quality and scores of 4 or less, low quality. All reviewed papers were found to be high quality.

Results

A total of eleven trials were identified and analyzed *(Table 2,Table 3).* One RCT have not announced results yet (Bonn et al., 2018). Two trials were conducted in USA, two in China, two in South Africa and one in Korea, Sweden, Sri Lanka and Spain. All RCts examined different kind of mHealth apps. Nine studies were two-arm RCts while two were three-arm RCts. Six RCTs investigated the use of an mHealth app in self-management of T2DM as shown in *Table 2* (Agarwal et al., 2019; Bonn et al., 2018; E.-Y. Lee et al., 2021; Li et al., 2021; Young et al., 2020; Zhang et al., 2019). The other five investigated the use of an text-message mHealth app in self-management of T2DM as shown in *Table 3* (Farmer et al., 2021; Gunawardena et al., 2019; Owolabi et al., 2019; Xu et al., 2020; Zamanillo-Campos et al., 2023) .In all trials outcomes were measured in baseline, in three months, in six months and in nine months depending on the duration of the study.

Table 2. RCTs that investigated the use of mHealth app in self-management of type 2 Diabetes Mellitus (T2DM)

Study, Setting and Sample Size	Study Design	Aim	Summary of Intervention	Summary of Findings	Risk of Bias Assesment
1. Bonn et al. 2018 Sweden **N=250**	**12-week two-arm, Randomized Control Trial,** patients with T2DM >18.	To evaluate a digital healthcare platform and the effect of a 12-week long smartphone-app physical activity intervention aiming at increasing physical activity (primary outcome) and improve levels of HbA1c (glycated hemoglobin), in patients with diabetes type 2.	**Two groups compared.** *Intervention group (N=125)* will the smartphone-app, during 12 weeks *Control Group* (N=125) **Primary outcome:** Physical Activity **Secondary Outcomes:** *HbA1c*, blood lipids, self-efficacy, Quality of Life.	Protocol only. Not announced yet	
2. Agarwal et al. 2019 Canada **N=223**	**6-month two-arm Randomized Control Trial**, patients with T2DM >18.	To determine if the use of an mHealth app (Bluestar app) leads to improved HbA_{1c} levels among diverse participants in real-life clinical contexts.	**Two groups compared.** *Intervention group* (N=110) received the intervention for 6 months, and *control group* (n=113) received usual care for the first 3 months and then received the intervention for 3 months. **Primary outcome:** *HbA_{1c} levels at 3 months.* **Secondary outcomes:** *Self-management,* Experience of care, and Self-reported health.	*No difference* between intervention and control-group for the primary clinical outcome of glycemic control measured by HbA_{1c} levels.	High dropout rate. Low app usage.

Study, Setting and Sample Size	Study Design	Aim	Summary of Intervention	Summary of Findings	Risk of Bias Assesment
3. Zhang et al. 2019 China **N=276**	**6-month three-arm, Randomized Controlled Trial,** patients with T1DM and T2DM 18-65.	To investigate the effectiveness of an app-based interactive management on glycemic control in patients with poorly controlled diabetes.	**Three groups compared.** *Group A* (n=78) received usual care without installing the app. *Group B* the self-management group (n=78) installed the smartphone-app, on their smartphones and *Group C* (n=78) besides app self-management, received interactive management online **Outcome:** *HbA1c levels changes.*	*No differences* in HbA1c reduction were observed between the app self-management and control groups at both months 3 and 6 (both P>.05). At months 3 and 6, all three groups showed significant decreases in HbA1c levels (all P<.05). Group C had a significantly lower HbA1c level than those in Group B at 6 months (P=.04). Multivariate line regression analyses also showed that the app interactive management group was associated with the larger reduction of HbA1c compared with groups A and B at both months 3 and 6 (all P>.05).	Unable to assess the long-term effects. Only those aged less than 65 years were enrolled.
4. Young HM et al. 2020, USA **N=287**	**9-Month two-arm, Randomized Controlled Trial,** patients with T2DM >18.	To evaluate the effectiveness of a nursing coaching program using motivational interviewing combined with mobile health technology (mHealth) on diabetes self-efficacy and self-management for people with T2DM.	**Two groups compared.** *Standard care group* (n=155), *Intervention group* (n=132) that included nurse-led health coaching and mHealth technology electronic health record at baseline, 3 months and 9 months. **Outcomes:** *Physical activity*,*Diabetes Self-Efficacy*, Depression	*Physical activity increased significantly in the intervention group* (from 23,770 steps per week to 39,167 steps per week at 3 months and 32,601 steps per week at 9 months).Significant improvements in diabetes self-efficacy (Diabetes Empowerment Scale, 0.34; 95% CI -0.15,0.53; P<.01) and reduction in depressive symptoms compared with usual care at 3 months (Patient Health Questionnaire-9; 0.89; 95% CI 0.01-1.77; P=.05), with no differences in other outcomes.	Sample might be biased to those ready to change. Older patients are not so exposed to new technology.
5. Li et al. 2021 China **N=85**	**3-month two-arm Randomised Control Trial** with patients with uncontrolled T2DM without severe complications or comorbidities >18.	To determine the efficiency of exercise using a fitness app and heart rate band to remotely monitor patients with type 2 diabetes in comparison with that of traditional exercise.	**Two groups compared.** *Control Group (N=41)* engage in moderate to vigorous physical activity for at least 150 minutes per week; each participant was prescribed individualized exercises.received and *Intervention Group (N=44)*follow exercise videos on the app and to wear a chest band; heart rate, exercise duration, and exercise intensity were recorded by the app *(N=65)* FBG data. **Outcomes:** *HbA_{1c} and fasting blood glucose (FBG)*, cardiorespiratory endurance, body fat percentage	*There was no difference in hemoglobin A1c level reduction between the two groups.* Both groups had clinically meaningful reductions in HbA1. Although self-reported exercise duration was longer than app-recorded exercise duration participants in the intervention group demonstrated greater improvements in cardiorespiratory endurance and greater reductions in body fat percentage.	Baseline differences between groups. Participants in the control group were older.
6. Lee EY et al. 2022, Korea **N=234**	**6-Month three-arm, Randomized Controlled Trial,** patients with T2DM and a hemoglobin A_{1c} (HbA_{1c}) ≥7.5%	To evaluate the effectiveness of a mobile phone application integrated into the electronic medical record on personalised diabetes self-care, focusing on self-monitoring of blood glucose and lifestyle modifications.	**Three groups compared.** Usual care group (*UC group*), mobile diabetes self-care (*MC group*), and MC with personalized, bidirectional feedback from physicians *(MPC group) iCareD* **Outcome:** HbA_{1c} levels	*HbA_{1c} decreased significantly* after the intervention in the MPC group compared with the change in the UC or MC group, especially in patients aged <65 years (P=.02), patients with a diabetes duration of ≥10 years (P=.02), patients with a BMI of ≥25.0 kg/m^2 (P=.004), patients with a C-peptide level of ≥0.6 ng/mL (P=.008), and patients who did not undergo treatment with insulin (P=.004) at 12 weeks.	Small sample Size.

Table 3. RCTs that investigated the use of text-based mHealth app in self-management of type 2 Diabetes Mellitus (T2DM)

Study, Setting and Sample Size	Study Design	Aim	Summary of Intervention	Summary of Findings	Risk of Bias Assesment
1. Gunawardena et al. 2019 Sri Lanka N=52	**6-month two-arm Randomised Control Trial** with T2DM patients with uncontrolled T2DM 18-80.	To examine the efficacy of a mobile application, (Smart Glucose Manager-SGM), in patients with diabetes.	**Two groups compared.** *Control Group (N=25)* received usual care and *Intervention Group (N=27)* received usual care + one text messages per day. **Outcomes**: HbA_{1c} Blood glucose, blood pressure and anthropometric measurements followed standard procedure.	The 6-month follow up, the SGM group had significant lower A1c levels than the control group (7.2% vs 8.17%, P < .0001). For both groups, A1c values decreased from baseline to the 3 months (SGM: 9.52% to 8.16%, P < .0001; control: 9.44% to 8.31%, P < .0001). From 3 months to 6 months, the SGM group showed further improvement of A1c (-0.96% P < .0001), whereas the control group did not (P = 0.19). A1c improvement was positively correlated with SGM usage (R = .81, P < .001).	Small sample size. Not including vulnerable populations such as those with comorbid conditions or steroid induced diabetes.
2. Owolabi et al. 2019 South Africa N=216	**12-month two-arm Randomised Control Trial** with T2DM patients with uncontrolled glycaemic status>18.	To determine the efficacy, acceptability and feasibility of text-messaging in improving glycaemic control.	**Two groups compared.** *Control Group (N=108)* received usual care and *Intervention Group (N=108)* received usual care + one text messages per day. **Outcomes:** *Blood glucose*, blood pressure and anthropometric measurements followed standard procedure	*No significant effect* to the mean change of blood glucose in the intervention group 0.26 (-0.81 to 1.32 p = 0.634). Both groups of the study showed improvement in their blood glucose levels.	Low income patients could not possessed a mobile phone so they excluded from the study.
3. Farmer et al. 2020 South Africa, Malawi N=1186	**12-month two-arm Randomised Control Trial** with T2DM patients>18.	To test the effectiveness of SMS-text messaging in improving outcomes in adults with T2DM (StAR2D).	**Two groups compared.** *Control Group* received usual care (N= 593) and *Intervention Group* received usual care + four text messages per week. **Primary outcome:** *HbA1c levels changes* **Secondary Outcomes:** Changes in systolic blood pressure, lipids, cardiovascular risk, and the proportion of the participants reaching treatment goals.	*No differences* in HbA1c mean change were observed between groups (95% CI) (− 0.08% (− 0.31 to 0.16) (IFCC − 0.82 mmol/mol (− 3.44 to 1.79). There was a reduction in HbA1c in both groups.	Wide inclusion criteria including participants with comorbid conditions.
4. Xu et al. 2020 USA N=130	**6-month two-arm Randomised Control Trial** with uncontrolled T2DM patients >18	To examine the effect of an SMS and phone call-based intervention (ExpDiabetes)t hat allows for bidirectional patient–provider communication In reducing HbA_{1c} and fasting blood glucose (FBG) among patients with type 2 diabetes mellitus (T2DM).	**Two groups compared.** *Control Group (N=65)* received usual care and *Intervention Group (N=65)* used an Mhealth intervention (ExpDiabetes) that collected Self-reported FBG data. **Outcomes:** *HbA_{1c} and fasting blood glucose (FBG).*	*There was a statistically significant HbA_{1c} reduction of 0.69% in the intervention group* (95% confidence interval [CI], -1.41 to 0.02) and an absolute reduction of 0.03% in the control group (95% CI, -0.88 to 0.82). For those with baseline HbA_{1c} >8%, HbA_{1c} decreased significantly by 1.17% in the intervention group (95% CI, -1.90 to -0.44), and decreased by 0.02% in the control group (95% CI, -0.99 to 0.94). FBG decreased in the intervention group by 21.6 mg/dL (95% CI, -37.56 to -5.639), and increased 13.0 mg/dL in the control group (95% CI, -47.67 to 73.69).	Small sample size.
5. Rocío Zamanillo-Campos et al. 2023 Spain N=179	**3-month two-arm, Randomized Control Trial with** patients with T2DM >18 and a HbA1c > 8%.	To develop and investigate the effectiveness of an Mhealth text message app to support diabetes self managemenet and glycaemic control.	**Two groups compared.** *Control Group* received usual care and *Intervention Group* (DiabeText group) received usual care + five text messages per week. **Outcomes:** *HbA1c mean levels; physical activity;* adherence to Mediterranean diet.	*No differences between-groups were observed* in mean HbA1c (p = 0.670). Non-statistically significant differences (p > 0.05) in physical activity (1.7; 0.9 to 3.1).	Relatively small sample size.

Measured Outcome: Reduction in HbA1c

Eight randomized controlled trials (RCTs) evaluated changes in HbA1c levels as the primary outcome. Among these trials, six of them (N=893) investigated mobile app-assisted self-care interventions but did not find significant reductions in HbA1c levels. In these six trials, no statistically significant differences between the intervention and control groups were observed at three, six, or nine months (Agarwal et al., 2019; Farmer et al., 2021; Li et al., 2021; Xu et al., 2020; Zamanillo-Campos et al., 2023; Zhang et al., 2019). However, in two other RCTs (N=286) conducted by Gunawardena et al. (2019) and E. Y. Lee et al. (2022), statistically significant differences were found between the intervention and control groups regarding reductions in HbA1c levels after six months. It's important to note that one of these two trials had a relatively small sample size (N=52) (Gunawardena et al., 2019).

In three-arm trials, a third group (Group C) was included. Group C was exposed not only to the use of a self-management app but also received interactive management online with personalized, bidirectional feedback from physicians (E. Y. Lee et al., 2022; Zhang et al., 2019). Both trials reported a significant decrease in HbA1c levels after the intervention in the group of patients that received interactive management online with personalized, bidirectional feedback from physicians compared to Group B, which only had exposure to the self-management app.

Moreover Zhang et al. (2019) reported that Group C (App +interactive) had a significantly lower HbA1c level than those in Group B (only App) at 6 months (P=.04). Multivariate line regression analyses also showed that the app interactive management group was associated with the larger reduction of HbA1c compared with groups A (control group) and B (only app) at both months 3 and 6 (all P>.05). Lee et al.(2022) also reported that HbA1c decreased significantly after the intervention in Group C compared with the change in Groups A (control group) or B (app only group), especially in patients aged <65 years (P = 0.02), patients with a diabetes duration of ≥10 years (P = 0.02), patients with a BMI of ≥25.0 kg/m2 (P = 0.004), patients with a C-peptide level of ≥0.6 ng/mL (P = 0.008), and patients who did not undergo treatment with insulin (P = 0.004) at 12 weeks.

In Six RCts a significant reduction in HbA_{1c} were found in all groups (both in control and investigation groups) (Farmer et al., 2021; Gunawardena et al., 2019; E. Y. Lee et al., 2022; Li et al., 2021; Owolabi et al., 2019; Young et al., 2020).

Measured Outcome: Increase in Physical Activity

Physical Activity evaluated in three studies (Li et al., 2021; Young et al., 2020; Zamanillo-Campos et al., 2023).Young et al (N=287) found that *Physical activity increased significantly in the intervention group* (from 23,770 steps per week to 39,167 steps per week at 3 months and 32,601 steps per week at 9 months) while Li at al. and Zamanillo-Campos at al. reported non statistically significant changes in physical activity.

Other outcomes that were investigated were Self-efficacy, Depression, Blood Pressure, Body Mass Weight, Insulin Management, adherence to Mediterranean diet and blood Lipids, but there outside of the spectrum of interest of this review.

Significant bias was present in certain studies mainly in terms of the small number of participants (Gunawardena et al., 2019; Li et al., 2021). In other studies there were bias in terms of the age of the participants as due to digital illiteracy some age groups >65 were excluded from the intervention group or placed in control group. It appeared that older patients are not so exposed to new technology (E.-Y. Lee et al., 2021; Li et al., 2021; Zhang et al., 2019). In some cases the participants' financial ability to afford a mobile phone led to their non-participation in the intervention group (Gunawardena et al., 2019). No study was extended beyond nine months therefore it was unable to assess the long-term effects.

Discussion

A systematic review was conducted to investigate the effectiveness of mHealth apps in self-management of T2DM in improving

patient outcomes. The primary outcome of interest in the included studies was the change in HbA1c levels or blood glucose levels. Overall, the findings regarding the effectiveness of mHealth apps in reducing HbA1c levels were mixed.

An interesting finding that emerged during the search phase in the Scopus database was that the initial search yielded only 43 studies in 2014, but it increased to 198 studies in 2022. This may indicate a trend within the international scientific community regarding the conduction of such studies, as well as the trend towards the use of Mobile Health tools in the self-management of Type 2 Diabetes.

A total of eleven RCts were identified and analyzed. Six RCTs examined the use of mHealth apps in T2DM self-management, while five RCTs focused on the use of text-message-based mHealth apps.

Findings from six studies (N=893), demonstrated that mobile app-assisted self-care interventions were not associated with significant reductions in HbA1c levels (Agarwal et al., 2019; Farmer et al., 2021; Li et al., 2021; Xu et al., 2020; Zamanillo-Campos et al., 2023; Zhang et al., 2019). No statistically significant differences were found between the intervention and control groups after three, six, or nine months. On the other hand two studies did found statistically significant differences between the groups but with small sample size (N=286) (Gunawardena et al., 2019; E. Y. Lee et al., 2022).

A statistically significant reduction in HbA1c levels among both the intervention and control groups was showed in a significant number of trials (Farmer et al., 2021; Gunawardena et al., 2019; E. Y. Lee et al., 2022; Li et al., 2021; Owolabi et al., 2019; Young et al., 2020). This finding can be explained by the fact that these patients did not have regulated HbA_{1c} values so that the mere fact that they joined a self-management program, even with the usual self-management (without the use of mHealth apps), led them to a better regulation of diabetes mellitus compared to their previous status.

These mixed results suggest that the use of mHealth apps alone may not consistently lead to significant improvements in glycemic control. This suggestion may be supported even more by the fact that when the app was combined with interactive online management, providing personalized, bidirectional feedback from physicians a significant reduction in HbA1c levels was demostrated (E. Y. Lee et al., 2022; Zhang et al., 2019).

It is worth noting that the duration of the interventions varied across the included studies, ranging from three to nine months. This variation might have contributed to the inconsistent findings, as longer interventions could potentially have a greater impact on HbA1c levels. Moreover, the specific features and functionalities of the mHealth apps used in the studies may have influenced the outcomes.

In addition to glycemic control, physical activity was assessed as a secondary outcome in a subset of studies. The results regarding the impact of mHealth apps on physical activity were also inconclusive. While some studies reported an increase in physical activity levels with the use of mHealth apps, (Young et al., 2020) others did not find a significant association (Li et al., 2021; Zamanillo-Campos et al., 2023). This suggests that mHealth apps alone may not be sufficient in promoting sustained physical activity in individuals with T2DM.

Beyond HbA1c levels and physical activity, the included studies examined various other outcomes, including self-efficacy, depression, blood pressure, body mass weight, and insulin management. Although not consistently investigated in all studies, some reported positive effects on self-efficacy and depression outcomes, indicating that mHealth apps have the potential to enhance self-management skills and mental well-being among individuals with T2DM. However, further research is needed to establish more robust evidence in these areas.

However, it is essential to recognize the limitations of the existing evidence, such as the heterogeneity of interventions, study designs, and outcome measures, which make it challenging to draw definitive conclusions.

Conclusions

The findings of this systematic review suggest that while mHealth apps are trying to support self-management in individuals with T2DM, their effectiveness in improving patient outcomes, particularly glycemic control and physical activity, is still uncertain. Future research should focus on developing more standardized interventions, incorporating interactive elements and personalized feedback, and conducting long-term follow-ups to better understand the true impact of mHealth apps in T2DM self-management. Studiess that incorporated interactive elements, such as personalized feedback from healthcare providers, which showed promising results in improving glycemic control.

Although mHealth apps show promise in enhancing diabetes self-management, further well-designed studies are warranted to establish their effectiveness, determine optimal interventions characteristics, and identify the specific subpopulations that may benefit the most from these interventions. Such knowledge will be invaluable in guiding the development and implementation of future mHealth interventio

Disclosures

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References

Agarwal, P., Mukerji, G., Desveaux, L., Ivers, N. M., Bhattacharyya, O., Hensel, J. M., Shaw, J., Bouck, Z., Jamieson, T., Onabajo, N., Cooper, M., Marani, H., Jeffs, L., & Bhatia, R. S. (2019). Mobile App for Improved Self-Management of Type 2 Diabetes: Multicenter Pragmatic Randomized Controlled Trial. *JMIR MHealth and UHealth*, *7*(1), e10321. https://doi.org/10.2196/10321

Bene, B. A., O'Connor, S., Mastellos, N., Majeed, A., Fadahunsi, K. P., & O'Donoghue, J. (2019). Impact of mobile health applications on self-management in patients with type 2 diabetes mellitus: Protocol of a systematic review. *BMJ Open*, *9*(6). https://doi.org/10.1136/bmjopen-2018-025714

Bonn, S. E., Alexandrou, C., Hjörleifsdottir Steiner, K., Wiklander, K., Östenson, C.-G., Löf, M., & Trolle Lagerros, Y. (2018). App-technology to increase physical activity among patients with diabetes type 2 - the DiaCert-study, a randomized controlled trial. *BMC Public Health*, *18*(1), 119. https://doi.org/10.1186/s12889-018-5026-4

Critical Appraisal Skills Programme (CASP) Randomised Controlled Trial. (2020). CASP Randomised Controlled Trial Standard Checklist - casp-uk.net. *CASP Checklists Oxford*, *2020*, 1–7. http://www.casp-uk.net

Farmer, A., Bobrow, K., Leon, N., Williams, N., Phiri, E., Namadingo, H., Cooper, S., Prince, J., Crampin, A., Besada, D., Daviaud, E., Yu, L.-M., N'goma, J., Springer, D., Pauly, B., Tarassenko, L., Norris, S., Nyirenda, M., & Levitt, N. (2021). Digital messaging to support control for type 2 diabetes (StAR2D): a multicentre randomised controlled trial. *BMC Public Health*, *21*(1), 1907. https://doi.org/10.1186/s12889-021-11874-7

Goyal, R., & Jialal, I. (2023). No Title. In *Goyal R, Jialal I. [Updated 2023 May 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK513253/*.

Gunawardena, K. C., Jackson, R., Robinett, I., Dhaniska, L., Jayamanne, S., Kalpani, S., & Muthukuda, D. (2019). The Influence of the Smart Glucose Manager Mobile Application on Diabetes Management. *Journal of Diabetes Science and Technology*, *13*(1), 75–81.

International Diabetes Federation. IDF Diabetes Atlas, 10th ed. Brussels, B. I. D. F. 2021. A. from: https://www. diabetesatlas. or. (2021). *IDF Diabetes Atlas Tenth edition 2021*. International Diabetes Federation.

Isaksson, U., Hajdarevic, S., Abramsson, M., Stenvall, J., & Hörnsten, Å. (2015). Diabetes empowerment and needs for self-management support among people with type 2 diabetes in a rural inland community in northern Sweden. *Scandinavian Journal of Caring Sciences*, *29*(3), 521–527.

Kralik, D., Koch, T., Price, K., & Howard, N. (2004). Chronic illness self-management: Taking action to create order. *Journal of Clinical Nursing*. https://doi.org/10.1046/j.1365-2702.2003.00826.x

Lee, E.-Y., Yun, J.-S., Cha, S.-A., Lim, S.-Y., Lee, J.-H., Ahn, Y.-B., Yoon, K.-H., & Ko, S.-H. (2021). Personalized Type 2 Diabetes Management Using a Mobile Application Integrated with Electronic Medical Records: An Ongoing Randomized Controlled Trial. *International Journal of Environmental Research and Public Health*, *18*(10). https://doi.org/10.3390/ijerph18105300

Lee, E. Y., Cha, S.-A., Yun, J.-S., Lim, S.-Y., Lee, J.-H., Ahn, Y.-B., Yoon, K.-H., Hyun, M. K., & Ko, S.-H. (2022). Efficacy of Personalized Diabetes Self-care Using an Electronic Medical Record-Integrated Mobile App in Patients With Type 2 Diabetes: 6-Month Randomized Controlled Trial. *Journal of Medical Internet Research*, *24*(7), e37430. https://doi.org/10.2196/37430

Li, J., Wei, D., Liu, S., Li, M., Chen, X., Chen, L., Wu, Y., Zhou, W., Ouyang, L., Tan, C., Meng, H., & Tong, N. (2021). Efficiency of an mHealth App and Chest-Wearable Remote Exercise Monitoring Intervention in Patients With Type 2 Diabetes: A Prospective, Multicenter Randomized Controlled Trial. *JMIR MHealth and UHealth*, *9*(2), e23338. https://doi.org/10.2196/23338

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., Antes, G., Atkins, D., Barbour, V., Barrowman, N., Berlin, J. A., Clark, J., Clarke, M., Cook, D., D'Amico, R., Deeks, J. J., Devereaux, P. J., Dickersin, K., Egger, M., Ernst, E., Gøtzsche, P. C., … Tugwell, P. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, *6*(7). https://doi.org/10.1371/journal.pmed.1000097

National Institute for Health and Care Excellence. (2019). *Type 2 diabetes in adults: management. NICE guideline NG28.* (Issue Updated 2015 document). https://www.nice.org.uk/guidance/ng28

Owolabi, E. O., Goon, D. Ter, & Ajayi, A. I. (2019). Efficacy, acceptability and feasibility of daily text-messaging in promoting glycaemic control and other clinical outcomes in a low-resource setting of South Africa: A randomised controlled trial. *PLoS ONE*, *14*(11), 1–17. https://doi.org/10.1371/journal.pone.0224791

Shan, R., Sarkar, S., & Martin, S. S. (2019). Digital health technology and mobile devices for the management of diabetes mellitus: state of the art. *Diabetologia*, *62*(6), 877–887.

Sherifali, D., Jones, H., & Mullan, Y. (2013). Diabetes Self-Management: What Are We Really Talking About? *Canadian Journal of Diabetes*, *37*(1), 2–3.

Xu, R., Xing, M., Javaherian, K., Peters, R., Ross, W., & Bernal-Mizrachi, C. (2020). Improving HbA(1c) with Glucose Self-Monitoring in Diabetic Patients with EpxDiabetes, a Phone Call and Text Message-Based Telemedicine Platform: A Randomized Controlled Trial. *Telemedicine Journal and E-Health : The Official Journal of the American Telemedicine Association*, *26*(6), 784–793.

Young, H. M., Miyamoto, S., Dharmar, M., & Tang-Feldman, Y. (2020). Nurse Coaching and Mobile Health Compared With Usual Care to Improve Diabetes Self-Efficacy for Persons With Type 2 Diabetes: Randomized Controlled Trial. *JMIR MHealth and UHealth*, *8*(3), e16665. https://doi.org/10.2196/16665

Zamanillo-Campos, R., Fiol-deRoque, M. A., Serrano-Ripoll, M. J., Mira-Martínez, S., & Ricci-Cabello, I. (2023). Development and evaluation of DiabeText, a personalized mHealth intervention to support medication adherence and lifestyle change behaviour in patients with type 2 diabetes in Spain: A mixed-methods phase II pragmatic randomized controlled clinical trial. *International Journal of Medical Informatics*, *176*, 105103. https://doi.org/10.1016/j.ijmedinf.2023.105103

Zhang, L., He, X., Shen, Y., Yu, H., Pan, J., Zhu, W., Zhou, J., & Bao, Y. (2019). Effectiveness of smartphone app-based interactive management on glycemic control in Chinese patients with poorly controlled diabetes: Randomized controlled trial. *Journal of Medical Internet Research*, *21*(12), e15401. https://doi.org/10.2196/15401