# The effectiveness of digital health technologies for patients with diabetes mellitus: A systematic review

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**Introduction:** Diabetes mellitus (DM) is a leading cause of morbidity and mortality worldwide. At the same time, digital health technologies (DHTs), which include mobile health apps (mHealth) have been rapidly gaining popularity in the self-management of chronic diseases, particularly following the COVID-19 pandemic. However, while a great variety of DM-specific mHealth apps exist on the market, the evidence supporting their clinical effectiveness is still limited.

**Methods:** A systematic review was performed. A systematic search was conducted in a major electronic database to identify randomized controlled trials (RCTs) of mHealth interventions in DM published between June 2010 and June 2020. The studies were categorized by the type of DM and impact of DM-specific mHealth apps on the management of glycated haemoglobin (HbA1c) was analysed.

**Results:** In total, 25 studies comprising 3,360 patients were included. The methodological quality of included trials was mixed. Overall, participants diagnosed with T1DM, T2DM and Prediabetes all demonstrated greater improvements in HbA1c as a result of using a DHT compared with those who experienced usual care. The analysis revealed an overall improvement in HbA1c compared with usual care, with a mean difference of −0.56% for T1DM, −0.90% for T2DM and −0.26% for Prediabetes.

**Conclusion:** DM-specific mHealth apps may reduce HbA1c levels in patients with T1DM, T2DM and Prediabetes. The review highlights a need for further research on the wider clinical effectiveness of diabetes-specific mHealth specifically within T1DM and Prediabetes. These should include measures which go beyond HbA1c, capturing outcomes including short-term glycemic variability or hypoglycemic events.

# Introduction

Diabetes is a leading cause of morbidity and mortality worldwide (1–3). The past three decades have seen a dramatic increase in the number of adults living with diabetes, with the World Health Organisation (WHO) highlighting an increase in prevalence from 108 million in 1980 to 422 million in 2014 (4), and forecasts suggesting this could be as high as 700 million by as early as 2045 (5). Unfortunately, most people living with diabetes do not meet International Diabetes Federation (IDF) treatment targets of glycemic control, i.e., glycosylated haemoglobin (HbA1c) ≤7% for those with Type 2 diabetes (T2DM) (6) and <6.5% for those living with Type 1 diabetes (T1DM) (7).

When diabetes is poorly managed, it can result in systemic complications such as coronary heart disease, stroke, kidney failure, retinopathy, and foot ulcers (8), these complications can further progress to severe disabilities or even death. As such, the WHO estimate diabetes to be the ninth leading cause of death worldwide, with an estimated 1.5 million deaths as a direct result of diabetes (4). Additionally, diabetes workforce shortages (9, 10), limited public funding, and increasing secondary care backlogs all complicate this picture, often resulting in those with diabetes failing to obtain the right support at the right time (11).

With the prevalence of diabetes only expected to increase, and no clear and scalable solution to solve the supply side issues faced by healthcare systems, there remains an urgent unmet need for cost-effective and widely accessible strategies which can empower and motivate people with diabetes to adhere to best-practice diabetes self-care behaviours. Over the years, there has been a growing body of evidence to support the role of self-management in treating Type 2 diabetes mellitus (T2DM) (12, 13).

Digital health technologies (DHTs), which include mobile applications (apps) have been rapidly gaining popularity in the self-management of chronic diseases (14), particularly following the COVID-19 pandemic (15). Given their widespread availability, minimal barriers to access and often low cost, DHTs have been proposed as cost-effective tools to supplement clinician visits and deliver continuity of care to those who may struggle to access incumbent services.

Specifically, the availability of these technologies for purposes including self-management of blood glucose (16), insulin dosing and adjustment (17) and dietary advice (18), has created further opportunities for self-management among patients with diabetes mellitus.

To date, there have been numerous systematic reviews of DHTs dedicated to the management of either Type 1 or Type 2 diabetes which report positive intervention effects (19–21). However, others have been less conclusive, with some reporting on the use of SMS messaging (22) and computer-based platforms (23), while many were also conducted several years ago (24, 25), limiting interpretation given the significant rate of technological change experienced in the past decade. It is therefore clear that differences in study design, intervention group, outcome measures and the specific functions and features of the technologies under consideration have led to widespread variation in the estimation of the impact of DHTs within diabetes.

The aim of this systematic review is to therefore summarise the available literature concerning the impact of using digital health technologies on laboratory confirmed HbA1c, for individuals diagnosed with T1DM, T2DM and Prediabetes.

# Methodology

## Design

In June 2020, we conducted a systematic search of randomised control trials published between 1 June 2010 and 1 June 2020 *via* the PubMed database. In addition, we manually searched reference lists and Google Scholar to identify further papers. The studies were screened and selected by two independent reviewers.

## Search strategy

After an initial pilot search, search terms listed in Table 1 were constructed around i) 'mHealth', ii) 'diabetes' and iii) 'clinical trials/RCTs' including the medical terms derived from WHO's Global Burden of Disease Report (26) and additional

TABLE 1  Search terms.

| |
|---|
| "mHealth" OR "m-health" OR "app" OR "mobile application" OR "mobile-application" OR "mobile app" OR "mobile app" OR "smartphone" OR "cell phone" OR "cellphone" OR "cell-phone" OR "mobile-phone" OR "ehealth" OR "e-health" OR "e health" |
| AND |
| "T2DM" OR "mellitus" OR "T1DM" OR "diabetes" OR "diabetic" OR "diabetics" OR "diabetic's" OR "pre-diabetes" OR "pre-diabetic" OR "pre-diabetics" OR "prediabetes" OR "prediabetic" OR "prediabetics" OR "pre diabetes" OR "pre diabetic" OR "pre diabetic*" OR "pre diabetic*" OR HbA1c OR "glycaemic control" OR "glycemic control" |
| AND |
| "Clinical Study" OR "Clinical Trial" OR "Clinical Trial" OR "Phase I Clinical Trial" OR "Phase II Clinical Trial" OR "Phase III Clinical Trial" OR "Phase IV Comparative Study" OR "Controlled Clinical Trial" OR "Randomized Controlled Trial" |

common terms associated with diabetes mellitus. Database searches were also supplemented with reference list searches to ensure sufficient coverage. A diabetes clinician also checked all search terms to ensure the accuracy of the search and sufficient coverage of the literature.

## Study selection

Studies were selected through a two-stage process. Firstly, two reviewers (SS and SL) independently examined all identified titles and abstracts (facilitated through the online systematic review application, Rayyan) using pre-defined inclusion and exclusion criteria outlined below. The inter-reviewer agreement was sought through consensus. A process was in place to resolve any disagreements by a third reviewer; however, this process was not required. The full article was retrieved when a decision could not be made from the abstract alone. After the initial abstract screening, the full text of potentially relevant articles was retrieved and independently assessed for inclusion by two reviewer.

## Inclusion criteria

As outlined in Table 2, studies reporting on randomised control trials demonstrating the clinical effectiveness of diabetes-specific mHealth technologies in patients diagnosed with T1DM, T2DM or Prediabetes were included. Included studies were published between 2010 and 2020 to ensure only the most current information was included, given the rapid changes to the digital health landscape. Only studies published in the English language were included due to a lack of resources available to conduct reliable translation. Only studies that reported HbA1c as a patient outcome were included for this systematic review as HbA1c is the most widely used and most studied clinical outcome related to technological therapy for DM, including DHTs (27). Furthermore, we also excluded

TABLE 2   Inclusion criteria.

Is the study published between 2010 and 2020?
Yes (proceed)No (reject)
Is the study available in the English language?
Yes (proceed)No (reject)
Is the study a Randomised Control Trial (RCT)?
Yes (proceed)No (reject)
Did the intervention involve the use of diabetes-specific digital health technology?
Yes (proceed)No (reject)
Were trial participants diagnosed with Type 1 Diabetes, Type 2 Diabetes or Prediabetes?
Yes (proceed)No (reject)
Does the article measure HbA1c as a patient outcome?
Yes (proceed)No (reject)

posters, commentary, protocols, theses, duplicates, and studies focused on the diagnosis of diabetes.

## Data collection and analysis

We synthesised the studies according to outcomes because the clinical perspective focuses on improving individual outcomes through the intervention. Using a piloted data extraction form, one reviewer extracted the study characteristics of included articles.

To determine the change in HbA1c, we pooled appropriate studies with intervention groups (using mHealth interventions) and control groups (usual care) and calculated the difference in mean average. We included studies that reported changes in HbA1c as a percentage from baseline to the end of the study for intervention and control groups. The findings and author conclusions of articles reviewed were extracted and reported in a systematic format (see Tables 3, 4).

## Risk of bias

Quality assessment was conducted using the controlled trials risk of bias checklist by SIGN (53). One author conducted a full quality appraisal of all included studies following a high level of interrater reliability (100%) achieved between two reviewers during a sub-sample (10%), quality appraisal analysis of included articles. The methodological quality of the included studies was not the main focus of this systematic review; therefore, content relevance took precedence over methodological rigour.

# Results

## Literature search results

Figure 1 illustrates the literature search and selection process. We identified a total of 311 studies from the PubMed database; no other studies were retrieved from citation searching. The full texts of 48 studies were screened, of which 23 were excluded due to the following reasons: i) they were not reporting the results of a mHealth intervention, iii) the study type was not an RCT (i.e., observational studies, systems reviews/meta-analyses, protocols, conference proceedings, theses), iv) the study did not report HbA1c as a patient outcome or v) other reasons. Twenty-five studies were ultimately included in our quantitative synthesis, with 4 focussed on T1DM, 20 studies on T2DM and 1 study on Prediabetes (see PRISMA flow diagram; Figure 1).

TABLE 3 Characteristics of included studies.

| Authors | Year | Diabetes Type | Study | | | | Participants | | | | Study Quality |
|---------|------|---------------|-------|---|---|---|--------------|---|---|---|---------------|
| | | | App (Intervention) | Control | Intervention (n) | Control (n) | Age (years, mean % and SD) | Gender (%) | Duration of Diabetes (years, mean % and SD) | Ethnic Groups (ethnic group, mean %) | |
| Valentiner et al. (28) | 2019 | Type 2 | InterWalk Smartphone App with additional support | InterWalk Smartphone App without additional support | 18 | 19 | Experiment; 66.7 ± 7.3 Control; 65.1 ± 6.4 | Experiment; Male = 64.9 Control; Male = 70.3 | N/A | N/A | Low |
| Heisler et al. (29) | 2019 | Type 2 | Peer Coaching with eHealth educational tool (iDecide) | Peer Coaching alone | 146 | 144 | Experiment; 64.3 ± 9.7 Control; 62.1 ± 10.5 | Experiment; Male = 96.6 Control; Male = 98.6 | Experiment; 15.0 ± 10.2 Control; 15.3 ± 9.9 | Experiment; African American = 63.4, White = 36.6 Control; African American = 61.8, White = 36.8 Other = 1.4% | Low |
| Wang et al. (30) | 2019 | Type 2 | Continuous care for patients with type 2 diabetes using mobile health application | Traditional discharge nursing | 60 | 60 | Experiment; 45.1 ± 7.8 Control; 45.8 ± 8.3 | Experiment; Male = 55.0 Control; Male = 51.6 | N/A | N/A | Acceptable |
| Skrøvseth et al. (31) | 2015 | Type 1 | Diabetes Diary (DD) Smartphone App | Usual Care | 15 | 15 | Experiment; 41.08 ± 13.5 Control; 38.33 +- 7.3 | Experiment; Male = 33.33 Control; Male = 40.00 | N/A | N/A | Low |
| Kooiman et al. (32) | 2018 | Type 2 | Fitbit Zip and Online Lifestyle Programme | Usual care | 40 | 32 | Experiment; 56.8 ± 11.4 Control; 55.8 ± 11.4 | N/A | Experiment; 15.5 ± 7.7 Control; 14.9 ± 5.3 | N/A | Low |
| Yu et al. (33) | 2019 | Type 2 | Smartphone App: Diabetes-Carer combined with Self-monitoring Blood Glucose | No Intervention | 45 | 47 | Experiment; 50.3 ± 10.4 Control; 56.2 ± 8.4 | Experiment; Male = 66.0 Control; Male = 61.7 | N/A | N/A | Low |
| Hansel et al. (34) | 2017 | Type 2 | Patient E-Coaching Nutritional Support | Usual Care | 60 | 60 | Experiment; 57.6 ± 8.1 Control; 55.5 ± 10.3 | Experiment; Male = 33.3 Control; Male = 33.3 | N/A | N/A | Acceptable |
| Klee et al. (35) | 2018 | Type 1 | Webdia Smartphone App | Usual Care | 28 | 27 | Experiment; 13.6 ± 2.4 Control; 13.7 ± 2.4 | Experiment; Male = 75% Control; Male = 37% | Experiment; 7.5 ± 4 Control; 5.5 ± 3.25 | N/A | Low |
| Agarwal et al. (36) | 2019 | Type 2 | BlueStar Mobile App for Self-management | Usual Care | 72 | 67 | Experiment; 51.5 ± 10.6 | Experiment; Male = 55.0 | N/A | Experiment; Caucasian = 41.8. Non-Caucasian = 58.2 | Low |

(Continued)

TABLE 3 Continued

| Authors | Year | Diabetes Type | Study | | | | Participants | | | | Study Quality |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | App (Intervention) | Control | Intervention (n) | Control (n) | Age (years, mean % and SD) | Gender (%) | Duration of Diabetes (years, mean % and SD) | Ethnic Groups (ethnic group, mean %) | |
| Sun et al. (37) | 2019 | Type 2 | Smartphone App for Self-management for Older People | Usual Care | 44 | 47 | Control; 52.1 ± 10.7 Experiment; 67.9 (66-71) Control; 68.04 (66-72) | Control; Male = 49.0 Experiment; Male = 43.0 Control; Male = 38.0 | Experiment; 11.19 ± 6.39 Control; 11.52 ± 7.73 | Control; Caucasian = 44.3, non-Caucasian = 53.0 N/A | Low |
| Kim et al. (38) | 2019 | Type 2 | mDiabetes Smartphone App for Self-management | Paper Version | 90 | 82 | Experiment; 60.0 ± 8.4 Control; 56.7 ± 9.1 | Experiment; Male = 55.60 Control; Male = 47.60 | Experiment; 13.2 ± 8.0 Control; 12.5 ± 7.3 | N/A | Low |
| Gunawardena et al. (39) | 2019 | Type 2 | Smart Glucose Manager (SGM) Smartphone App | Usual Care | 27 | 25 | Experiment; 52 ± 12 Control; 53 ± 11 | Experiment; Male = 63.0 Control; Male = 57.0 | Experiment; 11 ± 6 Control; 11 ± 7 | N/A | Acceptable |
| Kerfoot et al. (40) | 2017 | Type 2 | Team Based Online Game for Veterans with T2DM | Offline civics game | 277 | 229 | Experiment; 59.62 ± 10.3 Control; 59.9 ± 9.4 | Experiment; Male = 94.7 Control; Male = 93.0 | N/A | N/A | High |
| Frias et al. (41) | 2017 | Type 2 | Digital medicine offering (DMO) wearable sensor patches and a mobile device app | Usual Care | 80 | 29 | Experiment; 57.8 ± (SE) 1.1 Control; 61.6 ± (SE) 1.7 | Experiment; Male = 44.0 Control; Male = 65.0 | N/A | Experiment; Caucasian = 66.0, non-Caucasian = 44.0 Control; Caucasian = 66.0, non-Caucasian = 44.0 | Low |
| Kleinman et al. (42) | 2017 | Type 2 | Gather Health Smartphone App to Improve Medication Adherence and Frequency of Blood Glucose Self-Testing | Usual Care | 44 | 46 | Experiment; 48.8 ± 9.0 Control; 48.0 ± 9.5 | Experiment; Male = 81.8 Control; Male = 58.7 | Experiment; 10.0 (5-16) Control; 8.5 (4-14) | N/A | Acceptable |
| Quinn et al. (43) | 2016 | Type 2 | Web Portal to manage T2DM | Usual Care | 62 | 56 | 1) Age <55 Experiment; 47.3 ± 6.8 Age <55 Control; 47.4 ± 7.5 2) Age >55 Experiment; 59.0 ± 2.9 Age >55 Control; 59.5 ± 2.8 | 1) Age <55 Experiment Male; 37.8 Age <55 Control Male; 62.1 2) Age >55 Experiment Male; 68.0 Age >55 Control Male; 37.0 | 1) Age <55 Experiment; 6.8 ± 4.5 Age <55 Control; 8.9 ± 7.5 2) Age >55 Experiment; 10.3 ± 5.8 Age >55 Control; 9.2 ± 6.0 | 1) Experiment Age <55; Black = 32.4, White = 54.1, Other = 13.5 Control Age <55; Black = 55.2, White = 37.9, Other = 6.9 2) Experiment Age >55; Black = 20.0, White = 76.0, Other = 4.0 Control Age >55; Black = 40.7, White = 55.6, Other = 3.7 | Low |

(Continued)

TABLE 3 Continued

| Authors | Year | Diabetes Type | Study | | | | Participants | | | | Study Quality |
| | | | App (Intervention) | Control | Intervention (n) | Control (n) | Age (years, mean % and SD) | Gender (%) | Duration of Diabetes (years, mean % and SD) | Ethnic Groups (ethnic group, mean %) | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crowley et al. (44) | 2016 | Type 2 | Advanced Comprehensive Diabetes Care (ACDC) (telemonitoring) | Usual Care | 23 | 23 | Experiment; 60 ± 8.4 Control; 60 ± 9.2 | Experiment; Male = 100 Control; Male = 92 | Experiment; Median (IQR) 12 ± 13 Control; Median (IQR) 12 ± 9 | Experiment; White = 52.0, African American = 48.0, Other = 0.0 Control; White = 32.0, African American = 60.0, Other = 8 | Low |
| Kardas et al. (45) | 2016 | Type 2 | COMODITY12 mHealth System | Usual Care | 30 | 30 | Experiment; 59.9 ± 5.31 Control; 59.0 ± 8.09 | Experiment; Male = 57 Control; Male = 63 | N/A | N/A | Low |
| Fukuoka et al. (46) | 2015 | Type 2 | Mobile Phone–Based Diabetes Prevention Program (mDPP) App with Omron Pedometer | Omron Pedometer only | 31 | 30 | Experiment; 57.1 ± 9.1 (36–76) Control; 53.4 ± 8.7 (36–65) | Experiment; Male = 22.6 Control; Male = 23.3 | N/A | Experiment: Asian = 33.4, Hispanic/Latino = 13.3, White =43.3, More than 1 race = 10.0 Control; Asian = 12.9, African American = 9.7, Hispanic/Latino = 9.7, White = 61.3, More than 1 race = 6.4 | Acceptable |
| Block et al. (47) | 2015 | Prediabetes | Alive-PD Smartphone App and Email Support | Usual Care | 163 | 176 | Experiment; 55.0 ± 8.8 Control; 54.9 ± 9.1 | Experiment; Male = 68.1 Control; Male = 69.3 | N/A | Experiment; White = 66.9, Hispanic = 4.3, Asian = 25.2, Other = 3.7 Control; White = 68.2, Hispanic = 8.0, Asian = 16.5, Other = 7.4 | High |
| Wayne et al. (48) | 2015 | Type 2 | Connected Wellness Platform from NexJ Systems, Inc. | Usual Care | 48 | 49 | Experiment; 53.1 ± 10.9 Control; 53.3 ± 11.9 | Experiment; Male = 35 Control; Male = 20 | N/A | N/A | Acceptable |
| Shahid et al. (49) | 2015 | Type 2 | Smartphone Intervention (App not specified) | Usual Care | 220 | 220 | Experiment; 48.95 ± 8.83 Control; 49.21 ± 7.92 | Experiment; Male = 61.4 Control; Male = 61.4 | N/A | N/A | Low |
| Greenwood et al. (50) | 2015 | Type 2 | Care Innovations Health Suite online portal (Intel-GE Care Innovations, Roseville, CA, USA) | Usual Care | 45 | 45 | Experiment; 53.9 ± 10.4 Control; 57.5 ± 10.6 | Experiment; Male = 75 Control; Male = 79 | Experiment; 8.3 ± 5.5 Control; 8.1 ± 5.3 | Experiment; White = 33, Hispanic = 7, Black/African American = 1, American Indian = 2, Asian/Pacific Islander = 3, Other = 2 Control; White = 31, Hispanic = 9, Black/African American = 2, American Indian = 1. Asian/Pacific Islander = 5. Other = 1 | Acceptable |

(Continued)

**TABLE 3** Continued

| Authors | Year | Diabetes Type | Study | | Intervention (n) | Control (n) | Age (years, mean % and SD) | Gender (%) | Participants | | Study Quality |
| | | | App (Intervention) | Control | | | | | Duration of Diabetes (years, mean % and SD) | Ethnic Groups (ethnic group, mean %) | |
| Drion et al. (51) | 2015 | Type 1 | Diabetes Under Control (DBEES) | Usual Care | 31 | 32 | Experiment; 33 ± 23 Control; 35 ± 18 | Experiment; Male = 65 Control; Male = 61 | Experiment; 18 ± 17 Control; 15 ± 14 | N/A | Low |
| Kirwan et al. (52) | 2013 | Type 1 | Glucose Buddy Smartphone App | Usual Care | 36 | 36 | Experiment; 35.97 ±10.67 Control; 34.42 ± 10.26 | Experiment; Male = 52 Control; Male = 25 | Experiment; 19.69 ± 9.64 Control; 18.19 ± 9.77 | N/A | Low |

# Characteristics of included studies

## Trial characteristics

Table 3 summarises the main study characteristics of the 25 included trials. All studies included the outcome of HbA1c as either the primary or secondary outcome of the trial. As the review inclusion criteria required, all studies were randomised control trials, with different mHealth interventions evaluated in each clinical study. Additional patient outcomes reported in a number of these trials included (but were not limited to) blood markers (Fasting Blood Glucose/Fasting Plasma Glucose (FBG/FPG), 2-hour post-prandial blood glucose test (2-h PPG), 1,5-Anhydroglucitol test (1,5-AG)), triglycerides, cholesterol, blood pressure, insulin, aerobic capacity, body composition, hypoglycemic events, primary care visits, rates of rehospitalisation, and health-related quality of life.

A total of 3,360 participants were included in all 25 included studies, of whom 1735 received a mHealth intervention, and 1626 were included in a control group. The trial size varied from 30 to 440 participants. The mean age in the intervention group was 52.1 years and 52.0 years in the control group. Overall, females represented 39.4% of participants in the intervention group and 43.4% in the control group. Where reported, the average duration of diabetes in the intervention group was 12.49 years and 11.7 years in the control group.

## Results of the RCT's

Table 4 shows the change in HbA1c both between the intervention and control groups across the 25 studies included in this review. Overall, a reduction in HbA1c was observed in 23 intervention groups and 21 control groups across the 25 included trials. Two trials observed an increase in HbA1c in the intervention group, with 4 trials observing an increase in HbA1c in the control group.

Overall, the intervention favoured the control group in 19 of the 25 trials, with 5 trials favouring the control group and 1 trial observing no difference between intervention and control groups. The combined pooled average reduction in HbA1c across the trial study periods was -0.80% across all the intervention groups and -0.45% within the control groups.

## T1DM studies

Overall, 110 patients in the intervention groups and 110 patients in the control groups were investigated in the T1DM studies. Intervention favoured the control in 2 of the 4 studies (35, 52), with control favouring the other 2 studies (31, 51). Reduction in HbA1c levels was observed in 3 of 4 intervention groups (31, 35, 51), yielding a mean average reduction of -0.46% (Table 5).

## T2DM studies

In total, 1,642 patients in the intervention groups and 1,340 patients in the control groups were investigated in the T2DM

TABLE 4 Trial results according to HbA1c (%) values.

| Authors | Year | Diabetes Type | HbA1c (%) Experiment | | | HbA1c (%) Control | | |
|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Post Intervention | Change from Baseline | Baseline | Post Intervention | Change from Baseline |
| Valentiner et al. (28) | 2019 | Type 2 | 6.60 | 6.80 | 0.20 | 6.90 | 6.80 | -0.10 |
| Heisler et al. (29) | 2019 | Type 2 | 9.06 | 8.52 | -0.54 | 9.10 | 8.55 | -0.55 |
| Wang et al. (30) | 2019 | Type 2 | 8.62 | 7.12 | -1.52 | 8.68 | 7.92 | -0.76 |
| Skrøvsethet al. (31) | 2015 | Type 1 | 8.33 | 7.89 | -0.44 | 8.06 | 7.49 | -0.57 |
| Kooiman et al. (32) | 2018 | Type 2 | 8.50 | 8.22 | −0.28 | 8.60 | 8.60 | −0.0 |
| Yu et al. (33) | 2019 | Type 2 | 8.30 | 7.00 | -1.10 | 8.70 | 7.70 | -1.10 |
| Hansel et al. (34) | 2017 | Type 2 | 7.16 | 6.86 | -0.30 | 7.27 | 7.48 | 0.21 |
| Klee et al. (35) | 2018 | Type 1 | 8.10 | 7.77 | -0.33 | 8.10 | 7.89 | -0.21 |
| Agarwal et al. (36) | 2019 | Type 2 | 8.89 | 8.22 | -0.67 | 9.03 | 8.41 | -0.62 |
| Sun et al. (37) | 2019 | Type 2 | 7.84 | 6.84 | -1.00 | 7.88 | 7.22 | -0.66 |
| Kim et al. (38) | 2019 | Type 2 | 7.70 | 7.30 | -0.40 | 7.80 | 7.74 | -0.06 |
| Gunawardena et al. (39) | 2019 | Type 2 | 9.50 | 7.20 | -2.3 | 9.40 | 8.30 | -1.10 |
| Kerfoot et al. (40) | 2017 | Type 2 | 11.7 | 10.6 | -1.10 | 11.6 | 10.9 | -0.70 |
| Frias et al. (41) | 2017 | Type 2 | 8.66 | 8.47 | -0.19 | 8.28 | 8.54 | 0.26 |
| Kleinman et al. (42) | 2017 | Type 2 | 9.40 | 7.90 | -1.50 | 9.10 | 8.20 | -0.80 |
| Quinn et al. (43) | 2016 | Type 2 | 9.85 | 8.00 | -1.85 | 9.15 | 8.45 | -0.70 |
| Crowley et al. (44) | 2016 | Type 2 | 10.5 | 9.20 | -1.30 | 10.5 | 10.2 | -0.30 |
| Kardas et al. (45) | 2016 | Type 2 | 6.78 | 6.75 | -0.04 | 6.84 | 6.78 | -0.06 |
| Fukuoka et al. (46) | 2015 | Type 2 | 5.83 | 5.73 | -0.10 | 5.70 | 5.66 | -0.04 |
| Block et al. (47) | 2015 | Prediabetes | 5.60 | 5.34 | -0.26 | 5.60 | 5.42 | -0.18 |
| Wayne et al. (48) | 2015 | Type 2 | 8.69 | 7.88 | -0.82 | 8.89 | 8.13 | -0.76 |
| Shahid et al. (49) | 2015 | Type 2 | 10.09 | 8.63 | -1.46 | 9.85 | 9.36 | -0.48 |
| Greenwood et al. (50) | 2015 | Type 2 | 8.46 | 7.35 | -1.11 | 8.16 | 7.46 | -0.70 |
| Drion et al. (51) | 2015 | Type 1 | 7.70 | 7.90 | 0.20 | 7.80 | 7.90 | 0.10 |
| Kirwan et al. (52) | 2013 | Type 1 | 9.08 | 7.80 | -1.28 | 8.78 | 8.58 | -0.20 |

studies. Intervention favoured the control in 16 of 20 studies (30, 32, 34, 36–44, 46, 48–50) and no difference between intervention and control observed in one study (33). Reduction in HbA1c levels was observed in 19 of 20 intervention groups, with only one study observing an increase (28), yielding a mean average reduction of -0.90% (Table 5).

### Prediabetes studies

Only one study investigated HbA1c levels for patients with Prediabetes (47). Within this study, 163 patients took part in the intervention groups and 176 patients participated in the control. Intervention favoured control in the study, with a reduction in HbA1c levels reported at -0.26% (Table 5).

### Study quality

The methodological quality of included trials was mixed. Two studies were considered high quality (40, 47), 7 acceptable (30, 34, 39, 42, 46, 48, 50) and 16 low (28, 29, 31–33, 35–38, 41, 43–45, 49, 51, 52). Five of the 25 studies reported dropout rates above 20% before the study was complete (36, 38, 39, 48, 52)

leading to possible under or overestimated clinical impact. Many of the studies highlighted as low quality were associated with issues with generalisability of the findings beyond the patient group under observation, challenges in generalising groups who are less motivated and technologically inclined and challenges to generalisability due to underpowering caused by sample size restrictions or dropout rates. Other common methodological weaknesses were associated with randomisation, concealment and blinding between subjects and assessors.

## Discussion

### Summary

The findings of this study, examining outcomes from a total of 3,360 participants across 25 RCTs, have demonstrated that mHealth interventions for those with diabetes mellitus can improve glycemic control. This was achieved by effectively reducing HbA1c values in patients with T1DM (mean
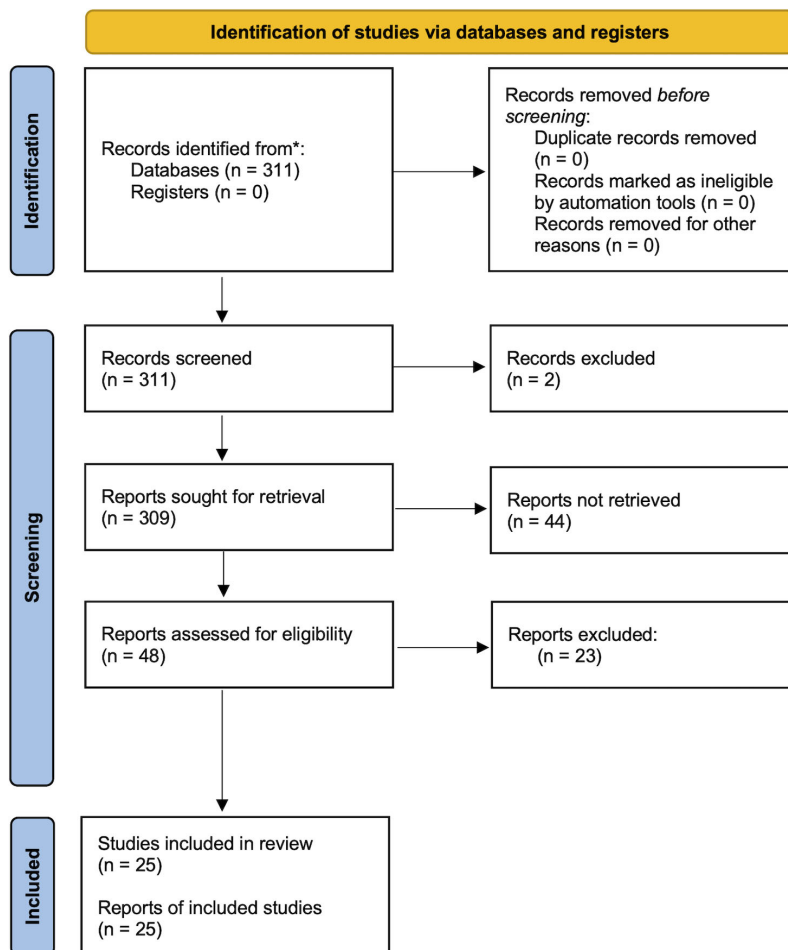
**FIGURE 1**
Overview of the screening process.

difference: −0.46%), T2DM (mean difference: −0.90%) and Prediabetes (mean difference: −0.26%), with reductions in HbA1c levels observed 95% of the studies included. Studies were diverse with respect to the type of DM, study design, number of participants, and DHT functions and features. Often, different DHT features were combined, or the DHT was used in conjunction with web portals, feedback from HCPs, pedometers or other Bluetooth-enabled devices. Because of that, it was not possible to distinguish a relationship between specific DHT features and health outcomes.

## Interpretation considering other evidence

Overall, mHealth solutions were generally discussed to be feasible solutions to support the management of diabetes. Improvements in HbA1c in people with T1DM or T2DM

observed in this review are consistent with the results of other reviews (27, 37, 54–58).

Alongside a reduction in HbA1c observed in the intervention group of the majority of included trials (as discussed above), a number of included trials also observed varying improvements in other patient outcomes including, but not limited to, fasting blood glucose, blood pressure, hypo and hyper glycemic events, cholesterol, body weight and self-care. Other reviews have analysed the impact on mHealth interventions of a number of these clinical outcomes (27, 37, 54, 57), however, unlike HbA1c, no consistent clinical impact has been identified.

A reduction in HbA1c was observed in 19 of the 20 intervention groups for T2DM, with only 1 study observing an increase (28), yielding an average reduction of -0.90% across all studies identified. This is similar to recent findings by Eberle et al. (27), who identified an average reduction in HbA1c of -1.1% for people with T2DM, however, others have observed

TABLE 5  Trial results according to HbA1c (%) values pooled by mean average for T1DM, T2DM and Prediabetes.

| Diabetes Type | HbA1c (%) Experiment | | | HbA1c (%) Control | | |
|---|---|---|---|---|---|---|
| | Baseline (Average) | Post Intervention (Average) | Change from Baseline (Average) | Baseline (Average) | Post Intervention (Average) | Change from Baseline (Average) |
| Type 1 (n=4) | 8.30 | 7.84 | -0.46 | 8.19 | 7.97 | -0.22 |
| Type 2 (n=20) | 8.61 | 7.73 | -0.90 | 8.57 | 8.12 | -0.47 |
| Prediabetes (n=1) | 5.60 | 5.34 | -0.26 | 5.60 | 5.42 | -0.18 |

smaller effects of -0.40% (54, 57) and 0.44% (58) when focussed on different patient populations and/or less recent publications.

Five of the 25 studies reported dropout rates above 20% before the study was complete (36, 38, 39, 48, 52), leading to possible under or overestimation of clinical impact. Observing rates of attrition above 20% in RCT's for app-based interventions is consistent with a recent systematic review and meta-analysis that observed an average dropout rate of 40% in RCT's of app-based interventions for chronic disease (59) compared with lower rates of attrition in trials of non-app-based interventions (60–62). Previous studies have demonstrated that up to 80% of all participants in mHealth interventions may engage in only minimal use of these interventions, defined as logging in to the service less than twice, and only a small fraction of users consistently use the intervention long term (63, 64). Low attrition rates characterised by perception of own health as poor (incentivizing the need to change) (65), those who wanted to be involved in their own health care (66) and those who are younger and have higher levels of health literacy (65, 67). Another association with low attrition was with those engaged in multiple interventions. Individuals engaged in internet or phone programs as well as apps were more likely to remain in research studies (68). These characteristics are an important consideration for clinicians in understanding those patients who are more likely to engage with DHT and also appreciating the potential for an additive value of DHT technology in complementing existing support, such as that of traditional healthcare.

Furthermore, one explanation for the modest improvements in HbA1c observed could be the experience level of those participating in the studies. Where reported, the average duration of diabetes in the intervention group was 12.49 years and 11.7 years in the control group.

This "learning effect" was captured in the finding that overall, a reduction in HbA1c was observed in 23 intervention groups and 21 control groups across the 25 included trials. Therefore, there is less likelihood of reducing HbA1c if people are already well acquainted with managing their condition. A study with a narrower focus on newly and recently diagnosed patients may yield different results.

Finally, we defined glycemic control as maintaining the blood glucose control within the normal or euglycemic blood glucose levels safely, i.e. no hypoglycemia or hyperglycemia. Although we observed overall improvements in HbA1c for people with T1DM or T2DM, HbA1c provides only an approximate measure of glucose control and does not address short-term glycemic variability or hypoglycemic events. This means that a raised or decline HbA1c may suggest an increase in hypoglycemic events which are associated with negative patient outcomes, including increased risks of non-fatal stroke, cardiovascular related death, and total mortality (69).

## Limitations

An important limitation of our review is that we excluded all studies that did not report the results of RCTs. Observational studies and non-randomized trials may provide important information useful for understanding the effectiveness of mHealth, as now suggested by regulators, including the National Institute for Health and Care Excellence (70).

Nevertheless, we opted for excluding these studies as non-randomized trial designs carry a greater risk of being affected by multiple known and unknown biases (71). Another limitation of the review process could have been that the review only reports on literature available at the time of the search and written in English. Although two experienced reviewers assessed the records, we cannot entirely rule out that we missed potentially relevant articles. Many of the primary studies were found to have low methodological quality and level of reporting, often impacted by randomisation, concealment, and blinding between subjects and assessors. However, it should be considered that randomisation, concealment, and blinding between subjects and assessors in digital health-based RCTs is challenging due to the nature of subjects receiving and potentially requiring support to use a digital health technology.

Furthermore, only one study included in this review focused on Prediabetes (47), so this result should be treated with caution. Additionally, articles focusing specifically on gestational diabetes were not included in this review. Finally, the effects of mHealth are likely to differ depending on the specific type of intervention, the specific disease, and the specific context. Due to the focus on diabetes-specific mHealth interventions for this review, it is not

possible to draw firm conclusions on the effectiveness of mHealth interventions in general.

The mean age in the intervention group was 52.1 years and 52.0 years in the control group. Prior analyses have demonstrated how older age can impact digital proficiency, and therefore a study with a greater proportion of people living with DM, who can be of any age, may yield different results.

From the clinical perspective, we defined glycemic control as maintaining the blood glucose control within the normal or euglycemic blood glucose levels safely, i.e. no hypoglycemia or hyperglycemia. HbA1c provides only an approximate measure of glucose control and does not address short-term glycemic variability or hypoglycemic events. This means that a raised or decline HbA1c may suggest an increase in hypoglycemic events which are associated with an increased risk of non-fatal stroke, cardiovascular related death, and total mortality (69).

Finally, the methodological quality of included trials was mixed. Two studies were considered high quality, seven acceptable and 16 low. Studies reported as low in quality were often associated with issues with generalisability of the findings beyond the patient group under observation, challenges in generalising groups who are less motivated and technologically inclined and challenges to generalisability due to underpowering caused by sample size restrictions or dropout rates.

## Conclusion

Our review identified 25 studies reporting results of RCTs of mHealth interventions for patients with T1DM, T2DM and Prediabetes. Overall, this review demonstrates that diabetes-specific mHealth interventions may reduce HbA1c levels in patients with T1DM, T2DM and Prediabetes. The review highlights a need for further research on the wider clinical effectiveness of diabetes-specific mHealth specifically within T1DM and Prediabetes. These should include measures which go beyond HbA1c, capturing outcomes including short-term glycemic variability or hypoglycemic events.

## Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material. Further inquiries can be directed to the corresponding author.

## Author contributions

SS, TA & SL conceived the review topic. SS and SL drafted the protocol, performed literature search and conducted data extraction and analysis. SG contributed clinical expertise. SS, SG, TA, LA-P, LH, and SL contributed to manuscript authorship and editing. All authors contributed to the article and approved the submitted version.

## Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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