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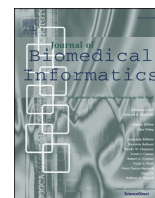
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# On the efficacy of behavior change techniques in mHealth for self-management of diabetes: A meta-analysis

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## ABSTRACT

**Background:** Diabetes prevalence has become a global crisis. Due to the substantial rise in smartphone use, a variety of mobile interventions have been developed to help improve the clinical outcomes of diabetes patients. **Objectives:** This study seeks to examine specific behavior change theories and techniques used in the design of self-management mobile app-based interventions aimed at achieving glycemic control in type 1 and type 2 diabetes.

**Methods:** A meta-analysis of randomized control trials published in PubMed/Medline and Web of Science between January 2010 and October 2020 was conducted using studies that included diabetes patients, reported on well-described mobile app-based interventions, compared mHealth to usual care, and evaluated glycated hemoglobin (HbA1c) at baseline and follow-up.

**Results:** We reported on 21 studies with a total of 1,920 diabetes patients. Our findings show that mHealth apps led to statistically significant clinical outcomes as compared to standard care for glycemic control ( $-0.38$ , 95% CI =  $-0.50$  to  $-0.25$ ,  $p < 0.0001$ ) indicating that such interventions result in a reduction in HbA1c. Interventions that used behavior theory for developing mHealth apps were not statistically different from those that did not ( $p = 0.18$ ). However, increased use of behavior change techniques (BCTs) may result in slightly higher HbA1c reduction. Among all BCTs, the most effective ones appear to be “Action planning” and “Self-monitoring of outcome(s) of behavior.”

**Conclusions:** The current meta-analysis provides evidence that mHealth is likely to be beneficial for diabetes patients when the right behavior change techniques are applied to realize the full advantage of the intervention. Further investigation of the role of theory in the design of mHealth app-based interventions is warranted.

## 1. Introduction

The rapid increase in the number of people living with diabetes is a global crisis that places a huge burden on public health systems. For example in the United States alone, 34.1 million adults (aged 18 years and above) – which represents 13% of population estimates – have diabetes [1]. An additional 88 million adults have prediabetes, a condition that can lead to type 2 diabetes within five years if left untreated. Further, Saeedi et al. [2] placed global estimates at 9.3% (463 million people), which is expected to rise to 10% (578 million people) and 10.9% (700 million people) by 2030 and 2045, respectively. The increasing number of diabetes patients, especially those with type 2 diabetes, has been attributed to obesity, aging, and increased urbanization. This issue is reflected in the elevated prevalence rates in urban

areas (10.8%) and high-income countries (10.4%) relative to rural areas (7.2%) and low-income countries (4.0%) [2].

Given these worrying trends, the development of diabetes solutions has remained at the forefront of medical and technological innovation especially regarding mobile health (mHealth) which supports the self-management of the condition. In fact, out of the approximately 325,000 mHealth applications on the Apple App and Google Play stores, diabetes is the second most popular use case after “connection to doctors” [3]. Studies show that mHealth interventions result in improvements in various clinical outcomes in diabetes patients. Past reviews [4–6] indicate, based on a qualitative synthesis of clinical trials, that mHealth interventions are effective for diabetes management. Additionally, various meta-analyses [7–12] corroborate the efficacy of mHealth interventions for improving clinical outcomes based on quantitative

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evidence. Yet, those studies did not focus on the role of behavior change or the underlying theoretical basis.

Since diabetes management is primarily a behavioral issue that requires extensive self-management [13], the role of specific behavior change techniques (BCTs) for improving health outcomes cannot be understated. BCTs are observable, replicable, and irreducible components of the interventions that lead to causal processes meant to regulate behavior [14]. Further, there are assertions that the use of theory leads to more effective intervention [15–21]. However, there is concern over the importance of theory [22], and little remains known of the specific BCTs that encourage health behavior change in diabetes patients leading to the clinical improvements reported. Out of the studies mentioned, only one qualitative review [6] identified the BCTs frequently used in effective interventions. While past studies quantified the effect of BCTs in Internet-based interventions [21], dietary interventions [23], and physical activity interventions [24], there has been no meta-analysis investigating the effect size of mobile-based interventions for diabetes self-management with a particular focus on exploring the role of behavioral change techniques and theory.

This study aims to systematically review and evaluate the quantitative effect of BCTs in mobile app-based self-management interventions for achieving glycemic control in diabetes patients as reflected by HbA1c values. Further, this study investigates which specific behavioral change theories and techniques are incorporated in the design of diabetes mobile app-based interventions, and their role in enacting behavioral change and ultimately glycemic control. Specifically, we aim to address the following questions: What is the efficacy of theory-based mobile app-based interventions for diabetes self-management? Which theories are associated with improved outcomes, and which behavior change techniques are effective when delivered via a mobile app employed over the Internet?

## 2. Methods

The current study follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for conducting systematic reviews [25]. PRISMA offers a standardized and replicable approach to identifying, selecting, and critically appraising extant literature.

### 2.1. Data sources and search strategy

We searched PubMed/Medline and Web of Science databases for relevant English-language peer-reviewed articles, conferences, and book chapters published between January 2010 and October 2020. This study period was appropriate to deliver an up-to-date review of current mobile app-based interventions for diabetes self-management. This is particularly important given the rapid change in technology and supporting infrastructure. The search terms targeted the root term *diabetes* combined with various combinations of *mobile technologies*, *mHealth*, and *behavior change*. The wildcard character (\*) was used to target variations on the term “behavior” in the literature such as behavioral, behaviors, and others. Table 1 demonstrates the search query used in PubMed/

**Table 1**  
Search query.

Database	Search Query
PubMed/ Medline	(diabetes) AND (((smartphone OR mobile OR android OR iphone) AND (app OR application)) OR (mhealth)) AND ((behavior* OR lifestyle) AND (change OR modification))
Web of Science	TS=(diabetes) AND ((TS=(smartphone OR mobile OR android OR iphone) AND TS=(app OR application)) OR TS=(mhealth))AND (TS=(behavior* OR lifestyle) AND TS=(change OR modification))

Medline, and the equivalent topic search applied in Web of Science. In order not to inadvertently rule out any potentially useful study, we carefully examined citations of prior related reviews [4–12].

### 2.2. Inclusion and exclusion criteria

With the research objectives in mind, studies were included if 1) the study participants were adults (older than 18 years) who had been diagnosed with type 1 diabetes (T1D) or type 2 diabetes (T2D). With a focus on behavioral changes, the nature and context for individuals under 18 can be substantially different than those 18 years or older. Further, there are unique challenges in managing diabetes through hormonal and physiological turbulence of puberty and adolescence [26]; 2) the primary intervention was a mobile application where a mobile application in the context of this review is a computer program that is designed to run on a mobile device such as a phone or another mobile device such as a tablet or a watch [27,28]; 3) the intervention was well described to allow coding of behavior change technique(s); 4) a randomized control trial (RCT) was used in the study design; 5) the RCT consisted of at least a control arm and one intervention. The control referred to ‘standard/usual/traditional’ whereas the intervention included such care in addition to the mobile application-based intervention, 6) outcomes included glycemic control as measured by a change in glycated hemoglobin (HbA1c) at baseline and follow-up, and 7) the intervention effects were reported in a manner that allows for the computation of effect size. When the study data was missing the standard deviation (SD) but reported the standard error (SE), the SD was computed per the Cochran guidelines [29]. If both the SD and SE were missing, the authors were emailed for study data. Studies were also included if either the evaluation or the intervention arm of the study was published in a separate paper not captured in our initial search. Only peer-reviewed studies published in the English language were considered for this meta-analysis. Nonrandomized studies, not controlled, quasi-experimental, and partial results were excluded. Studies involving mobile applications that primarily focused on mobile phones for connectivity, e.g., by transmitting short message service (SMS) or by the Internet for remote monitoring were excluded. For example, using a phone for solely sending blood glucose measurements via SMS or other means is outside the scope of this review. Studies that were aimed at health professionals were also excluded.

### 2.3. Data extraction

All identified studies were exported to the Zotero reference manager software [30]. After removing duplicates, two researchers independently read the title and abstracts of all studies and marked them for inclusion or exclusion. The full text of each of the remaining articles was then added to the reference manager for full-text synthesis. For studies that passed full-text screening, data included authors, year and country of publication, patient sample sizes, study design, diabetes type, intervention and control description, key outcome measure, and longest follow-up periods. If a study reported more than one intervention group, we included all interventions that encompassed variations in the extent of the supported behavioral change techniques. When the same participants were part of separate studies (duplicate publications), we reported on only one study. The primary outcome of interest was HbA1c as it is the gold standard to monitor glycemic control and hence the effectiveness of diabetes management [31,32]. HbA1c reflected the ultimate health outcome of an intervention, regardless of whether the behavioral change was considered as a mediator and whether it was explicitly measured across studies.

### 2.4. Coding of behavior change techniques

The current study employed the list of 93 hierarchically clustered BCTs taxonomy (v1) developed by Michie et al. [14] to code the

presence or absence of each technique. Both intervention and control conditions were coded separately and independently by two researchers using all available primary papers, related papers, and protocols for a comprehensive assessment of each included study. BCTs taxonomy (v1) application [33], the BCT training material (<http://www.bct-taxonomy.com>), and the original study [14] were used to aid with the coding of BCTs. Following the example of past studies [21], a BCT was coded as absent if it was present in both the experimental intervention and the control since it could not sufficiently explain the difference between the two groups. Inter-rater reliability for the entire process was calculated using Cohen's kappa to measure the rate of agreement between the two coders. Any discrepancy in the coding was resolved by revisiting the BCT guidelines and the supporting coding examples.

### 2.5. Assessment of bias and overall quality of evidence

Using Cochrane Collaboration's risk of bias tool, two authors independently assessed all studies for risk bias in 1) random sequence generation; 2) allocation concealment; 3) participant and personnel blinding; 4) outcome assessment blinding; 5) incomplete outcome data; and 6) selective reporting. A categorical ranking of low (green), unclear (yellow), and high (red) was assigned at each step. As suggested in the Cochrane Handbook [29], both reviewers resolved any disagreements via discussion and resorted to the third author to adjudicate the final judgement as needed. Publication bias was evaluated using Egger's test and visualized on a funnel plot [34].

Further, two reviewers assessed the evidence independently using the Grading Recommendations Assessment, Development and Evaluation (GRADE) tool [35] for the outcome under consideration. According to GRADE, the focus is on the body of evidence as opposed to an individual study. There are four categories: high, moderate, low, and very low. RCTs start with a 'High' rating. The quality is downgraded in light of five factors (Risk of Bias, Inconsistency, Indirectness, Imprecision, Publication Bias) and rated up for three factors (Large effect, Dose-response, All plausible residual confounding) [36]. We follow the recommendations in [37] in communicating the findings.

### 2.6. Data analysis and synthesis

Data analysis was conducted using the metafor package for conducting meta-analysis in R [38,39]. Review Manager Version 5.4 for Windows [40] was used to record the risk of bias assessment. Results were presented as mean difference (MD) using the follow-up score and SD for HbA1c with a 95% confidence interval (CI). Since mixing outcomes does not affect analysis [29], the change score was used whenever the follow-up score was not available.

Following the precedent set by earlier research [23,41,42], we defined the effectiveness of interventions based on glycemic control as  $\geq 0.3\%$  reduction in HbA1c. Further, effect sizes were interpreted in the context of prior related meta-analyses and Cohen's guidelines [43]. According to Cohen [44],  $d = 0.20$  is considered a "small" effect size,  $d = 0.50$  is a "medium" effect size, whereas  $d = 0.80$  is a "large" effect size. In all cases, the random-effects model was used. The random-effects model is appropriate when there is an expectation of complex differing study characteristics [45]. Study heterogeneity was evaluated using Higgins  $I^2$ . The results of heterogeneity were considered low at 25% and moderate between 50% and 75%.

We conducted moderator analyses to evaluate the role of theory and behavioral change techniques as well as the other moderators of effect size, e.g., the type of diabetes and the length of the intervention. For categorical variables, such as the presence of theory or a particular behavior change technique, we conducted a subgroup analysis. For continuous variables, such as the number of BCTs used or the duration of the intervention in months, we used a meta-regression. Where a meta-regression was performed, the estimate ( $\beta$ ) and  $p$ -value were used to interpret whether the predictor could significantly predict the effect size

differences in the regression model. In each case, the analysis was only conducted for variables present in more than two interventions to ensure reliability.

## 3. Results

### 3.1. Literature screening

As shown in Fig. 1, 21 studies were identified for inclusion in this meta-analytic review. These studies were identified from a total of 629 records obtained from a search in PubMed/Medline (404) and the Web of Science (225) databases. The search for citations of recent related reviews yielded 15 additional studies [4–12]. After combining all studies and removing duplicates, 488 records remained. Based on the inclusion and exclusion criteria, 85 records remained after screening the title and abstract and 21 studies remained after screening the full-text. Three studies [46–48] included more than two arms, hence we reported on 21 studies and 24 interventions.

### 3.2. Study and participant characteristics

The characteristics of the 21 selected studies are presented in Table 2. The studies included RCTs conducted in 19 countries including the United States (3) [49–51]; China (3) [48,52,53]; Netherland (2) [54,55]; Norway (2) [47,56]; Australia [57]; China and Taiwan [58]; Canada [59]; Finland [60]; France [46]; India [61]; Indonesia [62]; Italy [63]; Japan [64]; Sri Lanka [65] and the United Kingdom [66].

A total of 1,920 patients were involved in the studies with 1,040 of them participating in the mHealth interventions and 880 in the control group. The patients had a mean age of 51.2 years (32.9–68.1 years) and study durations ranged from 3 months to 18 months. Five studies designed interventions specifically for T1D [46,55–57,63] while two other studies involving applications aimed at both T1D and T2D [48,66]. All remaining interventions were designed for T2D. Initial coding of BCTs resulted in an inter-rater reliability Cohen's kappa of 0.67 indicating substantial agreement between the two coders. Any discrepancy in the coding was resolved by revisiting the BCT guidelines and the supporting coding examples.

### 3.3. Assessment of bias and overall quality of evidence

Most studies (81%) exhibited a low sequence generation Risk of Bias (RoB) while a lower percentage (57%) exhibited a low allocation concealment RoB. No study was identified as having a high risk of selection bias, while three studies exhibited an unclear risk of sequence generation and allocation concealment selection bias. However, and due to their nature, blinding of participants and personnel was not possible in any of the studies resulting in a high RoB. All studies relied on an objective measure (HbA1c) and thus were judged as being at low RoB for blinding of outcome assessment. All studies exhibited a low risk of attrition bias. Further, the final publication of the trial followed what had been planned in a published protocol paper, or in the case where no protocol paper was publicly available, the studies reported all the outcomes, namely, HbA1c, mentioned in the methodology and thus were judged as having a low risk for selective outcome reporting. Fig. 2 shows the risk of bias graph and summary for the selected studies.

Egger's test for publication bias did not indicate the presence of publication bias ( $p = 0.41$ ). This was confirmed visually by a funnel plot (Fig. 3).

Based on the GRADE quality of evidence assessment approach, the quality of evidence was rated as high with respect to the collective body of evidence regarding the use of mobile apps for diabetes self-management. However, when considering the use of theory and support for BCTs, the quality ranged from moderate to very low. The moderate rating was attributed primarily to the indirectness related to the intervention, i.e., that the intervention as defined by the presence of

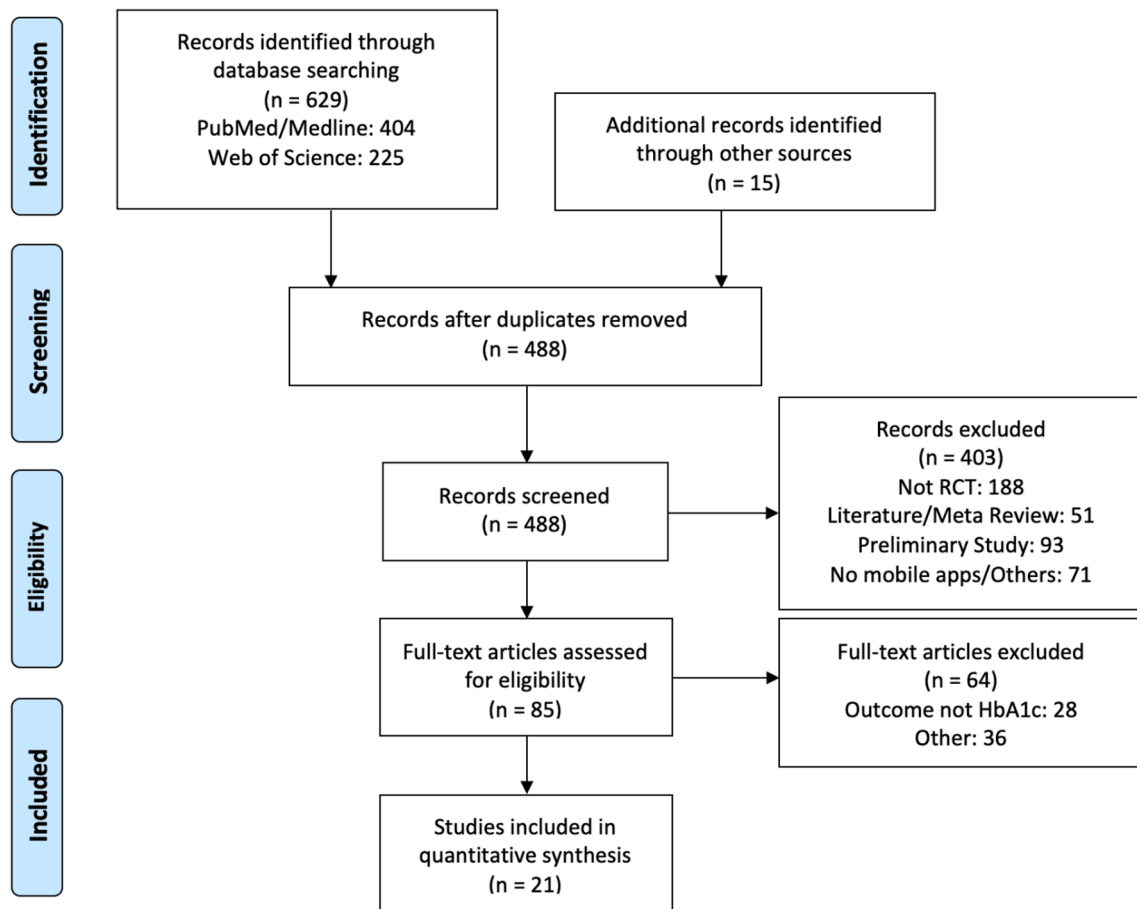


Fig. 1. PRISMA flow chart of the study selection process.

theory or specific BCT may differ from the intervention of interest as their interpretation and coding were dependent on the details provided in the literature reporting said interventions. This is a shortcoming that has been reported in reviews of this nature [6,21,23,24]. Further, in the moderator analysis, the evidence may be downgraded to low or very low mostly due to the low number of studies that may be present in a particular group resulting in imprecision, or in sub-groups exhibiting a high level of heterogeneity resulting in inconsistency. Below we present the results in accordance with the recommendations in [37] for communicating the findings.

### 3.4. Overall effect of mHealth interventions on glycemic control

As demonstrated in Fig. 4, the pooled estimate of study data demonstrated a statistically significant improvement in HbA1c levels of mHealth intervention participants as compared to standard care treatment ( $-0.38$ , 95% CI =  $-0.50$  to  $-0.26$ ,  $p < 0.0001$ ). Heterogeneity was low at  $I^2 = 0\%$  which indicated that variability across the trials was not an issue. Overall, mobile app-based interventions resulted in a reduction in HbA1c.

### 3.5. Moderator analyses

Moderator analyses were conducted to investigate the impact of the different participants, study, and intervention characteristics on the pooled effect size. We evaluated the presence of theory and various BCTs as well as the type of diabetes and intervention duration in mHealth intervention design with respect to improving glycemic control.

#### 3.5.1. Use of behavior theory

A summary of the effect of behavior theory and techniques is outlined in Table 3. A total of 8 interventions referenced a theoretical basis for their design, while the remaining 16 interventions did not include any reference to theory. Both groups resulted in a significant reduction in HbA1c with effect sizes of ( $-0.36$ , 95% CI  $-0.60$  to  $-0.13$ ,  $p = 0.002$ ) and ( $-0.39$ , 95% CI =  $-0.54$  to  $-0.24$ ,  $p < 0.0001$ ) for studies with theoretical basis and those without theoretical basis, respectively. However, there was no significant difference ( $p = 0.86$ ) between the two groups.

Studies that referred to a theory base often cited more than one theory. The highest number of theories used for any one intervention was four [54,61,66]. Two other studies utilized multiple theories [49,58] while the remaining interventions were based on a single behavior theory [50,60,62]. The two most prominent theories that were used in the studies were the Transtheoretical Model of Behavior Change (TTM) and the Social Cognitive Theory (SCT). TTM, which theorizes change as a progressive venture through pre-contemplating of behavior change to behavior maintenance [67], was applied in three studies [49,54,58]. SCT, which emphasizes knowledge acquisition through social contexts and includes self-efficacy as one of the four processes of goal realization, was applied in [49,61,62,66]. For both theories, the effect size was not significant as shown in Table 3. However, the quality of evidence exhibited indirectness (as noted earlier), and imprecision rendering it of low certainty. For TTM, inconsistency associated with heterogeneity ( $I^2 = 56\%$ ) was deemed of questionable importance as the difference was between large and small effects. Accordingly, interventions based on the TTM or the SCT may reduce HbA1c slightly. Further, comparing the studies that used any of these two theories against those that did not, revealed no statistically significant



**Table 2**  
Study characteristics.

	Intervention Description	Diabetes Type Targeted	Longest Follow-up (months)	BC Theory	Age [Mean, (SD)]	Gender [n, (%) Female]
(Baron et al., 2017) [66] United Kingdom	Mobile Telehealth (MTH) consisting of mobile and application, BG meter, BP monitor, and Bluetooth cradle to store and transmit diabetes-related data. Includes data visualization of recorded data and highlighting out-of-range readings.	T1D; T2D	9	Theory Application: Assessment  Theory(s) Used: Social Cognitive Theory; Self-Regulation Theory; Leventhal's Model of Illness Beliefs, and Technology Acceptance Model (TAM)	I: 58.2 (13.6); C: 55.8 (13.8)	I: 14 (31.11); C: 21 (58.33)
(Bender et al., 2017) [49] United States	PilAm Go4Health intervention consisting of a Fitbit accelerometer, a mobile app with a diary for health behavior tracking. Provided social support and education through social media	T2D	6	Theory Application: Intervention design  Theory(s) Used: Social Cognitive Theory; and Transtheoretical Model for Health Behavior Change	I: 57.4 (9.8); C: 57.7 (10.0)	I: 14 (63); C: 14 (60)
(Boels et al., 2019) [54] Netherlands	TRIGGER study consisting of a smartphone app to provide diabetes self-management education and support using text messages and prompts	T2D	6	Theory Application: Intervention design  Theory(s) Used: Health Belief Model; Self-Regulation Theory; Transtheoretical Model of Behavior Change; Fogg Behavior Model	I: 58.6 (8.2); C: 59.7 (6.8)	I: 48 (41.7); C: 43 (37.4)
(Chao et al., 2019) [58] Taiwan and China	Interactive Personalized Management Framework (IPMF) application cloud-based for smartphones to consolidate patient-related information to a dashboard. Included personal goal setting and diabetes education	T2D	18	Theory Application: Assessment  Theory(s) Used: Transtheoretical Model of Behavior Change, Theory of Planned Behavior	63.71	11 (39)
(Charpentier et al., 2011) [46] France	Diabeo software to support bolus calculation. Data recorded included self-monitoring plasma glucose, diet, and insulin treatment. One group received teleconsultation assistance.	T1D	6	N/A	I: 32.9 (11.7); C: 36.8 (14.1)	I: 37 (61.67); C: 40 (65.57)
(Drion et al., 2015) [55] Netherlands	Dbees application to support customized treatment plans, prompts and reminders, and visualize collated data	T1D	3	N/A	I: 33 (23); C: 35 (18)	I: 11 (35.48); C: 12 (37.5)
(Gunawardena et al., 2019) [65] Sri Lanka	Smart Glucose Manager (SGM) to remind and support medication and physical activity. Provided bolus insulin calculation.	T2D	6	N/A	I: 52 (12); C: 53 (11)	I: 13 (37); C: 14 (43)
(Holmen et al., 2014) [47] Norway	FTA app to aid the collection of glucose and dietary data and visualization. Includes support for physical activity and tailored feedback	T2D	12	N/A, (*used TTM for health counseling)	I: 58.6 (11.8); C: 55.9 (12.2)	I: 17 (33); C: 20 (40)
(Hsu et al., 2016) [50] United States	CollaboRhythm application for self-tracking of blood glucose and data visualization. Provides insulin titration support, carbohydrate counting, and telehealth consultations	T2D	3	Theory Application: Intervention design  Theory(s) Used: Situated Learning Theory	I: 53.3; C: 53.8	N/A
(Kirwan et al., 2013) [57] Australia	Glucose Buddy includes manual entry of diabetes-related data and physical activity. Supports goal setting and graphical display of data	T1D	9	N/A	I: 35.97 (10.67); C: 34.42 (10.26)	I: 17 (47.22); C: 27 (72.97)
(Kleinman et al., 2017) [61] India	Gather mHealth platform consists of an application and a web portal for providers. App has reminders, data visualization, and support for collaborative care decisions.	T2D	6	Theory Application: Intervention design  Theory(s) Used: Health Belief Model; Health Action Process Approach; Theory of Planned Behavior; and Bandura's Theory of Self-Efficacy	I: 48.8 (9.0); C: 48.0 (9.5)	I: 18.2 (8); C: 41.3 (19)
(Kusnanto et al., 2019) [62] Indonesia	DM-calendar app designed to support self-management with four main components; blood sugar control, education program, nutrition therapy, and physical activity.	T2D	3	Theory Application: Assessment  Theory(s) Used: Self Efficacy	N/A	I: 8 (53.3); C: 9 (60)
(Orsama et al., 2013) [60] Finland	Monica app and Medinet web interface for collecting diabetes-related data and receiving tailored feedback	T2D	10	Theory Application: Intervention design  Theory(s) Used: Information-Motivation-Behavioral Skills Model	I: 62.3 (6.5); C: 61.5 (9.1)	I: 11 (46); C: 11 (46)
(Quinn et al., 2011) [51] United States	Mobile Diabetes Management Application (MDMA) uses glucose meters and testing kits for self-management and provides medication support and education.  Diabetes Interactive Diary (DID) acts as a bolus insulin calculator using self-measured blood	T2D  T1D	12  6	N/A  N/A	I: 47.3 (6.8); C: 47.4 (7.5)  I: 38.4 (10.3); C: 34.3 (10.0)	I: 23 (62.2); C: 11 (37.9)  I: 54.0C; 50.9

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Table 2 (continued)

	Intervention Description	Diabetes Type Targeted	Longest Follow-up (months)	BC Theory	Age [Mean, (SD)]	Gender [n, (%) Female]
(Rossi et al., 2013) [63] Italy	glucose, dietary, and physical activity values. Supports telehealth using text messages					
(Skrovseth et al., 2015) [56] Norway	Diastat is a data-driven module that uses a blood glucose meter to provide data visualization and situation matching. Includes dietary and physical activity components.	T1D	3	N/A	I: 41.07 (13.5); C: 38.33 (7.3)	I: 66.67; C: 60.00
(Sun et al., 2019) [52] China	mHealth management application that collates glucometer data for health recommendations and reminders via text messaging and telephone calls. Supports dietary and physical activity	T2D	3	N/A	I: 67.9 (66–71); C: 68.04 (66–72)	I: 25 (56.82); C: 29 (61.70)
(Waki et al., 2014) [64] Japan	DialBetics is designed to aid diabetes data collection, evaluation of data, tailored feedback, and communication with healthcare providers	T2D	3	N/A	I: 57.1 (10.2); C: 57.4 (9.4)	I: 7/27; C: 6/27
(Wang et al., 2019) [53] China	mHealth application for blood glucose monitoring and reminders, dietary support, social support via online forums, and feedback from healthcare providers	T2D	6	N/A	I: 45.13 (7.83); C: 45.8 (8.38)	I: 27 (45); C: 29 (48.33)
(Wayne et al., 2015) [59] Canada	Connected Wellness Platform (CWP) is an application designed to track blood glucose, exercise, diet. Has goal setting and progress monitoring components	T2D	6	N/A; (*Both control and intervention received health coaching based on BC theory)	I: 53.1 (10.9); C: 53.3 (11.9)	I: 31 (65); C: 39 (80)
(Zhang et al., 2019) [48] China	Welltang consists of four main components: diabetes education, diabetes data collection (including blood glucose physical activity, and weight data), social support, and communication with healthcare providers	T1D; T2D	6	N/A	I: 52 (10); C: 55 (11)	I: 28 (35.90); C: 29 (37.17)

differences ( $p = 0.89$  and  $0.34$  for TTM and SCT, respectively) among the subgroups.

### 3.5.2. Support for behavior change techniques

A total of 17 distinct BCT were applied across the 24 intervention groups with an average of 6.71 BCTs per intervention. The most frequently applied BCTs to mHealth interventions were 2.3 Self-monitoring of behavior ( $n = 20$ ), 2.4 Self-monitoring of outcome(s) of behavior ( $n = 20$ ), 2.5 Feedback on outcome(s) of behavior ( $n = 18$ ), 4.1 Instruction on how to perform the behavior ( $n = 16$ ), and 9.1 Credible source ( $n = 15$ ). Only 2 distinct BCTs, 1.5 Review behavior goal(s) and 6.1 Demonstration of the behavior, were applied once.

Comparing the interventions that included a particular BCT with those that did not support that particular BCT showed that for the most part, there were no statistically significant differences between the subgroups. The exceptions were 1.4 Action planning ( $p = 0.004$ ) and 2.4 Self-monitoring of outcome (s) of Behavior ( $p = 0.03$ ) where the presence of these techniques showed a statistically significant reduction in HbA1c compared to the interventions not supporting these techniques. Taking the certainty of evidence and effect size into consideration, the certainty of evidence for interventions supporting 1.4 Action planning was moderate indicating that such interventions were likely to reduce HbA1c. On the other hand, the certainty of evidence for those supporting 2.4 Self-monitoring of outcome (s) of Behavior was low as a result of the indirectness and imprecision potentially present due to the low number of studies in the comparison group indicating that such interventions may reduce HbA1c.

Grouping interventions by the number of supported BCTs resulted in significant effect sizes across all groups as shown in Table 3. Specifically, there were 7 interventions employing 8 or more BCTs ( $-0.49$ , 95% CI =  $-0.76$  to  $-0.23$ ,  $p < 0.001$ ), 10 interventions employing between 6 and 7 BCTs ( $-0.36$ , 95% CI =  $-0.51$  to  $-0.20$ ,  $p < 0.0001$ ), and the remaining 7 interventions employing less than 6 BCTs ( $-0.33$ , 95% CI =  $-0.63$  to  $0.03$ ,  $p = 0.003$ ). While there was a decreasing trend in the effect size as the number of BCTs increased, there were no significant differences among the three groups ( $p = 0.65$ ) and a meta-regression on the number of BCTs ( $\beta = -0.02$ ,  $p = 0.46$ ) was not statistically

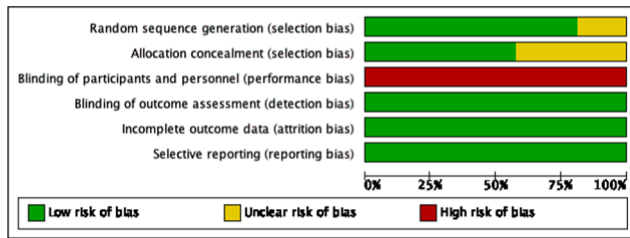
significant. The certainty of evidence for interventions supporting five or less BCTs was low due to inconsistency ( $I^2 = 66\%$ , and point estimates that vary widely across studies), and indirectness indicating that such interventions may reduce HbA1c slightly compared to interventions supporting 6 or more BCTs where the certainty of the evidence was moderate indicating that such interventions are likely to reduce HbA1c.

### 3.5.3. Diabetes type

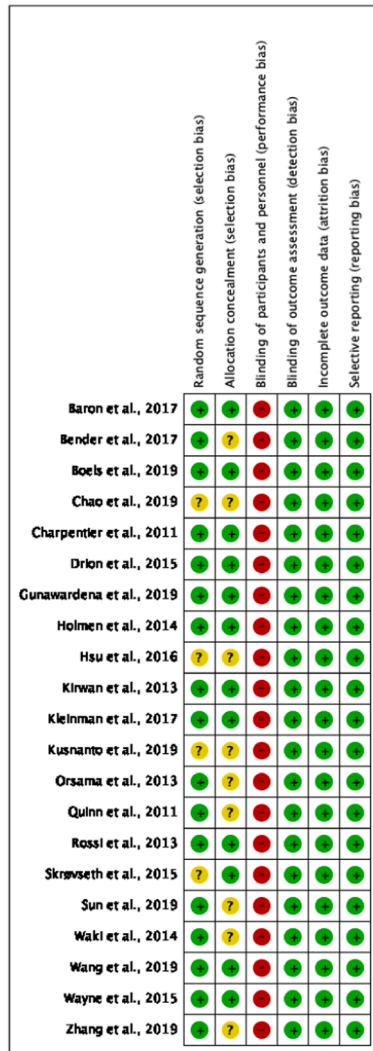
Table 4 depicts the results for diabetes type and intervention duration. Interventions had significant effect on glycemic control for T1D ( $-0.38$ , 95% CI =  $-0.63$  to  $-0.12$ ,  $p = 0.01$ ) and for T2D ( $-0.43$ , 95% CI =  $-0.58$  to  $-0.29$ ,  $p < 0.0001$ ). The three trials where the interventions were designed for both T1D and T2D did not result in reductions below the 0.30 decrease threshold ( $-0.08$ , 95% CI =  $-0.41$  to  $0.26$ ,  $p = 0.69$ ). Interventions targeting T2D had the least heterogeneity. Overall, the test for subgroup differences was not significant between the three groups ( $p = 0.16$ ) or between T1D and T2D ( $p = 0.69$ ). The certainty of evidence for T1D is low given the potential for inconsistency indicating that such interventions may reduce HbA1c, while the certainty of evidence for interventions targeting T2D is moderate, indicating that such interventions are likely to result in a reduction in HbA1c for T2D patients. The certainty of evidence for interventions targeting both T1D and T2D is low due to imprecision and the potential for risk of bias thereby indicating that such interventions aimed at T1D and T2D patients resulted in little to no difference in the outcome.

### 3.5.4. Intervention duration

Groups with longer intervention duration demonstrated a statistically significant improvement in glycemic control with ( $-0.51$ , 95% CI =  $-0.72$  to  $-0.30$ ,  $p < 0.0001$ ) for follow-up durations greater than 9 months, and ( $-0.35$ , 95% CI =  $-0.53$  to  $-0.16$ ,  $p < 0.001$ ) for follow-up greater than 3 months but less than 9 months. Shorter durations of 3 months or less had statistically insignificant reductions ( $-0.28$ , 95% CI =  $-0.67$  to  $0.11$ ,  $p = 0.16$ ). However, the test for subgroup differences did not indicate significant differences among the three time periods ( $p = 0.44$ ). Further, a meta-regression on the intervention duration was not statistically significant ( $\beta = -0.03$ ,  $p = 0.11$ ).



(a) Risk of bias graph



(b) Risk of bias summary

Fig. 2. Risk of bias graph and summary based on authors' judgments.

#### 4. Discussion

This meta-analysis examined the efficacy of mHealth based interventions for health behavior change in diabetes patients by evaluating their effect on glycemic control. The evidence demonstrated that the use of mHealth app-supported interventions likely result in improvements in HbA1c levels of participants as compared to standard care. An in-depth discussion of specific intervention characteristics and their effect on glycemic control is presented in the ensuing discussion.

##### 4.1. Behavior change theory

Consistent with Van Rhoon et al. [6] and Webb et al. [21], the SCT

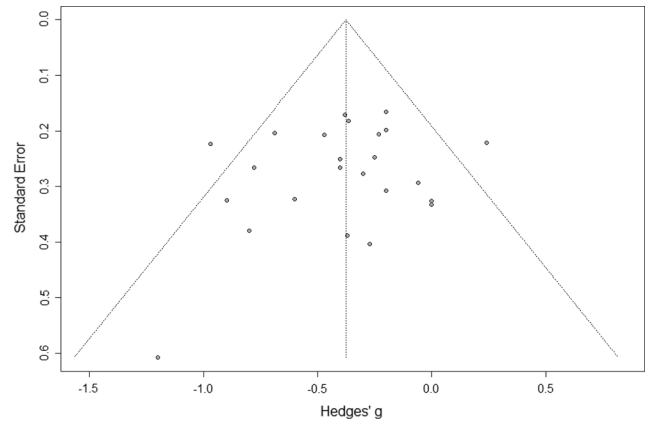


Fig. 3. Funnel plot of publication bias.

and the TTM were the most frequently encountered theoretical basis. This is in contrast to Webb et al. [21], where the Theory of Planned Behavior (TPB) was one of the most frequently used theoretical bases. TPB was referenced once by Kleinmann et al. [61]. Three studies [58,62,66] employed theory merely as an evaluative measure while those that incorporated theory as part of the study design delivered only a few details on the extent to which interventions incorporated said theory. In Bender et al. [49], a support group was created on Facebook based on principles drawn from SCT and TTM. Bender et al. [54] incorporated behavioral triggers, predicated on the Health Belief Model (HBM), the Self-Regulation Theory (SRT), the Trans Theoretical Model (TTM), and Fogg's Behavioral Model (FBM), for delivering text messages as part of their application design. Hsu et al. [50] and Wayne et al. [59] used theory mainly as part of health coaching to assist participants in some activities and decision making. Only Orsama et al. [60] and Kleinman et al. [61] employed various theories for application-specific features such as reminders, feedback, and data visualization among others to elicit behavior change.

Overall, most of the studies did not provide an explicit account of the role of theory in the development of the mHealth intervention making it particularly difficult to assess which is consistent with [68]. Future research should address this issue possibly by emphasizing the need for developing a theoretical understanding of the likely process of inducing behavior change at the early phases of the design of an intervention [69] and, by describing the role of theory in a 'standardized' form as described in Michie and Prestwish [70]. Explicit, systematic, and relatively standardized description of the role of theory in the design and development of the intervention will allow future research to not only assess the efficacy of the role of theory in such interventions but possibly the relation between the extent to which theory is used and the resulting improvement in behavior and associated health outcome.

##### 4.2. Behavior Change Techniques (BCT)

With the evidence from the current literature pointing to an apparent lack of details on theory, evaluating specific BCTs that promoted behavior change was important. Consistent with Van Rhoon et al. [6] and Webb et al. [21], BCTs associated with "goal planning", "feedback and monitoring", and "providing instruction" were the most frequently encountered. Similar to other studies [6,21], we found that the use of BCTs in mHealth applications was generally associated with effect sizes.

Our moderator analyses identified that interventions supporting "1.4 Action planning", "11.3 Conserving mental resources", "2.4 Self-monitoring of outcome(s) of behavior", "3.2 Social support (practical)", and "9.1 Credible source" likely result in a reduction in HbA1c. Although these BCTs resulted in the largest effect when present, only 1.4 Action planning and 2.4 Self-monitoring of outcome(s) of behavior were statistically different from those that did not apply them. The results are



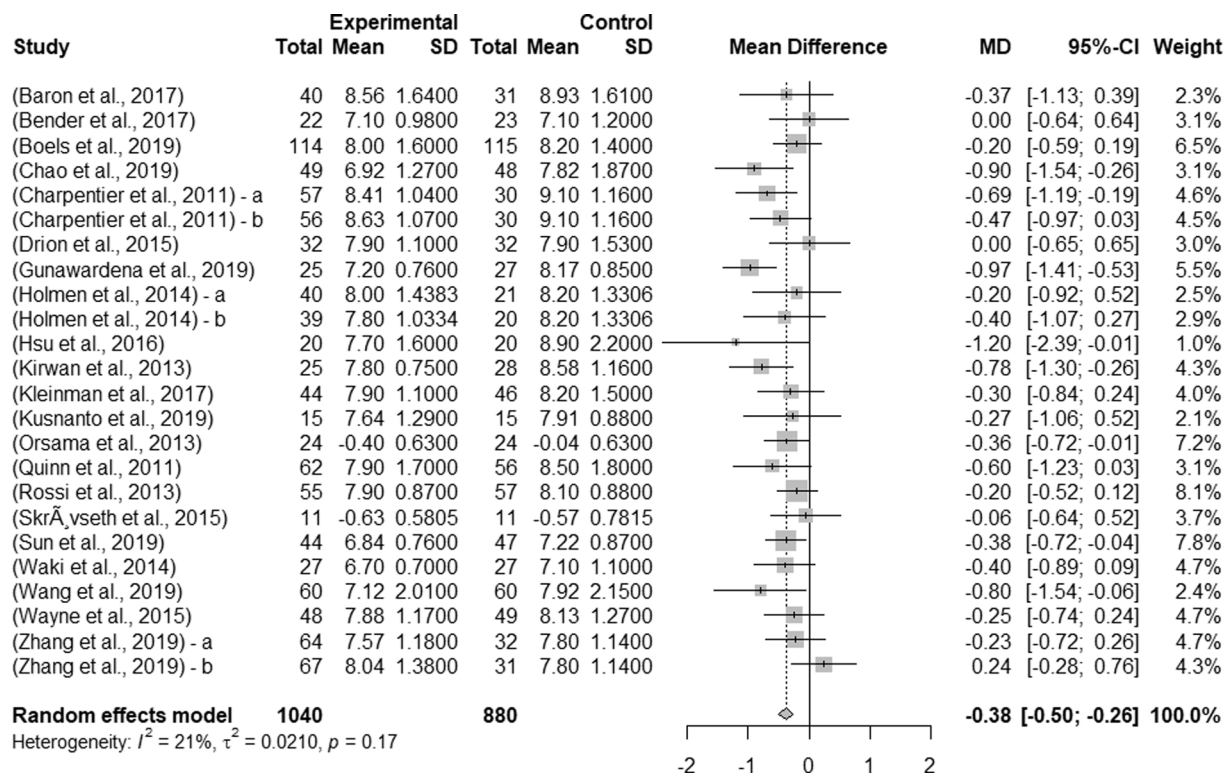


Fig. 4. Forest plot of mHealth interventions vs standard care for glycemic control.

generally consistent with Liu et al. [8] where the focus was on features (as opposed to behavior change techniques) related to monitoring, feedback, goal-setting, and patient-provider communication. In this review, a likely reduction in HbA1c was observed in interventions supporting these features. However, results were mixed when comparing between groups supporting such features versus those that did not. Further, we interpret this result to mean that the features involving reduced demands on mental resources of patients (conserving mental resources) such as automatic bolus insulin recommendation advice reported in some studies [46,50,65] instigated a reduction in the risk of diabetes burnout. Similarly, because diabetes management depends on the timing and amount of diet, exercise, and medication, detailed planning of specific behaviors and goals to be achieved (action planning and self-monitoring of outcomes of behaviors, respectively) contributed to an increase in the effectiveness of the interventions. As reported in a recent study [71], pairing such techniques with prompts and cues, and tailored feedback, assist in reinforcing the value of medication adherence in diabetes patients and contribute to the overall wellbeing of patients. For example, Kleinman et al. [61] included a blood glucose testing schedule which the authors posit as a possible intermediary to the improved HbA1c levels of intervention participants. A similar feature was available in an app designed by Kusnanto et al. [62] which also resulted in a likely reduction in HbA1c. However, it must be noted that Drion et al’s [55] app which allowed patients to personalize activities consistent with their schedule did not result in significant differences between intervention and control groups after 3 months.

It is worth noting that interventions that included significant provider involvement, coded as “9.1 Credible source” are likely associated with a moderate increase in the effectiveness of the interventions. However, the results are not statistically different from those that did not include such support. In essence, it appears that on average, mHealth interventions with clinical support might be associated with relatively larger improvements, but the evidence is inconclusive. Further research is warranted to assess the benefit provided by access to a credible source such as healthcare providers.

#### 4.3. Diabetes type

Subgroup analysis based on the types of diabetes targeted and the duration of the intervention showed that they influenced clinical outcomes. For the type of diabetes, the results are consistent with Wu et al. [11] where both T1D and T2D groups likely resulted in a negative effect size reflecting a reduction in HbA1c with no significant differences between the two groups. It is also consistent with Kitsiou et al. [72] where on average, mHealth interventions improve glycemic control (HbA1c) compared to standard care.

However, interventions targeting T2D had a sizable reduction in heterogeneity in contrast to the entire sample. Studies targeting T1D or a combination of T1D and T2D delivered mixed results. Some of these studies [48,56] reporting an opposite effect on the outcome appear to have contributed to the relatively higher heterogeneity of the sample. One possible explanation is that T1D is much harder to control as compared to T2D which can often be managed with lifestyle modifications alone [73,74]. Regardless, this result should be interpreted with caution since the difference between the three groups did not reach statistical significance and the number of studies in the T1D group and the T1D & T2D groups was relatively small.

#### 4.4. Intervention duration

We also observed a likely reduction in HbA1c in both long- and medium-term study durations (greater than 9 months and 3 to 9 months respectively). These interventions achieved the 0.3% HbA1c reduction threshold set to signal effectiveness as defined in this study. Shorter-term studies had small but statistically insignificant effect sizes. The finding that intervention effectiveness likely increases with trial duration are comparable to the results reported in a recent systematic review on T1D involving eight mobile applications and text message-based interventions [12]. However, we found that there were no significant differences between the three groups of short-, medium- or long-term follow-up durations. This non-significant difference was confirmed in

**Table 3**  
Moderator analysis based on behavior change theory and techniques.

	# Interv.	Effect Estimate (95% CI)	Q	I <sup>2</sup>	p
<b>Presence of Behavior Theory</b>					
Yes	8	-0.36 [-0.60; -0.13]	6.62	0%	0.002
No	16	-0.39 [-0.54; -0.24]	22.58	34%	<0.0001
<b>Theoretical Basis</b>					
Transtheoretical Model of Health Behavior Change (TTM)	3	-0.35 [-0.88; 0.18]	4.50	56%	0.2
Social Cognitive Theory (SCT) and Self-Efficacy	4	-0.23 [-0.56, 0.10]	0.70	0%	0.18
Health Belief Model (HBM)	2				
Self-Regulation Theory (SRT)	2				
Fogg Behavior Model (FBM)	1				
Situated Learning Theory (SLT)	1				
Theory of Planned Behavior (TPB)	1				
Information-Motivation-Behavioral Skills Model (IMBS)	1				
Health coaching	1				
<b>Number of BCTs Supported</b>					
<=5	7	-0.33 [-0.63; -0.03]	17.62	66%	0.003
>=6 & <=7	10	-0.36 [-0.51; -0.20]	2.85	0%	<0.0001
>=8	7	-0.49 [-0.76; -0.23]	7.51	20%	<0.001
<b>Behavior Change Techniques</b>					
<b>1 Goals and planning</b>					
1.1 Goal setting (behavior)	5	-0.37 [-0.53; -0.22]	25.83	30%	<0.0001
1.2 Problem solving	4	-0.32 [-0.60; -0.03]	4.66	14%	0.03
1.3 Goal setting (outcome)	4	-0.33 [-0.69; 0.02]	4.32	31%	0.07
1.4 Action planning	12	-0.33 [-0.54; -0.12]	14.53	24%	0.003
<b>2 Feedback and monitoring</b>					
2.2 Feedback on behavior	10	-0.61 [-0.81; -0.41]	10.31	13%	<0.0001
2.3 Self-monitoring of behavior	22	-0.39 [-0.53; -0.26]	28.39	26%	<0.0001
2.4 Self-monitoring of outcome(s) of behavior	9	-0.32 [-0.48; -0.17]	5.06	0%	<0.0001
2.7 Feedback on outcome (s) of behavior	20	-0.39 [-0.52; -0.26]	26.5	28%	<0.0001
3 Social support	20	-0.43 [-0.56; -0.31]	21.91	13%	<0.0001
	18	-0.39 [-0.54; -0.24]	18.88	10%	<0.0001
	7		6.21	3%	<0.001

**Table 3 (continued)**

	# Interv.	Effect Estimate (95% CI)	Q	I <sup>2</sup>	p
		-0.38 [-0.61; -0.14]			
3.1 Social support (unspecified)	3	-0.34 [-0.79; 0.11]	2.52	21	1.14
3.2 Social support (practical)	4	-0.40 [-0.71; -0.10]	3.57	16%	0.01
4.1 Instruction on how to perform the behavior	16	-0.38 [-0.53; -0.23]	15.4	3%	<0.0001
5.1 Information about health consequences	10	-0.26 [-0.46; -0.06]	11.03	18%	0.01
7.1 Prompts/cues	9	-0.39 [-0.58; -0.20]	11.83	32%	<0.0001
9.1 Credible source	15	-0.41 [-0.55; -0.28]	12.83	0%	<0.0001
11.3 Conserving mental resources	5	-0.59 [-0.87; -0.30]	9.53	58%	<0.0001

**Table 4**  
Subgroup analysis for diabetes type and intervention duration.

	# Interventions	Effect Estimate (95% CI)	Q	I <sup>2</sup>	p
<b>Diabetes Type</b>					
T1D	6	-0.38 [-0.63; -0.12]	7.54	34%	0.01
T2D	15	-0.43 [-0.58; -0.29]	15.38	9%	<0.0001
T1D&T2D	3	-0.08 [-0.41; 0.26]	2.37	16%	0.66
<b>Trial Duration (months)</b>					
<=3	5	-0.28 [-0.67; 0.11]	3.77	0%	0.16
>3 & <=9	12	-0.35 [-0.53; -0.16]	19.08	42%	<0.001
>9	7	-0.51 [-0.72; -0.30]	4.13	0%	<0.0001

a meta-regression analysis of the trial duration on intervention effectiveness. This finding suggests the need for further investigation into whether intervention effectiveness increases with sustained use.

**4.5. Limitations of the study**

One of the main strengths of this study lies in the use of replicable BCTs [14] to code intervention-specific features that foster behavior change. While BCT coding assisted in identifying the specific “active ingredients” in mHealth app-based interventions, their interpretation and coding were dependent on the details provided in the literature reporting said interventions. This is a shortcoming that has been reported in reviews of this nature [6,23,24]. Another limitation relates to the reliance on what is reported in the manuscripts concerning the techniques used or the theory cited. This has also been encountered in prior reviews [21]. Accordingly, in this study, we opted to investigate the presence versus absence of theory as opposed to attempting to infer the precise role of theory in driving the design of the intervention. Further, while there is a reasonable number of interventions included in the meta-analysis to evaluate the overall effect size as well as to conduct moderator analyses, the number of studies is not enough to evaluate

multiple moderators simultaneously to better assess possible interaction effects. Moreover, as BCTs provide a synthetic aggregation of implementation constructs that may be core to multiple behavior change theories, including the ones reported, theory use and BCT use can be seen as two inherently dependent tasks for the studies that mention theory use. A subcomponent analysis of BCT prevalence in studies driven by theory may offer interesting insights as more studies become available. On another note, the review relies on PubMed/Medline and Web of Science. While we carefully examined citations of prior related reviews [4–12] in order to not inadvertently rule out any potentially useful study, there is a possibility that eligible studies in other databases such as CENTRAL and EMBASE may have been missed. Last but not least, it is also worth noting that the current review focused on HbA1c as an outcome. However, minimizing glycemic variability has been advocated for the prevention of cardiovascular events [75]. The ubiquity and pervasiveness of mobile apps coupled with behavioral change may offer opportunities for reducing glycemic variability. Future research may emphasize interventions aimed at reducing such variability.

## 5. Conclusion

The potential for mHealth applications to foster health behavior change for diabetes self-management and regimen adherence is investigated in this meta-analysis. This study evaluates the efficacy of mHealth interventions compared to standard care for achieving glycemic control in diabetes patients with a particular focus on the role of theory and behavioral change techniques. Consistent with the results of prior studies, we found evidence from 21 studies that the use of mHealth app-supported interventions is likely to result in improvements in HbA1c levels of participants as compared to standard care. The results show that the use of BCTs is generally associated with likely higher HbA1c reductions. BCT 1.4 Action planning and BCT 2.4 Self-monitoring of (outcome of) behavior were the only two techniques that demonstrated statistically significant differences in effect sizes between interventions that supported these techniques compared to those that did not. Further, the use of behavior theory did not differ significantly from those not using theory for intervention design.

Overall, this study is the first meta-analysis specifically investigating the effect size and quality of evidence of mobile-based interventions for diabetes self-management with a particular focus on exploring the role of behavioral change techniques and theory. The study has several theoretical and practical implications. Most notably, despite the importance of theory-based interventions [6,21,76] and given that the use of theory was often unclear in how it influenced intervention components, this study highlights the importance of linking theoretical constructs to intervention components to increase their effectiveness. There is also a need for an explicit account of how theory is used as a basis for any proposed intervention. One possibility is to rely on some conceptualization of theory use such as the one proposed by Michie and Prestwich [70]. Further, while some interventions mention behavioral change as a focus, the nature of the targeted behavior change is not often obvious. Clearly articulating the targeted behavioral change that is used as a mediator for the intended health outcome can provide sufficient details for further exploring 1) the role of behavioral change as a mediator, and 2) understand which theoretical basis and BCTs are effective in inducing the needed behavioral change and associated health outcome.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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