A Systematic Literature Review of Randomized Controlled Trials to Prevent Type 2 Diabetes: Comparison of In-Person and Digital Interventions

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Abstract

Background: Digital lifestyle interventions to prevent type 2 diabetes mellitus (T2DM) have become more common in the past decade, particularly in the United States. However, how their effectiveness compares with interventions delivered in-person remains unclear, partly due to variability in study design, including format and content of the intervention. Understanding the relative impact of these two modalities is critical for informing evidence-based implementation of lifestyle interventions to prevent T2DM in diverse healthcare settings.

Objective: To compare the effectiveness of digital versus in-person interventions for preventing T2DM.

Methods: Following Cochrane methodology, a systematic literature review was conducted to identify and synthesize evidence from randomized controlled trials (RCTs). Searches were conducted in EMBASE, MEDLINE, and Cochrane CENTRAL from inception to December 2024. Completed and ongoing RCTs were eligible. There were no language restrictions to the searches, but to be included studies had to be published in English or Spanish. Studies comparing digital and in-person interventions were eligible. Outcomes for inclusion were selected based on a stakeholder consultation, and were classified as critical (such as body mass index and quality of life) or important (namely physical activity level, incidence of T2DM, and cost-effectiveness). Meta-analyses were performed where appropriate, and narrative syntheses were provided for the remaining outcomes. The GRADE approach was used to assess the certainty of evidence.

Results: Eight RCTs met the inclusion criteria, including six completed trials with published results and two ongoing trials. The completed trials encompassed a total of 2,450 participants across various healthcare settings. There was considerable methodological variation across trials, which included the format and content of the interventions, the setting where they were delivered and the outcomes definition.
At 12 months, digital interventions were associated with significantly greater weight loss than in-person interventions (n= 1459 participants, mean difference: –1.38 kg, 95% confidence interval [CI] –2.34 to –0.43), with moderate certainty of evidence. At shorter (3 and 6 months) and longer (15-18 months) time points, no relevant differences were observed for weight, body mass index, or glycosylated hemoglobin levels between the modalities, with the certainty of evidence rated as very low to low. Evidence about cost-effectiveness was scarce. No trials evaluated key outcomes such as quality of life or incidence of T2DM. For adverse events, no significant differences were found between modalities (incidence risk ratio: 1.06, 95% CI: 0.45 to 2.50).

Conclusions: This systematic literature review highlights that while digital and in-person interventions can both be effective for T2DM prevention, their relative benefits are still unclear. The limited certainty of evidence and the dearth of critical outcomes, such as T2DM incidence, underscore the need for further well-designed RCTs. Future research should prioritize equivalence in intervention intensity, longer follow-up durations, and standardized reporting of outcomes to better inform public health decision-

making.

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Content

ABSTRACT

Background: Digital lifestyle interventions to prevent type 2 diabetes mellitus (T2DM) have become more common in the past decade. However, how their effectiveness compares with interventions delivered in-person remains unclear, partly due to variability in study design, including format and content of the intervention. Understanding the relative impact of these two modalities is critical for informing evidence-based implementation of lifestyle interventions to prevent T2DM in diverse healthcare settings.

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Conclusions: This systematic literature review highlights that while digital and in-person interventions can both be effective for T2DM prevention, their relative benefits are still unclear. The limited certainty of evidence and the dearth of critical outcomes, such as T2DM incidence, underscore the need for further well-designed RCTs. Future research should prioritize equivalence in intervention intensity, longer follow-up durations, and standardized reporting of outcomes to better inform public health decision-making.

Keywords: digital health care services; deliver modality; systematic review; PRISMA; diabetes prevention

INSTRODUCTION

Type 2 diabetes mellitus (T2DM) represents one of the most significant global public health challenges of the 21st century. As of 2021, over 536 million adults worldwide were living with diabetes, with T2DM accounting for more than 90% of cases. Projections indicate that this number will rise to 783 million by 2045, driven by aging populations, urbanization, and lifestyle behaviors, such as lack of physical exercise and unhealthy eating habits[1, 2]. T2DM is a leading cause of morbidity and mortality, associated with complications such as cardiovascular disease, chronic kidney disease, and lower-limb amputations, as well as a substantial reduction in quality of life. Economically, the condition imposes a staggering burden on healthcare systems, with global health expenditures related to diabetes reaching $966 billion in 2021[1, 3].

Lifestyle interventions targeting weight loss, increased physical activity, and dietary changes have been shown to reduce the risk of developing T2DM by up to 58%, as demonstrated in landmark trials such as the U.S. Diabetes Prevention Program (DPP)[4, 5]. These programs, when effectively implemented, offer a critical strategy for alleviating the individual and societal burden of T2DM. However, scaling these interventions to diverse populations and healthcare settings remains a challenge.

In-person delivery of lifestyle interventions, sometimes also referred to as face to face delivery, typically conducted through structured group sessions led by trained professionals, has demonstrated high levels of engagement and efficacy in clinical trials[5, 6]. However, this modality can be resource-intensive, requiring significant investments in trained personnel, infrastructure, and participant time, which may limit its scalability and accessibility[7]. In contrast, digital interventions leverage technologies such as mobile applications, wearable devices, and online platforms to deliver content and support remotely. These approaches are cost-effective, scalable, and more flexible for participants, but they often face challenges such as lower adherence rates and variability in digital literacy[8, 9]. Both modalities have shown promise in reducing diabetes risk, but their comparative effectiveness in real-world settings remain underexplored.

Previous reviews addressing this question have often relied on observational designs or indirect comparisons. For instance, several cohort studies have examined the outcomes of DPPs implemented at scale, comparing digital and in-person interventions within separate cohorts[10]. Although these studies provide valuable insights, they are prone to confounding and selection bias, which limit their ability to establish causality. Similarly, meta-analyses that aggregate data from heterogeneous studies often lack the granularity needed to isolate differences between delivery modalities[11, 12]. Randomized controlled trials (RCTs) offer the highest level of evidence, minimizing biases through randomization and enabling direct comparisons.

The objective of this systematic literature review was to identify and synthesize evidence on the comparative effectiveness of in-person versus digital interventions for preventing T2DM, thereby providing insights to guide the design and implementation of effective diabetes prevention strategies.

METHODS

This systematic literature review was conducted following the methods from Cochrane Handbook for Systematic Reviews of Interventions [13]. The methods and findings of this manuscript are reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement[14].

Data sources and search methodology

The following databases were searched for eligible RCTs: MEDLINE (Ovid), EMBASE (EMBASE), and Cochrane Central Register of Controlled Trials (CENTRAL, Cochrane Library) using predefined search strategies from inception to December 2024. The search strategies (available in Appendix 1) combined Medical Subject Headings (MeSH) terms and keywords. There were no language restrictions to the searches. Due to constrained resources, only studies published in English or Spanish were eligible for inclusion.

Study selection

The following inclusion criteria were applied to the results of the searches:

Population: Prediabetic adult population (i.e., people with high risk of developing T2DM). There were no preset criteria for the definition of prediabetes, and RCTs were eligible if the population was defined as being prediabetic by the study authors.

Intervention: T2DM prevention intervention fully delivered remotely (digitally delivered). Interventions combining in-person and remote delivery were excluded.

Comparator: T2DM prevention intervention fully delivered in-person.

Outcomes: Outcomes were identified and prioritized by an international expert panel comprising clinicians, academics, and patient representatives (see Acknowledgements). The panel evaluated a comprehensive list of 28 potential outcomes identified from previous literature, rating each as critical (2 points), important (1 point), or not important (0 points) based on clinical relevance and patient-centered considerations. Mean scores were calculated and rescaled to a 0–10 scale (refer to Multimedia Appendix 2), and based on those scores outcomes were classified as critical (mean score 9 or 10) or important (mean score 7 or 8). In total, three outcomes were classified as critical (body mass index [BMI), glycosylated hemoglobin [HbA1c], and quality of life) and nine outcomes were classified as important (waist circumference, physical activity level, body weight, diet, incidence of T2DM, plasma glucose levels [2-hour oral glucose tolerance test], sedentary behavior, self-reported smoking behavior, and cost-effectiveness. In order to be eligible for inclusion, studies had to evaluate one critical or an important outcome.

Randomized trials and cluster randomized trials, completed or ongoing, were eligible for inclusion, whereas studies following other trial design were excluded. Conference abstracts, letters to the editor, and editorials were also excluded.

Search results were initially screened by a senior systematic reviewer (IRC) based on title and abstract, after which all shortlisted records were independently assessed at full-text by two reviewers (IRC and DMH). Disagreements were discussed, involving a third author when needed, until consensus was achieved.

Data extraction and risk of bias assessment

From each primary study, data on its study design, population, setting, length of follow-up, and results (including adverse events) were independently extracted by one reviewer (DMH) using a data extraction form purposely developed and piloted for this systematic literature review. For those trials including more than two arms (e.g., trials with a third arm with participants receiving a combination of digital and in-person intervention), data was extracted only from the arms that were relevant for this systematic review. A second author (of IRC, MFdR, and PRS) cross-checked the extracted data for accuracy.

The risk of bias of the included trials was assessed using the Cochrane RoB tool 2.0 [15]. The RoB was judged as “low”, “some concerns”, or “high risk” for each of the following domains: randomization sequence; deviation from intended interventions; missing outcome data; measurement of the outcome; and selection of the reported results. Risk of bias was measured at the outcome (rather than at the trial) level. One author determined the risk of bias of the included studies (PRS), and a second author validated the results for accuracy (DMH). Disagreements were resolved with support from a senior systematic reviewer (IRC).

Data synthesis

The interventions' characteristics and results were described narratively and as tabulated summaries. Possible methodological or clinical variation across trials, which may have modified the effects of the intervention, was considered. Findings were summarized by follow-up period (3 months, 6 months, 12 months, and beyond 12 months).

When appropriate, data were meta-analysed using the DerSimonian & Laird method. For continuous outcomes, change from baseline values were meta-analysed. Statistical heterogeneity was assessed with the Q-Cochran test and with the I^2 statistic[16]. A p-value of the Q-Cochran test <0.10 and an I^2>50% were considered to indicate substantial heterogeneity. All statistical analyses were performed using STATA software, v.15.

Certainty of the evidence

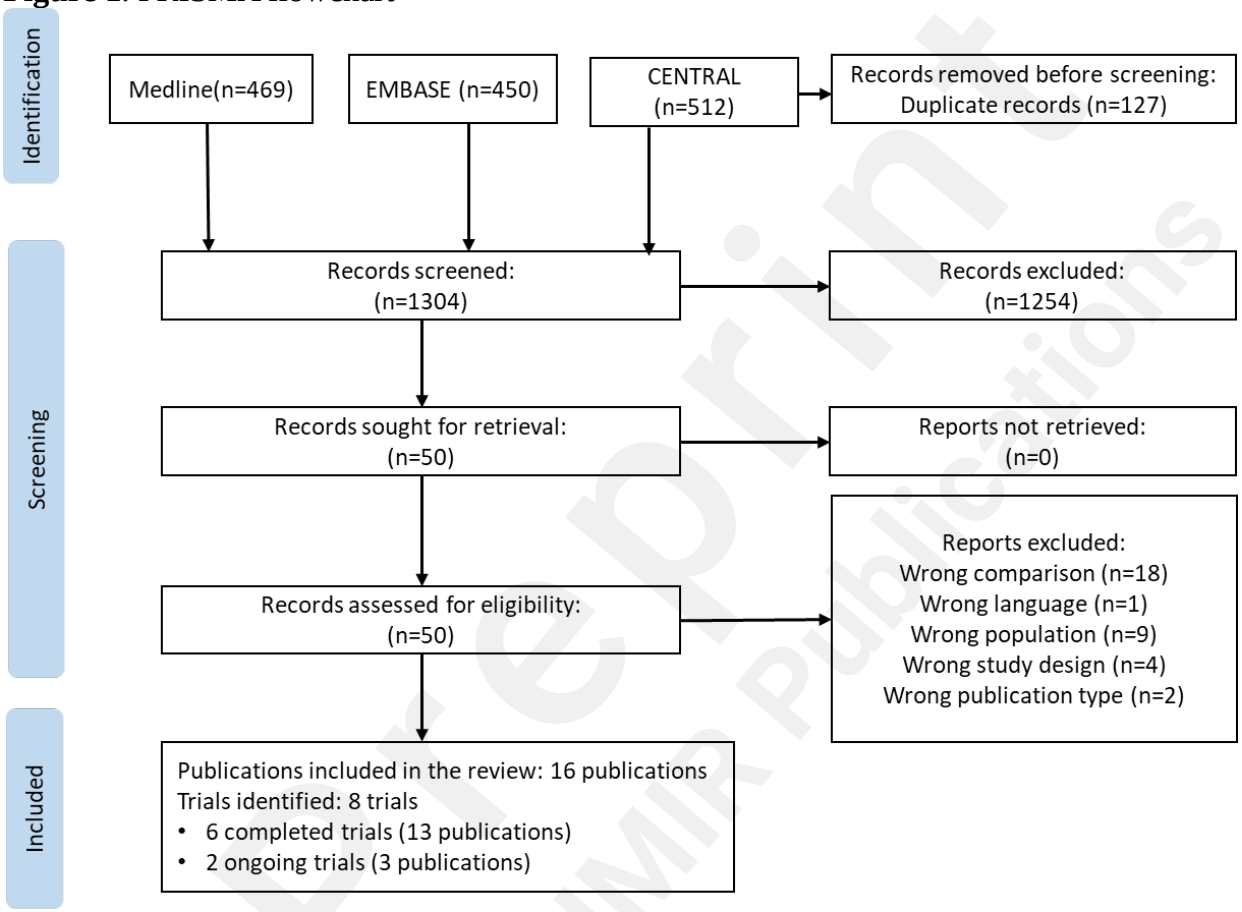
The certainty (quality) of evidence for each outcome was rated using the GRADE approach [17]. Certainty of evidence was rated as “high” (which means that the evidence identified provides a very good indication of the likely effect of the intervention), “moderate” (the evidence identified provides a good indication of the likely effect of the intervention) , “low” (the evidence identified provides a some indication of the likely effect of the intervention, but it is highly likely that the effect of the intervention is substantially different) or “very low” (the evidence identified does not provide a reliable indication of the likely effect), taking into consideration the risk of bias, imprecision, inconsistency, indirectness, and publication bias domains. Results were presented in a summary of findings tables [18]. One author graded the evidence of included studies (IRC), and a second author validated the results for accuracy (PRS). Disagreements were resolved with support from a third reviewer (MFdR).

RESULTS

Selection process

The eligibility process was summarized in a PRISMA flowchart (Fig. 1). We retrieved a total of 1,304 unique citations from database searches. We selected 50 references for full text revision, from which 16 publications [19-34] (reporting on eight different trials) were finally included in our systematic literature review. The reason for exclusion at full-text level are detailed in Multimedia Appendix 3. Two [19, 23, 31] of the eight trials had not been completed, and their results were unavailable at the time the searches were conducted (Multimedia Appendix 4). The remaining of the results focus on the six trials for which data were available.

Figure 1. PRISMA flowchart



Characteristics of the included trials: Study design and baseline characteristics

The characteristics of the six completed trials are described in Table 1. The trials were conducted in diverse settings, predominantly in the United States (five trials) and one in the Czech Republic[29]. The trial designs varied, including parallel-group randomized controlled trials [19, 20, 23-32, 34-36], and one hybrid preference-randomized design [21, 22]. Follow-up durations ranged from 6 months to 18 months. The sample sizes across trials varied significantly, ranging from 100 [21, 22] to 482 participants [25] (median = 241 participants). Participant age also varied, with mean ages ranging from 43.3 to 52.9 years. The six trials were moderately balanced regarding gender.

The trials used various methods to define and measure prediabetes. Three trials used screening questions to calculate risk scores: the City and County of San Francisco (CCSF) Diabetes Prevention Trial[24] relied on a CDC prediabetes screener with a high-risk score (≥9), whereas the DiaBEAT-it trial[21, 22] used a Diabetes Risk Calculator (DRC; test score of ≥5), and the Fuel Your Life trial[32, 34] targeted participants with a high-risk Diabetes Risk Screener score or a BMI ≥30. In general, all these risk scores contain questions about age, family history and lifestyle habits such as exercise; however, their specific content and scoring system varies. Two trials relied on fasting glucose data.

The trial by Moravcová et al[29] defined prediabetes as fasting glucose between 5.6–6.9 mmol/L or OGTT results of 7.8–11.0 mmol/L. The E-LITE trial[26] defined prediabetes by fasting plasma glucose levels of 100–125 mg/dL. Participants were also eligible if they were diagnosed with metabolic syndrome based on the American Heart Association (AHA) and National Heart, Lung, and Blood Institute (NHLBI) criteria, which include waist circumference, blood pressure and triglycerides. Lastly, the PREDICTS trial[27] identified prediabetes by baseline HbA1c levels between 5.7% and 6.4%.

[Table 1 around here]

Characteristics of the digital and in-person interventions compared by the trials

In the CCSF Diabetes Prevention Trial[24], the in-person intervention was delivered at participating worksites and consisted of 16 weekly group sessions of eight to 15 participants, lasting one hour each (core curriculum) followed by three biweekly and five monthly sessions (maintenance curriculum). These sessions were conducted at employees' worksites, accommodating their schedules during breaks or lunch hours. The digital intervention consisted of an in-person orientation session, 16 weekly educational sessions and eight monthly maintenance sessions. Sessions lasted between 25 and 45 min and were interactive, with audio and visual content.

In the DiaBEAT-it trial[21, 22], the in-person intervention consisted of a 2-hour in-person small group class focused on helping participants create a personalized action plan to prevent diabetes. This included setting a goal to lose 10% of their body weight within 12 months and committing to engage in 60 minutes of physical activity five days per week. Instructors provided detailed information on healthy eating and physical activity based on MyPlate guidelines and distributed workbooks covering 22 educational topics adapted from the original DPP. The digital intervention comprised a 60-minute educational DVD with segments addressing prediabetes, diabetes risk factors, action plan development, goal setting for physical activity and nutrition, resource building, and commitment to change. Additionally, participants in the digital intervention received 22 personalized interactive voice response (IVR) calls over 12 months, designed to reinforce weight loss and healthy behavior maintenance.

In the E-LITE trial [26], the in-person intervention consisted of three months of intensive intervention (12 weekly sessions of 90 to 120 minutes based on the Group Lifestyle Balance curriculum) followed by 12 months of maintenance. Sessions included food tastings, physical activity, and were led by a dietitian and fitness instructor. Participants in the digital intervention attended a single orientation session, after which they followed a self-directed approach utilizing DVDs that delivered the same DPP-based content. Participants engaged with the material independently, receiving guidance on implementing lifestyle changes to facilitate weight loss and improve health outcomes.

In the "Fuel Your Life" trial[32, 34], for the in-person intervention small groups of 8 to 10 people met biweekly for four sessions, monthly for four sessions, and bi-monthly during a 6-month maintenance phase. During the sessions participants engaged in discussions and activities led by a facilitator, focusing on diet, physical activity, and behavior change strategies. The digital intervention consisted of a telephone intervention. The telephone sessions were held one-on-one between the health coach and the participant, following the same schedule as the in-person intervention. Each session lasted around 20 minutes, with the coach calling the participant at a prearranged time. While the coach could better customize the discussion and actions to the individual, they were solely responsible for providing reinforcement and accountability, as there was no group support.

In the trial conducted Moravcová et al. (2024)[29], the in-person intervention comprised five regular sessions with a physician, dietitian, or nurse focusing on lifestyle modifications, including dietary changes and physical activity. The digital intervention utilized the Vitadio application, a digital care program with a 3-month intensive phase followed by a maintenance phase, utilizing personalized daily tasks and automated messages to help patients establish a healthy routine.

In the PREDICTS trial[20, 25, 27, 28, 30, 33], the in-person consisted of a 2-hour small group

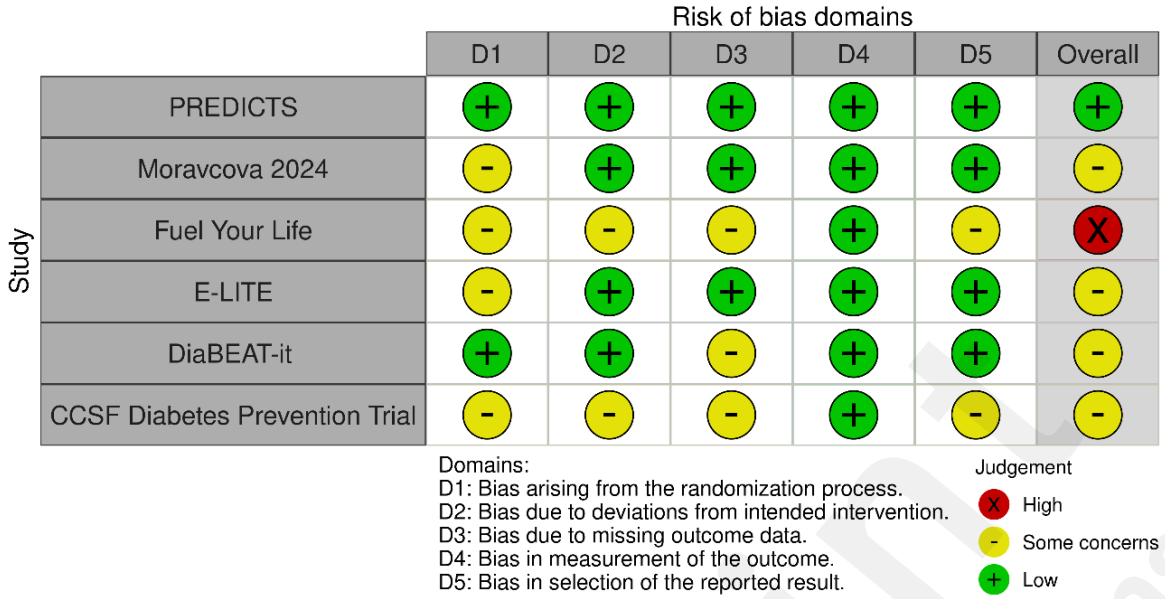
session focusing on action planning for increased physical activity, improved nutrition, weight loss, goal setting, and barrier resolution, with a resource booklet on local lifestyle support. The digital intervention consisted of an Internet-based intervention with small group support, personalized health coaching, digital tracking tools, and weekly behaviour change curriculum, approved by the Diabetes Prevention Recognition Program.

Risk of bias

Risk of bias of the included trials is depicted in Figure 2. Overall, one trial (PREDICTS)[20, 25, 27, 28, 30, 33] was rated as "low risk". Four trials [21, 22, 24, 26, 29]were classified as having "some concerns," primarily due to issues with randomization, protocol transparency, and handling of missing data. One trial (Fuel your Life) [32, 34] was judged as having "high risk" due to a general lack of specific details regarding randomization, blinding, allocation process and protocol availability

There were "some concerns" for the randomization process of most trials, due to incomplete or unclear information regarding allocation sequence and concealment methods. Regarding deviations from intended interventions, two trials (CCSF Diabetes Prevention Trial and Fuel Your Life) were assigned "some concerns," primarily due to lack of information about blinding or adherence to the intervention protocol. High dropout rates or insufficient justification for handling missing data resulted in "some concerns" for missing outcome data for three trials (Fuel Your Life, DiaBEAT-it and and CCSF Diabetes Prevention Trial). Measurement of the outcome was rated as "low risk" in all six trials, indicating robust and unbiased outcome assessment methods. Two trials (Fuel Your Life and CCSF Diabetes Prevention Trial) were rated as having "some concerns" for selection of the reported result, reflecting a lack of protocol availability or inconsistencies in reporting.

Figure 2. Risk of bias of the included trials



Comparison of the effects of digital vs in person interventions at three months

Table 2 presents a comparison of the effects of digital versus in-person interventions on the outcomes prioritized by the expert panel. The findings are based on the meta-analyses conducted at three months of follow-up and are accompanied by an assessment of the certainty of evidence using the GRADE approach.

Body mass index: Two trials [26, 34] assessed the impact of digital versus in-person interventions on BMI at three months. The meta-analysis (Multimedia Appendix 6) showed no significant differences between the two modalities (n=638 participants, mean difference: 0.12 higher, 95% confidence interval [CI] –0.26 to 0.50). The certainty of evidence was rated as moderate due to serious risk of bias.

HbA1c: One trial [25] assessed changes in HbA1c at three months. The digital intervention showed a small reduction in HbA1c compared to the in-person modality (n=599 participants, mean difference: –0.08%, 95% CI –0.12 to –0.04). The certainty of the evidence was rated as moderate due to serious indirectness.

Body weight: Two trials [25, 26] evaluated percentage weight change at three months. The pooled analysis indicated no significant differences between digital and in-person interventions (n= 759 participants, mean difference: –1.21%, 95% CI –5.39 to 2.97). The certainty of the evidence was rated as very low due to serious risk of bias, inconsistency across trials, and indirectness. Three trials [25, 26, 34] analysed weight change in kilograms at three months. The meta-analysis found no significant differences between the modalities (n= 1237 participants, mean difference: –0.86 kg, 95% CI –2.97 to 1.24). The certainty of the evidence was rated as very low due to serious risk of bias, inconsistency, and indirectness.

[Table 2 around here]

Comparison of the effects of digital vs in person interventions at six months

Body mass index: Three trials [21, 22, 26, 34] assessed the impact of digital versus in-person interventions on BMI at six months. The pooled analysis indicated no significant differences between the two modalities (n= 862 participants, mean difference: –0.02, 95% CI –1.13 to 1.1). The certainty of evidence was rated as low due to serious risk of bias and inconsistency across the trials (Table 3).

Body weight: Three trials [21, 22, 24, 26] evaluated percentage weight change at six months. The meta-analysis showed no significant difference between the modalities (n= 541 participants, mean difference: 0.47% higher, 95% CI –2.65 to 3.58). The certainty of the evidence was rated as low, due to serious concerns related to risk of bias and imprecision. Five trials [21, 22, 24, 26, 29, 34] examined weight change in kilograms at six months. The pooled results showed no significant differences between digital and in-person interventions (n= 1140 participants, mean difference: –0.23 kg, 95% CI –2.18 to 1.72). The certainty of the evidence was rated as low due to serious risk of bias and inconsistency.
Physical activity: Two trials [24, 34] evaluated the total volume of physical activity at six months, observing no significant differences between the in-person and digital interventions (n= 1140 participants, standarized mean difference: 0.03, 95% CI –0.17 to 0.24). The certainty of the evidence was rated as low due to serious risk of bias and imprecision.
Diet: One trial [24] assessed the impact of digital versus in-person interventions on food energy at six months, observing no significant differences (n= 158 participants, mean difference: 9.64 kcal, 95% CI –137.2 to 156.5). The certainty of the evidence was rated as low due to serious risk of bias and imprecision.

[Table 3 around here]

Comparison of the effects of digital vs in person interventions at 12 months
Body mass index: Two trials [21, 22, 34] evaluated the impact of digital versus in-person interventions on BMI at 12 months. The pooled analysis showed that the digital intervention resulted in a slightly lower BMI compared to the in-person modality (n= 702 participants, mean difference: –0.5, 95% CI –0.6 to –0.39). The certainty of evidence was rated as moderate due to serious risk of bias (Table 4).
HbA1c: One trial [25] assessed changes in HbA1c at 12 months. The digital intervention was associated with a small reduction in HbA1c compared to the in-person modality (n= 599 participants, mean difference: –0.08%, 95% CI –0.12 to –0.03). The certainty of evidence was rated as moderate due to serious indirectness, as the compared modalities differed significantly in intensity.
Body weight: Four trials [21, 22, 24, 25, 34] analysed weight change in kilograms at 12 months. The meta-analysis indicated that the digital intervention was associated with slightly greater weight loss compared to the in-person intervention (n= 1459 participants, mean difference: –1.38 kg, 95% CI –2.34 to –0.43). The certainty of the evidence was rated as moderate, primarily due to concerns about risk of bias.
Waist circumference: One trial [24] evaluated waist circumference at 12 months. The analysis showed no significant difference between the modalities (n= 158 participants, mean difference: 0.38 cm higher, 95% CI –2.19 to 2.95). The certainty of evidence was rated as low, due to wide confidence intervals and risk of bias.
Physical activity: Two trials [24, 34] evaluated the total volume of physical activity at 12 months, observing no significant differences between the in-person and digital interventions (n= 361 participants, standardized mean difference: -0.04, 95% CI 0.25 to 0.17). The certainty of the evidence was rated as low due to serious risk of bias and imprecision.
Diet: One trial [24] assessed the impact of digital versus in-person interventions on food energy at 12 months, observing no significant differences (n= 168 participants, mean difference: 1.37 kcal [-167.8 to 170.1]). The certainty of the evidence was rated as low due to serious risk of bias and imprecision.

[Table 4 around here]

Comparison of the effects of digital vs in person interventions at 15-18 months
Body mass index: Two trials [21, 22, 26] assessed the effects of digital versus in-person interventions on BMI at 15-18 months. The pooled analysis showed no significant differences between the modalities (n= 384 participants, mean difference: 0.00, 95% CI –1.18 to 1.18). The certainty of

evidence was rated as very low due to serious risk of bias and inconsistency across trials (Table 5).
Body weight: Two trials [21, 22, 26] evaluated weight change in kilograms at 15-18 months. The meta-analysis indicated no significant difference between digital and in-person interventions (n= 384 participants, mean difference: 0.2 kg, 95% CI –2.94 to 3.33). The certainty of the evidence was rated as low, primarily due to concerns about risk of bias and inconsistency.
Waist circumference: One trial [24] assessed waist circumference at 15-18 months. The analysis showed no significant differences between digital and in-person interventions (n= 160 participants, mean difference: –0.42 cm, 95% CI –2.20 to 1.36). The certainty of evidence was rated as low due to serious concerns about imprecision and bias.

[Table 5 around here]

Comparison of the adverse events of digital vs in person interventions
Three trials [22, 25, 26] compared adverse events associated with digital and in-person interventions for T2DM prevention, with pooled results showing no significant differences between the modalities (Incidence Rate Ratio 1.06, 95% CI: 0.45 to 2.50). Most reported adverse events were minor, such as musculoskeletal discomfort related to increased physical activity, and no serious adverse events attributable to either intervention were observed. However, the certainty of the evidence was rated as low due to inconsistent reporting across trials, variability in how adverse events were monitored, and imprecision stemming from the small number of studies.
Comparison of the cost-effectiveness of digital vs in person interventions
Cost-effectiveness was evaluated only in the PREDICTS trial [28, 33], which compared digital and in-person interventions from both private payer and societal perspectives. The digital intervention was slightly more expensive than the in-person modality from a private payer perspective ($4,556 vs. $4,177) but less expensive from a societal perspective ($13,093 vs. $14,731). In terms of health benefits, the difference in quality-adjusted life years (QALYs) between the modalities was minimal (0.019 QALYs, 95% CI: −0.003 to 0.040). The digital intervention was considered more cost-effective at willingness-to-pay thresholds of $50,000, $100,000, and $150,000 per QALY gained.

DISCUSION

Main findings

This systematic literature review included eight RCTs comparing digital and in-person interventions for T2DM prevention, with six completed trials recruiting 2,450 participants. At 12 months, digital interventions showed significantly greater weight loss (mean difference: –1.38 kg, 95% CI: –2.34 to –0.43), though evidence certainty was moderate. This means that the evidence identified provides a good indication of the likely effect of digital interventions for T2DM prevention on weight loss, when compared with in-person interventions.

At 3, 6, and more than 12 months, no relevant differences were observed for BMI, HbA1c, or weight, with consistently very low to low certainty. Due to this certainty of the evidence, it is highly likely that the effect of the interventions is substantially different, which means that for those outcomes it is not possible to draw robust conclusions about the comparative effectiveness of these interventions based on the existing evidence. No trials assessed outcomes rated as critical by a panel of relevant stakeholders, like glycosylated hemoglobin (HbA1c) or health-related quality of life.

Strengths and limitations

This systematic literature review has several strengths. Conducted using Cochrane methodology, it ensures transparency, reproducibility, and adherence to best practices. Comprehensive searches in EMBASE, MEDLINE, and Cochrane CENTRAL identified both completed and ongoing trials. By including only randomized controlled trials comparing digital and in-person interventions, the review minimizes bias and ensures internal validity. Outcomes were assessed at multiple follow-up points, providing insights into the sustainability of effects. Risk of bias was systematically evaluated, and outcomes prioritized by experts align with clinical and patient-centred priorities.

There are also some limitations that should be acknowledged. First, while comprehensive searches were conducted across major databases, excluding grey literature and non-indexed sources might have omitted studies with relevant data, particularly unpublished or ongoing research. Second, the inclusion of studies was restricted to those published in English or Spanish, potentially excluding relevant evidence available in other languages. Third, the limited number of randomized controlled trials identified reduced the robustness of publication bias assessments, as statistical tools for detecting such bias require a larger pool of studies to yield reliable results. Additionally, the inclusion criteria, while designed to ensure a focused comparison between digital and in-person interventions, excluded hybrid models that are increasingly relevant in real-world practice. This could limit the generalizability of the findings to mixed-delivery approaches, which are becoming more common. Finally, despite efforts to compare equivalent delivery modalities, differences in the intensity, structure, and duration of interventions potentially introduced heterogeneity, which hindered head-to-head comparisons between digital and in person interventions.

Comparison with previous literature

Our systematic literature review offers novel evidence due to its focus on clinical trials directly comparing digital and in-person interventions for T2DM prevention. This approach allows for a higher level of experimental evidence compared to the observational studies that dominate much of the existing literature. However, for most outcomes examined, the certainty of evidence was rated as low or very low, which limits the extent to which robust conclusions can be derived from the evidence, and key outcomes prioritized by our expert panel, such as HbA1c or health-related quality of life, were not assessed in the available trials.

Observational studies, while limited by potential confounding, offer complementary insights into the effectiveness of digital and in-person interventions. For example, Ely et al. (2023) [37] and Villegas et al. (2022) [38] found that digital interventions can achieve weight loss outcomes comparable to in-person modalities, particularly when participants are allowed to choose their preferred delivery method. Conversely, Bian et al. (2017) [39], observed slightly lower weight loss with digital interventions, which was attributed to challenges in engagement and accountability. These mixed findings reflect the variability in intervention designs and the contextual factors influencing their

effectiveness.

Our systematic literature review contributes to this body of evidence by identifying a statistically significant greater weight loss with digital interventions compared to in-person modalities at 12 months. At shorter follow-up periods (3 and 6 months), as well as at longer follow-up periods (>12 months) no significant differences between the two modalities were observed for most outcomes (with low or very low certainty), further emphasizing the need for additional high-quality trials with rigorous designs and long-term follow-up.

Key evidence gaps and future research needs

Despite advances in understanding the comparative effectiveness of digital and in-person interventions for T2DM prevention, significant evidence gaps still remain. A notable limitation is the lack of equivalence between the interventions being compared in the trials identified for inclusion. Digital and in-person interventions often differ significantly in intensity, structure, and participant engagement, making it challenging to understand to what extent the delivery modality impacts the results. For example, in some trials, in-person interventions involved structured group sessions with real-time interaction, while digital interventions relied on self-paced or asynchronous formats with limited feedback. Swift technological progress, namely machine learning and artificial intelligence, means that digital interventions have the potential to be specifically tailored and immediately responsive to individual needs, and thus more adequately deliver complex behavioral interventions. Future research should prioritize designing interventions that are equivalent in content, intensity, and support mechanisms to enable more accurate comparisons.

A notable gap is the geographic concentration of evidence, with most trials, including those currently underway (Abusamaan 2023[19, 31]; Beasley 2023[23]), conducted in the United States. Expanding research to other regions, such as Europe, where both modalities are commonly used, is essential to improve generalizability. Additionally, key outcomes prioritized by expert panels, such as quality of life and HbA1c, are underreported. Only the PREDICTS trial evaluated cost-effectiveness, and few studies included long-term follow-up data, limiting insights into the sustainability of intervention effects. There is also variability in how outcomes like weight loss and physical activity are measured across trials, which hinders meta-analyses. Standardized metrics and protocols are needed to enhance comparability[40].

Finally, the evidence lacks diversity in the characteristics of the participants eligible for the trials, with limited focus on rural, low-income, or older adult populations. Few studies address scalability factors, such as implementation fidelity, acceptability, or barriers in low-resource settings. Addressing these gaps with globally representative trials, standardized outcomes, and comprehensive implementation assessments will be critical to advancing diabetes prevention efforts and ensuring equitable access to effective interventions.

Conclusions

This systematic literature review highlights the potential of both digital and in-person interventions for the prevention of T2DM, with digital interventions showing greater weight loss at 12 months but no significant differences at shorter or longer follow-up periods. However, the certainty of evidence was predominantly very low to low, and several prioritized key outcomes remain underexamined. The heterogeneity in intervention designs, lack of equivalence between modalities, and limited representation of diverse populations further underscore the need for caution when interpreting these findings. To strengthen the evidence base, future randomized controlled trials should prioritize equivalence in intervention intensity, longer follow-up durations, and the inclusion of key outcomes, such as cost-effectiveness, incidence of T2DM, and quality of life. These efforts are essential to

guide the implementation of diabetes prevention programs and to ensure equitable access to effective interventions globally.

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Data availability: All the data and materials presented in this study are available within the respective articles cited in this review and from the corresponding author on reasonable request.

Authors' Contributions: IRC conceptualized this review. PRS, DMH and IRC screened the references and extracted the data. PRS conducted the meta-analysis and applied the GRADE framework to assess the certainty of the available evidence. IRC drafted the original manuscript. All authors commented on subsequent versions of the manuscript and approved the final version. All authors had access to the data and accepted responsibility for submitting it for publication.

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Abbreviations
BMI: Body Mass Index
CCSF: City and County of San Francisco
DPP: Diabetes Prevention Programm
HbA1c: glycosylated hemoglobin
IVR: interactive voice response
QALY: quality-adjusted life years
RCT: Randomized Controlled Trial
T2DM: Type 2 diabetes mellitus

Table 1. Characteristics of the completed trials identified

Trial name/ Trial registration code	Country/ number of participants	Trial design	Inclusion criteria	Trial follow-up	Proportion female	Mean (SD) age	Description of in-person intervention	Description of digital intervention
CCSF Diabetes Prevention Trial (Ferrara 2020)[24]/ not reported	US/ 158	2-arm, parallel, RCT	CCSF employees, CDC prediabetes screener score ≥9, BMI ≥25 kg/m² (≥23 kg/m² if Asian); prediabetes defined by high-risk screener score; no major health conditions; regular computer/internet access; not in weight loss programs.	6-month and 12-month follow up	56%	52.7 (8.7) in-person, 51.8 (7.8) digital	YMCA-DPP: in-person intervention with 16 weekly 1-hour sessions, 3 biweekly, and 5 monthly sessions, conducted for groups of 8-15 employees at convenient worksite times.	VLM-DPP: online intervention via Canary Health with 16 weekly educational sessions and 8 monthly maintenance sessions, supplemented by a single in-person orientation. Sessions (25-45 min) included audio and interactive visuals.
DiaBEAT-it[21, 22]/ NCT02162901	US/ 334	Hybrid 2-group preference (Choice) and 3-group RCT	Age ≥18, BMI ≥25 kg/m² (≥22 if Asian), prediabetes DRC test score ≥5, English-speaking, not pregnant, no T2D or major heart conditions, no physical activity/weight loss contraindications, phone access.	6, 12, and 18 months	68%	52,3 (12,1)	2-hour small group class focused on developing a personal action plan for T2D prevention, targeting 10% weight loss and 60 minutes of physical activity, 5 days/week, with guidance on diet and exercise.	DVD-based intervention (60 min) with 22 tailored IVR calls over 12 months, covering pre-diabetes, risk factors, action plans, goal setting, and behaviour change, targeting 10% weight loss and 60 min of activity, 5 days/week.
E-LITE[26]/ NCT00842426	US/241	3-arm, parallel, RCT (digital intervention, in-person intervention, and usual care)	Age ≥18, BMI ≥25, prediabetes (fasting glucose 100–125 mg/dL) or metabolic syndrome (AHA/NHLBI criteria).	3, 6, and 15 months	47%	52.9 (10.6)	3 months of intensive intervention (12-session GLB curriculum) followed by 12 months of maintenance. Sessions included food tastings, physical activity, and were led by a dietitian and fitness instructor.	3 months of intensive intervention (12-session GLB curriculum) and 12 months of maintenance. Participants used a home-based DVD, attended orientation, and used Heart360 for goal setting and monitoring
Fuel Your Life[32, 34]/ not reported	US/418	3-arm, parallel, RCT (1) self-study (no coaching), (2) small-group facilitated by a health coach (group coaching), and (3) individual health coaching by phone (phone coaching)	City-county government employees; all eligible, recruitment targeted to high-risk diabetes (Diabetes Risk Screener high-risk score or BMI ≥30).	6 months // 3 months (midpoint), 6 months, and 12 months (follow-up)	59% in-person, 64% digital // 58,2% in-person, 67,9% digital	47 // 45.91 in-person, 47.75 digital	Group coaching: 50-minute sessions at worksites with 5-10 participants. Small groups of 8-10 met biweekly for 4 sessions, monthly for 4 sessions, and bi-monthly during a 6-month maintenance phase.	Phone sessions: 20-minute one-on-one telephone sessions with a health coach, offering tailored support and accountability, but without group reinforcement or support, following the same schedule of in-person (group coaching) sessions
Moravcova 2024[29]/	Czech Republic/10	Prospective, double-armed,	Age ≥18, BMI >30, diagnosed with T2D or prediabetes	6 months	71%	43.3 ± 9.5	Five in-person lifestyle consultations with a physician,	Vitadio: digital care program with a 3-month intensive phase followed

NCT04573296	0	randomized non-inferiority trial	(fasting glucose 5.6–6.9 mmol/L, OGTT 7.8–11.0 mmol/L), or insulin resistance (HOMA-IR >2.7), smartphone for Vitadio app, able to comply with study procedures				dietitian, or nurse, focusing on healthy eating, balanced diets (fruits, vegetables, healthy fats, whole grains, lean proteins), and an online food diary for tracking.	by a sustaining phase, utilizing personalized daily tasks and automated messages to help patients establish a healthy routine.
PREDICTS[20, 25, 27, 28, 30, 33]/NCT03312764	US/482	Single-blind RCT	Age ≥19, BMI ≥25 kg/m² (≥22 if Asian), prediabetes (HbA1c 5.7%–6.4% mmol/L), medically stable (no uncontrolled hypertension, hyperlipidemia, cancer treatment, untreated metabolic condition), not a bariatric surgery candidate, capable of consent, email/internet access	4 and 12 months	not reported	≥ 19	2-hour small group session focusing on action planning for increased physical activity, improved nutrition, weight loss, goal setting, and barrier resolution, with a resource booklet on local lifestyle support.	Internet-based intervention with small group support, personalized health coaching, digital tracking tools, and weekly behaviour change curriculum, approved by the Diabetes Prevention Recognition Program.

AHA/NHLBI: American Heart Association and National Heart, Lung, and Blood Institute; **BMI:** body mass index; **CCSF:** City and County of San Francisco; **CDC:** Center for Disease Control; **DPP:** Diabetes Prevention Program; **IVR:** interactive voice response; **RCT:** randomized controlled trial; **T2D:** type 2 diabetes; **VLM:** virtual lifestyle management;

Table 2. GRADE evidence and summary of findings of the comparison of the effects at three months follow-up of digital vs in person interventions to prevent type 2 diabetes mellitus*

Certainty assessment							№ of patients		Effect	Certainty	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**in-person intervention**	**digital intervention**	**Absolute (95% CI)**		
Body mass index at 3 months											
2[26, 34]	randomised trials	serious[a]	not serious	not serious	not serious	none	315	323	MD **0.12 higher** (0.26 lower to 0.5 higher)	⨁⨁⨁◯ Moderate[a]	CRITICAL
HbA1c (%) at 3 months											
1[25]	randomised trials	not serious	not serious	serious[b]	not serious	none	300	299	MD **0.08 HbA1c (%) lower** (0.12 lower to 0.04 lower)	⨁⨁⨁◯ Moderate[b]	CRITICAL
Weight change (%) at 3 months											
2[25, 26]	randomised trials	serious[c]	serious[d]	serious[e]	not serious	none	379	380	MD **1.21 lower** (5.39 lower to 2.97 higher)	⨁◯◯◯ Very low[c,d,e]	IMPORTANT
Weight change (Kg) at 3 months											
3[25, 26, 34]	randomised trials	serious[a]	serious[d]	serious[f]	not serious	none	615	622	MD **0.86 Kg lower** (2.97 lower to 1.24 higher)	⨁◯◯◯ Very low[a,d,f]	IMPORTANT

CI: confidence interval; **GLB:** Group Lifestyle Balance; **MD:** mean difference

* No trials were identified examining the following outcomes prioritized by the expert panel: health-related quality of life (critical), waist circumference (important); physical activity behavior (important); diet behavior (important); incidence of type 2 diabetes mellitus (important); plasma glucose levels (important), sedentary behavior (important), and smoking behavior (important)

a. Fuel Your Life and E-LITE trials presented some concerns due to the randomization process (both trials), deviation from intended interventions (Fuel Your Life trial), missing outcome data (Fuel Your Life trial), and selection of the reported results (Fuel Your Life trial).

b. The compared modalities are not equivalent in terms of level of intensity: the digital intervention is substantially more intensive than the in-person modality.

c. E-LITE presented some concerns related to the randomization process (no specific allocation method process was reported). PREDICTS et al presented low risk of bias.

d. The PREDICTS trial observed significant results favoring the digital intervention whereas the E-LITE trial observed significant results favoring the in-person intervention.

e. In none of the trials, the compared modalities are equivalent in terms of level of intensity. In E-LITE trial, the in-person intervention is substantially more intensive than the digital modality. On the contrary, in the PREDICTS trial, the digital intervention is substantially more intensive than the in-person modality.

f. The compared modalities are not equivalent in terms of level of intensity. In E-LITE trial, the in-person intervention is substantially more intensive than the digital modality. On the contrary, in the PREDICTS trial, the digital intervention is substantially more intensive than the in-person modality.

Table 3. GRADE evidence and summary of findings of the comparison of the effects at six months follow-up of digital vs in person interventions to prevent type 2 diabetes mellitus*

Certainty assessment							№ of patients		Effect	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	in-person intervention	digital intervention	Absolute (95% CI)		
Body mass index at 6 months											
3[21, 22, 26, 34]	randomised trials	serious[a]	serious[b]	not serious	not serious	none	432	430	MD **0.02 lower** (1.13 lower to 1.1 higher)	⨁⨁◯◯ Low[a,b]	CRITICAL
Weight change (%) at 6 months											
3[21, 22, 24, 26]	randomised trials	serious	not serious	not serious	serious[c]	none	273	268	MD **0.47 % higher** (2.65 lower to 3.58 higher)	⨁⨁◯◯ Low[c]	IMPORTANT
Weight change (kg) at 6 months											
5[21, 22, 24, 26, 29, 34]	randomised trials	serious[d]	serious[e]	not serious	not serious	none	580	560	MD **0.23 Kg lower** (2.18 lower to 1.72 higher)	⨁⨁◯◯ Low[d,e]	IMPORTANT
Total volume of Physical activity at 6 months											
2[24, 34]	randomised trials	serious[f]	not serious	not serious	serious[c]	none	203	168	SMD 0.03 (0.17 lower to 0.24 higher)	⨁⨁◯◯ Low[c,f]	IMPORTANT
Diet (food energy, kcals) at 6 months											
1[24]	randomised trials	serious[f]	not serious	not serious	serious[c]	none	78	80	MD **9.64 Kcal higher** (137.2 lower to 156.49 higher)	⨁⨁◯◯ Low[c,f]	IMPORTANT

CI: confidence interval; **MD:** mean difference

* No trials were identified examining the following outcomes prioritized by the expert panel: health-related quality of life (critical), HbA1c (critical); waist circumference (important); incidence of type 2 diabetes mellitus (important); plasma glucose levels (important), sedentary behavior (important), and; smoking behavior (important)

a. The three trials presented some concerns, which were related to the randomization process (Fuel Your Life, E-LITE), deviation from intended interventions (Fuel Your Life), missing outcome data (Fuel Your Life, DiaBEAT-it), and selection of the reported results (Fuel Your Life).

b. Inconsistent results observed: two trials (Fuel Your Life, DiaBET-it) observed a significant effect favoring the digital delivery method, whereas one trial (E-LITE) observed a significant effect favoring the in-person method.

c. Wide confidence intervals

d. All the five trials presented some concerns

e. Two of the trials observed significant differences favouring the digital intervention and two trials observed significant differences favouring the in-person intervention

f. The CCSF Diabetes Prevention Trial and Fuel Your Life presented some concerns, which were due to the randomization process, deviation from the intended interventions, and selection of the reported results.

Table 4. GRADE evidence and summary of findings of the comparison of the effects at 12 months follow-up of digital vs in person interventions to prevent type 2 diabetes mellitus*

Certainty assessment							№ of patients		Effect	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	in-person intervention	digital intervention	Absolute (95% CI)		
Body mass index at 12 months											
2[21, 22, 34]	randomised trials	serious[c]	not serious	not serious	not serious	none	353	349	MD **0.5 lower** (0.6 lower to 0.39 lower)	⨁⨁⨁◯ Moderate[c]	CRITICAL
HbA1c (%) at 12 months											
1[25]	randomised trials	not serious	not serious	serious[a]	not serious	none	300	299	MD **0.8 HbA1c (%) lower** (0.12 lower to 0.03 lower)	⨁⨁⨁◯ Moderate[a]	CRITICAL
Weight change (kg) at 12 months											
4[21, 22, 24, 25, 34]	randomised trials	serious[d]	not serious	not serious	not serious	none	731	728	MD **1.38 Kg lower** (2.34 lower to 0.43 lower)	⨁⨁⨁◯ Moderate[d]	IMPORTANT
Waist circumference (cm) at 12 months											
1[24]	randomised trials	serious[e]	not serious	not serious	serious[b]	none	78	80	**0.38 higher** (2.19 lower to 2.95 higher)	⨁⨁◯◯ Low[b,e]	IMPORTANT
Total volume of Physical activity at 12 months											
2[24, 34]	randomised trials	serious[f]	not serious	not serious	serious[b]	none	200	161	SMD **-0.04** (0.25 lower to 0.17 higher)	⨁⨁◯◯ Low[b,f]	IMPORTANT
Diet (food energy, kcals) at 12 months											
1[24]	randomised trials	serious[f]	not serious	not serious	serious[b]	none	78	80	MD **1.37 Kcal higher** (167.8 lower to 170.51 higher)	⨁⨁◯◯ Low[b,f]	IMPORTANT

CI: confidence interval; **MD:** mean difference

* No trials were identified examining the following outcomes prioritized by the expert panel: health-related quality of life (critical); incidence of type 2 diabetes mellitus (important); plasma glucose levels (important), sedentary behavior (important), and smoking behavior (important)

a. The compared modalities are not equivalent in terms of level of intensity: the digital intervention is substantially more intensive than the in-person modality.

b. Wide confidence intervals

c. The two trials presented some concerns, which were related to the randomization process (Fuel Your Life), deviation from intended interventions (Fuel Your Life), missing outcome data (Fuel Your Life, DiaBEAT-it), and selection of the reported results (Fuel Your Life).

d. Three of the four trials (Fuel Your Life; DiaBEAT-it; CCSF Diabetes Prevention Trial) presented some concerns in relation to potential bias.

e. The CCSF Diabetes Prevention Trial presented some concerns due to deviation from intended interventions and selection of the reported results.

f. The CCSF Diabetes Prevention Trial and Fuel Your Life presented some concerns, which were due to the randomization process, deviation from the intended interventions, and selection of the reported results.

Table 5. GRADE evidence and summary of findings of the comparison of the effects at 15-18 months follow-up of digital vs in person interventions to prevent type 2 diabetes mellitus*

Certainty assessment							№ of patients		Effect	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	in-person intervention	digital intervention	Absolute (95% CI)		

Body mass index at 15-18 months											
2[21, 22, 26]	randomised trials	serious[b]	serious[c]	not serious	serious[a]	none	196	188	**0** (1.18 lower to 1.18 higher)	⨁◯◯◯ Very low[a,b,c]	CRITICAL
Weight change (Kg) at 15-18 months											
2[21, 22, 26]	randomised trials	serious[b]	serious[c]	not serious	not serious	none	196	188	MD **0.2 Kg higher** (2.94 lower to 3.33 higher)	⨁⨁◯◯ Low[b,c]	IMPORTANT
Waist circumference (cm) at 15-18 months											
1[26]	randomised trials	serious[d]	not serious	serious[e]	not serious	none	79	81	MD **0.89 cm higher** (0.58 higher to 1.2 higher)	⨁⨁◯◯ Low[d,e]	IMPORTANT

CI: confidence interval; **MD:** mean difference

* No trials were identified examining the following outcomes prioritized by the expert panel: health-related quality of life (critical), HbA1c (critical); waist circumference (important); physical activity behavior (important); diet behavior (important); incidence of type 2 diabetes mellitus (important); plasma glucose levels (important), sedentary behavior (important), and; smoking behavior (important)

a. Wide confidence intervals

b. Both trials presented some concerns, which were in relation to the randomization process (E-LITE trial), and missing outcome data (DiaBEAT-it)

c. The DiaBEAT-it trial observed significant results favoring the digital intervention whereas the E-LITE trial observed significant results favoring the in-person intervention.

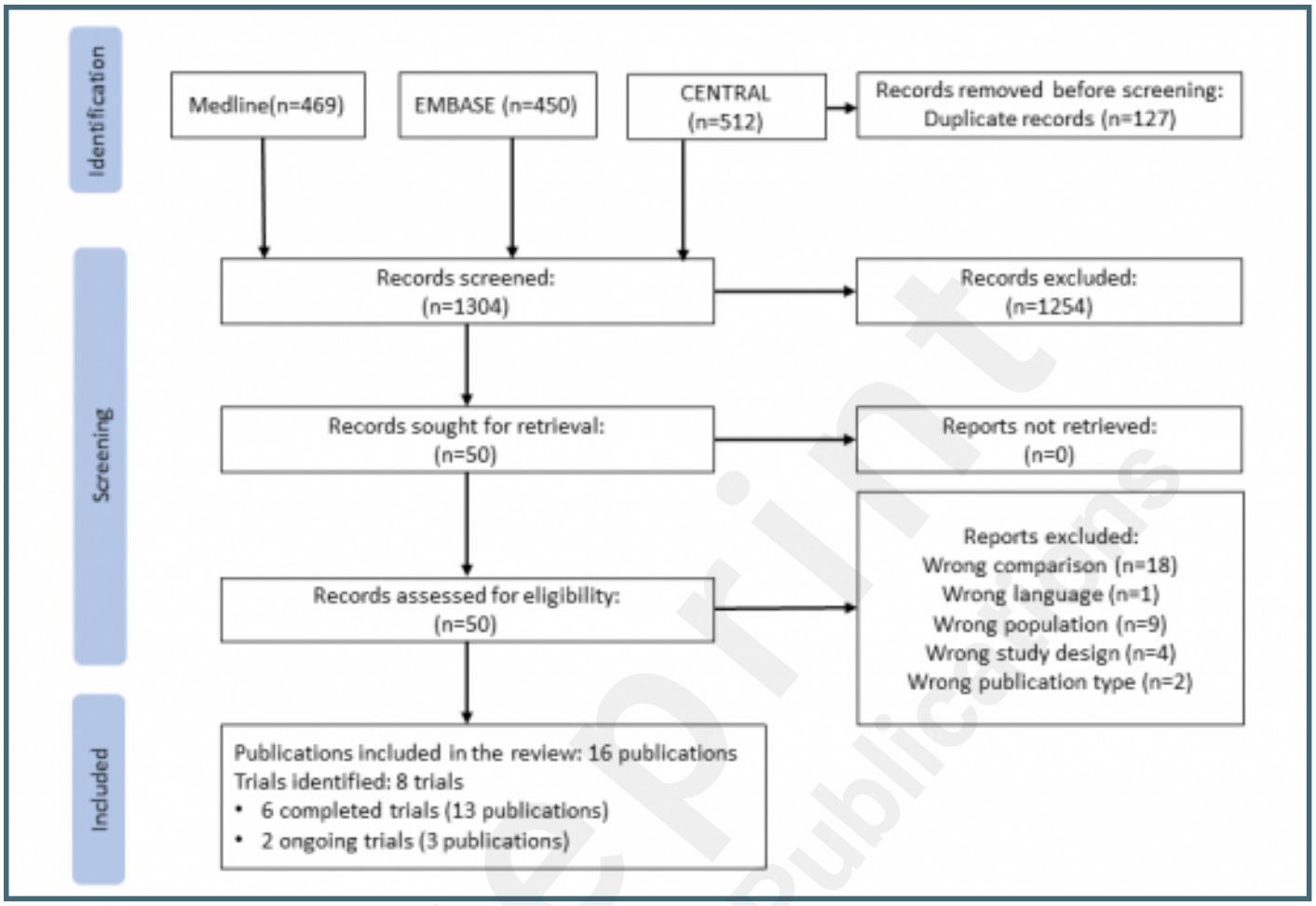
d. The E-LITE trial presented some concerns related to the randomization process

e. In the E-LITE trial, the compared modalities are not equivalent in terms of level of intensity: the in-person intervention is substantially more intensive than the digital modality.

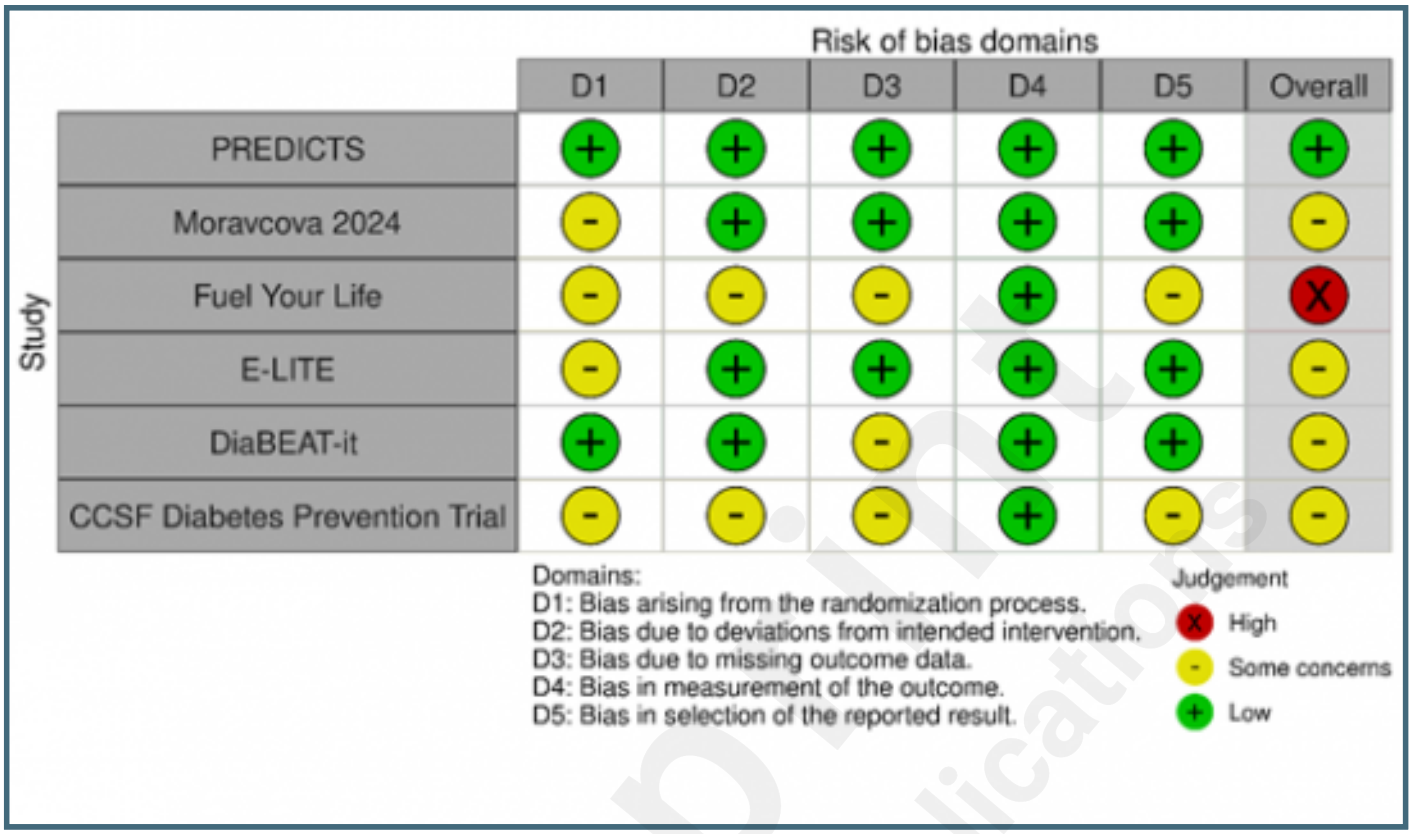
Supplementary Files

Figures

PRISMA flowchart.



Risk of Bias of the included trials.



Multimedia Appendixes

Search strategy.
URL: http://asset.jmir.pub/assets/d57850f91d2f7b18c07f0e6aad9cbe6e.pdf

List of outcomes prioritized by the international expert panel.
URL: http://asset.jmir.pub/assets/b2e33254d2e9805865f6a2c1bdc7de36.pdf

List of articles excluded after full text screening with reasons.
URL: http://asset.jmir.pub/assets/3062cc1b00d043491286adae0457fcc0.pdf

Characteristics of the ongoing trials identified.
URL: http://asset.jmir.pub/assets/d8e494a52e97ffa1937e00323b884b38.pdf

Risk of bias of the included trials (detailed description).
URL: http://asset.jmir.pub/assets/dc7b7609db6cb22aa071de98c09cea89.pdf

Forest plots of the random effects meta-analysis.
URL: http://asset.jmir.pub/assets/90c1411ebc71b19130db153033b22645.pdf