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Title Page

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ABSTRACT

Introduction Gestational diabetes mellitus (GDM) is one of the most prevalent diseases during pregnancy, which is closely associated with many short-term and long-term maternal and neonatal complications and can incur heavy financial burden on both families and the society. Web-based interventions have been utilized to manage GDM because of the advantages of high accessibility and flexibility, but the effectiveness has remained inconclusive. This systematic review and meta-analysis aims to determine the all-round efficacy of web-based interventions for pregnant women with GDM, thereby aiding implementation decisions in clinical settings.

Methods and analysis This systematic review protocol strictly adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines. Five electronic databases (PubMed, Web of Science, Cochrane Central Register of Controlled Trials, Embase and CINAHL) will be comprehensively searched from their inception to January 2022 to identify randomized controlled trials (RCTs) and controlled clinical trials (CCTs) regarding the efficacy of web-based interventions for pregnant women with GDM on glycemic control, behavioral outcomes, cognitive and attitudinal outcomes, mental health, maternal and neonatal clinical outcomes, and medical service utilisation and costs. Two reviewers will conduct the study selection, data extraction and quality assessment independently. The methodological quality of included studies will be assessed using the Effective Public Health Practice Project (EPHPP) assessment tool. The overall meta-analyses for each interested outcomes will be performed if the outcome data is sufficient and available, as well as subgroup analyses for glycemic control indicators based on the different type of intervention format, interactivity and technology. We will conduct a qualitative synthesis for studies that cannot be quantitatively synthesised.

Ethics and dissemination Ethics approval is not required for this review as no human participants will be involved. The results will be disseminated via a peer-reviewed

journal or an academic conference.

PROSPERO registration number CRD42022296625

Strengths and limitations of the study

► This will be the first systematic review to investigate the all-round efficacy of web-based interventions for pregnant women with GDM.

► We conduct and report this systematic review protocol following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines, which can ensure the quality in aspects of study planning, execution and reporting.

► Subgroup analyses will be performed if possible to elaborate the type of intervention format, interactivity and technology correlating with the increased effectiveness, thereby providing more specific suggestions to develop an optimal web-based interventions regimen.

► Anticipated high heterogeneity across studies may increase the difficulty in interpreting a meta-analysis.

► There may be language bias as this review will only include studies published in English.

INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most common comorbidities in pregnant women. A survey conducted by the International Diabetes Federation indicated that GDM affected 14.2% of pregnancies worldwide in 2013 and resulted in more than 20 million live births [1]. Moreover, as well-established risk factors for developing GDM, the rising obesity rates prior to pregnancy, excess weight gain during pregnancy, sedentary lifestyle and older maternal age result in the increasing prevalence of GDM in recent years [2]. According to the global statistics, the incidence of GDM in Southeast Asia, North America, Europe, Africa and Middle East had ranged from 7.5% to 27% up to 2019 [3]. With the introduction and wide application of a more rigorous diagnostic criteria, the rate of GDM is anticipated to grow even further [4], which will potentially challenge the medical resources and exert great impact on individuals and the society. As a matter of fact, GDM has

become an important public health issue both in the developed and developing countries [5].

GDM is initially diagnosed in the second or third trimester of pregnancy and features as hyperglycemia of variable severity without overt pregestational diabetes [6]. Although the pathogenesis of GDM has not been fully elucidated, the most plausible interpretation is the lack of sufficient insulin secretion matching with the increased insulin tolerance, which results in insulin resistance and finally causes GDM [6]. It has been demonstrated that GDM is closely related to obstetrical problems at the time of delivery as well as subsequent perinatal morbidity [7, 8]. The potential short-term impacts for mother include increased risk of preeclampsia, polyhydramnios, prematurity, shoulder dystocia, stillbirth, postpartum hemorrhage and infectious complications [9]. Worse still, although GDM is characterized as a transient condition and will resolve within a short period after delivery, it is an independent risk factor for many diseases. Specifically, the long-term maternal affects of GDM include but are not limited to GDM recurrence in the next pregnancies [10], as well as higher risks of developing type 2 diabetes (a nine-fold increased risk) [11] and cardiovascular diseases (2.3 times the risk) [12].

Likewise, a significant association between maternal anomalous hyperglycemia and many fetal and neonatal complications has also been clearly established [9], which include fetal intrauterine growth retardation, congenital anomalies, death in uterus, macrosomia, neonatal hypoglycemia, respiratory distress syndrome, hyperbilirubinemia, special care admission and so on. Furthermore, according to the concept of transgenerational programming, offsprings who exposure to hyperglycemia in the uterine has an increased risk of obesity, early onset metabolic syndrome and hypertension in their childhood and early adulthood [13].

Therefore, in view of the considerable short-term and long-term complications that GDM may cause, it is of great importance to manage GDM effectively via strategies aiming to maintain the maternal glycemia as close to normal as possible. Lifestyle interventions typically including healthy eating and physical exercise have been widely adopted to help optimizing blood glucose levels during the prenatal

period [14]. Actually, these interventions are the mainstay of therapy for GDM and may suffice for most patients, as studies have demonstrated that around 65%-90% of the pregnant women diagnosed with GDM can maintain euglycemia through lifestyle changes alone [15, 16]. Pharmacotherapies (oral hypoglycemic agents and insulin) will be added when non-pharmacological regimens fail to affect. However, regardless of whether drugs are involved, the traditional GDM management is achieved by intensive clinic attendance for receiving disease education, reporting symptoms and glycemic control levels, and adjusting therapeutic regimens [17-19], which will place increased demands on clinical services for providing diabetes care and aggravate the economic burden on individuals [17, 20]. Meanwhile, multiple barriers and disadvantages exist in the traditional mode of GDM management, such as unequal hospital resources distribution, high costs for transportation, time and energy lacking both for patients and health professionals, time-consuming waiting before seeing a doctor, and a limited intervention time window, which can reduce the efficiency of GDM management, decrease patients' satisfaction and cause poor pregnancy outcomes [19-21]. Consequently, it is essential to identify a more practical, scalable, sustainable and cost-effective mode of care to manage GDM effectively and simultaneously ease the medical service burden on the premise of not interfering with the current health care system or compromising the quality of care.

The rapid development and wide spread of information and communication technology worldwide has precisely provided an innovative perspective for disease management. Especially, due to the advantages of high accessibility, convenience, flexibility and efficiency [22], web-based interventions delivered by smartphone, computer, laptop and other internet-connected devices have attracted a great attention and been widely used in recent years for health and well being promotion in patients with cardiovascular diseases [23], metabolic syndrome [24] and other diseases [25-27]. These technologies can help to close the loop between patients and health professionals, overcome the inequivalent distribution of medical resources and realize the vision of pervasive healthcare [28, 29], which therefore have been regarded as an ideal medical and public health practice mode for disease management. Noteworthy,

pregnant women with GDM seemed to be an ideal population to target for using web-based technologies to improve health outcomes because of the high penetration rates and excellent grasp of web-based devices among reproductive-aged population, who have constraint time to attend conventional health services [18, 30-32]. At present, attempts have been made to improve health outcomes in pregnant women with GDM via web-based interventions; nonetheless, clinical trials of this topic have yielded mixed results. Some studies found that web-based interventions could significantly ameliorate glycemic control [29, 33], increase the compliance with self-monitoring of blood glucose (SMBG) [34], reduce the incidence of premature delivery [35] and medical service costs [17], as well as improve the satisfaction with care [17] for this crowd, while the others demonstrated a null effect [34, 36, 37]. Hence, it is critical to systematically evaluate the effectiveness of web-based interventions for pregnant women with GDM.

To date, two systematic reviews and meta-analyses have been conducted to evaluate the effectiveness of web-based interventions for pregnant women with GDM [38, 39]. One previous review [39] included pregnant women with GDM, type 1 diabetes and type 2 diabetes, while the results of GDM subgroup (N=5 studies) showed no significant between-group effect on glycated haemoglobin (HbA1c), caesarean rate, neonatal birth weight and hypoglycemia. On the contrary, a recent review (N=6 studies) [38] focused on the effectiveness of disease-specific mobile applications and reported that fasting blood glucose (FBG), 2-hour postprandial blood glucose (2hBG) and caesarean rate in pregnant women with GDM significantly improved after intervention compared to the control group. In addition, another five systematic reviews [40-44] investigated the effects of telemedicine on GDM, which included medical interventions both delivered by internet and early mobile technologies (e.g., phone call, short message service (SMS) and digital video disk (DVD)); but these reviews generated conflicting results on glycaemic control and maternal and neonatal clinical outcomes. In general, the existing systematic reviews of relevant topic reported mixed results on glycaemic control and clinical outcomes, whereas the other outcomes (such as maternal behavioral outcomes and medical

service utilisation and costs) were hardly assessed. Beyond that, in the majority of these reviews [40-44], web-based technologies were conflated with early labor-intensive technologies that have become not so popular under the rapidly evolving landscape of technology. More importantly, a growing number of primary studies [17, 34, 36, 45-49] with conflicting results regarding this topic have emerged after the above reviews, which may provide new evidence. Nevertheless, to the best of our knowledge, a systematic review evaluating the all-round efficacy of web-based interventions for pregnant women with GDM is still lacking.

OBJECTIVES

This systematic review and meta-analysis aims to integrate all existing evidence from randomized controlled trials (RCTs) and controlled clinical trials (CCTs) to comprehensively evaluate the efficacy of web-based interventions in pregnant women with GDM and attempts to find out an optimal web-based interventions regimen.

Specifically, the objectives of this study are:

(1) To investigate the effectiveness of web-based interventions on maternal glycemic control, behavioral outcomes, cognitive and attitudinal outcomes, mental health, maternal and neonatal clinical outcomes, as well as medical service utilisation and costs in pregnant women with GDM.

(2) To gain insight into whether the type of interactivity, the type of format and the type of technology of web-based interventions can influence the intervention effects, and which type of interventions regimen is the most effective.

METHODS AND ANALYSIS

Registration and study design

This paper presents a systematic review protocol that has been registered in PROSPERO (registration number CRD42022296625), and any future changes will be registered as amendments. We will complete and report the study protocol following the Preferred Reporting Items for Systematic Review and Meta-Analyses Protocol (PRISMA-P) guideline [50] (see online supplemental file for details). The research questions are developed based on the PICOS framework (population, intervention, comparator/control, outcome and study design), which are described in detail as

follows.

Eligibility criteria for selecting studies

Types of study

We will include RCTs and CCTs that published in peer-reviewed English journals. Single-group studies, reviews, case reports, cohort studies, letters to editors, conference abstracts and study protocols will be excluded.

Types of participant

Pregnant women ≥ 18 years old with GDM but without any severe diseases (such as severe symptoms of psychological disorders or fetal abnormalities) will be included, regardless of whether she had been diagnosed with GDM in previous pregnancies. Studies that included mixed types of diabetes mellitus (including GDM, type 1 diabetes and type 2 diabetes) will be considered as eligible as well, when the outcomes in GDM subgroup were reported separately.

Types of intervention

The intervention should be a digital one delivered by any types of web-based modalities, which may include but are not restricted to websites and mobile applications. However, studies that only used web-based interventions for observing the maintenance of outcome changes from previously administered health interventions, incorporated web-based components with face-to-face components, and lacked real web-based interventions for participants (for example, conducting interventions via video, DVD, television, radio, SMS or telephone calls) will be excluded.

Types of comparator/control

The following comparators will be regarded as eligible: a wait-list control, usual care, no interventions.

Types of outcome

(1) Primary outcome: the glycaemic control indicators during pregnancy including HbA1c, FBG, 1-hour postprandial blood glucose (1hBG) and 2hBG.

(2) Secondary outcomes: the following five categories of outcomes are interested:

► Maternal behavioral outcomes: insulin treatment rate, oral hypoglycemic

agents treatment rate and self-care behaviors (mainly inlcuding the compliance with SMBG, healthy diet and physical activity);

► Maternal cognitive and attitudinal outcomes: knowledge of disease, risk-perception of disease, self-efficacy and satisfaction with care;

► Maternal mental health: depression and anxiety;

► Maternal and neonatal clinical outcomes: gestational weight gain, induction of labor, vaginally delivery, normal vaginal delivery, assisted vaginal delivery, caesarean section, planned caesarean section, emergency caesarean section, gestational weeks at delivery, premature delivery, shoulder dystocia, pre-eclampsia/gestational hypertension, premature rupture of the membranes, macrosomia, admission to neonatal intensive care unit, low birth weight, birth weight, large for gestational age, small for gestational age, neonatal hypoglycemia, 1 minute apgar scores, 5 minute apgar scores, neonatal jaundice/hyperbilirubinemia, respiratory morbidityc, composite neonatal complicationd, phototherapy and neonatal death;

► Medical service utilisation and costs.

Studies that included at least one of the above outcomes will be considered as eligible.

Search methods for identification of studies

PubMed, Web of Science, Embase, Cochrane Library and CINAHL are anticipated to be comprehensively searched from the inception of each database to January 25, 2022. The search strategies of electronic databases are a combination of Medical Subject Heading (MeSH) and free-text words to represent the definitions of GDM, web-based interventions, RCTs and CCTs. The search strategies will be developed in collaboration with an academic librarian. Table 1 presents the queries in PubMed and similar strategies will be applied in other databases. Two authors will conduct the search process independently. Additionally, a snowball hand-search will be undertaken to retrieve additional eligible studies after database searches by reviewing the reference lists of included studies and the existing systematic reviews related to this topic.

Table 1. Search strategy in PubMed.

1.	"Diabetes, Gestational"[Mesh]
2.	"Diabetes, Pregnancy-Induced OR Diabetes, Pregnancy Induced OR Diabetes Mellitus, Gestational OR Diabetes, Gestational OR diabetes in pregnancy OR Gestational Diabetes OR Gestational Diabetes Mellitus OR GDM OR maternal diabetes OR Pregnancy-Induced Diabetes OR pregnancy diabetes mellitus" [Title/Abstract]
3.	1 or 2
4.	"Mobile Applications"[Mesh] OR "Telemedicine"[Mesh] OR "Internet"[Mesh] OR "Computers"[Mesh] OR "Telecommunications"[Mesh] OR "Online Systems"[Mesh] OR "Software"[Mesh] OR "Wireless Technology"[Mesh] OR "Cell Phone"[Mesh]
5.	"app OR apps OR application OR applications OR ipad OR blog OR blogging OR computer OR computer interface OR cell phones OR cell phone OR cellular phone OR digital OR digital health OR digital-health OR ehealth OR e-health OR e-mail OR electronic OR E-learning OR Facebook OR health, mobile OR health technolog OR health app OR Internet OR Internet forum OR iphone OR i phone OR i-phone OR ipad OR i pad OR i-pad OR laptop OR linkedin OR mobile OR mobile application OR mobile apps OR mobile app OR mobile phone OR mobile phones OR mhealth OR m-health OR mobile health OR mobile electronic device OR mobile technolog OR mobile communication OR mobile computing OR network OR online OR online intervention OR online interventions OR platform OR personal computer OR personal digital assistant OR QQ OR remote OR smartphone OR smart phone OR social media OR social networking OR telehealth OR tele-health OR telephone OR telemedicine OR tele-medicine OR tele-care OR telecare OR telecommunication OR telemonitor OR tele-monitor OR telemonitoring OR twitter OR web OR web-based OR website OR wireless OR WeChat"[Title/Abstract]
6.	4 or 5
7.	"Randomized Controlled Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Controlled Clinical Trial" [Publication Type] OR "Controlled Clinical Trials as Topic"[Mesh]
8.	"Clinical Trials, Randomized OR Trials, Randomized Clinical OR Controlled Clinical Trials, Randomized OR RCT OR Clinical Trials OR Controlled Clinical Trials OR CCT" [Title/Abstract]
9.	7 or 8
10.	3 and 6 and 9

Study selection

After the initial systematic searches, all retrieved records will be exported to Endnote X 8.2 reference management software. Then, the automated 'Find Duplicates' function of this software will be used to eliminate duplicate studies. Two authors will assess the remaining titles and abstracts independently and remove irrelevant citations in accordance with the selection criteria. Then, the full text of studies will be obtained if either of the two authors judges an publication to be potentially eligible for inclusion. Independent full text reading by the two authors will

follow. Any discrepancies between authors will be discussed first. When consistency cannot be reached, a senior reviewer will resolve the controversy. Reasons for excluding studies will be detailed on a PRISMA flow chart (Figure 1).

Data extraction and management

Data extraction will be carried out with a purpose-built, predesigned and structured template. We will first pilot the data extraction process using a subsample of included studies and make further refinements for the extraction sheet as necessary. The corresponding authors of included studies with any missing, uncertain or incomplete information will be contacted. The data of the final included studies will be independently extracted by two reviewers and checked for the accuracy by a third reviewer.

From all included studies, we will collect the following information:

► The general study information: the first author, year of publication, country and study design;

► Participants details: mean age, diagnostic criteria of GDM, gestational weeks at allocation, sample size (intervention/control);

► Intervention details: name of intervention, detailed regimen, duration, main technology (such as mobile application and website), interactivity (interactive/non-interactive) and format (personalized/non-personalized);

► Control group regimen;

► Outcomes: the primary and secondary outcomes (between-group significance: +/-);

► Attrition rates.

Methodological quality assessment

The Effective Public Health Practice Project (EPHPP) assessment tool will be applid to appraise the methodological quality of included studies [51], which showed better interrater agreement than the Cochrane Collaboration Risk of Bias tool [52]. Studies will be evaluated on the following six aspects: selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs. Finally, each aspect as well as the global rating will be rated as strong, moderate, or weak.

What need to be pointed out specially is that the aspect of blinding will be rated as 'strong' for studies only evaluating objective outcomes, as objective outcomes are unlikely to be affected by actual blinding implementation [53]. The methodological quality evaluation will be performed independently by two reviewers, and any controversial evaluation differences will be discussed for final decision.

Grading the quality of evidence

The GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) guidelines [54] will be used to assess the level of evidence for each indicators of the primary outcome (glycaemic control). After evaluations of the risk of bias, consistency, directness of evidence, imprecision and publication bias, a body of evidence across the outcome indicators will be specified as very low, low, moderate, and high quality.

Data analysis

Data synthesis

A meta-analysis will be conducted when there are sufficient studies (no less than two studies) investigating the same outcome using similar effect measures. A narrative approach will be applied for studies that could not be quantitatively synthesized. Stata 12.0 (Stata Corporation, College Station, Texas, USA) will be used for all statistical calculations, and a p value < 0.05 will be set as the significance level. For continuous variables, the mean differences (MDs) with 95% confidence intervals (CIs) will be selected only when the unit and the instrument of measurement are the same across trials; otherwise, the standardized mean difference (SMDs) with 95% CIs will be chosen [55]. According to Cohen's definition, the effect size of SMD is considered as small (<0.2), moderate (0.2–0.8) or large (>0.8) [56]. For dichotomous variables, we will use relative risks (RR) with 95% CIs for point estimates, and the cut-off values of 1.22, 1.86 and 3.00 represent small, medium and large effects, respectively [57]. The Inverse Variance method will be utilized to pool continuous outcome data and the Mantel Haenszel method for dichotomous outcome data.

Assessment of heterogeneity

The level of heterogeneity across studies will be evaluated by χ^2 test and I^2 test.

According to the Cochrane Handbook, a p value ≥ 0.1 of the χ^2 test or a I^2 value ≤ 50% are regarded as no observed heterogeneity [56]. We will use a fixed-effect model for analysis if the data are not significantly heterogeneous. Otherwise, a random-effect model will be employed, which can yield more conservative summary effect estimates and is more recommended when there is unexplained heterogeneity across studies [58].

Additional analysis for the primary outcome

(1) Subgroup analyses based on the intervention format (personalized and nonpersonalized), interactivity (interactive and non-interactive), and technology (such as mobile application and website) will be performed if possible to explore an optimal web-based interventions regimen and to identify the potential sources of heterogeneity; (2) The funnel plot and Egger's test will be employed to detect the potential publication bias, if there is a sufficient number of included studies (N ≥10) [56].

Patient and public involvement

Neither patients nor the public will be directly involved in the design, conducting, reporting and dissemination of this study, because this systematic review will be based on publicly available studies.

Validity, reliability and rigour

The systematic review protocol was completed following the PRISMA-P guidelines [50]. We will strictly follow the requirements of Cochrane Handbook [56] and the best practice PRISMA guidelines [59] when performing and reporting this systematic review.

DISCUSSION

This paper presents a protocol for a systematic review of literature investigating the effectiveness of web-based interventions among pregnant women with GDM. To this end, this systematic review will based on all existing evidence from RCTs and CCTs to examine the all-round efficacy of web-based interventions on the improvements of maternal glycemic control, behavioral outcomes, cognitive and attitudinal outcomes, mental health, maternal and neonatal clinical outcomes, as well

as medical service utilisation and costs. The conclusion of this study will provide comprehensive evidence on whether web-based interventions should be widely recommended for GDM management in future clinical practice. Moreover, the findings of three subgroup analyses regarding intervention format, interactivity and technology will enlighten health professionals on the development of an optimal web-based interventions regimen, so as to bring maximum benefits to pregnant women with GDM, clinicians and other relevant personnel.

However, several potential limitations for this study should be considered. First, the emerging use of web-based technologies in healthcare is relatively recent; hence, the number of study regarding this topic may limited. Second, given that the diagnostic criteria of GDM, gestational weeks at allocation, and web-based interventions program are likely to be quite different, there may be high heterogeneity across studies; therefore, we plan to conduct subgroup analyses to overcome this heterogeneity. Finally, since we will only include RCTs/CCTs published in English, there may be a loss of studies written in other languages.

ETHICS AND DISSEMINATION

Ethical approval will not be required for this study as no identifiable patient information and privacy will be involved. The findings will be published and diffused in a peer-reviewed English journal or disseminated through an academic conference.

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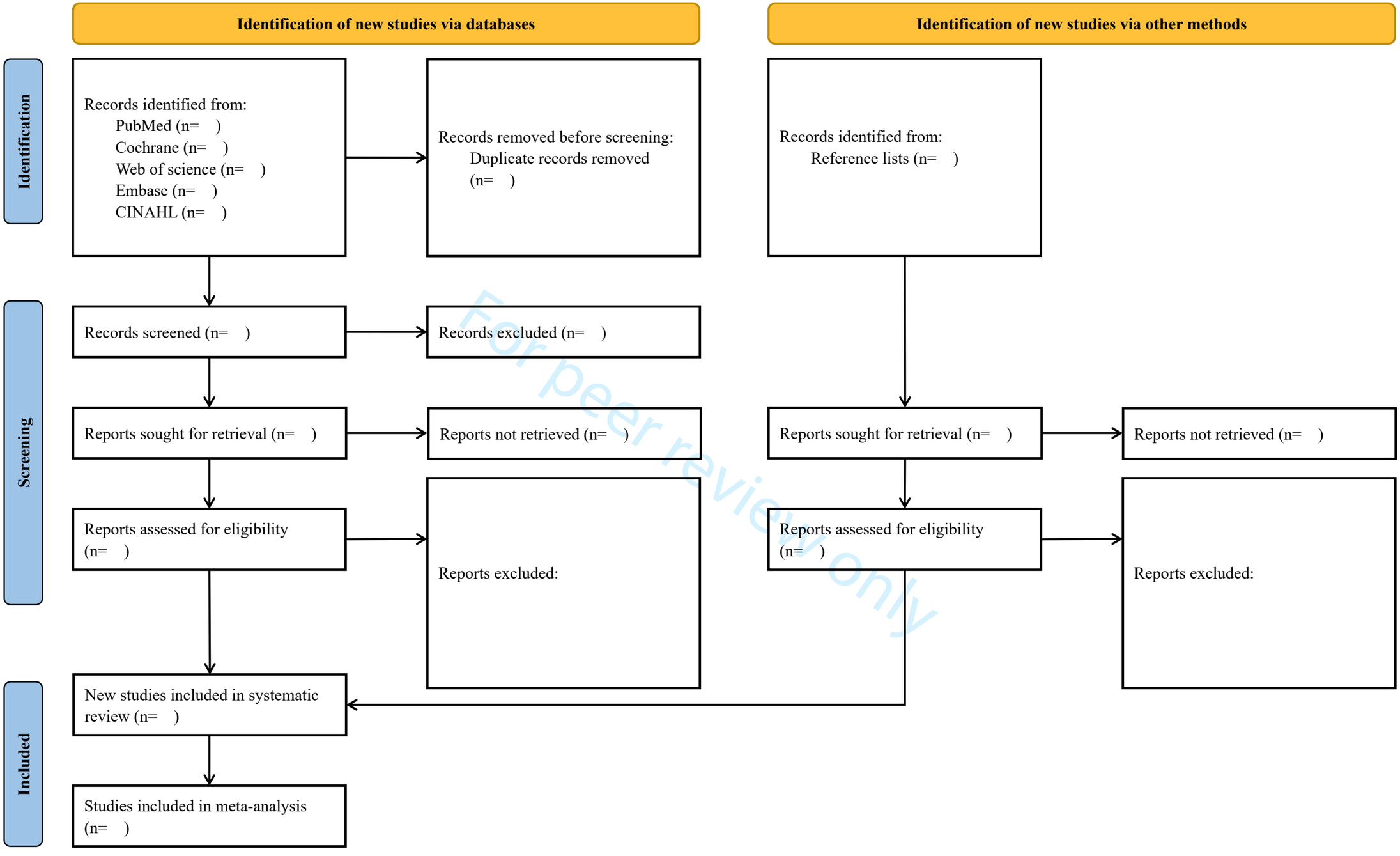

Figure 1. Flow diagram of article selection process.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section/Topic	Item No	Item	Reported on Page Number/Line Number (P/L)	Reported on Section/Paragraph
ADMINISTRATIVE INFORMATION				
Title	1a	Identification - identify the report as a protocol of a systematic review	P3/L35	Title
	1b	Update - if the protocol is for an update of a previous systematic review, identify as such	Non-update	Non-update
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P4/L65	Abstract
Authors	3a	Contact - provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P1-2/L5-32	Title page
	3b	Contributions - describe contributions of protocol authors and identify the guarantor of the review	P15/L393-397	Contributors
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Non-amendments	Non-amendments
Support	5a	Sources - indicate sources of financial or other support for the review	P15/L398-399	Funding
	5b	Sponsor - provide name for the review funder and/or sponsor	P15/L398-399	Funding
	5c	Role of sponsor or funder - describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P15/L398-399	Funding
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	P4-8/L82-191	Introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants,interventions, comparators, and outcomes (PICO)	P8/L193-204	Objectives
METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	P9-10/L215-260	Eligibility criteria for selecting studies
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	P10/L262-272	Search methods for identification of studies
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	P10-11/L273-274	Table 1
Study records	11a	Data management - describe the mechanism(s) that will be used to manage records and data throughout the review	P12/L285-304	Data extraction and management

	11b	Selection process - state the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	P11-12/L275-284	Study selection
	11c	Data collection process - describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	P12/L286-304	Data extraction and management
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	P10/L262-272	Search methods for identification of studies
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P9-10/L216-260	Eligibility criteria for selecting studies
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	P12-13/L306-316	Methodological quality assessment
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	P13/L326-327	Data analysis
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I_2, Kendall's τ)	P13-14/L330-347	Data analysis
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P14/L349-352	Data analysis
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P13/L327-328	Data analysis
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P14/L353-354	Data analysis
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	P13/L318-323	Grading the quality of evidence

* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated.

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

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Web-based interventions for pregnant women with gestational diabetes mellitus: a systematic review and meta-analysis protocol

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Title Page

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Web-based interventions for pregnant women with gestational diabetes mellitus: a systematic review and meta-analysis protocol

ABSTRACT

Introduction Gestational diabetes mellitus (GDM) is one of the most prevalent diseases during pregnancy, which is closely associated with many short-term and long-term maternal and neonatal complications and can incur heavy financial burden on both families and society. Web-based interventions have been utilized to manage GDM because of the advantages of high accessibility and flexibility, but their effectiveness has remained inconclusive. This systematic review and meta-analysis aims to comprehensively investigate the multidimensional effectiveness of web-based interventions for pregnant women with GDM, thereby aiding implementation decisions in clinical settings.

Methods and analysis This systematic review protocol strictly adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines. Six electronic databases (PubMed, Web of Science, Cochrane Central Register of Controlled Trials, Embase, CINAHL, and PsycINFO) will be comprehensively searched from their inception to January 26, 2022 to identify randomized controlled trials (RCTs) and controlled clinical trials (CCTs) regarding the efficacy of web-based interventions for pregnant women with GDM on glycemic control, behavioral outcomes, cognitive and attitudinal outcomes, mental health, maternal and neonatal clinical outcomes, and medical service utilisation and costs. Two reviewers will independently conduct the study selection, data extraction and quality assessment. The methodological quality of included studies will be assessed using the Effective Public Health Practice Project (EPHPP) assessment tool. The overall meta-analyses for each of the interested outcomes will be performed if the outcome data is sufficient and provides similar effect measures, as well as subgroup analyses for glycemic control indicators based on the different types of intervention format, interactivity, and technology. We will conduct a qualitative synthesis for studies that cannot be quantitatively synthesised.

Ethics and dissemination Ethics approval is not required for this review as no human

participants will be involved. The results will be disseminated via a peer-reviewed journal or an academic conference.

PROSPERO registration number CRD42022296625

Strengths and limitations of the study

► This systematic review protocol follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines.

► Rigorous methods of review will be followed with at least two independent reviewers to conduct study selection, data extraction, and quality assessment.

► Subgroup analyses will be performed if possible to elaborate on the type of intervention format, interactivity, and technology correlating with the increased effectiveness.

► Anticipated high heterogeneity across studies may increase the difficulty in interpreting a meta-analysis.

► There may be language bias as this review will only include studies published in English.

INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most common comorbidities in pregnant women, which is initially diagnosed in the second or third trimester of pregnancy and features as hyperglycemia of variable severity without overt pregestational diabetes.[1] According to the International Diabetes Federation, the worldwide prevalence of hyperglycemia in pregnancy ranged from 8.6% to 28.0% up to 2021, which affected 21.1 million of live births (16.7%), with the majority of the cases presenting with GDM (80.3%).[2] Moreover, as well-established risk factors for developing GDM, the rising obesity rates prior to pregnancy, excess weight gain during pregnancy, sedentary lifestyle, and older maternal age have resulted in the increasing prevalence of GDM in recent years,[3] which can potentially challenge medical resources and exert great impact on individuals and society. Actually, GDM has become an important public health issue both in developed and developing countries.[4]

It has been demonstrated that GDM is closely related to obstetrical problems at

the time of delivery as well as subsequent perinatal morbidity.[5, 6] The potential short-term impacts for mothers include increased risk of preeclampsia, polyhydramnios, shoulder dystocia, stillbirth, and infectious complications.[7] Worse still, although GDM will resolve within a short period after delivery, it is an independent risk factor for many diseases. Specifically, the long-term maternal effects of GDM include but are not limited to GDM recurrence in the next pregnancy,[8] as well as higher risks of developing type 2 diabetes (a nine-fold increased risk) [9] and cardiovascular diseases (2.3 times the risk).[10]

Likewise, a significant association between maternal anomalous hyperglycemia and many fetal and neonatal complications has also been clearly established,[7] which includes fetal intrauterine growth retardation, macrosomia, neonatal hypoglycemia, respiratory distress syndrome, and so on. Furthermore, according to the concept of transgenerational programming, offsprings who are exposed to hyperglycemia when in the uterus have an increased risk of obesity and metabolic syndrome in their childhood and early adulthood.[11]

Therefore, in view of the considerable short-term and long-term complications that GDM may cause, it is of great importance to manage GDM effectively via strategies aiming to maintain the maternal glycemia as close to normal as possible. Lifestyle interventions, typically including healthy eating and physical exercise, have been widely adopted to help optimize blood glucose levels during the prenatal period.[12] Actually, these interventions are the mainstay of therapy for GDM and may suffice for most pregnant women with GDM (65%–90%).[13, 14] When non-pharmacological regimens fail to affect, pharmacotherapies (oral hypoglycemic agents and insulin) will be added. However, regardless of whether drugs are involved, traditional GDM management is achieved by intensive clinic attendance for receiving disease education, reporting symptoms and glycemic control levels, and adjusting therapeutic regimens, [15-17] which will place increased demands on clinical services for providing diabetes care and aggravate the economic burden on individuals.[15, 18] Meanwhile, multiple barriers and disadvantages exist in the traditional mode of GDM management, such as unequal hospital resource distribution, high costs for

transportation, time and energy lacking for both patients and health professionals, time-consuming waiting before seeing a doctor, and a limited intervention time window, which can reduce the efficiency of GDM management, decrease patients' satisfaction, and cause poor pregnancy outcomes.[17-19] Consequently, it is essential to identify a more practical, scalable, sustainable, and cost-effective mode of care to manage GDM effectively and simultaneously ease the medical service burden on the premise of not interfering with the current health care system or compromising the quality of care.

The rapid development and wide spread of information and communication technology worldwide has precisely provided an innovative perspective for disease management. In particular, due to the advantages of high accessibility, convenience, flexibility, and efficiency,[20] web-based interventions delivered by smartphones, computers, laptops, and other internet-connected devices have attracted a great deal of attention and have been widely used in recent years for health and well-being promotion in patients with cardiovascular diseases,[21] metabolic syndrome, [22] and other diseases.[23-25] These technologies can help to close the loop between patients and health professionals, overcome the inequivalent distribution of medical resources, and realize the vision of pervasive healthcare,[26, 27] which is therefore regarded as an ideal medical and public health practice mode for disease management. Notably, pregnant women with GDM seemed to be an ideal population to target for using web-based technologies to improve health outcomes because of the high penetration rates and excellent grasp of web-based devices among the reproductive-aged population, who have limited time to attend conventional health services.[16, 28-30] At present, attempts have been made to improve health outcomes in pregnant women with GDM via web-based interventions; nonetheless, clinical trials on this topic have yielded mixed results. Some studies found that web-based interventions could significantly ameliorate glycemic control,[27, 31] increase compliance with self-monitoring of blood glucose (SMBG),[32] reduce the incidence of premature delivery [33] and medical service costs,[15] as well as improve satisfaction with care [15] for this crowd, while others demonstrated a null effect.[32, 34, 35] Hence, it is

critical to systematically evaluate the effectiveness of web-based interventions for pregnant women with GDM.

To date, two systematic reviews and meta-analyses have been conducted to evaluate the effectiveness of web-based interventions for pregnant women with GDM.[36, 37] One previous review [37] included pregnant women with GDM, type 1 diabetes, and type 2 diabetes, while the results of the GDM subgroup (N = 5 studies) showed no significant between-group effect on glycated haemoglobin (HbA1c), caesarean rate, neonatal birth weight, or hypoglycemia. On the contrary, a recent review (N = 6 studies) [36] focused on the effectiveness of disease-specific mobile applications and reported that fasting blood glucose (FBG), 2-hour postprandial blood glucose (2hBG), and caesarean rate in pregnant women with GDM significantly improved after intervention compared to the control group. In addition, another five systematic reviews [38-42] investigated the effects of telemedicine on GDM, which included medical interventions both delivered via internet and early mobile technologies (e.g., phone calls, short message service (SMS) and digital video disk (DVD)); but these reviews generated conflicting results on glycaemic control and maternal and neonatal clinical outcomes. In general, the existing systematic reviews of relevant topics reported mixed results on glycaemic control and clinical outcomes, whereas the other outcomes (such as maternal behavioral outcomes and medical service utilisation and costs) were hardly assessed. Beyond that, in the majority of these reviews,[38-42] web-based technologies were conflated with early labor-intensive technologies that have become less popular in the rapidly evolving landscape of technology. More importantly, a growing number of primary studies [15, 32, 34, 43-47] with conflicting results regarding this topic have emerged after the above reviews, which may provide new evidence. Therefore, it is necessary to conduct a new systematic review that focuses on web-based technologies and includes evidence from all existing studies to comprehensively evaluate the effectiveness of web-based interventions in pregnant women with GDM, so as to provide scientific and conclusive evidence for future clinical practice.

OBJECTIVES

This systematic review and meta-analysis aims to

(1) investigate the effectiveness of web-based interventions on maternal glycemic control, behavioral outcomes, cognitive and attitudinal outcomes, mental health, maternal and neonatal clinical outcomes, as well as medical service utilisation and costs in pregnant women with GDM by integrating all available evidence from randomized controlled trials (RCTs) and controlled clinical trials (CCTs); and

(2) innovatively gain insight into whether the type of interactivity, the type of format, and the type of technology of web-based interventions can influence the intervention effects and which type of intervention regimen is the most effective, thereby finding out an optimal web-based intervention regimen.

METHODS AND ANALYSIS

Registration and study design

This paper presents a systematic review protocol that has been registered in PROSPERO (registration number CRD42022296625), and any future changes will be registered as amendments. We will complete and report the study protocol following the Preferred Reporting Items for Systematic Review and Meta-Analyses Protocol (PRISMA-P) guidelines [48] (see online supplemental file: Table S1 for details). The research questions are developed based on the PICOS framework (population, intervention, comparator/control, outcome, and study design), which are described in detail as follows.

Eligibility criteria for selecting studies

Types of study

We will include RCTs and CCTs that have been published in peer-reviewed English journals, which are good standards for evidence-based clinical research.[49] Single-group studies, reviews, case reports, cohort studies, letters to editors, conference abstracts, and study protocols will be excluded.

Types of participant

Pregnant women with GDM but without any severe diseases (such as severe symptoms of psychological disorders or fetal abnormalities) will be included, regardless of whether she had been diagnosed with GDM in previous pregnancies.

Studies that included mixed types of diabetes mellitus (including GDM, type 1 diabetes, and type 2 diabetes) but reported the data specific to GDM separately will be included as well. Moreover, the present review is part of a research project aimed at developing a theoretically-informed and web-assisted behavior change intervention for pregnant adult women. Therefore, pregnant women ≥ 18 years old will be considered eligible in this study.

Types of intervention

The intervention should be a digital one delivered by any types of web-based modalities, which may include but are not restricted to websites and mobile applications. However, studies that only used web-based interventions for observing the maintenance of outcome changes from previously administered health interventions, incorporating web-based components with face-to-face components, and lacked real web-based interventions for participants (for example, conducting interventions via video, DVD, television, radio, SMS, or telephone calls) will be excluded.

Types of comparator/control

The following comparators will be regarded as eligible: a wait-list control, usual care, and no interventions.

Types of outcome

(1) Primary outcome: the glycaemic control indicators during pregnancy including HbA1c, FBG, 1-hour postprandial blood glucose (1hBG), and 2hBG.

(2) The following five categories of secondary outcomes are interested:

► Maternal behavioural outcomes: insulin treatment rate, oral hypoglycemic agents treatment rate and self-care behaviors (mainly inlcuding the compliance with SMBG, healthy diet and physical activity);

► Maternal cognitive and attitudinal outcomes: knowledge of disease, risk-perception of disease, self-efficacy, and satisfaction with care;

► Maternal mental health: depression and anxiety;

► Maternal and neonatal clinical outcomes: gestational weight gain, induction of labor, vaginal delivery, normal vaginal delivery, assisted vaginal delivery, caesarean

section, planned caesarean section, emergency caesarean section, gestational weeks at delivery, premature delivery, shoulder dystocia, pre-eclampsia/gestational hypertension, premature rupture of the membranes, macrosomia, admission to the neonatal intensive care unit, low birth weight, birth weight, large for gestational age, small for gestational age, neonatal hypoglycemia, 1 minute apgar scores, 5 minute apgar scores, neonatal jaundice/hyperbilirubinemia, respiratory morbidity, composite neonatal complications, phototherapy, and neonatal death;

► Medical service utilisation and costs.

Studies that included at least one of the above outcomes will be considered eligible.

Search methods for the identification of studies

PubMed, Web of Science, Embase, Cochrane Library, CINAHL, and PsycINFO are anticipated to be comprehensively searched from the inception of each database to January 26, 2022. The search strategies of electronic databases are a combination of Medical Subject Heading (MeSH) and free-text words to represent the definitions of GDM, web-based interventions, RCTs, and CCTs. The search strategies will be developed in collaboration with an academic librarian. The detailed retrieval strategies of all databases are available in the supplementary file: Table S2. Two authors (PPG and DDC) will conduct the search process independently. Additionally, a snowball hand-search will be undertaken to retrieve additional eligible studies after database searches by reviewing the reference lists of included studies and the existing systematic reviews related to this topic.

Study selection

After the initial systematic searches, all retrieved records will be exported to Endnote X 8.2 reference management software. Then, the automated 'Find Duplicates' function of this software will be used to eliminate duplicate studies. Two authors (YJ and PX) will independently assess the remaining titles and abstracts and remove irrelevant citations in accordance with the selection criteria. Then, the full text of studies will be obtained if either of the two authors judges a publication to be potentially eligible for inclusion. Independent full text reading by the same authors

will follow. Any discrepancies between the authors will be discussed first. When consistency cannot be reached, a senior reviewer (SWF) will resolve the controversy. Reasons for excluding studies will be detailed on a PRISMA flow chart (Figure 1).

Data extraction and management

Data extraction will be carried out with a purpose-built, predesigned and structured template. We will first pilot the data extraction process using a subsample of included studies and make further refinements to the extraction sheet as necessary. The corresponding authors of included studies with any missing, uncertain, or incomplete information will be contacted. The data from the final included studies will be independently extracted by two reviewers (ZZX and XJW) and checked for accuracy by a third reviewer (QZ).

From all included studies, we will collect the following information:

► The general study information: the first author, year of publication, country, and study design;

► Participants' details: mean age, diagnostic criteria of GDM, gestational weeks at allocation, and sample size (intervention/control);

► Intervention details: name of intervention, detailed regimen, duration, main technology (such as mobile application and website), interactivity (interactive/non-interactive), and format (personalized/non-personalized);

► Control group regimen;

► Outcomes: the primary and secondary outcomes (between-group significance: +/-);

► Attrition rates.

Methodological quality assessment

The Effective Public Health Practice Project (EPHPP) assessment tool will be applied to appraise the methodological quality of included studies,[50] which showed better interrater agreement than the Cochrane Collaboration Risk of Bias tool.[51] Studies will be evaluated on the following six aspects: selection bias, study design, confounders, blinding, data collection methods, as well as withdrawals and drop-outs. Finally, each aspect as well as the global rating will be rated as strong, moderate, or

weak. What needs to be pointed out specially is that the aspect of blinding will be rated as "strong" for studies only evaluating objective outcomes, as objective outcomes are unlikely to be affected by actual blinding implementation.[49] The methodological quality evaluation will be performed independently by two reviewers (WZ and MNM), and any controversial evaluation differences will be discussed for a final decision.

Grading the quality of evidence

The GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) guidelines [52] will be used to assess the level of evidence for each indicator of the primary outcome (glycaemic control). After evaluations of the risk of bias, consistency, directness of evidence, imprecision, and publication bias, a body of evidence across the outcome indicators will be specified as very low, low, moderate, and high quality.

Data analysis

Data synthesis

A meta-analysis will be conducted when there are sufficient studies (no less than two studies) with available data investigating the same outcome by similar effect measures. For outcomes that could not be quantitatively synthesised due to insufficient studies, unavailable data, or high heterogeneity of effect measures, a narrative approach will be applied for analysis. Stata 12.0 (Stata Corporation, College Station, Texas, USA) will be used for all statistical calculations, and a p value < 0.05 will be set as the significance level. For continuous variables, the mean differences (MDs) with 95% confidence intervals (CIs) will be selected only when the unit and the instrument of measurement are the same across trials; otherwise, the standardised mean difference (SMDs) with 95% CIs will be chosen.[53] According to Cohen's definition, the effect size of SMD is considered small (< 0.2), moderate (0.2–0.8) or large (> 0.8).[54] For dichotomous variables, we will use relative risks (RR) with 95% CIs for point estimates, and the cut-off values of 1.22, 1.86, and 3.00 represent small, medium, and large effects, respectively.[55] The Inverse Variance method will be utilised to pool continuous outcome data and the Mantel Haenszel method for

dichotomous outcome data.

Assessment of heterogeneity

The level of heterogeneity across studies will be evaluated by χ^2 test and I^2 test. According to the Cochrane Handbook, an I^2 value of 0-40 % represents insignificant heterogeneity; 30%-60% represents moderate heterogeneity; 50%-90% represents substantial heterogeneity; >75 % represents high heterogeneity.[56] We will use a fixed-effect model for analysis if there is no substantial heterogeneity (p value ≥ 0.1 of the χ^2 test and a I^2 value $\leq 50\%$). Otherwise, a random-effect model will be employed, which can yield more conservative summary effect estimates and is more recommended when there is unexplained heterogeneity across studies.[57]

Additional analysis for the primary outcome

(1) Subgroup analyses based on the intervention format (personalized and nonpersonalized), interactivity (interactive and non-interactive), and technology (such as mobile applications and websites) will be performed if possible to explore an optimal web-based intervention regimen and to identify the potential sources of heterogeneity; (2) The funnel plot and Egger's test will be employed to detect the potential publication bias if there is a sufficient number of included studies (N $\geq$10).[54]

Patient and public involvement

Neither patients nor the public will be directly involved in the design, conducting, reporting, or dissemination of this study because this systematic review will be based on publicly available studies.

Validity, reliability, and rigour

The systematic review protocol was completed following the PRISMA-P guidelines.[48] We will strictly follow the requirements of Cochrane Handbook [54] and the best practise PRISMA guidelines [58] when performing and reporting this systematic review.

DISCUSSION

GDM has been demonstrated to be closely associated with considerable maternal and neonatal short-term and long-term complications.[5, 7, 9, 11] The traditional

mode of GDM management is effective but requires intensive clinical input.[15, 18] In recent years, web-based interventions have become increasingly popular in the field of GDM management due to making treatments more accessible and affordable.[16, 31, 33] However, the benefit of web-based interventions for pregnant women with GDM is controversial, [15, 27, 32] and the existing systematic reviews [36, 37] also did not reach a consensus on this issue, which leads to confusion for clinical decision-making and restricts the application of these interventions. Hence, this paper presents a protocol for a systematic review based on all existing evidence from RCTs and CCTs to comprehensively investigate the multidimensional effectiveness of web-based interventions among pregnant women with GDM.

It is well known that maternal hyperglycemia of variable severity is the most important clinical manifestation of GDM and the pathological basis of related complications.[1] To this end, maternal glycemic control will be used as the primary outcome in this review, reflected by four commonly measured parameters (HbA1c, FBG, 1hBG, and 2hBG). Meanwhile, in order to elevate the comprehensive understanding of the effectiveness of web-based interventions, extensive secondary outcomes will also be assessed, including maternal behavioural outcomes, cognitive and attitudinal outcomes, mental health, maternal and neonatal clinical outcomes, as well as medical service utilisation and costs. The conclusions of this study will provide objective evidence on whether web-based interventions should be widely recommended for GDM management in future clinical practice.

In addition, three subgroup analyses regarding intervention format (personalized and nonpersonalized), interactivity (interactive and non-interactive), and technology (such as mobile applications and websites) will be performed. It is anticipated that the findings of subgroup analyses can enlighten health professionals on developing and implementing an optimal web-based intervention regimen for pregnant women with GDM and bring maximum benefits to the targeted crowd, clinicians, and other relevant personnel.

However, several potential limitations to this study should be considered. First, the emerging use of web-based technologies in healthcare is relatively recent; hence,

the number of studies regarding this topic may be limited. Second, given that the diagnostic criteria of GDM, gestational weeks at allocation, and web-based intervention programmes are likely to be quite different, there may be high heterogeneity across studies; therefore, we plan to conduct subgroup analyses to overcome this heterogeneity. Finally, since we will only include RCTs and CCTs published in English, there may be a loss of studies written in other languages.

ETHICS AND DISSEMINATION

Ethical approval will not be required for this study as no identifiable patient information or privacy will be involved. The findings will be published and diffused in a peer-reviewed English journal or disseminated through an academic conference.

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Contributors PPG, YJ and SWF contributed to the initial conception and design of the systematic review protocol. DDC, PX, XJW and MMN reviewed the initial framework and provided input. ZZX, WZ and QZ developed the database search strategy. PPG drafted the manuscript. PPG and ZZX critically revised the manuscript for important intellectual content. All authors approved the final version. SWF is the guarantor.

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Figure Legend

Figure 1. Flow diagram of article selection process.

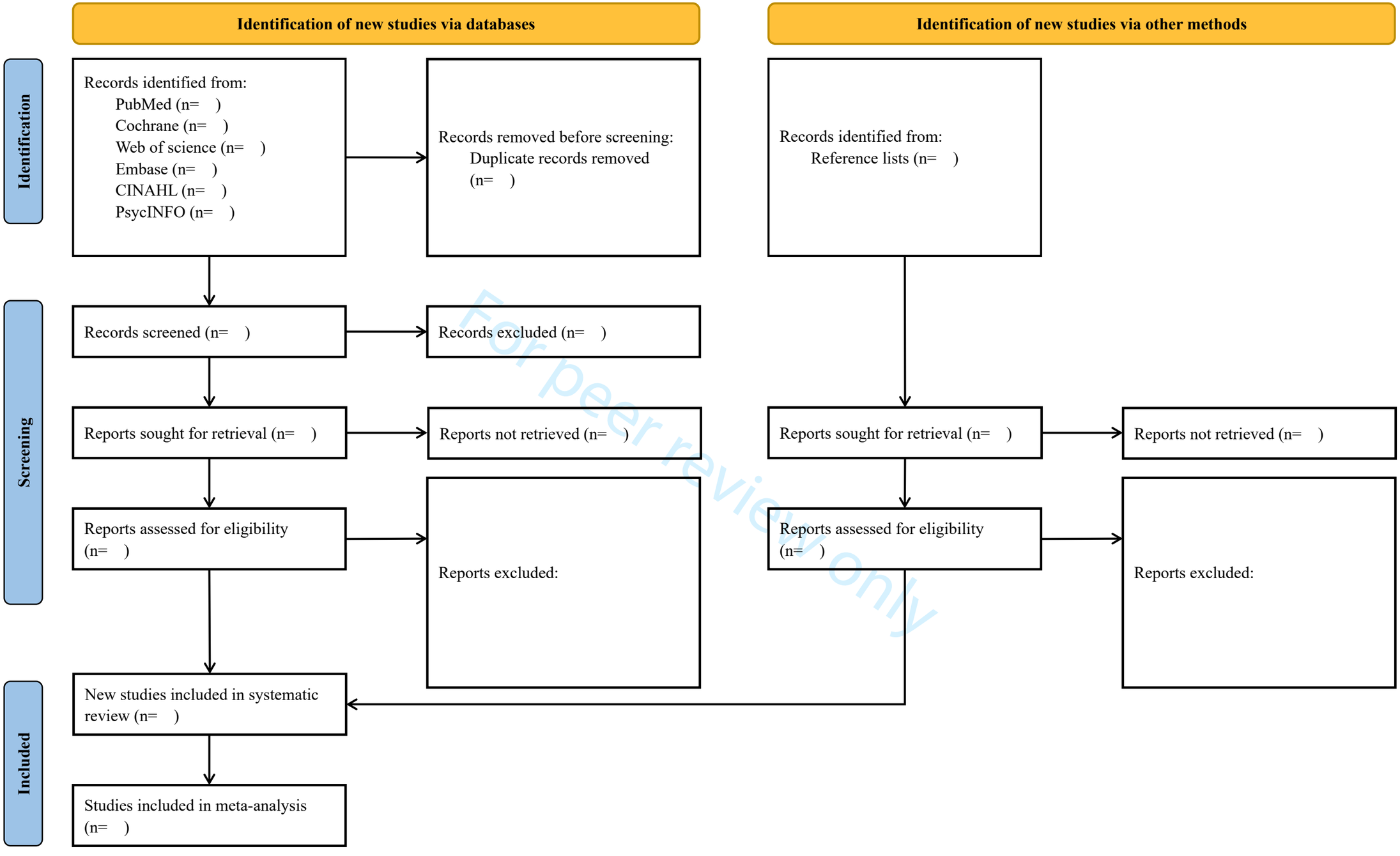

Figure 1. Flow diagram of article selection process.

Table S1. PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section/Topic	Item No	Item	Reported on Page Number/Line Number (P/L)	Reported on Section/Paragraph
ADMINISTRATIVE INFORMATION				
Title	1a	Identification - identify the report as a protocol of a systematic review	P3/L37	Title
	1b	Update - if the protocol is for an update of a previous systematic review, identify as such	Non-update	Non-update
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P4/L68	Abstract
Authors	3a	Contact - provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P1-2/L5-34	Title page
	3b	Contributions - describe contributions of protocol authors and identify the guarantor of the review	P15/L407-411	Contributors
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Non-amendments	Non-amendments
Support	5a	Sources - indicate sources of financial or other support for the review	P15/L412-413	Funding
	5b	Sponsor - provide name for the review funder and/or sponsor	P15/L412-413	Funding
	5c	Role of sponsor or funder - describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P15/L412-413	Funding
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	P4-8/L82-194	Introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants,interventions, comparators, and outcomes (PICO)	P8/L184-194	Objectives
METHODS				
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	P8-10/L206-254	Eligibility criteria for selecting studies
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	P10/L256-266	Search methods for identification of studies
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file: Table 1	
Study records	11a	Data management - describe the mechanism(s) that will be used to manage records and data throughout the review	P11/L279-297	Data extraction and management

	11b	Selection process - state the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	P10-11/L268-277	Study selection
	11c	Data collection process - describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	P11/L279-297	Data extraction and management
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	P10/L256-266	Search methods for identification of studies
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P8-10/L206-254	Eligibility criteria for selecting studies
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	P11-12/L299-310	Methodological quality assessment
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	P12/L320-322	Data analysis
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I_2, Kendall's τ)	P12-13/L325-344	Data analysis
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P13/L346-350	Data analysis
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P12/L322-324	Data analysis
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P13/L350-351	Data analysis
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	P12/L312-317	Grading the quality of evidence

* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated.

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

Table S2. Literature search strategy.

Electronic database	Search terms
PubMed	"Diabetes, Gestational"[Mesh] OR ((((((((((Diabetes, Pregnancy-Induced[Title/Abstract]) OR (Diabetes, Pregnancy Induced[Title/Abstract])) OR (Diabetes Mellitus, Gestational[Title/Abstract])) OR (Diabetes, Gestational[Title/Abstract])) OR (diabetes in pregnancy[Title/Abstract])) OR (Gestational Diabetes[Title/Abstract])) OR (Gestational Diabetes Mellitus[Title/Abstract])) OR (GDM[Title/Abstract])) OR (maternal diabetes[Title/Abstract])) OR (Pregnancy-Induced Diabetes[Title/Abstract])) OR (pregnancy diabetes mellitus[Title/Abstract]) AND (((((((("Mobile Applications"[Mesh]) OR "Telemedicine"[Mesh]) OR "Internet"[Mesh]) OR "Computers"[Mesh]) OR "Telecommunications"[Mesh]) OR "Online Systems"[Mesh]) OR "Software"[Mesh]) OR "Wireless Technology"[Mesh]) OR "Cell Phone"[Mesh] OR ((app[Title/Abstract]) OR (apps[Title/Abstract])) OR (application[Title/Abstract])) OR (applications[Title/Abstract])) OR (ipad[Title/Abstract])) OR (blog[Title/Abstract])) OR (blogging[Title/Abstract])) OR (computer[Title/Abstract])) OR (computer interface[Title/Abstract])) OR (cell phones[Title/Abstract])) OR (cell phone[Title/Abstract])) OR (cellular phone[Title/Abstract])) OR (digital[Title/Abstract])) OR (digital health[Title/Abstract])) OR (digital-health[Title/Abstract])) OR (ehealth[Title/Abstract])) OR (e-health[Title/Abstract])) OR (e-mail[Title/Abstract])) OR (electronic[Title/Abstract])) OR (E-learning[Title/Abstract])) OR (Facebook[Title/Abstract])) OR (health, mobile[Title/Abstract])) OR (health technolog[Title/Abstract])) OR (health app[Title/Abstract])) OR (Internet[Title/Abstract])) OR (Internet forum[Title/Abstract])) OR (iphone[Title/Abstract])) OR (i phone[Title/Abstract])) OR (i-phone[Title/Abstract])) OR (ipad[Title/Abstract])) OR (i pad[Title/Abstract])) OR (i-pad[Title/Abstract])) OR (laptop[Title/Abstract])) OR (linkedin[Title/Abstract])) OR (mobile[Title/Abstract])) OR (mobile application[Title/Abstract])) OR (mobile apps[Title/Abstract])) OR (mobile app[Title/Abstract])) OR (mobile phone[Title/Abstract])) OR (mobile phones[Title/Abstract])) OR (mhealth[Title/Abstract])) OR (m-health[Title/Abstract])) OR (mobile health[Title/Abstract])) OR (mobile electronic device[Title/Abstract])) OR (mobile technolog[Title/Abstract])) OR (mobile communication[Title/Abstract])) OR (mobile computing[Title/Abstract])) OR (network[Title/Abstract])) OR (online[Title/Abstract])) OR (online intervention[Title/Abstract])) OR (online interventions[Title/Abstract])) OR (platform[Title/Abstract])) OR (personal computer[Title/Abstract])) OR (personal digital assistant[Title/Abstract])) OR (QQ[Title/Abstract])) OR (remote[Title/Abstract])) OR (smartphone[Title/Abstract])) OR (smart phone[Title/Abstract])) OR (social media[Title/Abstract])) OR (social networking[Title/Abstract])) OR (telehealth[Title/Abstract])) OR (tele-health[Title/Abstract])) OR (telephone[Title/Abstract])) OR (telemedicine[Title/Abstract])) OR (tele-medicine[Title/Abstract])) OR (tele-care[Title/Abstract])) OR (telecare[Title/Abstract])) OR (telecommunication[Title/Abstract])) OR (telemonitor[Title/Abstract])) OR (tele-monitor[Title/Abstract])) OR (telemonitoring[Title/Abstract])) OR (twitter[Title/Abstract])) OR (web[Title/Abstract])) OR (web-based[Title/Abstract])) OR (website[Title/Abstract])) OR (wireless[Title/Abstract])) OR (WeChat[Title/Abstract]) AND ((("Randomized Controlled Trial" [Publication Type]) OR "Randomized Controlled Trials as Topic"[Mesh]) OR "Controlled Clinical Trial" [Publication Type]) OR "Controlled Clinical Trials as Topic"[Mesh] OR Clinical Trials, Randomized[Title/Abstract] OR Trials, Randomized Clinical[Title/Abstract] OR Controlled Clinical Trials, Randomized[Title/Abstract] OR RCT[Title/Abstract] OR Clinical Trials[Title/Abstract] OR Controlled Clinical Trials[Title/Abstract] OR CCT[Title/Abstract]

Embase	#1 'pregnancy diabetes mellitus'/exp OR 'diabetes, pregnancy-induced':ab,ti OR 'diabetes, pregnancy induced':ab,ti OR 'diabetes mellitus, gestational':ab,ti OR 'diabetes, gestational':ab,ti OR 'diabetes in pregnancy':ab,ti OR 'gestational diabetes':ab,ti OR 'gestational diabetes mellitus':ab,ti OR gdm:ab,ti OR 'maternal diabetes':ab,ti OR 'pregnancy-induced diabetes':ab,ti OR 'pregnancy diabetes mellitus':ab,ti #2 'mobile application'/exp OR 'telemedicine'/exp OR 'internet'/exp OR 'computer'/exp OR 'telecommunication'/exp OR 'online system'/exp OR 'software'/exp OR 'wireless communication'/exp OR 'mobile phone'/exp OR app:ab,ti OR apps:ab,ti OR application:ab,ti OR applications:ab,ti OR blog:ab,ti OR blogging:ab,ti OR computer:ab,ti OR 'computer interface':ab,ti OR 'cell phones':ab,ti OR 'cell phone':ab,ti OR 'cellular phone':ab,ti OR digital:ab,ti OR 'digital health':ab,ti OR 'digital-health':ab,ti OR ehealth:ab,ti OR 'e-health':ab,ti OR 'e-mail':ab,ti OR electronic:ab,ti OR 'e-learning':ab,ti OR facebook:ab,ti OR 'health, mobile':ab,ti OR 'health technolog':ab,ti OR 'health app':ab,ti OR internet:ab,ti OR 'internet forum':ab,ti OR iphone:ab,ti OR 'i phone':ab,ti OR 'i-phone':ab,ti OR ipad:ab,ti OR 'i pad':ab,ti OR 'i-pad':ab,ti OR laptop:ab,ti OR linkedin:ab,ti OR mobile:ab,ti OR 'mobile application':ab,ti OR 'mobile apps':ab,ti OR 'mobile app':ab,ti OR 'mobile phone':ab,ti OR 'mobile phones':ab,ti OR mhealth:ab,ti OR 'm-health':ab,ti OR 'mobile health':ab,ti OR 'mobile electronic device':ab,ti OR 'mobile technolog':ab,ti OR 'mobile communication':ab,ti OR 'mobile computing':ab,ti OR network:ab,ti OR online:ab,ti OR 'online intervention':ab,ti OR 'online interventions':ab,ti OR platform:ab,ti OR 'personal computer':ab,ti OR 'personal digital assistant':ab,ti OR qq:ab,ti OR remote:ab,ti OR smartphone:ab,ti OR 'smart phone':ab,ti OR 'social media':ab,ti OR 'social networking':ab,ti OR telehealth:ab,ti OR 'tele-health':ab,ti OR telephone:ab,ti OR telemedicine:ab,ti OR 'tele-medicine':ab,ti OR 'tele-care':ab,ti OR telecare:ab,ti OR telecommunication:ab,ti OR telemonitor:ab,ti OR 'tele-monitor':ab,ti OR telemonitoring:ab,ti OR twitter:ab,ti OR web:ab,ti OR 'web-based':ab,ti OR website:ab,ti OR wireless:ab,ti OR wechat:ab,ti #3 'randomized controlled trial'/exp OR 'randomized controlled trials as topic'/exp OR 'controlled clinical trial'/exp OR 'controlled clinical trials as topic'/exp OR 'clinical trials, randomized':ta,ab OR 'trials, randomized clinical':ta,ab OR 'controlled clinical trials, randomized':ta,ab OR rct:ta,ab OR 'clinical trials':ta,ab OR 'controlled clinical trials':ta,ab OR cct:ta,ab #4 #1 AND #2 AND #3
the Cochrane library (CENTRAL)	#1 [Diabetes, Gestational] explode all trees OR (Diabetes, Pregnancy-Induced OR Diabetes, Pregnancy Induced OR Diabetes Mellitus, Gestational OR Diabetes, Gestational OR diabetes in pregnancy OR Gestational Diabetes OR Gestational Diabetes Mellitus OR GDM OR maternal diabetes OR Pregnancy-Induced Diabetes OR pregnancy diabetes mellitus):ti,ab,kw #2 [Mobile Applications] explode all trees OR [Telemedicine] explode all trees OR [Internet] explode all trees OR [Computers] explode all trees OR [Telecommunications] explode all trees OR [Online Systems] explode all trees OR [Software] explode all trees OR [Wireless Technology] explode all trees OR [Cell Phone] explode all trees OR (app OR apps OR application OR applications OR ipad OR blog OR blogging OR computer OR computer interface OR cell phones OR cell phone OR cellular phone OR digital OR digital health OR digital-health OR ehealth OR e-health OR e-mail OR electronic OR E-learning OR Facebook OR health, mobile OR health technolog OR health app OR Internet OR Internet forum OR iphone OR i phone OR i-phone OR ipad OR i pad OR i-pad OR laptop OR linkedin OR mobile OR mobile application OR mobile apps OR mobile app OR mobile phone OR mobile phones OR mhealth OR m-health OR mobile health OR mobile electronic device OR mobile technolog OR mobile communication OR mobile computing OR network OR online OR online intervention OR online interventions OR platform OR personal computer OR personal digital assistant OR QQ OR remote OR smartphone OR smart phone OR social media OR social networking OR telehealth OR tele-health OR telephone OR telemedicine OR tele-medicine OR tele-care OR telecare OR telecommunication OR telemonitor OR tele-monitor OR telemonitoring OR twitter OR web OR web-based OR website OR wireless OR WeChat):ti,ab,kw #3 [Randomized Controlled Trial] explode all trees OR [Randomized Controlled Trials as Topic] explode all trees OR [Controlled Clinical Trial] explode all trees OR [Controlled Clinical Trials as Topic] explode all trees OR (clinical trials, randomized OR trials, randomized clinical OR controlled clinical trials, randomized OR rct OR clinical trials OR controlled clinical trials OR cct):ti,ab,kw #4 #1 AND #2 AND #3

Web of Science	TS = (Diabetes, Pregnancy-Induced OR Diabetes, Pregnancy Induced OR Diabetes Mellitus, Gestational OR Diabetes, Gestational OR diabetes in pregnancy OR Gestational Diabetes OR Gestational Diabetes Mellitus OR GDM OR maternal diabetes OR Pregnancy-Induced Diabetes OR pregnancy diabetes mellitus) AND TS = (app OR apps OR application OR applications OR ipad OR blog OR blogging OR computer OR computer interface OR cell phones OR cell phone OR cellular phone OR digital OR digital health OR digital-health OR ehealth OR e-health OR e-mail OR electronic OR E-learning OR Facebook OR health, mobile OR health technolog OR health app OR Internet OR Internet forum OR iphone OR i phone OR i-phone OR ipad OR i pad OR i-pad OR laptop OR linkedin OR mobile OR mobile application OR mobile apps OR mobile app OR mobile phone OR mobile phones OR mhealth OR m-health OR mobile health OR mobile electronic device OR mobile technolog OR mobile communication OR mobile computing OR network OR online OR online intervention OR online interventions OR online system OR platform OR personal computer OR personal digital assistant OR QQ OR remote OR smartphone OR smart phone OR social media OR social networking OR Software OR telehealth OR tele-health OR telephone OR telemedicine OR tele-medicine OR tele-care OR telecare OR telecommunication OR telemonitor OR tele-monitor OR telemonitoring OR twitter OR web OR web-based OR website OR wireless OR wireless technology OR WeChat) AND TS = (Randomized Controlled Trial OR Randomized Controlled Trials as Topic OR Controlled Clinical Trial OR Controlled Clinical Trials as Topic OR clinical trials, randomized OR trials, randomized clinical OR controlled clinical trials, randomized OR rct OR clinical trials OR controlled clinical trials OR cct)
CINAHL	MH Diabetes, Gestational OR AB (Diabetes, Pregnancy-Induced OR Diabetes, Pregnancy Induced OR Diabetes Mellitus, Gestational OR Diabetes, Gestational OR diabetes in pregnancy OR Gestational Diabetes OR Gestational Diabetes Mellitus OR GDM OR maternal diabetes OR Pregnancy-Induced Diabetes OR pregnancy diabetes mellitus) AND MH Mobile applications OR MH Telemedicine OR MH internet OR MH Computers OR MH Telecommunications OR MH online system OR MH Software OR MH wireless technology OR MH cell phones OR AB (app OR apps OR application OR applications OR ipad OR blog OR blogging OR computer OR computer interface OR cell phones OR cell phone OR cellular phone OR digital OR digital health OR digital-health OR ehealth OR e-health OR e-mail OR electronic OR E-learning OR Facebook OR health, mobile OR health technolog OR health app OR Internet OR Internet forum OR iphone OR i phone OR i-phone OR ipad OR i pad OR i-pad OR laptop OR linkedin OR mobile OR mobile application OR mobile apps OR mobile app OR mobile phone OR mobile phones OR mhealth OR m-health OR mobile health OR mobile electronic device OR mobile technolog OR mobile communication OR mobile computing OR network OR online OR online intervention OR online interventions OR platform OR personal computer OR personal digital assistant OR QQ OR remote OR smartphone OR smart phone OR social media OR social networking OR telehealth OR tele-health OR telephone OR telemedicine OR tele-medicine OR tele-care OR telecare OR telecommunication OR telemonitor OR tele-monitor OR telemonitoring OR twitter OR web OR web-based OR website OR wireless OR WeChat) AND MH randomized controlled trials OR MH Randomized Controlled Trials as Topic OR MH Controlled Clinical Trial OR MH Controlled Clinical Trials as Topic OR AB (Clinical Trials, Randomized OR Trials, Randomized Clinical OR Controlled Clinical Trials, Randomized OR RCT OR Clinical Trials OR Controlled Clinical Trials OR CCT)
PsycINFO	(Diabetes, Pregnancy-Induced OR Diabetes, Pregnancy Induced OR Diabetes Mellitus, Gestational OR Diabetes, Gestational OR diabetes in pregnancy OR Gestational Diabetes OR Gestational Diabetes Mellitus OR GDM OR maternal diabetes OR Pregnancy-Induced Diabetes OR pregnancy diabetes mellitus)[Any Field] AND (app OR apps OR application OR applications OR ipad OR blog OR blogging OR computer OR computer interface OR cell phones OR cell phone OR cellular phone OR digital OR digital health OR digital-health OR ehealth OR e-health OR e-mail OR electronic OR E-learning OR Facebook OR health, mobile OR health technolog OR health app OR Internet OR Internet forum OR iphone OR i phone OR i-phone OR ipad OR i pad OR i-pad OR laptop OR linkedin OR mobile OR mobile application OR mobile apps OR mobile app OR mobile phone OR mobile phones OR mhealth OR m-health OR mobile health OR mobile electronic device OR mobile technolog OR mobile communication OR mobile computing OR network OR online OR online intervention OR online interventions OR online system OR platform OR personal computer OR personal digital assistant OR QQ OR remote OR smartphone OR smart phone OR social media OR social networking OR Software OR telehealth OR tele-health OR telephone OR telemedicine OR tele-medicine OR tele-care OR telecare OR telecommunication OR telemonitor OR tele-monitor OR telemonitoring OR twitter OR web OR web-based OR website OR wireless OR wireless technology OR WeChat) [Any Field] AND (Randomized Controlled Trial OR Randomized Controlled Trials as Topic OR Controlled Clinical Trial OR Controlled Clinical Trials as Topic OR clinical trials, randomized OR trials, randomized clinical OR controlled clinical trials, randomized OR rct OR clinical trials OR controlled clinical trials OR cct) [Any Field]