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Review title

mHealth as a primary mode of intervention for women at risk of, or diagnosed with, gestational diabetes: a systematic scoping review protocol

Abstract

Objective: To synthesize current knowledge on the use of mHealth as a primary mode of intervention for the prevention and management of gestational diabetes mellitus (GDM) and its long-term implications among women at risk of, or diagnosed with, GDM.

Introduction: Prevention and management of GDM and its associated adverse outcomes are of paramount importance to both maternal and infant health. However, women with experience of GDM report several barriers to effective disease management and lifestyle change. Supporting women through use of mHealth technology may help overcome these barriers. Recent evidence suggests mobile apps may be useful for prevention and management of GDM, however less is known about the broader application of mHealth from preconception to interconception.

Inclusion criteria: Studies considered for inclusion are those focused on the use of mHealth as primary mode of intervention for the prevention and management of GDM and its long-term implications among, women at risk of, or diagnosed with, GDM. Studies will be limited to those published in English.

Methods: The following Databases will be searched: MEDLINE (Ovid), CINAHL (EBSCO), EMBASE (Ovid), Cochrane Database (Wiley), Scopus, and TRIP. Unpublished studies and grey literature will be searched using Open Grey, ISRCTN Registry, ClinicalTrials.gov, EU Clinical Trials register and ANZCTR. Two reviewers will independently screen abstracts. Reviewers will assess full texts of selected citations against the inclusion criteria. Any disagreements will be discussed with a third reviewer. Data will be extracted and presented in diagrammatic or tabular form with an accompanying narrative in line with review objectives.

Keywords: GDM; mHealth; digital health; mobile applications; gestational diabetes

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Introduction

Gestational Diabetes Mellitus (GDM) has been defined as 'carbohydrate intolerance resulting in hyperglycemia of variable severity with onset or first recognition during pregnancy'.[1] Despite a lack of consensus regarding screening and diagnostic criteria, there is widespread agreement that the prevalence of GDM is increasing worldwide.[2] In the United Kingdom (UK) an estimated 16 out of every 100 women will develop GDM.[3] Development of fetal macrosomia, or birthweight greater than 4000g, is a key perinatal consequence of GDM and is associated with increased likelihood of birth injuries, caesarean delivery, and shoulder dystocia.[4] Infants are also more likely to experience respiratory distress syndrome, neonatal hypoglycemia, hyperbilirubinemia, polycythemia, and hypocalcemia.[4] Both genetic and environmental risk factors play a role in the pathogenesis of GDM.[5] High maternal body mass index (BMI) (≥25kg/m^2) and prior GDM are both independently associated with increased GDM risk as well as longer term adverse outcomes such as development of type 2 diabetes.[6,7]

Preventing GDM onset by tackling modifiable lifestyle factors has shown mixed results regarding effectiveness.[8] However, a recent meta-analysis of data from 11,487 pregnant women concluded that lifestyle interventions implemented before 15 weeks gestation were able to reduce the risk of GDM by 20%.[9] For women who already have a GDM diagnosis, the importance of effectively managing the condition is central for reducing the likelihood of adverse outcomes. For those who had mild GDM (defined as a fasting glucose level of less than 5.3mmol/l, and two or three timed glucose measurements exceeding established thresholds), dietary intervention, self-monitoring of blood glucose and insulin therapy significantly reduced the risk of macrosomia compared to those who received standard care.[10] Reoccurrence of GDM is thought to arise in 30% to 84% of subsequent pregnancies, making the interconception and postpartum periods key windows of opportunity to reduce the likelihood of future GDM pregnancies, as well as providing women with interventions aimed at preventing potential type 2 diabetes onset.[2,11]

While it is clear that effectively preventing and managing GDM is crucial for improving maternal and infant outcomes, women report difficulties in managing the condition once diagnosed, as well as making lifestyle modifications, particularly postpartum.[12,13] Women with previous diagnosis of GDM encounter a unique set of barriers to engaging in face-to-face lifestyle interventions, including time and financial constraints, childcare duties, fatigue and lack of motivation.[13] Thus, delivery of care via telephone or through internet has been suggested as an optimal way of supporting this population.[14]

mHealth has been defined as the "use of mobile and wireless technologies, such as mobile phones and personal digital assistants (PDAs), to support the achievement of health objectives".[15] Commonly used mHealth technologies include smartphone apps, wearable sensors, and social media use. It is estimated that 79% of adults in the UK own a smartphone, with ownership as high as 95% for 16-24 year olds.[16] The average monthly consumption of mobile network data in the UK has increased by 25% since 2018, suggesting people are increasingly accessing the internet through their mobile

phones.[16] Pregnant and postpartum women are high users of mobile phone devices and increasingly rely on social media and mobile apps as sources of pregnancy and health information.[17] The use of apps during pregnancy has been found to be feasible and acceptable among women, however, because of heterogeneity in interventions, comparators and outcome measures, it is difficult to draw conclusions on the effects of apps on maternal knowledge, behavior change and perinatal health outcomes.[18,19]

Diabetes self-management and remote monitoring was one of the earliest focuses for the application of mHealth.[20] However, interventions aimed specifically at supporting women with GDM have significantly lagged in comparison. However, the use of technology in GDM care has evolved in recent years, most notably in the domain of smartphone-facilitated remote blood glucose monitoring, telehealth for supervision of glycemic control during pregnancy and text messaging reminders for diabetic screening postpartum.[21,22,23]

The most recent scoping review by Chen et al.[24] of mobile apps for gestational diabetes, consolidated knowledge around functionality, implementation, impact, and role of health literacy. The review included 12 articles focusing on seven different mobile apps, aimed at the prevention and management of GDM. The authors concluded that mobile apps have the potential to help prevent GDM and improve GDM management, however, the impact of mobile apps on relevant outcomes needs to be addressed using larger scale randomized controlled trials (RCTs). Additionally the authors suggested that health literacy should be considered more readily during mobile app development and evaluation in order to increase usability and engagement. Nikolopoulos et al. recently published a literature review aiming to identify and appraise major mobile apps for GDM that were tested and evaluated by clinical studies published in MEDLINE and Scopus.[25] The review included 19 studies focused on three apps, and concluded that apps for blood glucose monitoring were a practical and useful way of tackling the growing burden of GDM. While both these reviews demonstrate promising support for mobile apps for use in GDM care, particularly during pregnancy, we aim to broaden the scope of this knowledge by conducting a scoping review focused on all types of mHealth (rather than just apps), that are available to support women at risk of or diagnosed with GDM.

The objective of this scoping review is, therefore, to provide an overview of the extent of knowledge related to the use of mHealth as primary mode of intervention for the prevention and management of GDM and its long-term implications among women at risk of or diagnosed with GDM. We aim to determine what kind of evidence is available and identify gaps for future research. We aim to better understand how mHealth interventions have been evaluated, the timing and context of their implementation, and their purpose of use. We also aim to summarize study key findings and outcome measures.

A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews and the JBI Database of Systematic Reviews and Implementation Reports was conducted and no current

or underway systematic or scoping reviews on the topic were identified. To the best of our knowledge, the protocol outlined for this scoping review is the first to address the concept of mHealth for GDM, across the full pregnancy journey from preconception, pregnancy, postpartum and interconception.

Review question

What is known about using mHealth as a primary mode of intervention for the prevention and management of GDM and its long-term implications among women at risk of and diagnosed with, gestational diabetes?

Inclusion criteria

Participants

The review will consider studies that include women who are at risk of GDM, currently have or have previously had a diagnosis of GDM. We acknowledge that women who have a history of diabetes (type1 or type 2) will experience diabetes during pregnancy, however, because the focus of this review will be on GDM, we will exclude studies primarily focused on women with pre-existing Type 1 or Type 2 diabetes. Because we wish to understand use of mHealth among women with a previous diagnosis of GDM (inter-conception and postpartum periods) we will consider studies that include participants of any age.

Concept

This review will consider studies examining mHealth for GDM. mHealth has been defined as the use of mobile and wireless technologies to support the achievement of health objectives.[15] We will include studies examining a range of mHealth technologies including, but not limited to, smartphone apps, wearable sensors such as smartwatches, and social media use. As mHealth technologies continue to be developed at a rapid pace, any newly emerging technologies that appear in the literature between protocol development and study selection will also be considered for inclusion. Studies focused on telehealth or telemedicine for GDM care, will be excluded as these have been systematically reviewed elsewhere.[26] In cases where studies include mHealth as one component of a broader interventional approach, mHealth must be the primary mode of intervention delivery to be considered for inclusion in this review.

Context

This review will consider studies that are conducted in any geographical location. Possible settings of mHealth use among women with experience of GDM include diabetes clinics, other hospital settings, primary care, community care and at home. With no commonly established implementation route, we aim include all settings in this review. With reference to our aim of understanding mHealth use for GDM before, during and after pregnancy we will consider studies that examine mHealth during preconception, pregnancy, inter-conception and postpartum periods. Studies published in English will

be included. We propose no limit on study date as mHealth is a relatively new concept and we aim to ensure the retrieval of all relevant studies.

Types of Sources

This scoping review will consider both experimental and quasi-experimental study designs including randomized controlled trials, non-randomized controlled trials, before and after studies and interrupted time-series studies. Study protocols will also be considered for inclusion. Any systematic reviews that meet the inclusion criteria will be retrieved and their original source papers will be searched for eligibility for inclusion.

In addition, analytical observational studies including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies will be considered for inclusion. This review will also consider descriptive observational study designs including case series, individual case reports and descriptive cross-sectional studies for inclusion. Qualitative studies will also be considered that focus on qualitative data including, but not limited to, designs such as phenomenology, grounded theory, ethnography, qualitative description, action research and feminist research.

Methods

The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews.[27,28]

Search strategy

The search strategy will aim to locate both published and unpublished studies. An initial limited search of Scopus and MEDLINE was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (see Appendix I). The search strategy, including all identified keywords and index terms, will be adapted for each included information source. The reference list of all studies selected for critical appraisal will be hand searched for additional studies.

Information sources

The databases to be searched include MEDLINE (via Ovid), CINAHL (via EBSCOhost, USA), EMBASE (via Ovid), Cochrane Database (via Wiley, USA) Scopus, and TRIP. Sources of unpublished studies and grey literature to be searched using Open Grey, ISRCTN Registry, ClinicalTrials.gov, EU Clinical Trials register and ANZCTR.

Study selection

Following the search, all identified citations will be collated and uploaded into Endnote X8, 2018 (Clarivate Analytics, PA, USA) and duplicates removed. Titles and abstracts will then be screened by two independent reviewers (KE, KM) for assessment against the inclusion criteria for the review. Potentially relevant studies will be retrieved in full and their citation details imported into the Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (JBI SUMARI; Joanna Briggs Institute, Adelaide, Australia).[29] The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (KE,KM). Reasons for exclusion of full text studies that do not meet the inclusion criteria will be recorded and reported in the systematic scoping review. Any disagreements that arise between the reviewers at each stage of the study selection process will be resolved through discussion, or with a third reviewer (JS). The results of the search will be reported in full in the final systematic scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.[30]

Data Extraction

Data will be extracted from full papers included in the scoping review by two independent reviewers (KE, KM) using the draft data extraction table available in Appendix II. This draft data extraction table is adapted from the JBI results extraction instrument. Data extracted will be tabulated and include the following: Author, year of publication, origin, study design, intervention, implementation context, and key findings related to the review objectives. The draft data extraction table may be modified and revised as necessary during the process of extracting data from each included study. Any modifications will be detailed in the full scoping review report. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer (JS). Authors of papers will be contacted to request missing or additional data, where required.

Data Presentation

Data extracted from included full text articles will be presented in diagrams and/or tables in a way that supports the objective of our planned review. We anticipate the results tabulated will include study design, type and purpose of mHealth intervention, study sample (e.g. women at risk, diagnosed during pregnancy, postpartum after diagnosis), key findings. Tabulated and/or charted results will be accompanied by a narrative summary that will describe how the results relate to the review question and objective.

Funding

The development of this protocol has not received funding.

Conflicts of interest

All authors declare no conflict of interest.

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Appendix I: Search strategy

Ovid MEDLINE(R) and In-Process & Other Non-Indexed Citations 1946 to April 02, 2020

Search conducted on 03.04.2020

#	Searches	Results
1	Diabetes, Gestational/	10407
2	"gestational diabet*".ab,kf,ti.	14724
3	GDM.ab,kf,ti.	7201
4	(pregnancy adj3 diabetes).ab,kf,ti.	5535
5	((pregnan* or gestation* or maternal) adj3 glucose intolerance).ab,kf,ti.	358

6	((pregnan* or gestation* or maternal) adj3 impaired glucose tolerance).ab,kf,ti.	318
7	(hyperglyc#emia adj3 pregnan*).ab,kf,ti.	159
8	(hyperglyc#emia adj3 gestation*).ab,kf,ti.	54
9	(maternal adj2 hyperglyc#emia).ab,kf,ti.	127
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	20345
11	Telemedicine/	21670
12	telemedicine.ab,kf,ti.	12006
13	(ehealth or "e health").ab,kf,ti.	6180
14	(mhealth or "m health").ab,kf,ti.	4817
15	("mobile health" or "mobile technolog*").ab,kf,ti.	5827
16	("digital health" or "digital technolog*").ab,kf,ti.	3209
17	Smartphone/	4038
18	(smartphone* or "smart phone*").ab,kf,ti.	11639
19	Cell Phone/	8334
20	("cell* phone*" or "mobile phone*").ab,kf,ti.	11222
21	Mobile Applications/	5456
22	("mobile app" or "mobile apps" or "mobile application*").ab,kf,ti.	4384
23	Text Messaging/	2716
24	"text messag*".ab,kf,ti.	4010
25	Social Media/	7260
26	"social media".ab,kf,ti.	10701
27	(website* or online or internet).ab,kf,ti.	169350
28	(whatsapp or facebook or twitter or instagram).ab,kf,ti.	6038
29	Internet/	71659
30	Computers, Handheld/	3535
31	("personal digital assistant" or PDA).ab,kf,ti.	11765
32	(tablet* adj3 (comput* or device*)).ab,kf,ti.	1632
33	bluetooth.ab,kf,ti.	1082
34	"monitoring device*".ab,kf,ti.	3609
35	"wireless device*".ab,kf,ti.	400
36	(smartwatch* or "smart watch*").ab,kf,ti.	403
37	("fitness tracker*" or fitbit*).ab,kf,ti.	694
38	Fitness Trackers/	480

39	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38	282726
40	10 and 40	250

315 # Appendix II: Data extraction instrument

Main category	Subcategory	Description
1. Authors		
2. Title		
3. Journal		
4. Year of publication		
5. Origin/country of origin		
6. Description of study	Type	Specify the type of study (e.g, Review, study protocol)
	Design	Specify the study design (e.g. RCT, qualitative study, quasi-experimental)
	Objective	Describe the study objective(s)
	Population	Describe the study population (e.g. at risk, pregnant, postpartum women) and their geographical location
	Outcome	State what the primary and secondary study outcomes are, where applicable
	Comparator	Describe the comparator intervention used, where applicable
7. Intervention implementation	Timing	Specify if the study states the timing of intervention implementation (e.g. Preconception, during pregnancy (weeks gestation), postpartum)
	Context	Specify if the study focuses on intervention delivery in a particular care setting (e.g. Primary, secondary, community care)
		Describe how and by whom the intervention is delivered
8. Description of the intervention	Type	Describe the type of intervention (e.g. app, wearable, social media,)
	Purpose	Describe the stated purpose of the intervention (e.g. Information giving, behavioural change, BGL monitoring, weight management)
	Length/intensity	Describe for how long and how often the intervention is delivered
	Theoretical background	Describe the theoretical background included in intervention development, where applicable

9. Key findings	Engagement	Describe where applicable, study findings on engagement of intervention (e.g. motivation to use intervention, time spent using intervention)
	Usage/adoption/adherence	Barriers and facilitators to intervention use/adoption among stakeholders
	User experience	Description of study reporting on user experience (e.g. satisfaction, perception)
	Intervention feasibility	Barriers and facilitators to study implementation (e.g. recruitment, retention, study processes, study burden)

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