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Experiences of pregnant women with gestational diabetes mellitus: a systematic review of qualitative evidence protocol

Jing He [1], Yuchen Wang [1], Yanqun Liu,[1] Xiaoli Chen [1], Jinbing Bai[2]

¹School of Health and Sciences, Wuhan University, Wuhan, China
²Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, Georgia, USA

Correspondence to
Associate Professor Yanqun Liu; liuyanqun1984@163.com and Associate Professor Xiaoli Chen; chenxl201313@163.com

ABSTRACT

Introduction The incidence of gestational diabetes mellitus (GDM) is increasing and an issue of global concern. GDM can cause severe adverse effects for pregnant women and their fetuses. This systematic review is proposed to explore women's experiences during the pregnancy with GDM. This review will provide insights into the physical, psychological and social adaptation experiences of women with GDM that can help to identify challenges of glycaemic control and provide targeted care and interventions to improve maternal and child health.

Methods and analysis The databases we will search include English databases (ie, PubMed, CINAHL, Embase, the Cochrane Library, Web of Science, Joanna Briggs Institute (JBI) Database of Systematic Reviews, PsycINFO, OpenGrey and Deep Blue) and Chinese databases (ie, China Biology Medicine disc, China National Knowledge Infrastructure, and VIP Database for Chinese Technical Periodicals). Published qualitative evidence of life changes or experiences of the women with GDM will be searched. There will be no limits on publication year. Two reviewers will independently use the JBI Critical Appraisal Checklist for Qualitative Research for methodological validity prior to inclusion in this review. Any disagreements regarding article evaluation will be resolved through discussion or with a third reviewer. Data will be extracted using the standardised data extraction tool from JBI System for the Unified Management, Assessment and Review of Information. Synthesis will include in-depth reading of the original text and the discovery of the results, and then summarising similar categories for more advanced synthesised findings. The final synthesised findings will be graded according to the ConQual approach for establishing confidence.

Ethics and dissemination This study does not require ethical approval as primary data will not be collected. Results of this systematic review will be submitted to peer-reviewed international journals for publication and be presented in relevant international conferences.

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Strengths and limitations of this study

► There is an urgent need to synthesise qualitative evidence about gestational diabetes mellitus (GDM) women's experiences from diagnosis to the end of childbirth so that we can provide insights into GDM management and interventions.
► Results of this review will identify strengths and weaknesses of the current literature regarding GDM women's experiences.
► Systematic review of qualitative empirical evidence from multiple regions and cultures will facilitate the dissemination of findings regarding GDM and promote nursing practice in GDM.
► This review will not analyse the experiences of postpartum women.

INTRODUCTION

During the pregnancy, the body is resistant to insulin in response to physiological changes, which may lead to a high risk of gestational diabetes mellitus (GDM) for some pregnant women.[1] GDM is defined as the first abnormal glucose metabolism during the pregnancy.[2] Prevalence of GDM is influenced by screening methods, diagnostic criteria and the inherent characteristics in every study population, making it difficult to estimate global prevalence, but the prevalence of GDM poses significant challenges to global public health.[3] Using IADPSG (International Association of Diabetes and Pregnancy Study Groups) diagnostic criteria, the study found that the incidence of GDM fluctuated between 5.12% and 33.3% in mainland China.[4] The primary risk factors for GDM include maternal age, race/ethnicity, parity, body mass index, hypertension and smoking status.[5]

As there are few or no symptoms, pregnant women are usually not aware of the GDM until it is diagnosed at a routine prenatal screening.[6] Compared with healthy pregnant women, many serious pregnancy complications are associated with GDM. GDM has serious adverse effects on the health of both the mother and the infant. GDM can directly lead to caesarean section, and many other complications such as hypertension, abortion

Summary JBI Qualitative Assessment and Review Instrument (QARI)													
Record details/ Full reference	Is there congruity between the stated philosophical perspective and the research question or methodology?	Is there congruity between the research methodology and the research question or objectives?	Is there congruity between the research methodology and the methods used to collect data?	Is there congruity between the research methodology and the representation and analysis of data?	Is there congruity between the research methodology and the interpretation of results?	Is there a statement locating the researcher culturally or theoretically?	Is the influence of the researcher on the research, and vice-versa, addressed?	Are participants, and their voices, adequately represented?	Is the research ethical according to current criteria or, is there evidence of ethical approval by an appropriate body?	Do the conclusions drawn in the research report flow from the analysis, or interpretation of data?	Score	seek further into	Comments (including reason for exclusion)
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	/10		

Figure 1 Joanna Briggs Institute quality appraisal tool.

and fetal malformation.[7 8] For the fetus, high risks of complications of GDM include fetal intrauterine growth retardation and macrosomia.[9] Further more, studies also showed that GDM had long-term negative effects in offspring, such as high risk of type 2 DM (T2DM), obesity and cardiovascular diseases.[10–13] Additionally, exposure to maternal GDM is an independent risk factor for long-term neuropsychiatric morbidity in the offspring.[14] Women with GDM have seven-fold increased risk for T2DM compared with normal pregnant women.[15 16] There are 35%–50% of women with GDM may have recurrence in subsequent pregnancies.[17]

Due to negative consequences of GDM to pregnant women and infants, intervention programmes on GDM treatments have been developed to improve maternal and newborn health outcomes.[18] Current interventions primarily include glucose monitoring dietary, physical activity, pharmacological hypoglycaemic agents (oral hypoglycaemic agents or insulin), health education, psychological and selective combine intervention.[19] Many studies have been published on the issue of diagnosis, testing and treatment of GDM. However, the experiences of women diagnosed with GDM during treatment are still not well studied.[20] GDM is associated with lifestyle changes and emotional reactions due to treatment.[21] Information about the diagnosis may be distressing to pregnant women.[22 23] Pregnant women may receive certain types of

health-related guidance from medical institutions after the diagnosis of GDM. However, how they accept and manage the required behavioural changes needs to be further studied.[24] For instance, many women with GDM perceive family guidance as a responsibility and also lack support from family. An inadequate social and family support can create barriers to behavioural changes and social isolation, and therefore, these healthy behavioural changes will be difficult to be maintained.[25 26]

Women who suffer from GDM may have distressing experiences such as self-accusation and anxiety for the new baby. Besides, women may change their lifestyles to manage pregnant blood glucose.[27–29] But there are also a large number of women who are not trying to change their behaviours.[30] Quantitative studies related to GDM have provided some clinical guidance, such as the need for dietary management to effectively control blood glucose.[31 32] However, there are many challenges in the process of self-management, and it is very difficult for women to maintain a reasonable blood glucose level.[33]

The purpose of this review is to gain a deeper understanding regarding diagnosis and knowledge of the disease of pregnant women with GDM, pregnant women's beliefs about health, expectations of pregnancy outcomes and maternal and child's future health, as well as challenges and needs during pregnancy. This review will provide insights into the physical, psychological

Modified JBI Qualitative data extraction tool										
Study (Name and Authors)	Phenomena of interest	Methodology	Methods	Setting	Geographical	Cultural	Participants (Age, relevant number, sample)	Data analysis	Authors Conclusion	Comments

Figure 2 Data extraction tool to include all the results and findings sections of each included study. JBI, Joanna Briggs Institute.

Systematic review title: the experiences of the pregnant with gestational diabetes: a systematic review of qualitative evidence

Population: persons who have been diagnosed with GDN during pregnancy

Phenomena of interest: the exposition of the experiences of women with GDM during pregnancy

Context: in the experiences and feelings of women with GDM during pregnancy

Synthesized finding	Type of research	Dependability	Credibility	ConQual score

Figure 3 ConQual summary of findings. GDM, gestational diabetes mellitus.

and social adaptation experiences of women with GDM that can help identify challenges of glycaemic control and provide targeted care and interventions to improve maternal and child health.

METHODS

This review aims to synthesise experiences of women with GDM during the pregnancy. The research question will be appropriately answered by qualitative studies. The initial scope of the literature search provides recommendations for the proposed syntheses. The topic synthesis approach
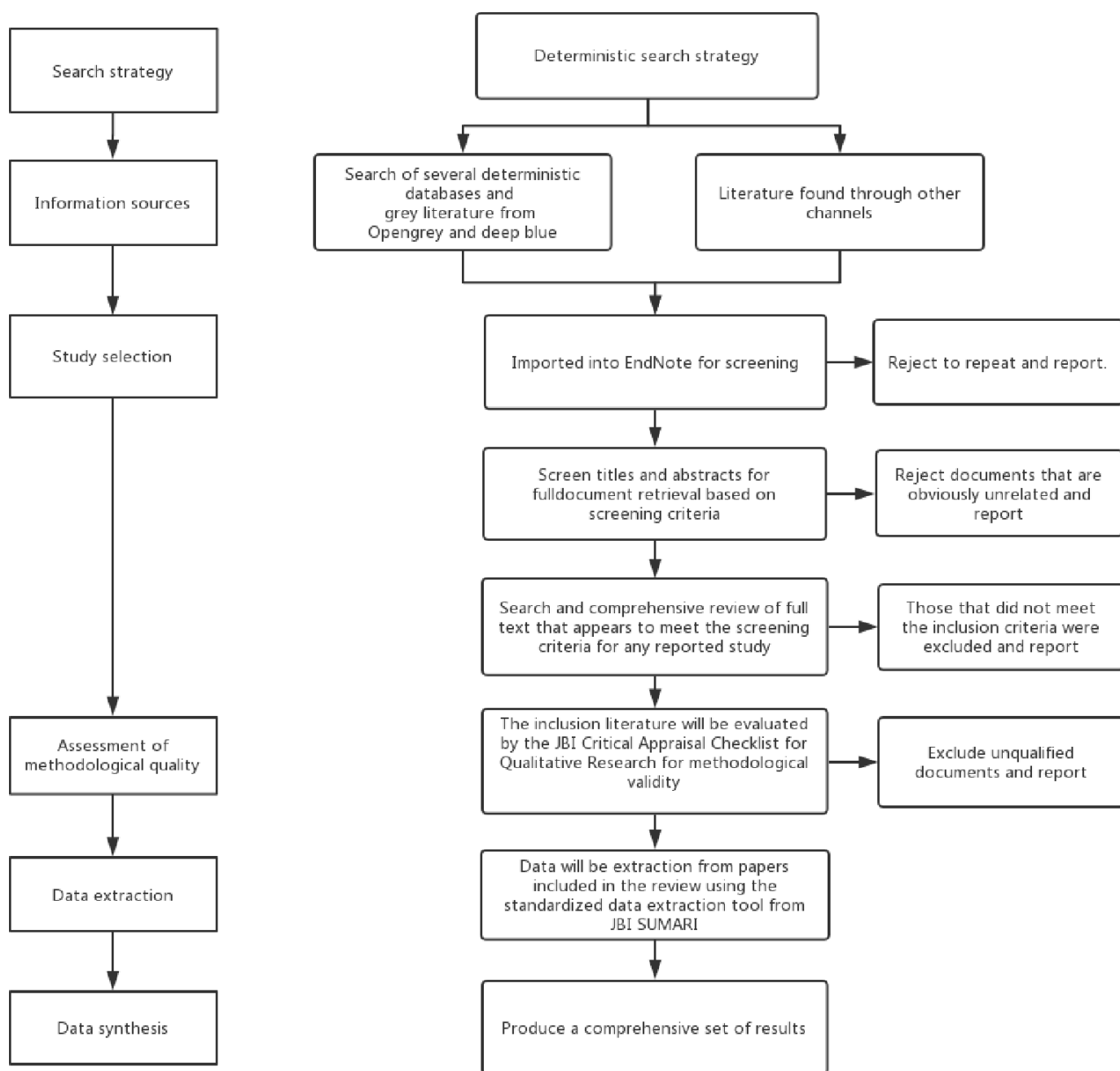
Figure 4 Search and selection process. online supplementary appendix 1: search strategy. JBI, Joanna Briggs Institute; SUMARI, System for the Unified Management, Assessment and Review of Information.

Table 1 Summary of the Enhancing Transparency in Reporting the Synthesis of Qualitative Research statement

No	Item
1	Aim
2	Synthesis methodology
3	Approach to searching
4	Inclusion criteria
5	Data sources
6	Electronic search strategy
7	Study screening methods
8	Study characteristics
9	Study selection results
10	Rationale for appraisal
11	Appraisal items
12	Appraisal process
13	Appraisal results
14	Data extraction
15	Software
16	No of reviewers
17	Coding
18	Study comparison
19	Derivation of themes
20	Quotations
21	Synthesis output

involves the use of topic analysis techniques to identify key concepts or topics in primary studies, then form the title and complete the title registration in Joanna Briggs Institute (JBI) System and PROSPERO.

Inclusion criteria
Types of participants
This review will search and integrate studies of women with GDM during pregnancy. Searched studies will be eligible regardless of women's age and whether they have pregnancies for the first time or not.

Phenomenon of interest
This review will include studies that describe the experiences of women with GDM during the pregnancy.

Context
The context will consider in the experiences and feelings of women with GDM during the pregnancy.

Types of studies
The review will consider qualitative studies including, but not limited to, designs such as phenomenology, grounded theory, ethnography and feminist research.

Patient and public involvement
No patient will be involved in the design, planning and conception of this study.

Search strategy
The search strategy aims to find both published and grey literature. An initial limited search of PubMed will be conducted, following by an analysis of MeSH terms contained in the title and abstract, as well as the index terms used to describe the articles. This will inform the development of a search strategy which will be tailored for each database source. A second and complete search using all identified keywords and index entries will take place in all the relevant databases. Third, the reference list of all identified original studies will be examined for additional studies that may be relevant to this review. Previously published studies in English and Chinese will be considered for inclusion in the database. A full search strategy has been done (online supplementary appendix 1).

Information sources the Cochrane Library, Web of Science, JBI Database of Systematic Reviews and PsycINFO) and Chinese databases (ie, China Biology Medicine disc, China National Knowledge Infrastructure and VIP Database for Chinese Technical Periodicals). The search for grey literature will include OpenGrey and Deep Blue.

Study selection
All searched studies will be collated and uploaded into our software of EndNote X9. The duplicated studies will be removed.[34] Two independent reviewers (JH and YW) will screen the title and abstract of the article based on the reviewer's inclusion criteria. Studies identified as potentially eligible or those without an abstract will have their full text retrieved and their details will be imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI).[35] The two independent reviewers (JH and YW) will retrieve and evaluate full texts of selected citations in detail which meet the inclusion criteria. Full texts that do not meet our inclusion criteria will be excluded, and excluding reasons will be attached as an appendix in the final systematic review report.[34] Included studies will go through a critical screening process, and any differences between the two reviewers will be resolved through discussion. If no agreement is reached, a third reviewer (XC) will be involved.

Assessment of methodological quality
Qualitative papers selected for inclusion will be assessed by two independent reviewers (JH and YW) according to the 10 items checklist of the JBI Qualitative Assessment and Review Instrument for methodological validity prior to inclusion in the review.[36] This tool has been found to be more coherent and sensitive to effectiveness assessments than other commonly used tools. The evaluation content includes: methodology and philosophical perspective of the research, the research objectives, the methods used to collect data, analysis of data, the interpretation of results, if have statement for the influence of the researcher on the research, representativeness of the participants and the ethical and so on. All items were evaluated by using

'yes', 'no' and 'unclear' to appraisal. An extract summary of the appraisal items is listed in figure 1. The scores for these 10 items are similar to quantitative measures, with a score below or equal to 6 for a weak rating, 7–8 for a medium rating and 9–10 for a strong rating. References of the moderate rating or above will be included. Any disagreements that arise between the reviewers will be resolved through discussion by agreement or with a third reviewer (XC). Studies of the moderate rating or above will be included, extracted, synthesised from the data, and reflected in the results and conclusions of this system review. Low quality literature will be reported.

Data extraction

Two reviewers (JH and YW) will independently extract data from papers by using the standardised data extraction tool from JBI SUMARI. The extracted data will include specific details (figure 2) about the study groups, context, culture, geographical location, study methods, the phenomena of interest relevant to the review question (ie, experiences of women with gestational diabetes during pregnancy in mental, physical and family life), and detail research objectives. Findings and their illustrations will be extracted and assigned a level of credibility.

Data synthesis

Qualitative research findings will be aggregated using JBI SUMARI with the meta-aggregation approach. There are three steps to integrate findings of the original study. First, individual findings will be appraised and will achieve one of three outcomes: unequivocal (evidence beyond reasonable doubt); credible (contains illustrations that may be challenged) or unsupported (when findings are not supported). Second, findings of all included studies will be extracted and categorised to create a set of categories representing meaningful similarities. Third, these similar categories are subjected to a synthesis in order to obtain a single comprehensive set of synthesised findings, which can be used as a foundation for evidence-based practice. For example, findings included 'husband's support' and 'mother in-law's support' that can be summarised as a category of 'family support'. The finding about 'support of nurses and midwives' will be summarised as a category for 'professional support'. Then, the two categories are subjected to create a set of synthetic results called 'social support'. If textual pooling is not possible, findings will be presented in a narrative form. Coding of findings, in time of the aggregation process to explore the influence, will be considered, about experiences of women with GDM during pregnancy. Two review authors will independently cluster identified findings, compare the generated categories and discuss discrepancies until reaching agreement. Finally, two authors of this study will work together to create a comprehensive set of synthesised findings.

Assessing certainty in the finding

The final findings will be graded according to the ConQual approach for establishing confidence in the output of research synthesis and presented in a summary of findings.[37] The ConQual process was used to analyse the level of confidence or trust that exists in the value and level of evidence of each synthesised finding (figure 3). The figure will include the major elements of this systematic review and details on how the ConQual score is developed. The summary of findings will include the primary study title, phenomena of interest and context for the special review. The flow chart (figure 4) shows the whole protocol process, which will be completed by two reviewers independently, and then combined with our analysis.

PRESENTING AND REPORTING THE REVIEW

The resulting review will be reported in accordance with the 'Enhancing Transparency in Reporting the Synthesis of Qualitative Research' statement,[38] which consists of 21 items and is appropriate for qualitative evidence synthesis (table 1).

DISCUSSION

This systematic review will discover women's experiences after being diagnosed with GDM during the pregnancy and integrate these findings for a comprehensive and in-depth understanding of their difficulties and needs. Specific personal experiences of women with GDM can inform professional healthcare and provide personalised care and education for these women. Improved care will promote maternal and child health, and therefore, reduce the medical burden.

This systematic review of qualitative evidence will be published in an open access, peer-reviewed and international journal for dissemination.

ORCID iDs

Jing He http://orcid.org/0000-0001-7654-1872
Yuchen Wang http://orcid.org/0000-0003-2433-4905
Xiaoli Chen http://orcid.org/0000-0001-6835-7768

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