INPLASY

Barriers and facilitators to pregnant women's participation in clinical research: A mixed-methods systematic review

INPLASY202430055

doi: 10.37766/inplasy2024.3.0055

Received: 14 March 2024

Published: 14 March 2024

Corresponding author:
Yicheng Gao

feiyt@bucm.edu.cn

Author Affiliation:
Centre for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine.

Gao, YC[1]; Yu, ZJ[2]; Guo, YX[3]; Guo, TT[4]; Zeng, XY[5]; Yan, XY[6]; Cao, R[7]; Liu, ZH[8]; Fei, YT[9].

ADMINISTRATIVE INFORMATION

Support - The Key Research and Development Program of Xinjiang Uygur Autonomous Region.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202430055

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 March 2024 and was last updated on 14 March 2024.

INTRODUCTION

Review question / Objective What are the barriers and facilitators for pregnant women to participate in clinical research?

Rationale Pregnant women are not fully involved in clinical research, and there are many obstacles to prevent pregnant women from participating in clinical research. This study aims to identify these barriers and facilitators through a systematic approach, mapping them to theoretical domain frameworks and behaviour change techniques to inform the development of behaviour change interventions that promote participation of pregnant women in clinical research.

Condition being studied Pregnant women have complex physiological changes during pregnancy, and are prone to chronic major diseases such as hypertension, diabetes and heart disease. They have a large need for medication during pregnancy, and the phenomenon of medication during pregnancy is more common. In clinical studies in recent decades, pregnant women do not belong to the routinely included population. There are many barriers to pregnant women participating and researchers conducting clinical research, and it is necessary and valuable to develop appropriate behavior change strategies for the barriers and facilitators.

METHODS

Search strategy We searched China National Knowledge Infrastructure, Wanfang, VIP Database for Chinese Technical Periodicals, Chinese Biomedical Literature Database, PubMed, Embase, Cochrane Library, APA PsycInfo, CINAHL.

Participant or population Pregnant women.

Intervention Not applicable.

Comparator Not applicable.

Study designs to be included Qualitative, quantitative and mixed-methods study.

Eligibility criteria Inclusion criteria: literature published in peer-reviewed journals. Exclusion criteria: study protocol or abstract.

Information sources China National Knowledge Infrastructure, Wanfang, VIP Database for Chinese Technical Periodicals, Chinese Biomedical Literature Database, PubMed, Embase, Cochrane Library, APA PsycInfo,CINAHL.

Main outcome(s) Barriers and facilitators.

Data management We used Endnote to screen the literature according to the volume standard, and extracted the data according to the pre-formulated data extraction table. The extraction contents included (1) the basic information of the literature: the name of the first author, publication time, data collection method, and (2) the obstacles and promoting factors for pregnant women's participation in clinical research described in the study. Literature screening, data extraction were performed independently by two fellows, and any disagreement was resolved by discussion or by a third author with methodological expertise.

Quality assessment / Risk of bias analysis We assessed study quality using Mixed Methods Appraisal Tool. The quality assessment process was performed independently by the two authors.

Strategy of data synthesis The main method used in mixed-methods systematic review ——convergence design was used. Transformation of the quantitative data into the qualitative data.

Subgroup analysis Not applicable.

Sensitivity analysis Not applicable.

Country(ies) involved China.

Keywords Barriers and facilitators; Pregnant women; Mixed-methods systematic review; Theoretical Domains Framework; Behaviour Change Techniques.

Contributions of each author

Author 1 - Yicheng Gao - Conceptualization, Investigation, Formal analysis, Writing original draft.
Email: 20210941071@bucm.edu.cn
Author 2 - Zijin Yu - Extracting data, Formal analysis, Writing original draft.
Email: 543909562@qq.com
Author 3 - Yixuan Guo - Extracting data, Formal analysis, Writing original draft.
Email: gyx_5678@163.com
Author 4 - Tiantian Guo - Extracting data, Formal analysis, Writing original draft.
Email: slhsxguotiantian@126.com
Author 5 - Xinyu Zeng - Extracting data, Formal analysis, Writing original draft.
Email: zxy202401@126.com
Author 6 - Xinyi Yan - Extracting data, Formal analysis, Writing original draft.
Email: 2773521961@qq.com
Author 7 - Rui Cao - Extracting data, Formal analysis, Writing original draft.
Email: caorui0706@163.com
Author 8 - Zhihan Liu - Extracting data, Formal analysis, Writing original draft.
Email: liuzhihan262@163.com
Author 9 - Yutong Fei - Conceptualization, Funding acquisition, Investigation, Formal analysis, Methodology, Writing - review & editing, Project administration.
Email: feiyt@bucm.edu.cn