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Clinical trials design characteristics and reporting quality in obstetrics and gynecology in China: A scoping review

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ADMINISTRATIVE INFORMATION

Support - No support.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 June 2026 and was last updated on 18 June 2026.

INTRODUCTION

Review question / Objective In the past decade in China, what are the similarities and differences in the design, disease spectrum distribution, and intervention measures of the interventional clinical trials involving pregnant women and postpartum women that have been conducted using both traditional Chinese and Western medical approaches? And what are the key methodological challenges that exist?

Background Pregnant and postpartum women are recognized as a vulnerable population deserving heightened clinical vigilance and protection. During pregnancy and the puerperium, a considerable number of women experience complications—including gestational hypertension, gestational diabetes, and postpartum hemorrhage —that demand pharmacological or other active interventions. Yet, the dramatic physiological adaptations of pregnancy can profoundly modify drug absorption, distribution, metabolism, and elimination, rendering efficacy and safety predictions highly uncertain. Historically, out of ethical prudence, concern over fetal-maternal risks, and liability considerations, this population has been largely excluded from modern clinical trials, creating a persistent and critical evidence gap in obstetric medicine. This deficiency leaves practitioners navigating treatment decisions without robust data, perpetuating the status of pregnant and postpartum women as "therapeutic orphans" . Although international health authorities and researchers have long advocated for their inclusion, tangible progress in trial enrollment and evidence generation has remained disappointingly limited.

Rationale Despite the growing body of literature,a systematic bibliometric analysis that comprehensively and multidimensionally compares Western medicine (WM) and traditional Chinese medicine (TCM) research from a macro perspective remains conspicuously absent. This gap precludes a nuanced understanding of how study design characteristics differ across regions, healthcare

systems, and specific perinatal stages, thereby hindering targeted improvements in trial methodology and evidence synthesis.There is still a lack of systematic bibliometric research that, from a macro perspective, comprehensively and multidimensionally compares Western medicine research and traditional Chinese medicine research in China, making it impossible to precisely reveal differences in design characteristics across regions, medical systems, and the stages of pregnancy and the postpartum period.

METHODS

Strategy of data synthesis Seach terms include 孕妇、产妇、孕产妇、产科、怀孕、产后、产前、围产期、试验、疗效观察、临床观察、Pregnancy、Pregnant Women、Postpartum Period、Obstetrics、Pregnant、trial

Pubmed:
#1 "Obstetrics"[MeSH Terms] OR "Pregnancy"[MeSH Terms] OR "Pregnant Women"[MeSH Terms] OR "Postpartum Period"[MeSH Terms] OR "Obstetrics"[Title/Abstract] OR "Pregnancy"[Title/Abstract] OR "Pregnant"[Title/Abstract] OR "Fetus"[Title/Abstract] OR "Birth"[Title/Abstract] OR "Perinatal"[Title/Abstract] OR "Newborn"[Title/Abstract] OR "Postpartum"[Title/Abstract] OR "Prenatal"[Title/Abstract] OR "Maternal"[Title/Abstract] OR "Maternity"[Title/Abstract] OR "Birth Outcome"[Title/Abstract]
#2 "Randomized Controlled Trial"[Publication Type] OR "Randomized Controlled Trials as Topic"[MeSH Terms] OR "Random Allocation"[MeSH Terms] OR "Controlled Clinical Trial"[Publication Type] OR "Controlled Clinical Trials as Topic"[MeSH Terms] OR "random*"[Title/Abstract] OR "trial*"[Title/Abstract]
#3 #1 AND #2
CNKI:
#1 (SU %='孕妇' + '产妇' + '孕产妇' + '产科' + '怀孕' + '产后'+ '产前'+ '围产期' + '胎儿' + '出生' + '新生儿' + '出生结局')
#2 (SU%= '试验' + '临床研究' + '临床观察' + '疗效评价' + '疗效观察')
#3 #1 AND #2.

Eligibility criteria ① Interventional clinical trials conducted after peer review and involving pregnant women and postpartum mothers as the research subjects.

② If more than one version is retrieved, the one with the most comprehensive information or the latest version will be included.
③ Trials published in both Chinese and English.
④ Literature published after January 1, 2016.

Source of evidence screening and selection The retrieved literature was summarized in the Endnote X9 software. After eliminating duplicate documents, two people conducted a preliminary screening of the literature by reading the titles and abstracts. On this basis, they read the full texts again and conducted a full-text screening of the literature. The literature screening was carried out independently by two researchers, and any differences were resolved through discussion or consultation with a third researcher.

Data management According to the pre-designed data extraction form, two researchers independently extracted the data, and then cross-checked each other. In case of any disagreement, it was resolved through discussion or consultation with a thirdresearcher.

Language restriction English and Chinese.

Country(ies) involved China.

Keywords Clinical trials; Obstetrics; Gynecology; Traditional Chinese medicine; Western medicine; Research trends; China.

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