

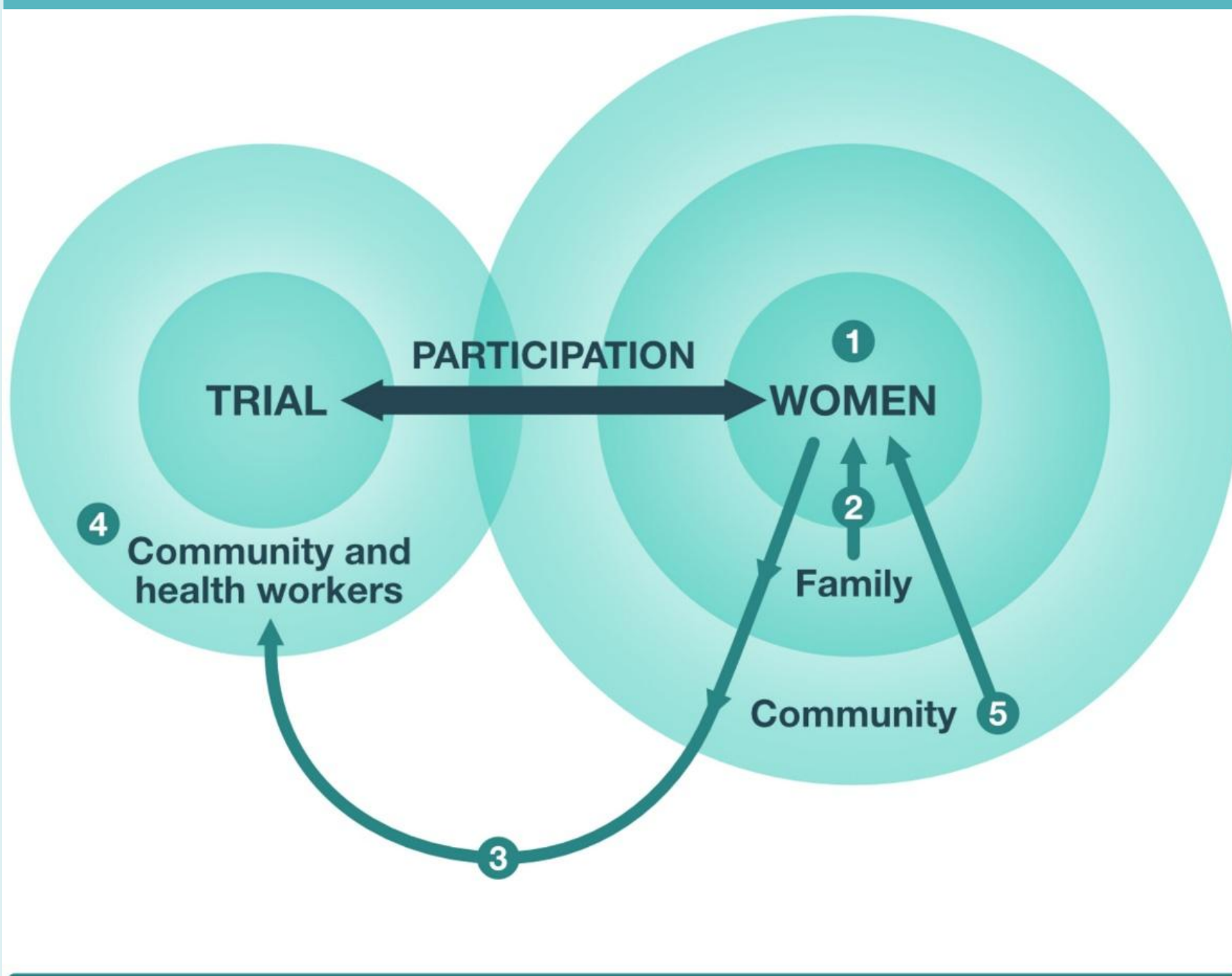
Factors influencing pregnant women's participation in clinical trials in India

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1 Limited research literacy and expectations of health benefits can override women's fears and doubts

Many women didn't know about clinical trials in their communities or mistook them for regular care. Research participation was seen as a way to improve health and access high quality care.

2 Family members must give permission for women to participate in trials

In the marital home, research participation was influenced by gender roles, with mothers-in-law, husbands, and fathers-in-law being the key decision-makers.

3 Health and community workers rely on trust to recruit women

Using trust to recruit for trials increased accountability and raised families' expectations for safe pregnancies and careful monitoring of participants' health.

4 Health workers must accept the trial intervention before they recommend it

Health workers assured trial safety and took responsibility for participants' well-being, based on their knowledge of the intervention's benefits, safety, and expected results.

5 Community beliefs affect trial participation

Community beliefs focused on reducing risks and protecting mother and baby. If trial procedures conflicted with these beliefs, women were hesitant to join.

Background

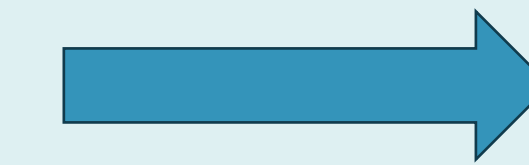
The participation of pregnant women in clinical trials remains limited, particularly in low- and middle-income countries (LMICs). Despite their distinct physiological needs and the high burden of pregnancy-related complications, pregnant women are often excluded from research that could directly benefit them. Understanding the factors that shape their willingness and ability to participate in clinical trials is essential for ethical and equitable research practices. This is especially important in settings where healthcare access and cultural dynamics may further influence participation decisions.

This published study explored factors influencing pregnant women's participation in clinical research in Belagavi, Karnataka, India, focusing on the intersection of research, health systems, and communities. It aims to inform ethical, culturally appropriate strategies to improve clinical research on pregnancy-specific therapeutics in India and similar contexts.¹

Methodology

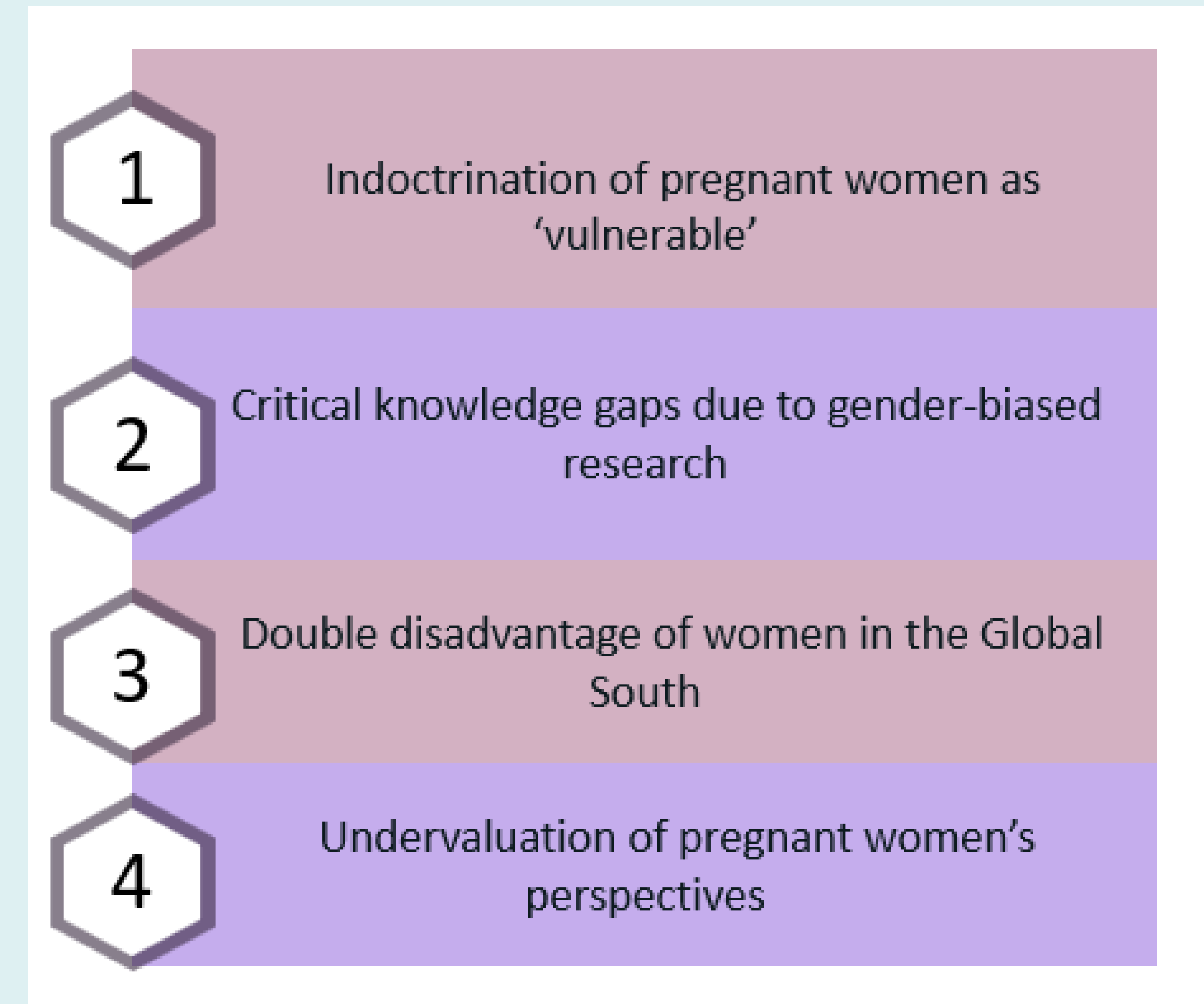
We purposively selected 10 health facilities in Belagavi, Karnataka, to capture diverse perspectives across the public health system and levels of research exposure. Participants included health workers, Accredited Social Health Activists (ASHAs), pregnant women (both research-naïve and experienced), and community members. We conducted in-depth interviews with health workers and research-experienced women to explore individual experiences, and focus group discussions with ASHAs, research-naïve women, and community members to understand broader attitudes toward research participation. Data were analysed using inductive thematic analysis in NVivo.

The Concept Foundation-led 'Accelerating Innovation for Mothers'- Gender (AIM-Gender) project seeks to conduct primary research to identify and address gendered barriers hampering research and development of medicines for pregnancy-related conditions. We have taken a gender lens to the issue and identified four critical roadblocks that must be overcome to better represent pregnant women's interests in the global biomedical research agenda:



Implications for policy and practice

Pregnant women remain underrepresented in biomedical research, contributing to persistent gender bias in maternal health. Addressing this requires equitable partnerships, multidisciplinary research, and greater awareness of the ethical importance of inclusion. Ethics committees and regulatory systems, particularly in the Global South, must be reoriented to support responsible and equitable participation.



Results

This qualitative study involving five stakeholder groups found that pregnant women were primarily motivated to join trials by the prospect of better care. Participation was shaped by household gender dynamics, while recruitment depended on health workers' and ASHAs' support, which was rooted in community trust. These workers were also held accountable by families for participants' safety and outcomes. Effective trial implementation required navigating traditional community beliefs and practices. The qualitative findings are organised into five themes that outline factors influencing participation in drug trials during pregnancy (Figure 1).

Conclusion

In this context, anticipated health benefits and access to better care drive trial participation. Successful enrollment depends on engaging household decision-makers to navigate gender dynamics. Trust in health and community workers, key to recruitment and follow-up, heavily influences decisions. Our findings highlight the need to improve health and research literacy by clearly distinguishing research from routine care. Future studies should explore trial designs that avoid reinforcing structural inequities.

References:

1) Shankar M, et al. Factors influencing pregnant women's participation in randomised clinical trials in India: a qualitative study. *BJOG* 2025; 132:772–781

Figure 1: This figure presents a visualisation and summary of the thematic findings.

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