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Closing the Rehabilitation Gap: Co-Designing Equitable Obstetric and Gynecological Physiotherapy Services in South India

Running title: Co-designing equitable OBG physiotherapy in India

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ABSTRACT: Obstetric and gynecological (OBG) physiotherapy supports women during pregnancy, labor, the postnatal period, and recovery from gynecological conditions and surgery, addressing pelvic floor dysfunction, incontinence, musculoskeletal pain, and post-operative recovery. Rehabilitation is recognized as integral to Universal Health

Coverage, yet in India and other low- and middle-income countries it is seldom commissioned as a discrete hospital service: referral is informal, private assessment space is limited, and staffing and documentation remain undefined, so care is delayed. This sequential, multi-phase study will run for 12 months in a government medical college hospital in Puducherry, South India. Phase 0 audits service readiness and care pathways using the Tanahashi coverage model. Phase 1 maps published evidence and policy in a scoping review following Joanna Briggs Institute guidance and PRISMA-ScR. Phase 2 identifies barriers, facilitators, and equity determinants through stakeholder interviews guided by the updated Consolidated Framework for Implementation Research (CFIR 2.0), analyzed by Framework Analysis, reported per COREQ, with a PROGRESS-Plus equity lens. Phase 3 co-designs a tiered, low-resource service framework with clinical, administrative, community, and patient stakeholders. Phase 4 validates the draft by modified Delphi across five domains (four-point scale; 80% consensus; 15–25 panelists). Phase 5 field-tests four core tools over three to four weeks against Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) indicators. The study will yield an evidence-based, feasible, and replicable OBG physiotherapy service model for public hospitals in India and comparable settings, intended to strengthen service organization and inform policy and workforce planning.

1. INTRODUCTION

Obstetric and gynecological (OBG) physiotherapy covers pregnancy, labor, the puerperium, and recovery from gynecological illness and surgery. Presenting problems include pelvic floor dysfunction with urinary or fecal incontinence, pregnancy-related pelvic girdle and lumbar pain, diastasis recti, recovery after cesarean and other gynecological surgery, sexual dysfunction, and rehabilitation after cancer treatment (Dumoulin et al., 2018; Ministry of Health and Family Welfare, 2013; Woodley et al., 2020). Left untreated, these problems restrict movement, interfere with self-care, work, sexual health, and family life, and reduce quality of life for months or years (Nelson et al., 2019).

The 2023 World Health Assembly resolution on rehabilitation (World Health Organization, 2023), the World Health Organization (WHO) Rehabilitation 2030 initiative, and global estimates that one in three people worldwide would benefit from rehabilitation all treat rehabilitation as part of Universal Health Coverage (Cieza et al., 2020; World Health Organization, 2017). Where care is judged only by survival and clinical stability, pain often goes unrelieved, the pelvic floor is not assessed, continence problems become chronic, and women do not regain work and family life (Cieza et al., 2020).

In India and similar low- and middle-income countries (LMICs), OBG physiotherapy is seldom commissioned as a service in its own right. Referral is usually informal, and obstetric and gynecological teams may not know what physiotherapy can offer. The private space needed for pelvic health assessment is often undefined, and staffing and documentation are unspecified (World Health Organization, 2022). Interventions supported by trials therefore fail to reach women, because no organizational pathway carries them into practice. The relevant questions are practical: which services are needed, what the institution can sustain, and how delivery can be made equitable.

The study site is a government medical college hospital in Puducherry, South India, serving a large, diverse population of women who receive antenatal, labor, postnatal, gynecology, and post-operative care at minimal or no cost. This case mix makes equity analysis possible, and all relevant stakeholders work within the institution.

1.1. Background and rationale

Pregnancy, childbirth, the postnatal period, and menopause bring physical, functional, and psychosocial changes that affect continence, mobility, pain, sexual health, work, and caregiving (Milsom and Gyhagen, 2019). Pelvic floor muscle training is well supported for preventing and treating urinary and fecal incontinence in pregnancy and postpartum (Woodley et al., 2020), and guidelines recommend conservative pelvic floor rehabilitation as first-line management for dysfunction (National Institute for Health and Care Excellence, 2021). Exercise and education reduce pregnancy-related pelvic girdle and low back pain (Liddle and Pennick, 2015). Pelvic physiotherapy improves symptoms and quality of life (Dumoulin et al., 2018), and rehabilitation

based on Enhanced Recovery After Surgery principles supports post-surgical recovery (Nelson et al., 2019). The reproductive, maternal, newborn, child, and adolescent health (RMNCH+A) initiatives in India provide a continuum of care into which these contributions could fit, and aligned services are adopted more readily than separate ones (Greenhalgh et al., 2004; Ministry of Health and Family Welfare, 2013).

Limited space, undefined referral pathways, uneven provider awareness, workforce constraints, poor documentation, privacy concerns, and absent leadership can all obstruct integration, whatever the strength of the evidence (Bright et al., 2018). The study therefore draws on four established frameworks. The updated Consolidated Framework for Implementation Research (CFIR 2.0) examines innovation characteristics, inner and outer settings, individuals, and the implementation process (Damschroder et al., 2022). The Place of residence, Race, Occupation, Gender, Religion, Education, Socioeconomic status, Social capital (PROGRESS-Plus) framework keeps equity in view, covering language, parity, income, and digital access (O'Neill et al., 2014). The Tanahashi model treats coverage as a sequence of availability, accessibility, acceptability, contact coverage, and effective coverage, at any point of which provision and use can diverge (Tanahashi, 1978). Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) supplies indicators for judging whether services reach women and are adopted and sustained (Glasgow et al., 1999). Because a framework also has to fit local context, resources, and culture (Greenhalgh et al., 2004), the study is stakeholder-driven and uses co-design (Slattery et al., 2020) and consensus validation.

1.2. Aim and objectives

This study aims to develop and test an equity-informed, implementation-science-based framework for OBG physiotherapy services in a public hospital in Puducherry, South India. The specific objectives are:

- (i) to determine current capacity, map care pathways, and locate coverage gaps using the five Tanahashi domains as the audit structure (Tanahashi, 1978) (Phase 0);
- (ii) to map published evidence on OBG physiotherapy roles, service models, competencies, referral criteria, and implementation determinants in low-resource hospitals, following Joanna Briggs Institute guidance (Peters et al., 2020) and PRISMA-ScR (Tricco et al., 2018) (Phase 1);
- (iii) to identify barriers, facilitators, and equity determinants in CFIR 2.0-guided interviews (Damschroder et al., 2022), analyzed by Framework Analysis (Ritchie and Spencer, 1994) and reported per COREQ (Tong et al., 2007) (Phase 2);
- (iv) to co-design a tiered service framework with clinical, administrative, community, and patient stakeholders (Table 3) (Slattery et al., 2020) (Phase 3);
- (v) to validate the framework for relevance, feasibility, acceptability, resource appropriateness, and equity sensitivity by modified Delphi consensus (Jünger et al., 2017) (Phase 4); and
- (vi) to test the feasibility of the core tools — a screening checklist, referral pathway, Tamil-language patient education material, and documentation template — in a three- to four-week pilot (Bowen et al., 2009; Glasgow et al., 1999) (Phase 5).

Table 3. Stakeholder groups for Phase 2 interviews and rationale for inclusion.

Stakeholder group	Reason for inclusion
Physiotherapists	Current practice, workload, referral barriers, service priorities
Obstetricians & gynecologists	Referral needs, clinical integration, multidisciplinary team expectations
Nurses & labor-ward staff	Screening, early education, discharge counseling, ward feasibility
Hospital administrators	Staffing, infrastructure, documentation, and governance feasibility
Antenatal & postnatal women	Needs, acceptability, access barriers, preferred education methods
Women post-gynecological surgery	Post-operative recovery needs and follow-up barriers
ASHA / ANM / community health officers	Community referral, follow-up, linkage with primary care
Public health / NHM program officers	Alignment with maternal health and the RMNCH+A continuum of care

Abbreviations: ANM, Auxiliary Nurse Midwife; ASHA, Accredited Social Health Activist; NHM, National Health Mission; RMNCH+A, reproductive, maternal, newborn, child and adolescent health.

2. MATERIALS AND METHODS

2.1. Study design

The design is sequential, with six phases (Table 1), moving from institutional assessment and evidence synthesis to stakeholder-informed co-design, then consensus validation and feasibility testing. Each phase informs the next, and the outputs are brought together in a Framework Development Matrix. Table 7 gives the schedule of enrollment, activities, and assessments across the 12 months, following the structure recommended for protocol reporting (Chan et al., 2013). Figure 1 shows participant and data-source flow, including screening, consent, exclusion, and withdrawal. Table 8 summarizes the timeline.

Table 1. Phases of the framework-development design.

Phase	Component	Purpose
Phase 0	Service-Readiness & Care-Pathway Audit	Document service availability, referrals, infrastructure, workforce, and access barriers using the Tanahashi framework
Phase 1	Evidence & Policy Mapping (scoping review)	Systematically map clinical, service-delivery, workforce, and policy evidence relevant to OBG physiotherapy
Phase 2	CFIR 2.0-Guided Stakeholder Interviews	Identify barriers, facilitators, and equity concerns via semi-structured qualitative interviews
Phase 3	Framework Co-Design	Develop a tiered, low-resource OBG physiotherapy service model through participatory co-design
Phase 4	Modified Delphi Consensus Validation	Validate relevance, feasibility, acceptability, resource appropriateness, and equity sensitivity of the draft framework (single primary round)
Phase 5	Feasibility Pilot	Field-test screening checklist, referral pathway, education materials, and documentation templates under routine conditions (3–4 weeks)

Abbreviations: CFIR, Consolidated Framework for Implementation Research; OBG, obstetric and gynecological.

Table 7. Schedule of enrollment, activities, and assessments across the 12-month study period.

	STUDY PERIOD (months from ethics approval)						
TIMEPOINT	M1–2	M3–4	M5–6	M7–8	M9	M10–12	Close-out
ENROLLMENT							
Eligibility screen		X	X	X	X		
Informed consent		X	X	X	X		
Allocation	n/a	n/a	n/a	n/a	n/a	n/a	n/a
PHASE ACTIVITIES							
Phase 0 audit	X						
Phase 1 mapping	X						
Phase 2 interviews		X					
Phase 3 co-design			X				
Phase 4 Delphi				X			
Phase 5 pilot					X		
ASSESSMENTS							
Facility Readiness Checklist	X						
Patient-flow mapping	X						
Data Charting Form	X						

CFIR 2.0 interview guide		X					
PROGRESS-Plus equity prompts	X	X	X	X			
Structured Feedback Proforma			X				
Delphi Rating Questionnaire				X			
Staff Feedback Form					X		
Patient Acceptability Questionnaire					X		
RE-AIM indicators					X		X
Data integration & synthesis						X	X

An X indicates that the activity or assessment occurs during that period. Allocation is not applicable (non-randomized design). M, month.

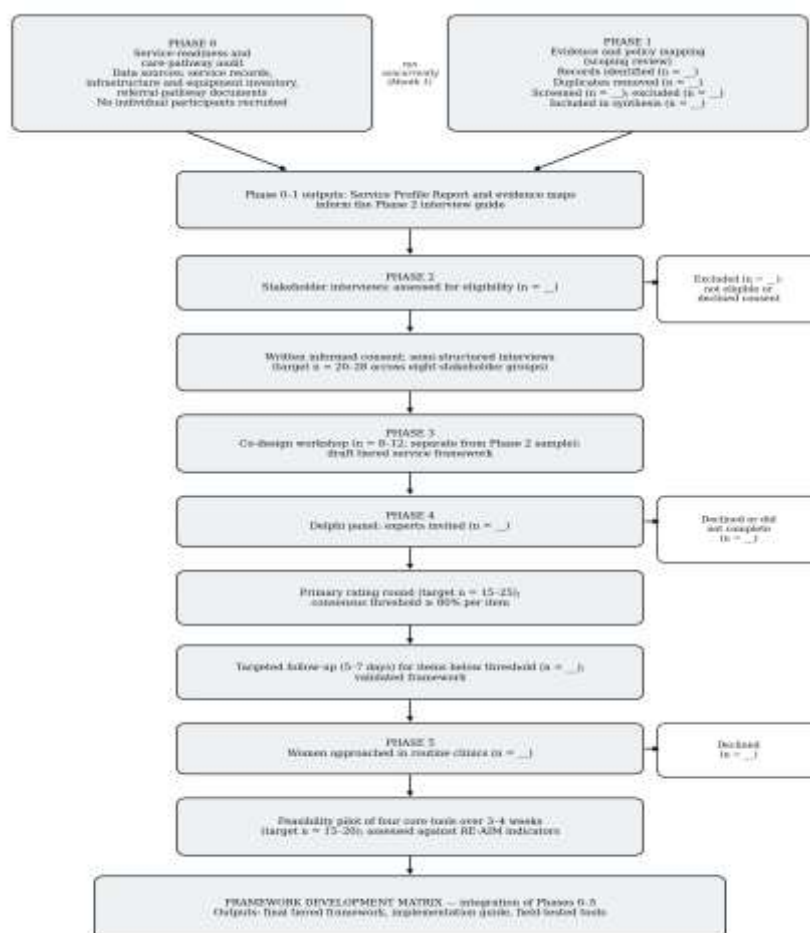


Figure 1. Flow of participants and data sources across the six study phases. Phases 0 and 1 run concurrently from Month 1 and generate the Service Profile Report and evidence maps that inform the Phase 2 interview guide. Subsequent boxes show eligibility screening, consent, exclusions, and target sample sizes for the stakeholder interviews (Phase 2), co-design workshop (Phase 3), modified Delphi panel (Phase 4), and feasibility pilot (Phase 5), with outputs integrated in the Framework Development Matrix.

Table 8. Summary of the phase-wise study timeline, methods, participants, and outputs.

Stage	Months 1–2	Months 3–4	Months 5–6	Months 7–8	Month 9	Months 10–12
Phase	Phase 0 + Phase 1 (concurrent)	Phase 2	Phase 3	Phase 4	Phase 5	Finalization
Activity	Service-readiness audit; evidence & policy mapping	CFIR 2.0 interviews & framework analysis	Co-design workshop & framework drafting	Modified Delphi validation	Feasibility pilot (3–4 weeks)	Integration, write-up, dissemination
Method	Tanahashi audit; JBI scoping review	Qualitative; purposive sampling	Participatory co-design	Consensus; four-point scale	RE-AIM indicators	Framework Development Matrix
Participants	None (records/docu-ments)	n = 20–28 stakeholders	n = 8–12 stakeholders	n = 15–25 experts	n = 15–20 women	—
Output	Service Profile Report; evidence map	Barrier/facilitator & equity themes	Draft tiered framework	Validated framework (≥80% consensus)	Feasibility classification per tool	Implementati on guide; publication

Abbreviations: CFIR, Consolidated Framework for Implementation Research; JBI, Joanna Briggs Institute; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance.

2.2. Study setting and duration

The research is coordinated from the Department of Obstetric and Gynaecological Physiotherapy, Mother Theresa Postgraduate and Research Institute of Health Sciences, Puducherry, India. Data are collected at Indira Gandhi Medical College and Research Institute (IGMC&RI), Puducherry, a government medical college hospital providing comprehensive obstetric and gynecological services. The study runs for 12 months from ethics approval, and three scheduling choices make this workable. Phases 0 and 1 run concurrently from Month 1, because audit and literature search draw on independent sources. Phase 4 rests on one rating round, with a five- to seven-day follow-up for unresolved items only. Phase 5 is limited to three to four weeks, and the month gained goes to integration and write-up (Table 2).

Table 2. Phase-wise activities and timeline.

Phase	Activity	Duration
Phase 0	Service-Readiness & Care-Pathway Audit (parallel with Phase 1)	1 month
Phase 1	Evidence & Policy Mapping / Scoping Review (parallel with Phase 0)	2 months
Phase 2	CFIR-Guided Stakeholder Interviews & Analysis	2 months
Phase 3	Framework Co-Design Workshop & Drafting	2 months
Phase 4	Modified Delphi Validation (single primary round; brief follow-up if needed)	2 months
Phase 5	Feasibility Pilot (focused 3–4 week pilot)	1 month
Finalization	Data integration, write-up, dissemination	3 months

Abbreviation: CFIR, Consolidated Framework for Implementation Research.

2.3. Study population

The population differs by phase. Phase 0 uses service documentation, hospital records, an infrastructure and equipment inventory, and referral-pathway documents, with brief clarification from staff, and recruits no individual participants. In Phase 1 the unit of analysis is the published record: primary studies, syntheses, and policy documents on physiotherapy roles, service models, competencies, referral criteria, and implementation in low-resource hospitals. Access to all seven databases was confirmed before submission; other full texts will be requested from repositories, interlibrary loan, or the authors. Phase 2 recruits purposively from eight stakeholder groups (Table 3), and Phase 4 convenes 15–25 multidisciplinary experts, including patient representation (Jünger et al., 2017).

2.4. Inclusion and exclusion criteria

Phase 2 interviews. Eligible participants are healthcare professionals in relevant roles at the study hospital or linked facilities, women who received antenatal, postnatal, or gynecological care in the past year, public-health officers responsible for maternal or reproductive health in Puducherry, and community health workers in the catchment area with at least six months' experience, all consenting voluntarily and able to speak English or Tamil. Staff working outside maternal, obstetric, or gynecological care are not approached, nor are women who are acutely unwell or in established labor, nor anyone declining consent.

Phase 4 Delphi panel. Panelists must have recognized expertise in women's-health physiotherapy, obstetrics, gynecology, urogynecology, nursing, hospital administration, public health, implementation science, or health equity, with at least three years' experience, and must agree to complete the rating round and any follow-up. Lack of expertise, declining consent, and late completion are exclusions.

2.5. Sample size

Sample sizes are set on methodological grounds within the 12-month window. Phase 2 targets 20–28 participants, chosen purposively for maximum variation across the groups in Table 3, with collection continuing until interviews add no new themes. Because the guide is tightly scoped and theory-informed, this range is defensible on information-power grounds rather than by a fixed saturation count (Malterud et al., 2016). Phase 4 involves 15–25 panelists, typical of published Delphi studies, no number being prescribed (Jünger et al., 2017). Consensus is set in advance as at least 80% of respondents rating an item 3 or 4 on the four-point scale in each domain. Phase 5 uses a convenience sample of about 15–20 women. A power calculation is not appropriate: the pilot asks whether the tools work in everyday use, not whether they change outcomes (Bowen et al., 2009).

2.6. Sampling technique

Phase 0 (audit): review of all service records, infrastructure data, and referral documents.

Phase 1 (evidence mapping): systematic search using the Population-Concept-Context framework (Peters et al., 2020) across seven databases (PubMed/MEDLINE, PEDro, CINAHL, Scopus, Web of Science, Cochrane Library, Google Scholar), with gray literature including WHO documents and Indian maternal-health policy.

Phase 2 (interviews): purposive maximum-variation sampling using a representation matrix, with snowball sampling added if any group is underrepresented (Palinkas et al., 2015).

Phase 4 (Delphi): expert sampling based on domain expertise, diversity, and geographic representation.

Randomization and allocation concealment are not applicable. The study uses qualitative, scoping-review, and consensus methods, with no randomized allocation.

2.7. Data collection tools and instruments

Instruments are specific to each phase and mapped to the framework each supports (Table 4). The Tanahashi acceptability domain cannot be measured from the institution alone, so Phase 0 covers only its structural precursors, called here acceptability-readiness: whether patient information exists in Tamil, whether a private assessment space is available, whether clinic timings suit the population, and whether any charge falls on the patient. Each is established by observation, document review, and

clarification with staff, without approaching patients. Acceptability as women themselves experience it is examined in Phases 2 to 5 (Tanahashi, 1978).

Table 4. Data collection tools and instruments by phase.

Phase	Instrument	Content / domains covered	Framework
Phase 0	Facility Readiness Checklist	Staff, space, equipment, referral systems, documentation, cost, timing	Tanahashi
Phase 0	Patient Flow Mapping Template	Antenatal OPD, labor ward, postnatal ward, gynecology OPD, post-operative ward, discharge	Tanahashi
Phase 0	Document Review Proforma	Referral protocols, job descriptions, service statistics, patient education materials	Tanahashi
Phase 0	Brief staff discussions	Clarification only; not formal interviews; not audio-recorded	—
Phase 1	Database search strategies	Pre-specified strategies for seven databases plus gray literature	JBIC / PCC
Phase 1	Standardized Data Charting Form	Clinical domain, service level, intervention type, workforce, competencies, referral pathway, infrastructure, implementation determinants, outcome indicators, equity variables, LMIC relevance	JBIC / PRISMA-ScR
Phase 2	Semi-structured interview guide	Intervention characteristics, inner setting, outer setting, individuals, implementation process	CFIR 2.0
Phase 2	Equity Prompting Supplement	Residence, education, language, parity, mode of delivery, income, travel burden, digital access	PROGRESS-Plus
Phase 2	Audio recording & Reflexive Memo Template	Verbatim transcription; Tamil–English translation; reflexive notes and audit trail	COREQ
Phase 3	Framework Draft Template; Structured Feedback Proforma	Clinical roles, tiers, referral criteria, competencies, documentation, indicators, micro-costing	Co-design
Phase 4	Delphi Rating Questionnaire	Each item rated 1–4 on relevance, feasibility, acceptability, resource appropriateness, equity sensitivity; open-text comment per item	Modified Delphi
Phase 5	Screening Checklist; Referral Criteria Document	Case identification and referral thresholds in routine workflow	RE-AIM
Phase 5	Tamil-language education handout / QR-linked video	Patient-facing education content	RE-AIM
Phase 5	Documentation Template; Staff Feedback Form; Patient Acceptability Questionnaire	Fidelity, adoption, acceptability, practicality, equity	RE-AIM

Abbreviations: CFIR, Consolidated Framework for Implementation Research; COREQ, Consolidated Criteria for Reporting Qualitative Research; JBIC, Joanna Briggs Institute; LMIC, low- and middle-income country; OPD, outpatient department; PCC,

Population-Concept-Context; PRISMA-ScR, Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews; PROGRESS-Plus, place of residence, race, occupation, gender, religion, education, socioeconomic status and social capital, plus context-specific factors; QR, quick response; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance.

2.8. Data collection process

Phase 0. The Facility Readiness Checklist is completed from direct observation, service records, and brief clarification with staff. Patient flow is traced from each entry point: antenatal clinic, labor ward, postnatal ward, gynecology clinic, and post-operative pathway. These outputs form a Service Profile Report, shaping the Phase 1 search and the Phase 2 interview guide (Tanahashi, 1978).

Phase 1. Search strategies are finalized with a health-sciences librarian. Two reviewers screen titles, abstracts, and then full texts independently, resolving disagreements by discussion. Data are charted on the Data Charting Form and synthesized into evidence maps, tabular summaries, and narrative synthesis, per PRISMA-ScR (Peters et al., 2020; Tricco et al., 2018). Evidence on women's preferences, privacy, and cultural sensitivity is mapped to the Tanahashi acceptability field.

Phase 2. The interview guide is built from the Phase 0 and Phase 1 outputs, organized by the CFIR 2.0 domains, and piloted with two interviewees. Interviews take place in English or Tamil in a private setting and are recorded with consent. Transcription is verbatim, with translation where needed, and Framework Analysis begins once a transcript is translated (Ritchie and Spencer, 1994). A fifth of transcripts are double-coded independently. Reflexive notes and an audit trail are kept, and reporting follows COREQ (Tong et al., 2007).

Phase 3. The Phase 0 to Phase 2 results are synthesized in the Framework Development Matrix and drafted into a tiered service framework covering clinical roles, referral criteria, documentation templates, competency levels, outcome indicators, digital support, and micro-costing. A co-design workshop of 8–12 participants, chosen purposively from the Table 3 groups and separate from the Phase 2 sample, critiques and refines it (Slattery et al., 2020). This size keeps the work to one facilitated session while still representing each stakeholder category.

Phase 4. The rating round produces a median, interquartile range, and percentage agreement for each item. Items below the 80% cutoff go to a targeted follow-up covering those items only, with anonymized summary feedback and a five- to seven-day turnaround, instead of a routine second round. Items still below threshold are dropped or made optional, and the reasoning is documented (Jünger et al., 2017). Attrition is addressed by consent covering both rounds, recruitment at the higher end of the range, keeping the mobile-friendly instrument to about 20–30 minutes, sending dated reminders, and monitoring response rates against an 80% per-round target.

Phase 5. After a short staff orientation, the four core tools are used in routine antenatal, postnatal, and gynecology workflows for three to four weeks. The pilot adds no staff, imposes no charge, changes no clinical decision, and involves about 15–20 women. Feasibility is judged against RE-AIM-based indicators of reach, adoption, implementation fidelity, acceptability, and practicality, plus an equity indicator (Glasgow et al., 1999). Each tool is classified as feasible, feasible with modification, or not feasible. These judgments inform refinements and the implementation guide. Micro-costing informs possible scale-up, which lies outside this study.

2.9. Variables, data entry, and plan of analysis

Operational definitions appear in Table 5 and the study variables in Table 6. Structured data from Phases 0, 4, and 5 are entered in KoBoToolbox. Tamil interviews are translated into English, with a sub-sample back-translated as a fidelity check, and transcripts held in Dedoose under participant codes. Phase 1 output is screened and de-duplicated in Rayyan (Ouzzani et al., 2016), and data extracted on a standardized Data Charting Template.

Table 5. Operational definitions of key terms as used in this study.

Term	Definition as used in this study
OBG physiotherapy	Physiotherapy for women during pregnancy, labor, the postnatal period, and gynecological recovery, addressing pelvic floor dysfunction, incontinence,

	musculoskeletal pain, post-operative rehabilitation, and related functional impairments. (Dumoulin et al., 2018; Woodley et al., 2020)
Service-readiness assessment	Assessment of whether the hospital has the staff, space, referral systems, documentation, and resources for OBG physiotherapy, based on Tanahashi's five coverage domains. (Tanahashi, 1978)
Framework	A structured, evidence-based, consensus-validated document outlining the organization, components, roles, competencies, and implementation needs of OBG physiotherapy services.
CFIR 2.0	The updated Consolidated Framework for Implementation Research, evaluating factors affecting implementation across innovation characteristics, inner and outer settings, individuals, and process. (Damschroder et al., 2022)
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance — a framework for assessing public-health impact and sustainability. (Glasgow et al., 1999)
PROGRESS-Plus	A health-equity framework identifying socially stratifying factors that influence differential health outcomes and service access. (O'Neill et al., 2014)
Tanahashi framework	A health-service coverage model — availability, accessibility, acceptability, contact coverage, and effective coverage — each a potential gap between provision and utilization. (Tanahashi, 1978)
Modified Delphi	A structured, iterative expert-consensus method; consensus defined a priori as $\geq 80\%$ of panelists rating an item 3 or 4 on a four-point scale. (Jünger et al., 2017)
Co-design	A participatory approach involving end-users and stakeholders as active partners in framework design rather than passive recipients. (Slattery et al., 2020)
Tiered service model	A five-level framework: Tier 1, universal health education; Tier 2, screening; Tier 3, basic rehabilitation; Tier 4, specialist pelvic health; Tier 5, multidisciplinary referral.
Micro-costing	Bottom-up costing estimating the resources needed per service — staff time, materials, equipment, and patient-side costs such as transport.
Information power	A qualitative sampling principle whereby a sample is sufficient when it provides adequate information to illuminate the study aim, given the analytic approach and quality of participant dialogue. (Malterud et al., 2016)

Abbreviations: CFIR, Consolidated Framework for Implementation Research; OBG, obstetric and gynecological; PROGRESS-Plus, place of residence, race, occupation, gender, religion, education, socioeconomic status and social capital, plus context-specific factors; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance.

Table 6. Study variables and constructs by phase.

Construct type	Constructs	Phase
Service context	OBG physiotherapy workforce capacity; infrastructure and private space; referral pathways; documentation systems; patient-flow entry points	Phase 0
Equity-stratifying (PROGRESS-Plus)	Place of residence; education; language; parity; mode of delivery; income/ration card; travel distance; digital access	Phases 0, 2, 3, 4
Implementation determinants (CFIR 2.0)	Intervention characteristics; inner and outer settings; individual stakeholder factors; implementation processes	Phase 2
Evidence	Clinical roles; service models; workforce competencies; referral pathways; implementation strategies; outcome indicators; policy alignment	Phase 1
Framework output	Clinical roles, tiers, referral criteria, documentation templates, competency levels, outcome indicators, micro-costing estimates	Phase 3

Consensus	Delphi ratings per item: relevance, feasibility, acceptability, resource appropriateness, equity sensitivity	Phase 4
Coverage indicators (RE-AIM)	Reach; referral rates; timeliness; adoption; implementation fidelity; patient and staff acceptability; equity in follow-up	Phase 5

Abbreviations: CFIR, Consolidated Framework for Implementation Research; OBG, obstetric and gynecological; PROGRESS-Plus, place of residence, race, occupation, gender, religion, education, socioeconomic status and social capital, plus context-specific factors; RE-AIM, Reach, Effectiveness, Adoption, Implementation, Maintenance.

Phase outputs come together in the Framework Development Matrix, where charted evidence, audit gaps, stakeholder feedback, co-design outcomes, and Delphi consensus are triangulated into the final framework (Fetters et al., 2013). Audit data are summarized descriptively by Tanahashi domain (Tanahashi, 1978). Scoping-review data are presented as evidence maps and narrative synthesis (Peters et al., 2020; Tricco et al., 2018). Interview data are analyzed by Framework Analysis structured on CFIR 2.0 with PROGRESS-Plus (Damschroder et al., 2022; O'Neill et al., 2014; Ritchie and Spencer, 1994). Delphi data are reported as a median, interquartile range, and percentage agreement against the 80% threshold, and pilot data against the RE-AIM indicators (Glasgow et al., 1999; Jünger et al., 2017).

2.10. Ethical considerations

The Institutional Ethics Committee of Indira Gandhi Medical College and Research Institute, Puducherry, has approved the protocol (Approval No. 931/IEC-47/IGMC&RI/pp-13/2026). Conduct follows the Declaration of Helsinki (World Medical Association, 2013) and the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (Indian Council of Medical Research, 2017). Participants in Phases 2, 3, 4, and 5 give written consent after receiving a Participant Information Sheet in English or Tamil covering the purpose of the study, what participation involves, the right to withdraw, confidentiality, data storage, and contacts. Consent for audio recording is taken separately; refusal excludes no one, the interview proceeding with written notes.

Study codes replace identifiers in analysis. Audio records are held on password-protected, encrypted devices accessible only to the principal investigator and supervisor, and transcripts on a secure server. No identifiable information will appear in publications. Data are kept for at least five years after publication and then securely destroyed, as ICMR guidelines require (Indian Council of Medical Research, 2017).

The study carries no physical risk: it involves no physical examination, clinical intervention, blood draw, or invasive procedure. Interview-related risk is low; participants may skip questions or stop at any time. Antenatal, postnatal, and post-surgical women are potentially vulnerable. They are approached only when clinically stable, told that refusal does not affect their care, interviewed for no more than 30–45 minutes, and free to pause or stop (Indian Council of Medical Research, 2017). Phase 5 tests tool feasibility rather than clinical effectiveness, and care is unaffected by participation.

All findings, including those from the Phase 0 audit, are reported in aggregated, de-identified form, and no result ranks or compares the study site against any named facility. Coverage gaps and barriers are reported as design inputs — conditions the framework must accommodate — not as deficiencies of the institution or its staff.

2.11. Trial registration

The protocol has been registered prospectively with the Clinical Trials Registry - India (CTRI), registration number CTRI/2026/08/116650, registered on 17 August 2026, available at <https://ctri.nic.in>. Registration was undertaken to support transparency and to make the planned methods publicly auditable before data collection, notwithstanding that the study is non-randomized and non-interventional.

3. Anticipated Results and Discussion

As this is a study protocol, no results are yet available; the outputs anticipated from each phase are set out in Table 8 and are discussed here against the rationale for the design. Rehabilitation is widely recognized within Universal Health Coverage (World Health Organization, 2017), yet a gap remains between the evidence supporting OBG physiotherapy (Dumoulin et al., 2018; Liddle and Pennick, 2015; Woodley et al., 2020) and its organized delivery in public hospitals in India and comparable LMICs (Bright et al., 2018). This protocol approaches that gap by treating OBG physiotherapy as a health-system implementation

problem rather than an isolated professional role, combining service-readiness assessment, evidence mapping, stakeholder engagement, equity analysis, and co-design within one design.

Phase 0 is expected to yield a Service Profile Report locating coverage gaps across the five Tanahashi domains, and Phase 1 an evidence map of service models, competencies, and referral criteria applicable to low-resource hospitals. Phase 2 should generate a determinant set describing why provision and use diverge locally, and Phase 3 a draft tiered framework spanning universal education, screening, basic rehabilitation, specialist pelvic health, and multidisciplinary referral. Phase 4 is expected to return item-level consensus across the five validation domains, and Phase 5 a feasibility classification for each of the four core tools.

The four frameworks are used together for specific reasons. Tanahashi shows where provision and use diverge (Tanahashi, 1978), and CFIR 2.0 helps explain why (Damschroder et al., 2022). PROGRESS-Plus keeps equity explicit, so that the framework is designed to reach women who would otherwise be underserved by residence, language, income, or digital access (O'Neill et al., 2014). RE-AIM supplies the indicators against which the tools are field-tested (Glasgow et al., 1999). Bringing these together in the Framework Development Matrix should produce a framework that is evidence-based, workable in context, and equitable (Fetters et al., 2013).

A high-volume government hospital serving a diverse population at minimal or no cost supports both the equity analysis and external validity. Co-design with stakeholders and with women who have lived experience (Slattery et al., 2020), with modified-Delphi validation (Jünger et al., 2017), should improve adoption and reduce the risk of a framework that is sound on paper but unworkable in practice (Greenhalgh et al., 2004).

Several limitations are anticipated. The framework is developed at one site, so it will need adaptation and further validation before transfer elsewhere. The pilot tests feasibility rather than clinical effectiveness (Bowen et al., 2009), and scale-up lies outside its scope. Qualitative and consensus methods carry the usual risks of interpretive and panel-composition bias (Jünger et al., 2017; Palinkas et al., 2015). These are addressed by purposive maximum-variation sampling, independent double-coding of a subset of transcripts, reflexive memoing, an audit trail (Tong et al., 2007), and multidisciplinary panel representation. Recruitment and retention within the 12 months are addressed by the timeline redistribution, the single primary Delphi round, and the safeguards described above.

3.1. Dissemination and reporting

Findings will be disseminated by peer-reviewed publication and conference presentation, and shared with participating institutions and, where appropriate, participants. Reporting follows the guideline appropriate to each phase: PRISMA-ScR for the scoping review (Tricco et al., 2018), COREQ for the interviews (Tong et al., 2007), SPIRIT-informed conventions for the protocol schedule (Chan et al., 2013), and CREDES-informed reporting for the Delphi component (Jünger et al., 2017).

4. CONCLUSIONS

This protocol sets out how an equity-informed, implementation-science-based framework for OBG physiotherapy services will be developed and tested in a public hospital in South India. Its intended outputs are a tiered service framework, an implementation guide, and field-tested core tools — a screening checklist, referral pathway, Tamil-language patient education material, and documentation template — aligned with the RMNCH+A continuum (Ministry of Health and Family Welfare, 2013) and WHO Rehabilitation 2030 (World Health Organization, 2017). The purpose is to strengthen service organization, not to assess institutional performance. By combining service-readiness audit, evidence mapping, stakeholder-informed co-design, consensus validation, and feasibility testing in a single 12-month design, the study is intended to produce a model that is replicable in other public hospitals in India and comparable low- and middle-income settings, and to inform policy and workforce planning for women's-health rehabilitation. Future work should test the framework's transferability across multiple sites and evaluate its clinical and service-level effectiveness beyond feasibility.

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Author contributions

Beulah Jebakani D: conceptualization, study design, definition of intellectual content, manuscript preparation, manuscript editing, and manuscript review; guarantor and corresponding author. Vijayakumar P: study design, definition of intellectual content, manuscript editing, and manuscript review; guarantor and corresponding author. Jeyakumar S: study design, definition of intellectual content, manuscript editing, and manuscript review. Sabitha P: clinical input, definition of intellectual content, manuscript editing, and manuscript review. Ajith Soman: definition of intellectual content, literature search, and manuscript review. Anbupriya M: definition of intellectual content, literature search, and manuscript review. Aarthi S: literature search and manuscript review. All authors have read and approved the final manuscript, meet the four International Committee of Medical Journal Editors (ICMJE) criteria for authorship, and agree to be accountable for all aspects of the work.

Conflict of interest

All seven authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. A completed ICMJE uniform disclosure form has been submitted for each author.

Ethics statement

The protocol was reviewed and approved by the Institutional Ethics Committee of Indira Gandhi Medical College and Research Institute (IGMC&RI), Puducherry, India (Approval No. 931/IEC-47/IGMC&RI/pp-13/2026). The study will be conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013) and the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (Indian Council of Medical Research, 2017). Written informed consent will be obtained from every participant in Phases 2, 3, 4, and 5, with separate written consent for audio recording.

Registration

Prospectively registered with the Clinical Trials Registry - India (CTRI): CTRI/2026/08/116650, registered 17 August 2026, <https://ctri.nic.in>.

Data availability statement

This is a study protocol. Ethical approval has been obtained and data collection had not begun at the time of submission, so no datasets were generated or analyzed for this article. On completion of the study, de-identified Phase 0 audit records, Phase 4 item-level ratings, and Phase 5 indicator data will be deposited in a public repository (Zenodo) together with codebooks and analysis scripts. Full interview transcripts will not be deposited openly, because contextual detail could allow individual staff members to be re-identified and participants consent on that understanding; anonymized excerpts supporting each theme will appear in the results manuscript, and broader access will be decided case by case by the Institutional Ethics Committee under a data-sharing agreement. Study instruments will accompany the results manuscript as supplementary information.

Consent to participate

Written informed consent will be obtained from all individual participants included in Phases 2, 3, 4, and 5 of the study.

Guarantors

Dr. Beulah Jebakani D, PhD, and Dr. Vijayakumar P, PhD, accept full responsibility for the integrity of the work as a whole, from inception to the published article.

Statement of authorship approval

The manuscript has been read and approved by all authors; the requirements for authorship stated in the journal's instructions have been met; and each author believes that the manuscript represents honest work.

Statement on prior presentation and redundant publication

The manuscript has not been presented, in whole or in part, at any meeting. The authors confirm that this manuscript is original, is not under consideration by any other journal, and has not been published elsewhere. There are no prior or concurrent submissions or reports that could be regarded as redundant publication of the same or substantially similar work.

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