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Study protocol: 'a large cohort study of postnatal events in a not-for-profit referral centre in Vellore, South India'

Grace Mano R,[1] Ruby Angeline Pricilla,[2] Suja Kurian,[3] Santosh Joseph Benjamin,[1] Swati Rathore,[4] Hilda Yenuberi,[1] Shanti dani Minz,[5] Manish Kumar,[6] Benjamin Jeyanth Ross,[6] Reeta Vijayaselvi,[1] Anuja Abraham,[1] Annie Prasanthi,[1] Thenmozhi Mani ![ORCID],[7] Sunil George Abraham,[2] Emily Divya Ebenezer,[1] Anne George,[8] Rohin Mittal,[9] Lakshmanan Jeyaseelan ![ORCID],[10,11] Jiji Elizabeth Mathews ![ORCID],[1] The PoNTiS Collaborative Group

Correspondence to
Dr Jiji Elizabeth Mathews;
og5@cmcvellore.ac.in

ABSTRACT

Introduction In a large developing country, with diverse population characteristics and differential access to healthcare, it is important to identify factors that influence postnatal health. This knowledge will help frame recommendations to enhance universal postnatal care.

Methods and analysis A prospective cohort study will be conducted by recruiting all participants who deliver in a referral centre in South India during a 1-year period after written consent is obtained from them. In addition to clinical information pertaining to their delivery and demographics, details of physical health, mental health socioeconomic status and emotional support will also be collected. Every participant will be followed up physically and/or by telephonic consultation at 3, 9 and 18 months of their postnatal period to reassess their status and that of their babies. As there are several independent and dependent variables requiring multivariate analysis, a sample size of 10 000 is considered adequate. Any unplanned visits to a health facility will be enquired into and documented for analysis.

During data analysis, the effect of Caesarean section, high-risk characteristics and gestational age of the baby at delivery on various outcome measures and postnatal status will be evaluated. Interpretation of the large volume of collected data will help frame recommendations to improve postnatal care

Ethics and dissemination The study is approved by the Institutional Review Boards (Research and Ethics Committees) of Christian Medical College, Vellore, Tamil Nadu, India (IRB 12178 date 24 June 2020).

Women are provided with a detailed information sheet and written consent is obtained. They are reassured that their care will not be compromised if they do not consent to the study. Data will be available on the clinical trial portal to assist in the dissemination of results after the project is published.

Trial registration number CTRI/2022/03/041343.

INTRODUCTION

The focus of the global health community has shifted from coverage to quality of care, from antenatal and intrapartum care to postnatal care. There has been an impressive improvement in maternal and new born mortality with the completion of the millennium development goals. However, in this era of sustainable development goals, emphasis on morbidity and quality of care has taken centre stage. Very little is known about the postpartum phase in our subcontinent. Substantial improvements in antenatal and intrapartum care have made research into this phase of care important for the improvement of the well-being of both mother and child. There is an urgent need to comprehend details of maternal medical, physical and mental health, newborn health, social support system and barriers to breast feeding, contraception and sexual activity, all of which are interlinked for optimal healthcare. This protocol aims to address this lacuna. Outcomes of a cohort of about 14 000 deliveries per year for 18 years in a tertiary centre in south India have been published in the British Journal of Obstetrics and Gynecology in June 2019.[1] The overall caesarean section rate is close to 33% with an overall perinatal mortality of 16 per 1000. This study aims to identify postnatal concerns in the year after delivery.

The women who delivered in our tertiary centre will be contacted telephonically to arrange for face-to-face interviews by the research coordinator, with the help of a field worker, at 3, 9 and 18 months. A detailed health assessment questionnaire for the mother and child will be completed by a telephonic and a physical interview by the research assistants or trained health nurses. This comprehensive health questionnaire will help identify women with problems that may or may not require admission. This could include disorders under the salient domains of postnatal care, namely, maternal medical and physical health, mental health, newborn health, social support system and barriers to contraception. In addition to the health assessment questionnaire, all women will have one visit at the health facility at the 3-month follow-up when their blood pressure, Body Mass Index (BMI) and haemoglobin (Hb) levels will be checked. Anthropometry of the newborn will be done at the same visit. Women with significant postpartum disorders, as deduced from the health assessment questionnaire, will be assessed by a team of specialists. These include a gynaecologist, neonatologist, public health physician, psychiatrist, urogynaecologist and a colorectal surgeon, who will use specialised tools to assess their respective domains and offer treatment.

Review of knowledge

Several international health committees have made recommendations for postnatal care.[2 3] Region-specific guidelines have also been suggested for optimal care.[4–6] A comprehensive postpartum visit evaluates physical, social and psychological well-being, offers advice on contraception and birth spacing, chronic disease management and health maintenance. It is estimated that up to two-thirds of maternal deaths occur after delivery.[7] Therefore, postnatal care is the most crucial maternal healthcare intervention in preventing impairments and disabilities and reducing maternal mortality. The WHO recommends postnatal visits within 6–12 hours after birth, 3 to 6 days, 6 weeks and at 6 months (6-6-6-6 model) in order to ensure a woman's physical and mental well-being.[8] Despite this recommendation, 7 out of 10 women do not receive any postpartum care.[9] Moreover, mothers often only seek postnatal care in the event of complications after birth. Socioeconomic inequalities also constrain postnatal care in low and middle-income countries.

The Government of India recommends that all mothers and newborns receive three postnatal check-ups within 42 days of delivery: within 48 hours, between 3 and 7 days and within 42 days of delivery.[10] However, postnatal care acceptance is still very limited.[11] There are various aspects of postnatal and postpartum care. The effects of pregnancy on many organ systems begin to resolve spontaneously after birth of the infant and delivery of the placenta. But, the timeline for resolution is not necessarily linear and not the same for all organs or tissues. Women in the postpartum period should be monitored for postpartum complications. The frequency of follow-up depends on specific issues encountered during childbirth

and the immediate postpartum period. An assessment of a spectrum covering anaemia, hypertensive diseases, diabetes and obesity is required.[12–16] Perineal pain, dyspareunia, low libido, loss of desire, loss of vaginal lubrication, postcoital bleeding, itching and burning may occur after childbirth and, if persistent and untreated, may lead to long-term physical, psychological and emotional difficulties.

Other sources of postpartum pain include abdominal, pelvic, musculoskeletal pain and pain at the wound site, especially when there is an infection. Wound infection is seen in about 2%–4% of abdominal wounds and 1%–3% of perineal wounds.[17–19] Postpartum urinary retention is due to injury to the pudendal nerve and the risk factors are primpara, instrumental delivery and episiotomy. It usually resolves in 2–3 months, but rarely the retention may take longer to resolve.[20] Urinary incontinence is seen in almost 11% of postpartum cases and remains the same over a 12-month period.[21] Faecal incontinence or incontinence of flatus in women with obstetric anal sphincter injury has been described in 6% of women.[21] Confidential Enquiries into Maternal Death and Morbidity from the United Kingdom ranked suicides as the fifth most common cause of mortality in pregnant women and during the first 6 weeks after delivery.[22]

Given that infant mortality in India is 41 per 1000 live births,[23] the study of this cohort will help understanding this aspect . According to WHO, there are 214 million women of the reproductive age in developing countries who want to avoid pregnancy but are not using any modern contraceptive methods.[24] Family planning methods reduce the need for abortion, especially unsafe ones. Studies show disparities in breastfeeding rates in women who are young, low-income, African American, American Indian, or Alaska Native, or Native Hawaiian.[25] Social support has a positive influence on general and psychological well-being and provides better coping skills during illness and stress. Our study will use established assessment tools to gauge family and social support, starting from simple genogram, eco-map to family Apgar.[26]

A systematic review[27] of clinical guidelines for postpartum women and infants in primary care in 2014 found six guidelines from Australia, two from United Kingdom and one from the USA. However, there was only one guideline on comprehensive recommendations for the care of postnatal women. None of these guidelines was from India. The review reiterated the need for region-specific guidelines. Collecting and evaluating relevant postnatal information from our region will help establish contextual, reasonable and cost-effective guidelines.

Objectives

The main objectives of this study are to assess maternal medical, physical and mental health, newborn health, barriers to breast feeding, social support systems, and contraceptive use in order to develop guidelines for

pragmatic, cost-effective postpartum care in the year following delivery.

METHODS

This study is funded by an Indian Council of Medical Research (ICMR) grant received from the Department of Health Research, Ministry of Health and Family Welfare, Government of India. The study has been approved by the Institutional Review Board (Number 12178 date 24 June 2020) of Christian Medical College Vellore, Tamil Nadu and is a registered clinical trial.

Design

This is an observational cohort study that will compare relevant prespecified exposed and non-exposed cohorts of postnatal women to analyse outcomes in the mother and child in the year following delivery.

Setting

This cohort study will be conducted in the department of Obstetrics and Gynaecology, Christian Medical College Vellore a large, private tertiary health centre in South India, that is self-financed and a not-for-profit organisation.

Participants

All women delivering after 22 weeks of gestation in the specified centre, irrespective of where they had antenatal care or the outcome of the pregnancy, will be included in the study. Women will be approached postnatally by trained research assistants and written consent for participation will be obtained from them. Women who conceive again and deliver in the same year will be excluded from the study, but their offspring will be followed up at the specified time points. Therefore, every woman is included only once in the study and is eligible for follow-up until she becomes pregnant, or at the end of follow-up at 18 months, whichever is earlier. Comprehensive baseline delivery data of all women, delivering in the specified centre from 1 January to 31 December, will be captured (see online supplemental file 1—PDF of electronic data set using RedCap software). Women and their children will then be followed—up at 3, 9 and 18 months and outcomes will be collected at these time points with a detailed postnatal health assessment questionnaire (PNHAQ) (see online supplemental file 2—PDF of electronic data set for three postnatal visits). The participants' flowchart is described in online supplemental file 3.

Exposure

The prespecified exposures will be the mode of delivery, that is, women who delivered by caesarean section versus those who delivered vaginally, women who delivered at term (after 37 weeks) versus those who had preterm delivery (delivery before 37 weeks) and presence or absence of significant high-risk factors (see online supplemental file 4). These three exposure pairs, arrived at

following intensive discussions, were chosen as the main common factors that could influence outcomes.

Patient and public involvement

The engagement with women and their families is unprecedented during the conduct of this study. Awareness of maternal mental health and other issues will be highlighted directly or indirectly. The questions were formulated by the investigators after identifying gaps in holistic care during their years of practical experience while engaging with postnatal women. The outcomes of the study will help in enhancing patient and public involvement.

Details of study implementation and tracing women for follow-up

Each woman who consents to be recruited into the study will be followed-up for 18 months after delivery. An elaborate consenting process by trained research assistants will be followed. The research assistants will be Good Clinical Practice certified. All women will be informed with a detailed information sheet translated into the local languages on the purpose of the study and their role in it. They will be reassured that their participation is entirely voluntary and that they can withdraw from the study at any time point without their care being affected. The intrapartum and immediate postnatal details will be captured in the electronic data set of the Redcap software system. Following delivery, women will be given a discharge card with warning signs for the mother and the baby (see online supplemental files 5, card 1 and 2) to pre-empt a near miss. They are advised to document all the details of unscheduled visits, with symptoms and the diagnoses at consultation with any healthcare provider, during the first 3 months. Women who need a special visit (see online supplemental file 6) will be given dates for the visits. If they do not need a special visit, they are advised to come for a scheduled visit at 14 weeks following delivery, during the visit to a facility for the immunisation of the child. The contact details of each of woman and her family members are documented in detail to ensure optimal tracing of women.

A week before the 14th week visit, they will be contacted by phone and a telephonic interview for each of these women is completed. A face-to-face visit is fixed and women will have a repeat detailed interview and basic check-up. This visit will be conducted at the facility where the woman takes her child for immunisation. The check-up will include blood pressure monitoring for the mother, measurement of weight and general examination for both the mother and child. Abdominal examination or pelvic examination will be done for mother only when required.

The Hb will be checked for every recruited woman at the 14 weeks scheduled postnatal check-up. Results of glucose tolerance test for women with gestational diabetes will be recorded. PNHAQ will be completed at this visit. Patients will be informed that they will be contacted

Sl.No.	Variables	Exposure I— mode of delivery LSCS vaginal	Exposure II—high risk factors (see online supplemental file 4) present–absent	Exposure III— gestation term preterm

Table 1 Baseline characteristics—demography and intrapartum details

Sl.No.	Variables
1	Age *
2	Religion † a, b, c, d (n%)
3	Unbooked ‡ n (%)
4	Final socio-economic score § *
6	Nulliparous (n%)
7	Gestational age at delivery*
8	ªPrepregnancy BMI after delivery *
	ᵇPrepregnancy BMI after delivery *
9	ªInduction of labour (n%)
	ᵇInduction of labour for PROM (n%)
10	Total duration of labour Hours*
11	Total duration of ROM Hours *
12	Antibiotics in labour (n%)
13	Epidural in labour (n%)
14	Blood transfusion (n%)
15	Multiple pregnancies (n%)
16	Episiotomy/second degree Perineal tear (n%)
17	Additional surgical procedures at LSCS—n%

*Mean/median/SD/IQR.
†a—Hindus, b—Muslims, c—Christians, d—others.
‡No antenatal care in the institution—admitted directly to labour ward.
§Socio economic score<5 lowest, >26–29 upper class.
BMI, Body Mass Index- Defined as persons' weight in kilograms divided by square of height in metres.; LSCS, Lower segment Caesarean section; PROM, Premature rupture of membranes; ROM, Rupture of membranes.

again at 9 months and 18 months and the PNHAQ will be completed telephonically during these time points. Women, who do not respond, despite repeated reminders, will be contacted by the field staff, and the check-up will be completed at the home of the woman.

Variables

The baseline characteristics for the prespecified exposures are enumerated in tables 1–3

The primary and secondary outcomes are covered in tables 4 and 5, respectively.

The primary outcomes are the number of unscheduled visit and the indications for the same. The potential indications for unscheduled visits in the mother are: (1) fever, (2) wound infection, (3) secondary Post Partum Haemorrhage spelt out (PPH), (4) redness and tenderness of breast, (5) redness and pain in legs, (6) breathlessness, (7) bowel or urinary reports.

The indications for an unscheduled visit in the child are : (1) fever, (2) jaundice, (3) abdominal distension, (4) lethargy, (5) poor feeding, (6) rapid breathing, (7) noisy breathing and chest retractions, (8) discolourations of lips and oral cavity, (9) foul smelling discharge

of umbilical cord, (10) loss of weight of more than 10th percentile, (11) recurrent vomiting and blood or bile of vomits and (12) incessant crying, irritability and twitching movements that is persisting.

The secondary outcomes in mother include unhealed wound site, anaemia, increase in BMI, pain in abdomen or pelvis, urinary or bowel problems, musculoskeletal pain, breast-related issues and other problems and barriers for breast feeding, contraception and sexual activity.

This study will be a platform for a substudy on nutrition and cost analysis of postnatal care.

Variables of baseline characteristics and outcomes that need definition or explanation

1. BMI of the mother after delivery.
2. Socioeconomic status:

This was measured using the Kuppusamy socioeconomic status scale 2021.[28] This scale uses the occupation and education of the head of the family and the total monthly income of the family to calculate the scores. Scores <5 and >26–29 denoted the lowest and the upper most class, respectively, of postnatal women. The head of the family is the husband or father-in-law in a nuclear

Table 2 Baseline characteristics—post-natal complications and maternal and neonatal health before discharge in relation to exposure I, II, III

SI. No.	Variables	Exposure I—mode of delivery LSCS vaginal	Exposure II—high risk factors (see online supplemental file 4) present–absent	Exposure III—gestation term preterm
	Mother			
1	Shoulder dystocia n (%)			
2	Retained placenta/adherent placenta n (%)			
3	Third or fourth degree tear with episiotomy n (%)			
	Third or fourth degree tear without episiotomy n (%)			
4	Colporrhesis/traumatic PPH n(%)			
5	Atonic PPH n (%)			
6	Vulval haematoma, vaginal haematoma or broad ligament haematoma paramatrial phlegmon n (%)			
7	Rupture uterus n (%)			
8	Retention of urine requiring catheterisation n (%)			
9	Pueperal sepsis or septicaemia n (%) a, b, c, d, e			
	Urosepsis			
	Endometritis			
	Wound infection			
	Mastitis spectrum			
	Others			
10	Urinary incontinence or VVF n(%)			
11	Bowel incontinence or RVF n(%)			
12	Postpartum pulmonary oedema n (%)			
13	Postpartum thromboembolic phenomenon n (%)			
14	Total duration of hospital stay (days)*			
15	Special visit advised (n%)			
16	Special visit reason (refer online supplemental file 6) (n%)			
	Visit for suture removal (n%)			
	Visit for wound-related problems (n%)			
	Visit for hypertensive disease (n%)			
	Visit for diabetes cardiac and other medical disorders (n%)			
	Others (n%)			
	Neonatal health at discharge			
1	Neonatal weight (g)*			
2	Apgar score at 5 min (1–10)*			
3	Head circumference of the baby (cm)*			
4	Admitted to nursery (n%) a,b,c,d,e,f,g			
	Asphyxia n (%)			
	Birth injury n (%)			
	Preterm n (%)			
	Hyperbilirubemia n (%)			
	Congenital anomaly n (%)			
	Genetic or metabolic disorders n (%)			
	Risk of sepsis or sepsis n (%)			
5	Special visit for above reason n (%)			
6	Antibiotics given (n%)			
7	Duration of hospital stay (days)*			
8	Delayed discharge (n%)			
9	Not exclusively breastfed			

*Mean/ median/SD/IQR.
LSCS, Lower segmnet Caesarean Section; PPH, Post Partum Haemorrhage, Defined as an estimated blood loss of more than 500ml after vaginal delivery and more than 1000 ml after Caesarean delivery.; RVF, Recto Vaginal Fistula; VVF, Vesico Vaginal Fistula.

Table 3 Baseline characteristics—mental health and contraception details

Sl. No.	Variables	Exposure I—mode of delivery LSCS vaginal	Exposure II—high risk factors (see online supplemental file 4) present–absent	Exposure III—gestation term preterm
1	Final family Apgar score (0–10)* †			
2	Opportunities to discuss Psychiatry concern (n%)			
3	Fear of COVID-19 (n%)			
4	Family history of mental illness (n%)			
5	Risk Factor Assessment Score (0–11)†			
6	NICE question (0–100%) †			
7	Permanent sterilisation (n%)			
8	Woman preferring spacing (n%)			
9	Women preferring delayed sterilisation (n%)			
10	Women who used any spacing method (n%)			
11	Woman who had induced abortion before pregnancy (n%)			
12	Women who used			
	Condom			
	Depo-provera			
	IUCD			

*Score 0–3 severely dysfunctional, 3–7 moderately dyfunctional, >7–10 functional family.
†Mean/ median/SD/IQR.
IUCD, Intra Uterine Contraceptive Device; LSCS, Lower Segment Caesarean section; NICE, National Institute for Health and Care Excellence.

or joint family, respectively. Occupation of the head of family is scored from 1 to 10; education from 1 to 7 and total monthly income of the family as 1, 2, 4, 6, 10 and 12.

3. Obstetric, surgical and medical risk factors were defined as per standard definitions followed in the obstetric text book.[29]
4. Social Framework was assessed by a family Apgar questionnaire, with scores of 0–3, 3–7 and 7–10 categorised as severely dysfunctional family, moderately dysfunctional and functional family, respectively.[30]
5. Estimated blood loss was an estimation made by the caregiver at delivery if there was postpartum haemorrhage.
6. Urinary problems: potential urinary problems are retention of urine, urgency or passing urine before reaching the toilet, hesitancy or straining to initiate micturition, increased frequency and incontinence.
7. Bowel problems include a spectrum of symptoms, ranging from incontinence to constipation.
8. Mental health assessment at discharge is done using the Risk Factor Assessment (RFA) and NICE questionnaire. The RFA questionnaire has scores ranging from '0 to 11'.[31] A starred response of yes/no indicate mental distress. The reverse scoring is intentionally done to prevent people from automatically choosing the same option. Any score above 3 highlighted the need for further evaluation. The NICE questionnaire[32] with more than 50% of questions being yes

also reiterated the need for additional mental status evaluation. It comprises of four questions, two each for depression and anxiety, with any one positive response indicating further evaluation. The Research assistants sensitise the women to the questions that will be asked, and the answers obtained only on the next day to ensure adequate time for each patient to understand and introspect before answering questions. The RFA and NICE questionnaires at discharge help to identify women that require further evaluation.

9. Special scheduled visits: these are visits that are planned by caregiver because of the presence of any obstetric, medical, surgical, intrapartum or postpartum complications either for the mother or baby (see online supplemental file 6).
10. *Unscheduled visits:* women are being advised to come only at 14 weeks as part of the child's immunisation schedule for their first postnatal visit. Visits before that will be called unscheduled visits. Women are given a discharge card with warning signs for the mother and child, which could give rise to an unscheduled visit, thereby pre-empting any near miss incidents.
11. Edinburgh postnatal depression scale is a 10-item questionnaire which can be completed in less than 5 min. Responses to items are scored 0–3, with a maximum score of 30. Scores ≥12 identify most women with postpartum depression.[33 34]

Table 4 Primary outcomes—follow-up outcome measures

Sl. No.	Variables	Exposure I—mode of delivery LSCS	vaginal	Exposure II—high risk factors (see online supplemental file 4) present	absent	Exposure III—gestation term	preterm
1 *	Primary outcome Number of unscheduled visits (n)						
	For mother (total)	M	M	M	M	s	s
i	Fever (n%)	M	M 1	s	s	M	M
ii	Wound site infection (n%)	M	M 1	s	s	s	s
iii	Secondary PPH (n%)	M	M 1	M	M	M	M
iv	Redness and tenderness of breast (n%)	s	s	s	s	M	M
v	Redness, pain and swelling of legs (n%)	M	M 1	M	M	–	–
vi	Breathlessness (n%)	M	M	M	M	–	–
vii	Urinary problem (n%) Others/bowel	M	M 1	–	–	–	–
iii	Minor complaints (n%)	s	s	s	s	s	s
2	**For baby (total)**		–	M	M	M	M 2
i	Fever>100.4/<97.5 f (n%)	–	–	–	–	M	M 2
ii	Jaundice beyond 14 days (n%)	–	–	–	–	M	M 2
iii	Abdominal distension (n%)	–	–	s	s	M	M 2
iv	Lethargy (n%)	s	s	–	–	M	M 2
v	Poor feeding (n%)	s	s	–	–	M	M 2
vi	Rapid breathing>60/min (n%)	–	–	–	–	M	M 2
vii	Noisy breathing, retractions (n%)	–	–	–	–	M	M 2
viii	Blue colouring on lips and oral cavity (n%)	–	–	–	–	M	M 2
ix	Foul smelling discharge or bleeding from umbilical cord (n%)	M	M 2	–	–	M	M 2
x	Loss of weight more than 10th percentile (n%)	–	–	–	–	M	M 2
xi	Recurrent vomiting blood and bile in vomitus (n%)	–	–	–	–	M	M 2
xii	Crying, irritability and twitching movements without improvement (n%)	–	–	–	–	M	M 2

For subgroup analysis: 1. Instrumental versus normal/vaginal delivery, 2. Very preterm < 32 weeks/preterm 32–37 weeks, 3. NICE <50% >50%.
*Included as events.
LSCS, Lower Segment Caesarean section; M, main outcome; NICE, National Institute for Health and Care Excellence; PPH, Post Partum Haemorrhage; s, secondary outcome.

12. Perceived stress scale: this is a 10-item scale that assesses stress perceived during the previous month.[35] It is scored from 0 to 4, with a total score of 40. Scores of 0–13 indicate low stress, 14–26, moderate stress and 27–40, severe stress.

13. Barriers to breast feeding: difficulties in breast feeding before discharge was documented as baseline information. Infants who need supplements to breast milk are identified. At postnatal assessment, reasons for not breast feeding such as infection, job/work requirements, poor milk secretion, pain in the breast, sickness in the mother or neonate or any other reasons are captured.

14. The milestones of the baby are assessed using the Trivandrum developmental screening chart.[36]

15. Barriers to contraception: contraceptive methods of choice will be documented. Women who opt not to have a permanent method of contraception will be interviewed regarding their desire for spacing and the reasons for the same.

16. Barriers to sexual activity: information on Dyspareunia, loss of libido, cultural practices, family dispute, lack of free time and fear of pain in the episiotomy will help understand barriers to sexual activity.

Table 5 Secondary outcomes—3, 9 and 18 months

Sl. No.	Variables	Exposure I—mode of delivery LSCS vaginal		Exposure II—high risk factors (see online supplemental file 4) present–absent		Exposure III—gestation term preterm	
	Maternal physical and medical conditions						
1*	Unhealed infected sited requiring additional surgical treatment (n%)	M	M 2	–	–	–	–
2*	Anaemia a (n%)	M	M	s	s	–	–
3*	Increased BMI (n%)	M	M	M	M	s	s
4*	BP >130/90 (n%)	s	s	M	M	s	s
5*	Pain in abdomen(n%)	M	M	–	–	–	–
6*	Pain in pelvis (n%)	M	M 2	–	–	–	–
7*	Abnormal bleeding	M	M				
8*	Abnormal discharge	M	M				
9*	Urinary problem (n%)	M	M 2	–	–	–	–
10*	Bowel problem (n%)	M	M 2	–	–	–	–
11*	Musculoskeletal pain (n%)	s	s	–	–	–	–
12*	Other (n%)	s	s	s	s	s	s
13	Breast-related problems (n%)	–	–	–	–	M	M
14	Partial breast feed †(n%)	s	s	s	s	M	M
15	No breast feeding †(n%)	s	s	s	s	M	M
16	Desiring contraception/interval sterilisation (n%)	s	s	s	s	s	s
17	Resumption of sexual activity (n%)	M	M 2	s	s	s	s
18	Benefitted by a 6-week post-natal visits (n%)	M	M 2	–	–	M	M
19	Special visits yes/no (n%)						
20	Number of special visits†						
21	Noncompliance of special visits (n%)						
22	Barriers for sexual activity						
23	Barriers for contraception						
	Maternal mental status						
1*	EPDS (score>10) (n%)	M 3	M 3	M 3	M 3	M 3	M 2,3
2*	PSS (moderate to severe stress) (n%)	M 3	M 3	M 3	M 3	M 3	M 2,3
3	Family Apgar score (0–10)†	s	s	s	s	s	s
	Neonatal status						
1*	Inadequate weight gain (n%)	–	–	–	–	M	M 2
2	Vaccination–complete n (%)	–	–	–	–	–	–
3	Vaccination–partial n (%)	–	–	–	–	–	–
4*	Any significant illness in 3 months apart from unscheduled visit n(%)	–	–	s	s	M	M 2
5	Any admissions n (%)	–	–	s	s	M	M 2
6*	Delayed milestones n(%)	–	–	s	s	M	M 2
7	Exclusive breast feeding n(%)						
8	Barriers for breast feeding n(%)						
9	Any unhealthy practices (n%)						

Subgroup analysis: 1. Instrumental versus normal delivery, 2. Very preterm < 32 weeks/preterm 32–37 weeks, 3. NICE questionnaire assessment: >50% at discharge/<50% (a) Hb less than 10 mg/dL (b) Increase in BMI by 3.
*Included as events.
†Mean/median/SD/IQR.
BMI, Body Mass Index; BP, Blood Pressure; EPDS, Edinburgh Postnatal Depression Scale; Hb, Haemoglobin mg/dl; LSCS, Lower Segment Caesarean Section; PSS, Perceived stress Scale.

17. Nutrition: the adequacy of the nutrition of the mother and child will be documented using the dietary recall method.

18. Costing information on the hospital bills of the mother and child, cost of special visits, unscheduled visits and scheduled visits, distance from the health facility and time spent by the doctor and nurse will be used for basic economic analysis.

Confounders, effect modulators and bias

Each of the baseline variables collected as data captured in tables 1–3 has the potential to be confounders or effect modifiers.

Prespecified outcomes of interest among the exposures that were studied will help in avoiding bias, while interpreting the findings of data that are analysed.

Data management

Data collection will be completed after 1.6 years following the recruitment of the last woman in the study on 31 December 2022. The consent forms of every participant are archived. Data are entered, using the Redcap software system, at discharge, at 14 weeks, 9 months and 1.6 years postnatally. Women who become pregnant during this time will be excluded for subsequent analysis. Therefore, denominators will change accordingly. The determinants of denominators for outcomes in mother and child will factor in exclusions for death, too sick to give consent, pregnancy, loss to follow-up and unwillingness of the woman to continue in the study (refer to flowchart in online supplemental file 3).

Data validation: monthly validation of all e baseline data collected will be ensured.

Data will be available on request from the corresponding author.

Reliability: the follow-up at 3 months will be done both with a telephonic interview and a face-to-face interview. The follow-up at 9 months and 1.6 years will be done only with a telephonic interview. The discharge card will help in ensuring the capture of information at visits to a healthcare provider during the period of follow-up. Details from hospital notes to confirm events will be recorded in the PNHAQ

Statistical analysis plan

Descriptive analysis population: refer tables 1 to 3

All women in the study will have demographic and relevant baseline clinical details of their pregnancy and delivery collected. This will be for exposed and unexposed pairs, in the three prespecified domains as a descriptive analysis of population with mean (SD) used for continuous variables, and number and percentages for categorical variables. Baseline characteristics of women who have had no follow-up assessment will be compared with those who have had follow-up assessment using tests of statistical significance, in the overall population and for pre-exposure pairs.

Comparative analysis population: refer tables 4 and 5

The denominators during analysis for outcomes in the mother and child may vary at 3, 9 and 18 months due to death, pregnancy, losses to follow-up or unwillingness to participate in the study, and they may be excluded at different points of the follow-up period (see online supplemental file 3).

Principal outcomes of interest in prespecified exposures or non-exposure pairs:

The outcomes are not necessarily relevant to all comparison pairs. Therefore, only outcomes of relevance to the exposure pairs will be analysed (tables 4 and 5). Some of the outcomes will be the main comparison of interest (M) and others will be of secondary comparison of interest (S). The prespecified subgroup analysis will be performed on selected comparisons. For example, occurance of fever in the mother is the main outcome for comparision pairs of mode of delivery, and the presence of risk factors, but only a secondary outcome for gestational age at delivery. Urinary and bowel problems are not an outcome of interest when gestation age at delivery is the exposure factor that is being assessed. Outcomes will be summarised by pre-exposure group using appropriate summary statistics (counts and percentages, mean and SD or median and IQRs).

The comparators, namely, the exposure and non-exposure groups, will be the mode of delivery, categorised as Lower segment Caesarean section (LSCS) versus vaginal delivery, presence or absence of high-risk factors and preterm and term deliveries. There will be unequal distribution across the pairs of exposures. The incidence of events will be measured. Relative risk and 95% CI will be calculated for dichotomous or continuous outcomes, mean differences for normally distributed continuous variables or median differences for skewed continuous variables. Independent t test/Mann–Whitney U test will be used. To find the association between two categorical variables in baseline characteristics, analysis with the χ^2 test/Fisher's exact test will be done. Multivariable analysis or logistic regression will be used with logit link function for outcomes that are less than 10% and with log link function if the event rate is ≥10%. If the outcome measured is a continuous variable, then multivariable regression analysis will be done. If the follow-up is at more than a one time point, then repeated Analysis of Variance (ANOVA) and the generalised estimating equation will be used for the categorical or continuous outcome.

For child outcomes, multiple births will be treated as separate events to calculate relative risks. Subgroup analysis for some outcomes such as instrumental delivery versus normal vaginal delivery and preterm versus very preterm delivery, highlighted NICE questionnaire scoring versus normal score will be done.

Sensitivity analysis of the main comparison of interest (tables 4 and 5) will be carried out at 1.6 years. If the

missing observation for an outcome variable is less than 20%, then the Expectation Maximization (EM) algorithm will be used to impute the missing values using the completely random missing method. Baseline data will be used to impute the outcome. All the analyses will be carried out using STATA V.16.0 and SPSS V.21.0.

Sample size and power

About 12 000 deliveries are anticipated during the fixed 12-month period. The pre-exposed and exposed pairs will be equal. Expecting an 80%–85% follow-up rate, approximately 10 000 women will be followed up in total. Approximately 6500 will deliver vaginally, and 3500 will deliver by caesarean section. High-risk factors may be seen in around 4000 of the 10 000 women, and about 3000 of 10 000 women will deliver preterm before 37 weeks. Events include the primary outcome and variables marked as '+' in the secondary outcomes (tables 4 and 5). Assuming an event rate of 20% to estimate precision of 1% with a 95% CI with the 10% dropout rate, we will need to study 6830 women, and 7684 women for a 20% dropout rate.

DISCUSSION

The resultant data from this cohort of women and children, collected at 3, 9 and 18 months, will provide an understanding of the challenges faced by a mother and her family in the first year following delivery. Since most of the cohort belongs to the low to middle-income group, it will be largely representative of contexts and conditions in a middle-income setting. However, our cohort has referrals from peripheral and government hospitals and so also caters to high-risk women from the low socioeconomic group.

Our study, prospective in nature, aims to capture vital information on the need for additional interventions, over and above that which is normally practiced. There is a paucity of literature, for instance, on the persistence of high blood pressure beyond 6 months or the incidence of serious bowel and bladder complications. Several studies have identified a high prevalence of postpartum depression in Indian mothers.[37] Our study, building on this information, will identify appropriate tools that can be used to identify mothers in need of postpartum mental health support. Similarly, information on social support and contraceptive usage is also being collected to identify strategies to enhance these aspects.

Information on the effects of anaemia of the postpartum period is not well elaborated. Few studies before and after anaemia screening programmes have shown an improvement in anaemia detection and consequently improved health.[38]

There are very few research publications on the postpartum period from India; most of the information is primarily from health surveys.[39–41] The Government of India guidelines are perhaps extrapolated from other guidelines, since there is little institutional-based data

in literature from India.[42–45] Therefore, our study will shed light on the concerns of postpartum women, many of which can be addressed with good health education prior to discharge and avert unnecessary visits to a health facility. This, currently, is not the mainstay practice. Appropriate health education has the potential to pre-empt unnecessary visits to health providers, while at the same time increasing awareness of potential illness and sickness.

The WHO postnatal[8] guidelines are generic in nature, covering low and middle-income countries. Though the WHO guideline recommended the 6-6-6-6 model, this is not being followed in our country. Most women are discharged only after 24 hours even in government hospitals. The findings from our study will help identify region-specific concerns that are representative of a large and growing middle-income population in India, and other similar settings. Our study has the potential to influence and contribute to the development of pragmatic postnatal guidelines relevant to our country. It will help address the needs of vulnerable groups, appropriate resource utilisation and highlight areas of postnatal health that need attention. It is hoped that results from the study will emphasise new priorities, while also modifying public health policies and guidelines. Identifying women who need close monitoring and others who do not may foster the prevention of unnecessary visits to the facility and has the potential to evolve cost-cutting strategies. This study is unique, in that we are going to be capturing the social support that is available to women after discharge in our society. It is an opportunity to identify harmful postnatal practices. Even though we know that women in the postpartum period are subjected to mental stress, a prospective assessment to look for risk factors for mental illness in the postpartum period has not been done in a prospective cohort study in our region. Thus, this study will be instrumental in identifying several of these important issues that need attention.

The publication of this protocol will enable us to consider all important aspects for accurate data capture. The development of this protocol will help us ensure precise implementation with minimal protocol amendments in the future.

This protocol will help with future research and publications that are likely to stem from the data collected. The PoNTiS collaborative group will ensure the dissemination of results to a wide audience. They will use the results to help formulate guidelines for cost-effective, rational guidelines for postnatal care.

A limitation of the study is that the findings of this study may be relevant to the low to middle-economic class and may not be representative of the population of the country where the majority of deliveries are at home. A detailed health economic assessment is not possible within the ambit of this protocol. Therefore, extrapolation of the results to all spectrums of socioeconomic classes and regions within the country will have to be done cautiously. However, this study will provide a platform to foster other

studies that will address relevant research questions, including the health economics and detailed cost analysis of optimal postnatal care in our region.

Even though this study does not include women who deliver at home, this number comprises less than 1% of deliveries in our region of Tamil Nadu, South India.[46]

ETHICS AND DISSEMINATION

Ethical approval was obtained from Institutional Review Boards (Research and Ethics Committees) of Christian Medical College, Vellore, Tamil Nadu, India (IRB 12178 dt 24.06.2020), and a detailed written consenting process is followed for each recruited case. The trial has been registered with CTRI and data will be available for public viewing after the study is published. The findings of the study will be presented at scientific conferences and eventually published.

Author affiliations
[1]Obstetric and Genecology, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[2]Low Cost Effective Care Unit, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[3]Mental Health Centre, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[4]Department of Obstetrics and Gynaecology, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[5]Rural Unit for Health and Social Affairs, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[6]Neonatology, CMC Vellore, Vellore, Tamilnadu, India
[7]Biostatistics, Christian Medical College Vellore, Vellore, Tamil Nadu, India
[8]Community Health and Development Unit, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[9]General Surgery, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India
[10]College of Medicine, MBRU College of Medicine, Dubai Healthcare City, UAE
[11]Biostatistics, Christian Medical College and Hospital Vellore, Vellore, Tamil Nadu, India

ORCID iDs
Thenmozhi Mani http://orcid.org/0000-0002-3932-5625
Lakshmanan Jeyaseelan http://orcid.org/0000-0002-9090-3005
Jiji Elizabeth Mathews http://orcid.org/0000-0002-9366-9090

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