






STUDY PROTOCOL

A multi-site, non-randomized study of the feasibility and acceptability of a family-led postnatal care model in the Ada District, Ethiopia [version 1; peer review: 1 approved with reservations]

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Abstract

Background: Postnatal care is a critical intervention to reduce newborn and maternal mortality in high-mortality settings. However, it is underutilized in many countries. Family-led postnatal care (FPNC) is an innovative postnatal care service delivery model that leverages self-care principles to address key barriers identified in the Ethiopian context, including women's preference to stay home in the first week after delivery and receive support from trusted family members. Utilizing an improved discharge process, coupled with user-friendly monitoring devices made available as a home care kit kept with preferred community custodians, this self-care model for postnatal care will be evaluated as a potential solution to very low coverage of postnatal care in the first week of life.

Methods: The study will use mixed sequential methods: quantitative pre-intervention and post-intervention survey and phenomenological qualitative study. Four health centers in Ada District of Oromia, Ethiopia will be purposively selected. A pre-intervention survey will measure coverage and content of postnatal checks and care-seeking behavior. Health centers will then implement family led postnatal care. Once FPNC is initiated, post-intervention quantitative data will be collected. Approximately 218 postnatal women are to be included in the quantitative survey. Qualitative interviews with approximately 20 mothers, 20 partners, 20 families, eight health managers, 12 postnatal discharge counselors, 20 health extension workers, and eight home care kit custodians will be conducted. A quantitative measurement of sustainability six months after the endline will also be assessed.

Conclusions: Optimally, the study will contribute evidence to inform

Open Peer Review

Approval Status ?

1

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?

[view](#)

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Any reports and responses or comments on the article can be found at the end of the article.

decision makers locally and globally on whether FPNC is a feasible and acceptable service delivery model for postnatal care, and whether it improves women's empowerment and/or increases men's support and connection to women and newborns in the early postnatal period.

Keywords

Postnatal care, family-led care, community-based intervention, self-care, Ethiopia

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Introduction

Each year globally, approximately 295,000 maternal deaths and 2.4 million neonatal deaths occur^{1,2}. Approximately 66% of maternal deaths and 73% of neonatal deaths occur in the first week following delivery of life^{3,4}. Postnatal care (PNC)—inclusive of care for both postpartum mothers and newborns in the first 42 days after birth—is widely recognized as critical to prevent these deaths. The World Health Organization (WHO) recommends two postnatal assessments during the first 24 hours after birth, followed by postnatal assessments between 48–72 hours, between Days 7–14, and Day 42⁴. Coverage of any PNC in the first six weeks after birth is only 52% in sub-Saharan Africa, based on pooled analysis of demographic health survey (DHS) data from 36 countries⁵. In many countries, women who give birth in a health facility are not guaranteed to receive PNC before discharge⁶. Early postnatal care (PNC) in the first seven days is a critical time period for frequent care contacts, given that the majority of maternal and newborn deaths occur in the first week following delivery of life³.

In many countries, PNC, if it occurs, is generally provided within facilities. Efforts to increase access to PNC through community-based interventions, such as home visits by community health workers, have improved essential newborn care practices and reduced newborn mortality in high-mortality settings^{7,8}. Community-based approaches, despite this promising evidence, have struggled to gain traction. Data from sub-Saharan Africa show low coverage of postnatal home visits by community health workers in the first week after birth: only 11% of women received a PNC visit within three days of delivery in Malawi, 15% received a PNC visit within two days in Tanzania, and 38% received a visit on the first or second day in Ghana⁹.

In Ethiopia, the 2018 Ministry of Health (MOH) guidelines recommend PNC for mothers and newborns on postnatal Day 1, Day 3, Day 7, and Day 42—noting three of four PNC checkups occur in the first week after birth¹⁰. The 2016 Ethiopia Demographic and Health Survey (EDHS) found that only 17% of women and 13% of newborns received PNC within the first two days after birth, with 81% receiving no PNC at all¹¹. A secondary analysis of the EDHS datasets found that only 13% of women used PNC services within 42 days, with only 2% of women receiving PNC within 24 hours, 5% within 48–72 hours, and 2% with 7–14 days¹². The Performance Monitoring for Action (PMA) 2020 survey, administered at six weeks postpartum, found that 35% of women had PNC within 48 hours of birth, and an additional 15% had PNC between 48 hours and 6 weeks¹³. Nearly 50% of women received no PNC at all. MOH policy promotes community-based care through health extension workers (HEWs) conducting PNC home visits. The 2016 EDHS however found that only 1% of postnatal checks were conducted by HEWs.

WHO guidelines on self-care interventions declare that, “Self-care interventions are among the most promising and exciting approaches to improve health and well-being, both from a health systems perspective and for the users of these

interventions. Self-care interventions hold the promise to be good for everyone and to move us closer to realizing universal health. They represent a significant push towards greater self-determination, self-efficacy, autonomy and engagement in health for self-carers and caregivers.”¹⁴ WHO defines self-care interventions as “evidence-based, high-quality drugs, devices, diagnostics and/or digital interventions that can be provided fully or partially outside formal health services and be used with or without a health worker.” The availability of user-friendly technologies such as digital blood pressure machines and infrared thermometers offers an opportunity to test a self-care model for PNC to increase the very low coverage of PNC for mothers and newborns in the first week of life.

Family-led postnatal care (FPNC) is an innovative model for reaching postnatal women and newborns with key PNC services during the first week of life that leverages self-care principles. The design of the model reflects key insights about the local context that were gathered through human-centered design (HCD) activities conducted by ThinkPlace, Kenya-based private consulting firm that specializes in HCD:

- Postnatal women and their family members do not want women and newborns to leave the home in the first 42 days after birth, and particularly in the first 10 days after birth
- In the postnatal period, women most trust their immediate family members, religious leaders, and neighbors when making seeking care/advice or making decisions.
- A postnatal woman must “prove herself” as a good mother, and she fears not knowing how to care for her newborn, or how to recognize problems.
- If a maternal and newborn problem occurs, the family is regarded as having done something wrong.
- Postnatal women and their families only seek out health providers and health facilities as a last resort, when they are in dire need.

The HCD-informed intervention (described in more detail in the intervention section) starts with an assessment by a discharge counselor in a health center, followed by a self-care model, whereby a postnatal woman and her family conduct daily assessments of the postnatal woman and her newborn, using screening devices and visual cues. We hypothesize that this FPNC model will increase coverage of key components of PNC within 24 hours, 24–72 hours, and 73 hours–7 days; and it will increase detection of danger signs and care-seeking behavior.

To our knowledge, no family-led care model for routine PNC has been implemented or studied in a low-resource setting. Our observations in Ethiopia and other sub-Saharan African countries indicate low levels of PNC coverage and poor-quality PNC when it is offered. Given the lack of substantial progress in improving quality and coverage in recent years,

innovative PNC models may be useful to inform national and global investments. This study aims to assess the feasibility and acceptability of a family-led care model to increase coverage and quality of postnatal care in Ethiopia. The study will draw on perspectives of women and men to evaluate the impact of self- and family- care on gender norms at the individual and couple/family levels during the postnatal period. If study results are positive, a self-care model for PNC could inspire the development of self-care approaches for other primary health care services.

Protocol

Ethics

Ethics approval was obtained by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (IRB No. 21096) and the Addis Continental Institute of Public Health Institutional Ethical Review Board (IRB No. 0029).

Study setting

This study will take place in health centers and their catchment areas in Ada'a District, Oromia Region, Ethiopia. The Ada'a District Profile is summarized in [Table 1](#). It is one of the districts in East Showa zone, where most of the population resides in rural areas¹¹. The district primary health care system in Ethiopia consists of a primary hospital, five health centers and five health posts under each health center. Health extension workers (HEWs) provide preventative and curative services, including maternal, newborn and child health services, at health posts and through home visits. Deliveries are expected to take place in health centers and hospitals.

Four health centers in Ada District were purposively selected to participate, and all surrounding communities will be invited to participate. One health center has been involved in the conceptualization, design, and beta testing of the FPNC model components and will be excluded from the study.

Study design

This study will use a sequential mixed methods design: repeated cross-sectional quantitative pre-intervention and post-intervention surveys and phenomenological qualitative study design.

Prior to FPNC introduction, we will conduct a quantitative pre-intervention survey over approximately eight weeks to measure coverage of postnatal checks within 24 hours, 24–72 hours, and 73 hours–seven days and care-seeking behavior.

Following FPNC introduction, for approximately eight weeks, we will use a mixed methods approach to measure primary and secondary outcomes through face-to-face interviews, health facility data abstraction, checklist reviews, in-depth interviews, clinical observations, and key informant interviews. The qualitative guides include questions assessing the perspectives of different genders on their experiences with the intervention, as well as self-reported changes in knowledge, attitudes, and behaviors related to gender norms in the early postnatal period. Costs associated with resource adaptation and production for the FPNC intervention package will be assessed by project monitoring data. Six months after study completion, we will conduct a quantitative measurement of sustainability of the FPNC intervention through site visits to check the functionality of the devices kept in the community homecare kits (HCKs) and the registers used to track and manage the devices in the HCKs.

The study was registered at ClinicalTrials.gov (NCT05563974), first posted on 3rd October 2022.

Participants

The study population will be: 1) eligible women who deliver at the four study health centers; 2) eligible partners; 3) eligible women's family members; 4) discharge counselors on staff at the four health centers; 5) health extension workers in the catchment area of the four health centers; 6) home care kit custodians in the community; and 7) health managers (district health managers and health center managers). The sex of participants is defined based on self-report. All participants will be a minimum of 15 years old, with women and men eligible for participation. [Table 2](#) presents eligibility criteria.

Sample size

The sample size is calculated using the 2016 EDHS coverage of PNC within 24 hours of 17%. There are no data on current coverage of PNC beyond the first 24 hours, and we

Table 1. Ada'a District profile.

Indicator	Number
Population	204,847*
Number of health centers	5
Number of kebeles (villages)	22
Number of health posts	22
Number of births	7,109/year
Number of discharge counselors in district (at health center)	8 (1–2 per health center)
Number of health extension workers	37

*2007 Population and Housing Census, FDR Ethiopia Population Census Commission, 2008.

estimate that it is less than 17%. With a desired increase to 45% due to the intervention, a 5% level of significance, 80% power, a design effect of 2.0, and a non-response rate of 10%, the minimum sample size required to measure our primary outcome is 109 postnatal women at both pre-intervention and post-intervention, for a total of 218 postnatal women. There will be up to 20 key informant interviews (KIIs) and 88 in-depth interviews. The qualitative interviews will continue until information saturation.

The sample size for quantitative and qualitative data collection are presented in [Table 3](#).

Sampling procedure

Postnatal women who give birth at the study health centers will be included sequentially until the sample size is fulfilled for the quantitative component. For the qualitative component, purposive sampling will be employed, based on the checklists and consultation with HEWs and the HCK custodians.

Table 2. Inclusion and exclusion criteria for each type of study participant.

Participants	Inclusion criteria	Exclusion criteria
Health center discharge counselors	<ul style="list-style-type: none"> Provides postnatal care at intervention health center Willing to participate in study 	
Postnatal women and family members	<ul style="list-style-type: none"> Per participant report, age 15 years or older Delivered at the intervention health centers Maximum of Postnatal Day 1-3 at HC Intends to remain within catchment area for first week after birth Has family members who are willing to participate in the study Able and willing to provide consent 	<ul style="list-style-type: none"> Women who are unable to provide valid information because of mental or other serious health condition
Partners	<ul style="list-style-type: none"> Per participant report, age 15 years or older Partner of eligible postnatal woman who has consented to participate Able and willing to provide consent 	
Family members	<ul style="list-style-type: none"> Per participant report, age 15 years or older Family members of eligible postnatal women who have consented to participate Able and willing to provide consent 	<ul style="list-style-type: none"> 15–18 year old members who are not emancipated minors (married or have children of their own)
Health extension workers	<ul style="list-style-type: none"> Works within catchment area of intervention health center Willing to participate in study 	<ul style="list-style-type: none"> Is not selected to participate (i.e., if there is more than one HEWs per health post)
Home care kit custodian	<ul style="list-style-type: none"> Able and willing to provide consent 	
Health managers	<ul style="list-style-type: none"> Able and willing to provide consent 	

Table 3. Sample size per respondent.

Respondent type	Quantitative measures	Qualitative measures
Health center discharge counselors	0	Up to 12
Postnatal women	218	Up to 20
Family members	0	Up to 20
Partners	0	Up to 20
Health extension workers	0	Up to 20
HCK custodians	0	Up to 8
Health managers	0	Up to 8

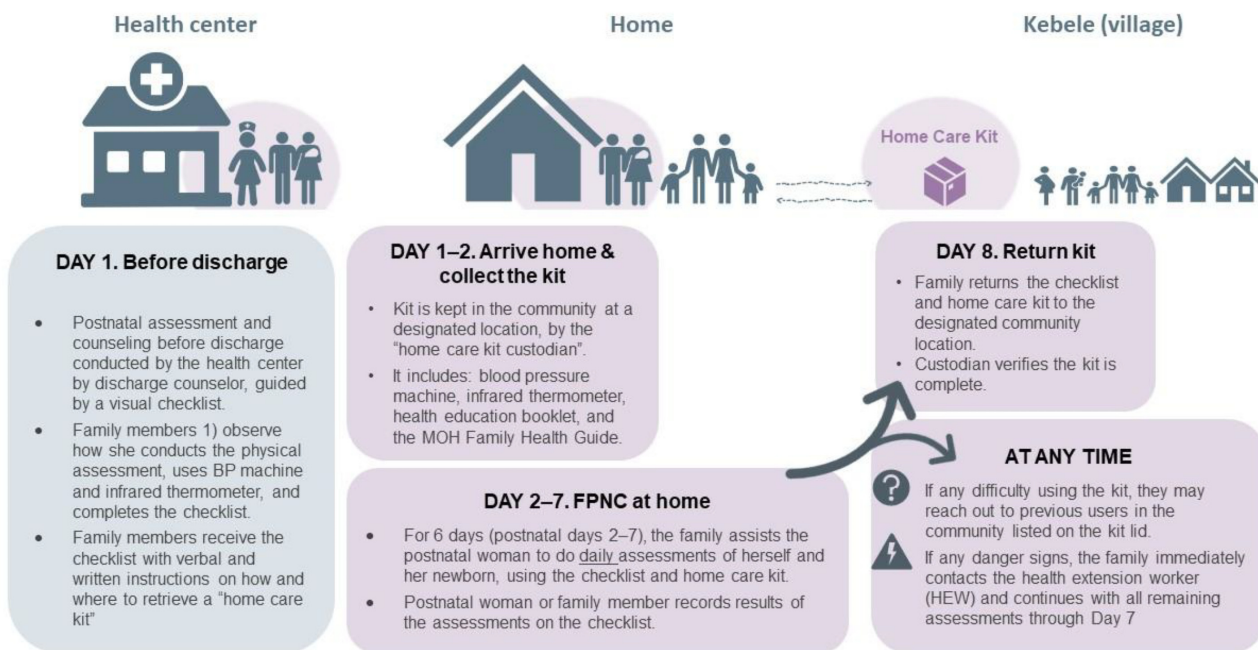
Description of the FPNC Intervention

FPNC is a novel model for reaching postnatal women and newborns with key PNC services during the first week of life that is founded on self-care principles. Informed by HCD findings, FPNC consists of the following components (see Figure 1):

- Facility-based postnatal assessment and counseling, prior to discharge from the health center (within 24 hours of delivery): a postnatal assessment is conducted by the health center discharge counselor, guided by a step-by-step discharge script and a visual checklist. The discharge counselor invites family members into the postnatal room for them to 1) observe how he or she conducts the physical assessment; 2) observe how he or she operates the blood pressure machine and infrared thermometer; 3) participate in the counseling; and 4) observe how he or she completes the checklist.
- At the time of discharge, the discharge counselor gives the checklist to the family with verbal and written instructions on how and where to retrieve a “home care kit (HCK)” that includes blood pressure machine, infrared thermometer, health education booklet, and the Ministry of Health’s Family Health Guide.
- After arriving home, a family member retrieves the HCK from the designated community location. The “HCK custodian” checks out the care kit to the family

member and records the check-out date and location in a register.

- For six days (postnatal days 2–7), the family assists the postnatal woman to do daily assessments of herself and her newborn, using the checklist and HCK. If a family has difficulty using the devices in the HCK, they may reach out to other families who have previously used the HCK. A log on the lid of the HCK indicates who else in the community has used the HCK.
- The postnatal woman or family member records results of the assessments on the checklist. If the assessment reveals any danger signs, the checklist instructs the family to immediately contact the HEW and to continue with all remaining assessments through Day 7.
- On approximately the eighth day after delivery, the family returns the checklist and HCK to the designated community location. The HCK custodian verifies that all equipment is in place and records in the register that the care kit has been returned. The custodian asks the family for permission to record the family’s contact information on the HCK log in case other families need guidance on how to use the HCK devices. If the family member grants permission, the information is recorded in the HCK log.



Leader by OIIM; Pharmacy and Nurse by Adrien Coquet; Family Home by corpus delicti; backpack person and priest by Gan Khoon Lay from NounProject.com

Figure 1. Implementation of the FPNC intervention.

- At least monthly, the HEW collects the completed checklists and records the assessments in the Integrated Maternal Newborn Child Health Card and health post Health Management Information System (HMIS) reporting form.
- In the event that a woman delivers at home, has heard about the HCK, and a family member arrives to retrieve the HCK, the custodian will have extra checklists available to give to the family member, together with the HCK. Those checklists will be printed on a different color of paper so that the investigators may determine how often postnatal women who deliver at home hear about and utilize the FPNC approach.

Outcomes

Primary outcomes

Proportion of women and newborns who have a postnatal check within 24 hours, 24–72 hours, and 73 hours–7 days

- Proportion of women and newborns who assess key PNC components within 24 hours, 24–72 hours, and 73 hours–7 days
- Average number of days any PNC assessed (women and newborns)

Secondary outcomes

Care-seeking

- Proportion of postnatal women who identified having a danger sign
- Proportion of newborns with a danger sign identified
- Proportion of women and newborns who seek care from a health provider when a postnatal danger sign is identified (disaggregated by type of provider and type of facility)

Feasibility

- Proportion of women discharged from facility whose family member retrieves the HCK
- Proportion of families who report successful use of BP cuff by women
- Proportion of families who report successful use of thermometer by women for woman and for newborn
- Proportion of HCKs returned by Day 8
- Proportion of checklists returned with the HCK
- Proportion of checklists collected by HEW
- Proportion of HCKs that are 100% functional upon monthly checks of a random sample of HCKs
- Proportion of registers that are filled completely by HCK custodian
- Proportion of families who communicate with past HCK users

Acceptability

- Proportion of women who give birth at health facility and accept a checklist from the discharge counselor
- Proportion of postnatal women who report they prefer this PNC approach
- Proportion of postnatal women who report confidence in this PNC approach
- Perceptions of discharge counselors regarding acceptance/support of the FPNC approach (including discharge process)
- Perception of HCK custodians regarding the FPNC approach
- Perception of health managers regarding the FPNC approach
- Perceptions of HEWs regarding the FPNC approach
- Woman's perception of changes in her empowerment/agency
- Family's perception of changes in their empowerment/agency
- Partner and family perception of Partner's engagement in PNC

Data analysis and statistical plan

Quantitative: Among all participating women, we will describe the proportion of women and newborns who have a postnatal check within 24 hours, 24–72 hours, and 73 hours–7 days. Moreover, the percentage of women who assess key PNC components within 24 hours, 24–72 hours, and 73 hours–7 days; the mean/median number of days any PNC assessed will be described. Our first comparative contrast of interest will be to compare the proportion of women who have a postnatal check within 24 hours, 24–72 hours, and 73 hours–7 days between pre-intervention and end-line. We will estimate the difference in proportion along with a 95% confidence interval. We will repeat this analysis for newborns and other primary outcomes. When conducting these analyses, we will incorporate as necessary covariates that might confound the true relationship between intervention and outcome.

To estimate the impact of the FPNC approach, as this intervention of interest is allocated at the health facility level, our estimate of the standard error in the difference in proportions and mean will be underestimated unless we account for the correlation within health posts/clusters (or equivalently, the difference between health posts/clusters). Generalized estimation equations (GEE) with logit link with binomial distribution family for binary outcomes and identity link with Gaussian distribution family for numeric outcomes will be used to consider the clustered nature of the data. Crude and adjusted odds ratios for binary outcomes and beta coefficients for numeric outcomes will be estimated along with corresponding 95% confidence intervals to control potential confounders

like educational status and age. STATA version 15 software will be used to analyze the data¹⁵. We will not impute any outcome data. If it is required to provide adjusted estimate of the effect sizes for the primary or secondary study outcomes, we may use multiple imputation to replace missing covariate data, if there are missing data of sociodemographic characteristics of >5% and the data are assumed to be missing at random.

Similar analysis methods will be used to address the secondary outcomes.

Qualitative: Thematic analysis is an appropriate method of analysis for seeking to understand experiences with FPNC and self-reported, thoughts, knowledge, attitudes and behaviors related to self-and family-care and gender norms in the early postnatal period. Themes will be inductively constructed and patterns (or meanings) will be derived. Themes will be generated by familiarization with the data, generating initial codes, searching for themes, reviewing themes, and defining and naming themes. When feasible, women's and men's perspectives will be analyzed separately and triangulated to determine sex and gender implications of the study. Data will be transcribed and translated to English language. Open code software will be used for analyzing the qualitative data.

Dissemination of study results

The study team plans to disseminate findings among global, national and sub-national stakeholders through in-country dissemination events and globally through peer-reviewed journal manuscripts and international conference presentations. One journal manuscript is planned to report on study results.

Study status

The study is active. Pre-intervention data collection has been completed. Post-intervention data collection began in February 2023.

Conclusions

The study will contribute to the body of evidence that will inform decision makers locally and globally on whether FPNC is a feasible service delivery model that is more acceptable and effective than existing PNC delivery. The findings of this study, collating women's, men's, and varied health service delivery actors' perspectives, are expected to inform decision-making at different levels on whether to adopt the model as a matter of policy, and how FPNC can be integrated into routine service delivery.

Data availability

No data are associated with this article.

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Open Peer Review

Current Peer Review Status: ?

Version 1

Reviewer Report 10 October 2023

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I believe, it is implementation research using mixed method. The study design seems more appropriate for the babies born in health facilities. As it also mentions including homebirth, but is not explicit how they will be sampled. More importantly, the sample size estimation is not well explained. It is anticipated that variation will occur while assessing acceptability and feasibility. Given that, you may consider to expand the study sites. In addition, please mention if you also include very low birthweight babies and twin babies in the sample. For the qualitative component, how will the phenomenology be used to explain embodied experience of mothers?

Please provide visual image of FPNC kit including checklist. For homebirth, intervention package does not seem strong. Can you involve trained health extension workers to orient the family to use the FPNC package. How will the very low birthweight babies and the twin babies be managed? Will you include exclusive breastfeeding in FPNC package? How will the mothers with insufficient milk flow be supported? In addition, the package seems to be useful for literate participants. How will the package be made user-friendly even for the illiterate ones?

Please find further comments in the [attached pdf](#)

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
