

A Community-Based Family-Focused Experiential Learning Intervention to Improve Micronutrient Status and Maternal-Infant Outcomes Among Rural Antenatal Women in India: Study Protocol for a Randomized Controlled trial

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Abstract

Background: Micronutrient deficiency, a global issue, especially affects pregnant women and children, leading to health problems(1–3). The issue is more severe in low-income countries due to poor diets, causing multiple deficiencies (4). During pregnancy, meeting nutritional needs like iron, calcium, and vitamin D through diet alone is challenging (3). In India, low intake of these nutrients contributes to anemia and vitamin D deficiency. We aim to determine the effectiveness of community-based family-focused experiential learning intervention to improve micronutrients, maternal and infant outcomes. **Methods:** A parallel-group, two-arm randomized controlled trial of a community-based, complex intervention in rural India aims to decrease micronutrient deficiency, including anemia, calcium, and vitamin D deficiency. The primary outcomes are defined as hemoglobin < 11 g/dL, serum calcium < 8.6 mg/dL, and 25(OH)D ≤ 20 ng/mL, which will be assessed using biochemical methods. Secondary outcomes, including maternal behavioral changes, infant growth, and development, will be assessed using questionnaires in the third trimester and six months after delivery. The Primary Health Center (PHC) is the unit of randomization.

Twenty PHCs in Thiruvallur district, Tamil Nadu, will be randomized in a 1:1 ratio based on inclusion criteria. The intervention comprises two phases. Phase I will be conducted in the PHC and will include teaching and discussion, food plate counseling, a food selection workshop, and a cooking demonstration on a group basis, with handouts on micronutrients provided. Phase II will take place at home and will consist of a home visit featuring a modified Paramapadham mini flash card game and a cooking demonstration, along with micronutrient handouts to reinforce learning. For the control group, only routine care will be provided by healthcare professionals at the PHCs. **Discussion:** Engaging rural antenatal women in reducing micronutrient deficiencies (iron, calcium, and vitamin D) remains a challenge and is often a missed opportunity for prevention. The community-based, family-focused experiential learning intervention primarily targets these deficiencies and aims to bridge evidence gaps on utilizing pregnancy as a key period to improve micronutrient status. If successful, this approach could significantly enhance the health of women in resource-limited settings worldwide. **Trial registration:** Clinical Trial Registry, REF/2022/06/055817 N

Keywords: Micronutrients, pregnant women, infants, family focused experiential learning intervention.

Introduction and Need for the study

Micronutrient deficiencies affect over two billion people globally, particularly in low-income countries. (4) emphasized that inadequate micronutrient intake during pregnancy, especially iron, leads to poor fetal growth, preterm birth, reduced infant survival, and increased risk of chronic diseases. Maintaining optimal micronutrient levels and adopting healthy dietary practices during pregnancy are crucial for positive birth outcomes. Research suggests an interrelationship between minerals in metabolism. Low vitamin D levels exacerbate iron deficiency, increasing anemia risk (5). (6) reported that calcitriol (1,25(OH)2D) enhances calcium absorption, bone resorption, and reduces renal calcium excretion. Cultural factors also influence maternal nutrition. (7) noted patriarchal family structures often dictate pregnant women's dietary practices. (8) found folic acid and vitamin D intake during pregnancy below recommended levels. (9) highlighted that local knowledge-based interventions help counter anemia linked to cultural food taboos. Experiential learning-based training improves facilitator effectiveness in group antenatal care(10). Given the lack of iron, calcium, and vitamin D interventions, this study explores a family-focused experiential learning approach to enhance micronutrient knowledge and improve maternal-infant outcomes.

Despite the recognized importance of micronutrients, there is a lack of interventional studies focusing on improving iron, calcium, and vitamin D status among pregnant women. This study introduces a community-based, family-focused experiential learning intervention designed to enhance micronutrient knowledge and promote healthy dietary behaviors among rural antenatal women. By actively engaging pregnant women and their families, the intervention aims to improve maternal and infant outcomes through interactive learning strategies, including discussions, food selection

workshops, cooking demonstrations, and play-based activities. This approach empowers families to make informed nutritional choices, fostering sustainable dietary improvements within the community.

Materials and Methods

Research approach

A quantitative approach was adopted for this study.

Objectives

1. Evaluate the effectiveness of community-based based family-focused experiential learning interventions on

i) Maternal Biochemical measures:

- hemoglobin
- Serum calcium
- Vitamin D: Serum 25 (OH)D

ii) Maternal Behavioural measure:

Maternal Knowledge and practice on Iron, calcium and vitamin D, micronutrient intake, gestational weight gain, gestational age at birth and antepartum, intrapartum, and postpartum complications.

iii) Infant outcomes:

Birth weight and infants' development on Cognitive, motor, socio-emotional, language, adaptive behavior, length-for-age, weight-for-age, and weight-for-length at 6 months.

Trial design :This is a community-based, non-blinded, parallel-group, two-arm randomized controlled trial, with an allocation ratio 1:1, conducted in a primary health center in Thiruvallur district, Tamil Nadu. PHC is the unit of randomization. PHC was randomized to the family-focused experiential learning intervention and routine arm

Manipulation: Rural antenatal women in the intervention group will receive a family-focused experiential learning intervention in addition to routine care. The family-focused experiential learning intervention will be given to rural antenatal women and their family members. This intervention will consist of two phases. Phase I will be an experiential learning session that will include four sessions: teaching and

discussions, micronutrient food plate counseling, food selection workshops, and cooking demonstrations. Each session will be carried out for 40 minutes once every two weeks, for four consecutive weeks (two months) on a group basis (7-9 members) at selected primary health centers. During Phase II, an interactive learning session will involve a home visit and will contain two sessions, such as a Paramapatham mini flashcard game and a cooking demonstration for two hours. Rural antenatal women and their families will participate in these sessions.

Control: The rural antenatal women in the control group will receive routine care provided by the health care professionals at the primary health center. Women in the control group will usually be encouraged to attend follow-up visits until six months after delivery. Additionally, the control group will receive a brief intervention at the end of the study to ensure justice and to achieve a high degree of post-recruitment satisfaction.

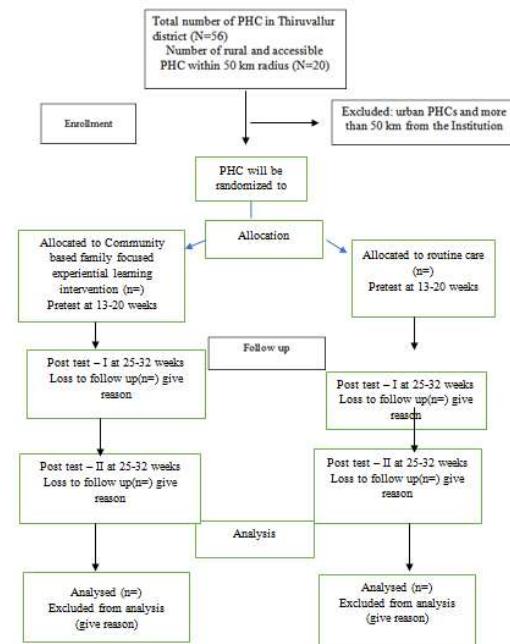
Study setting: The study will be conducted in rural primary health centers in the Thiruvallur district of Tamil Nadu. The district will have 56 primary health centers, covering 303 health sub-centers. The researcher will select 20 PHCs based on their rural location and accessibility within a 50 km radius of the institution.

Randomization and Allocation

Concealment: The unit of randomization will be PHCs. The Thiruvallur district will contain 56 PHCs. Out of these, 20 will be selected based on their rural location and accessibility from the institution. Using simple randomization, two PHCs will be chosen and allocated to the intervention arm, while another two will be assigned to the control arm in a 1:1 ratio.

Implementation: Enrollment in the study will be proposed to all eligible rural antenatal women attending antenatal visits in the selected primary health centers during recruitment. Purposive random sampling techniques will be used to select participants by choosing any one micronutrient-deficient rural antenatal woman. From each PHC, 35 participants will be recruited to attain the required sample size.

The consort diagram of the study flow is illustrated



Study Variables

Independent Variable

- Family-focused experiential learning intervention delivered by the researcher and routine care provided by healthcare providers.

Dependent Variables

1. Maternal Outcomes:
 - o Biochemical assessment: Hemoglobin, serum calcium, and 25(OH)D concentration.
 - o Behavioral assessment: Knowledge and practice questionnaire on micronutrients (anemia, calcium, and vitamin D).
 - o Dietary assessment: 24-hour recall and semi-quantitative food frequency questionnaire.
 - o Clinical outcomes: Gestational weight gain, gestational age at delivery, mode of delivery, and antepartum, intrapartum, and postpartum complications.
2. Infant Outcomes:
 - o Birth weight and growth indicators (length-for-age, weight-for-age, and weight-for-length).

- Developmental outcomes: Cognitive, motor, socio-emotional, language, and adaptive behavior.

Population

The study will focus on antenatal women from rural areas who visit primary health centers. The accessible population will include antenatal women attending antenatal clinics at selected rural primary health centers in the Thiruvallur district.

Sample

The study will include antenatal women from rural areas in the Thiruvallur district who meet the inclusion and exclusion criteria and attend the selected PHC during the enrollment period.

Sampling Criteria

Inclusion Criteria

This study will include rural antenatal women who:

- Are between 18 to 40 years old and are between 13 to 20 weeks of gestation.
- Have mild anemia (10-10.9 g/dL) or moderate anemia (7-9.9 g/dL) or experience calcium deficiency (< 8.6 mg/dL) or vitamin D deficiency (< 20 ng/mL).
- Can understand Tamil or English.

Exclusion Criteria

This study will exclude rural antenatal women who:

- Have a past or present history of liver or renal disease.
- Have a past or present history of psychiatric illness.
- Have severe anemia.
- Not willing to participate

Sample Size Calculation

The sample size was calculated based on the variable "hemoglobin level". the mean and standard deviation are 0.56 ± 0.40 in the intervention group and 0.16 ± 0.82 in the control group respectively. μ_d 2: the mean difference between the samples = 0.4, α : significance level =5, $1-\beta$: power = 90. So, the

sample calculated was 55 to account for follow-up 20% attrition is $55+11=66$ as 70 samples in each group

Data Collection and Instruments

Tool 1: Background Variable Proforma

Section A: Demographic Variable Proforma

The researcher will develop and administer this tool at enrollment (13-20 weeks gestation) to collect demographic data such as age, education, occupation (of both women and husbands), family type, diet, income, food selection, cell phone type, and the number of accompanying persons. The aim will be to investigate how these variables affect study outcomes among rural antenatal women.

Section B: Obstetric Variable Proforma

Obstetric history will be collected to identify factors influencing study outcomes. This section will include 17 pregnancy and delivery-related variables (e.g., age at marriage, age at menarche, gestational week, children, pregnancy frequency, spacing, breastfeeding duration, abortion history, complications, cesarean section, and diseases such as malaria, parasites, thyroid disorders, hypertension, and excessive menstrual bleeding).

Section C: Biochemical and Physiological Variable Proforma

The study will measure maternal micronutrients such as hemoglobin, serum calcium, and 25(OH)D levels at three points: baseline (13-20 weeks), post-test I (25-32 weeks), and post-test II (6 months after delivery). PHC laboratory technicians will collect blood samples. Maternal height and weight will also be measured at enrollment, and BMI will be calculated. Maternal weight at delivery will be noted from medical records.

Biochemical Measures Interpretation

Hemoglobin: Measured using photometric cyanmethemoglobin (normal ≥ 11 g/dL, mild anemia 10-10.9, moderate 7-9.9, severe 4-6.9).

Serum Calcium: Measured using Arsenazo III colorimetric (normal 8.6-10.3 mg/dL, deficient <8.6).

25(OH)D: Measured using electro-chemiluminescence (normal ≥ 30 ng/ml, insufficiency 20-29.9, deficiency ≤ 20).

Tool 2, the Knowledge and Practice Questionnaire on Micronutrients, will be a structured questionnaire designed to evaluate knowledge and practice regarding anemia, calcium, and vitamin D at three time points: baseline, post-test I, and post-test II. A trained outcome assessor will administer this tool. The questionnaire will consist of two main parts. Part I, Knowledge, will include Section A with 20 multiple-choice questions on anemia—covering awareness, investigation, treatment, prevention, and complications—with a total possible score of 50. Section B will include 15 multiple-choice questions on calcium and vitamin D, focusing on awareness, diagnosis, and treatment, with a total possible score of 30. Part II, Practice, will comprise Section A with 15 yes/no items on anemia-related food practices (scored out of 10) and Section B with 10 yes/no items on sun exposure and dietary intake of calcium and vitamin D (also scored out of 10). For scoring and interpretation, knowledge scores will be categorized as 0–40 (inadequate), 41–60 (moderately adequate), and 61–80 (adequate), while practice scores will be classified as 0–10 (unsatisfactory), 11–15 (moderately satisfactory), and 16–20 (satisfactory), with a total possible score of 100 combining knowledge and practice. The tool will be validated by 10 experts, translated into Tamil, and back-translated for accuracy. Pretesting will be conducted with 12 rural antenatal women to ensure clarity and reliability.

Tool 3: Dietary Assessment Scale

This tool will consist of two parts: a 24-hour dietary recall and a semi-quantitative food frequency questionnaire. The 24-hour dietary recall will be used to assess the impact of the intervention and routine care at baseline, post-test I, and post-test II. To

ensure variability, a three-day recall—including two weekdays and one weekend—will be conducted. Portion sizes will be estimated using models and pictures, and each interview will take approximately 20 minutes. The semi-quantitative food frequency questionnaire will record the frequency and quantity of food intake using household measures and units. It will be developed based on the Indian Food Composition Tables (IFCT 2017) to select nutrient-rich foods, and will also be administered at baseline, post-test I, and post-test II. For validity and reliability, the tool will be validated by 10 experts, translated into Tamil, and back-translated. Pretesting will be conducted with 12 rural antenatal women to ensure clarity and appropriateness.

Ethical consideration

The Institutional Ethics Committee (IEC-II) approved the study concerning IEC NI/22/APR/82/52 of Sri Ramachandra Institute of Higher Education and Research (DU) on 07.06.2022. Administrative permission was obtained from the Director of the Directorate of Public Health of Teynampet, Poonamallee, and Thiruvallur. This trial was registered under the clinical trial registry of India with Trail No: REF/2022/06/055817. Written informed consent in Tamil and English languages was obtained from the rural antenatal women before recruiting them into the study. The researcher assured the right to withdraw from the study at any time during the study period with voluntary participation. Confidentiality and anonymity of the rural antenatal women were maintained throughout the study.

Plan of analysis

Data analysis was planned in consultation with a Statistician using R software. Based on the objectives and Hypothesis of the study descriptive (Frequency and percentage) inferential statistics (Independent t-test, Paired t-test, Repeated measures ANOVA, Post-hoc test using Bonferroni, and Chi-square test were planned.

Conclusion

This study protocol outlines a rigorous, community-based, family-focused experiential learning intervention designed to address micronutrient deficiencies—specifically iron, calcium, and vitamin D—among rural antenatal women in India. By integrating group education, practical workshops, home-based reinforcement, and family involvement, the intervention seeks to empower women and their families with the knowledge and skills necessary to improve maternal and infant health outcomes.

If proven effective, this approach has the potential to inform scalable, sustainable strategies for reducing micronutrient deficiencies and associated adverse outcomes in resource-limited settings. The findings from this trial will contribute valuable evidence to the field of maternal and child nutrition, supporting the development of culturally appropriate, community-driven interventions. Ultimately, this protocol aims to bridge critical gaps in preventive nutrition during pregnancy and foster long-term improvements in maternal and child well-being.

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