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An evaluation of community prevention of acute malnutrition (CPAM) in Jharkhand, India

Submission date	**Recruitment status**
10/11/2021	Stopped
Registration date	**Overall study status**
10/11/2021	Stopped
Last Edited	**Condition category**
30/10/2026	Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Nearly half of deaths in children in low and middle-income countries are caused by undernutrition. Undernutrition is caused by pregnant mothers and their children consuming too little food and nutrients, illness, and carers not knowing the best ways to feed and care for young children. When children become too thin for their height they develop acute malnutrition, which makes them more likely to get ill or even die. Acute malnutrition is a major problem in Jharkhand state in India, especially amongst scheduled tribes and scheduled castes, so we need to find out the best way to prevent it.

The aim of the Community Prevention of Acute Malnutrition (CPAM) evaluation project is to understand if and how participatory group meetings and home visits by Accredited Social Health Activists (ASHAs, or Sahiyas) and their supervisors (Sahiya Sathis) can help improve the health and nutrition of women and children in Jharkhand.

Who can participate?
All pregnant women and mothers or other caregivers of children under three years are invited to participate in the project if they are residents in any of the 76 selected villages in the 6 months before the survey. We will not include children whose mothers have died or who have severe congenital anomalies, nor deaf women or others with whom we cannot communicate.
We will interview and measure around 4540 pairs of mothers and children in 76 villages across 15 blocks in 9 districts between November 2021 and March 2022. Then three years later we will come back to the same villages and interview and measure another 4540 pairs of mothers and children between November 2025 and March 2026.

What does the study involve?
Sahiyas and Sahiya Sathis working in all the villages within Bero, Chakradharpur, Gobindpur, Mahagama, Manjhiaon, Markaccho blocks in West Singhbhum, Dhanbad, Garhwa, Ranchi, Godda, Koderma districts respectively, will carry out CPAM project activities. In each village, they will organise a monthly women's group and visit mothers and children who are at risk of being undernourished. In both the groups and the home visits the Sahiyas will discuss problems associated with undernutrition and how to solve them.
The purpose of group meetings is to help people in the communities to understand

undernutrition and to take action individually and as a community to overcome it. First, the groups will assess the health and nutrition situation, then they decide what actions to take and take action, and finally, they evaluate progress.
During home visits, Sahiyas will ask mothers about their health and that of their newborn or young child and discuss any problems that the family may be having. They will carry out some basic examinations to identify any nutritional or health problems and give counselling on how to overcome the problems discussed.
In the areas where participatory groups and home visits are being organised, anyone is welcome to attend the groups, but we will be encouraging pregnant women and mothers or carers of children under 3 to come in particular. Sahiyas will focus their home visits on mothers and children who belong to scheduled tribes or castes, who live in hamlets or who have children that are sick or thin, or who are very small at birth.

To test whether the CPAM programme works to reduce the number of children and mothers suffering from undernutrition in Jharkhand, Ekjut interviewers will visit all pregnant women and mothers or other caregivers of children under three in 76 villages in 15 blocks in 9 districts. At each visit, the interviewers ask questions about the health and nutrition of the children and mothers and measure the children's height and weight. This will be done once from November 2021 to March 2022 and again from November 2025 to March 2026.

As well as visiting the CPAM programme districts named above, Ekjut interviewers will also visit 38 villages where CPAM programme is not taking place in Bishrampur, Chas, Dumka, Hariharganj, Husainbad, Kasmar, Masalia, Nawadih, Shikaripara blocks within the 3 districts of Bokaro, Dumka and Palamu in Jharkhand. By comparing the nutrition of children in the CPAM programme areas with those in the areas without the programme, we will be able to see if the CPAM programme is effective in preventing acute malnutrition (extreme thinness) in children and in improving other aspects of their health and nutrition.

What are the possible benefits and risks of participating?
There are no immediate benefits for those people participating in the project, but it is hoped that this work will help shape future programmes with Sahiyas and their supervisors (Sahiya Sathis). If a child is severely malnourished, we will refer them to the Anganwadi for further care. Those living in intervention areas may benefit from support and opportunities to learn about health and nutrition if they take part in participatory groups or who have visits from the Sahiyas or Sahiya Sathis.
Participants may find talking about their own or their child's health and diet upsetting. If this happens, they can stop the interview at any time without giving a reason. To prevent the spread of COVID we will follow local, State, and national government guidance on social distancing, mask-wearing, and travel in and out of districts. Interviewers or Sahiyas and participants will keep six feet apart and wear masks wherever possible. All equipment will be cleaned with alcohol or disinfectant before and after use. We think there are no other risks of participating.

Where is the study run from?
A non-governmental organisation called Ekjut is running the CPAM evaluation study from their offices in Chakradharpur and Ranchi in Jharkhand. The address is Plot no. - 556B, Potka, Chakradharpur, West Singhbhum, Pin - 833102, Jharkhand, India.

When is the study starting and how long is it expected to run for?
The CPAM programme is running from 2021 to 2026, and this project to evaluate CPAM will last from November 2021 until March 2026. There will be 2 surveys, the first from November 2021 till March 2022 and the second from November 2025 until March 2026.

Who is funding the study?
The study is funded by the Children's Investment Fund Foundation (CIFF) (International)

Who is the main contact?
India - Principal Investigator: Shibanand Rath, Ekjut, shibanand.ekjut@gmail.com
UK Main point of contact: Naomi Saville, University College London, n.saville@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Naomi Saville

ORCID ID
https://orcid.org/0000-0002-1735-3684

Contact details
Institute for Global Health
University College London
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)20 7242 9789
n.saville@ucl.ac.uk

Type(s)
Public

Contact name
Mr Shibanand Rath

ORCID ID
https://orcid.org/0000-0002-8781-9566

Contact details
EKJUT
Plot no. - 556B, Potka
West Singhbhum
Chakradharpur
India
Pin - 833102
+91-9437229651
shibanand.ekjut@gmail.com

Additional identifiers

Protocol serial number

UCL contract reference 5884134

Study information

Scientific Title
Accredited Social Health Activists (ASHA) and ASHA Facilitators supporting participatory learning and action meetings with women's groups, home visits and referrals to reduce wasting among children aged 0-36 months in Jharkhand, India: a mixed-methods evaluation

Acronym
CPAM evaluation

Study objectives
Our principal hypothesis is that the Community Prevention of Acute Malnutrition (CPAM) programme in Jharkhand, India comprising participatory learning and action women's groups focused upon nutrition, home visits by ASHAs to at-risk pregnant women and children 0-36 months, together with improved referral and linkages to health services, will be associated with a higher mean Weight-for-Height/Length (WHZ) z score in intervention areas relative to control areas where usual government services are available.

Our secondary hypothesis is that the Community Prevention of Acute Malnutrition (CPAM) programme will be associated with improvements in intervention areas relative to control areas in some or all of the following: women's decision-making power over diets, healthcare-seeking for themselves or their child, acute malnutrition preventive practices, and mental health.

The research questions to be answered are as follows:
Impact evaluation
• What are the effects of CPAM on selected preventive and care-seeking practices for pregnant women and children aged 0-36 months?
• What are the effects of CPAM on women's decision-making power over diets, healthcare-seeking for themselves or their child, and mental health?
Process evaluation
• Was the intervention implemented as planned?
• What are the pathways to impact?
• What factors enabled and hindered impact and scale-up?
Economic evaluation
• How cost-effective is CPAM to improve nutritional outcomes compared to usual care?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 13/10/2021, University College London's Research Ethics Committee (Office of the Vice Provost Research, University College London, 2 Taviton Street, London, WC1H 0BT, United Kingdom; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 1881/006

2. Approved 30/10/2021, Ethics committee of Ekjut (Ekjut Institutional Ethics Committee, Ward No.17, Plot No 556B, Potka, Chakradharpur, West Singhbhum, 833102, Jharkhand, India; -; email@unavailable.com), ref: IEC/EKJUT/2021/3

Primary study design

Interventional

Study design
Single-centre non-randomized controlled community interventional trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of acute malnutrition (wasting) in children 0 to 36 months

Interventions
This non-randomised controlled trial has one intervention and one control arm. Participants are eligible to participate in interventions if they are resident in the 18 clusters across the 6 early-implementation districts of Jharkhand state where the Community Prevention of Acute Malnutrition (CPAM) programme is being implemented. They are invited to participate in the control arm if they reside in one of the 18 non-CPAM study clusters.

Allocation of study blocks (sub-divisions of Districts in Jharkhand state, India):
The unit of allocation to intervention and control is a block. Six early CPAM intervention blocks were deterministically selected by the Health Mission in 6 intervention districts on the basis of programmatic priorities. Then in stage 1, nine control blocks were selected deterministically, three per district, to best match the six intervention blocks in terms of the proportion with two key characteristics: scheduled caste or scheduled tribe and female literacy. In the second and third stage of sampling we sampled clusters, and then villages within these clusters respectively, using constrained random sampling to ensure balance between arms in our two key characteristics. Specifically, we sampled three clusters per intervention block and two per control block to give 18 clusters per arm in stage two. We then sampled 38 villages per arm, three from each of the two biggest clusters sampled per arm, and two otherwise in stage 3. In each stage we deleted outliers and then generated a large number of possible random samples. Next, we identified which have close balance between arms (absolute difference less than 1% in each characteristic, and in the third stage a difference in average village population less than 100), and finally we selected one of these at random. In the second stage 5000 possible samples of clusters were randomly drawn of which 104 were closely balanced, and in the third stage 182 possible samples were closely balanced from among 10,000 randomly drawn to provide sufficient population to reach our target sample size of 2,270 children aged 0-36 months in CPAM blocks and 2,270 in non-CPAM blocks. Village representatives will be invited to consent for participation on behalf of their community. Written consent will be sought from women as individual participants.

INTERVENTIONS
The intervention will be led by Sahiya and Sahiya Sathi. Sahiya Sathi receive an incentive of INR 1000 (USD 13) to conduct 10 meetings a month, and Sahiya received INR 100 (USD 1.3) per meeting. Both Sahiya and Sahiya Sathi will receive training using Ekjut's existing women's group facilitation training materials. The training will cover knowledge and skills for counselling to improve Infant and Young Child Feeding (IYCF) practices, prevention of illness, care during illness, and referrals. It will also include practical sessions on conducting participatory group meetings and interacting with other frontline workers.

Sahiya and Sahiya Sathi will carry out two main activities: (a) home visits to at-risk mothers and children aged 0-36 months ; (b) a monthly participatory meeting with their local women's groups.

Previous studies suggest that strengthening problem-solving skills improves self-efficacy and community involvement for health. The Sahiya and Sahiya Sathi will use a problem-solving approach in both of these activities: during home visits they will prioritise mothers' current concerns with feeding and care, and discuss possible solutions and barriers to putting them in practice; during participatory meetings they will help women's groups identify health and nutrition problems and find locally feasible strategies to address them. A detailed description of these activities follows.

Home visits:
Sahiyas will conduct home visits using a combined module based on existing Home-Based Newborn Care modules 6 and 7 used by the National Health Mission, and an additional module on Home-Based Care for the Young Child (HBYC). For CPAM, home visits will be prioritized for (a) children who are low birthweight, sick or have Severe Acute Malnutrition; (b) mothers with three or more children; (c) homes with Scheduled Caste or Scheduled Tribe residents; (d) homes located in hamlets or outskirts of villages. During the home visits, the Sahiya will ask mothers about their health and that of their newborn or young child, carry out simple examinations and offer counselling as recommended in existing government HBNC and HBYC modules.

Participatory meetings with women's groups: The Sahiya and Sahiya Sathi will also carry out a cycle of 24 monthly participatory meetings with women's groups focusing on maternal and child health and nutrition. These meetings will primarily target pregnant and lactating mothers, mothers of children under-2, and adolescent girls but will however be open to other community members. The purpose of group meetings is to increase community understanding of undernutrition and catalyse individual and community-level action to address it. The meeting cycle is structured in four phases: (1) assessing the health and nutrition situation; (2) deciding on actions to take; (3) taking action; (4) evaluating the process. In the first phase, the Sahiya and Sahiya Sathis introduce groups to the meeting cycle as well as seek to understand the impact of the COVID-19 pandemic on health and nutrition in the community. They will then discuss services and entitlements available to mothers and children in the first 1000 days of life, and plan strategies to better access these. The Sahiya and Sahiya Sathis will then describe the intergenerational cycle of undernutrition using a pictorial diagram and encourage groups to discuss local views and practices relating to undernutrition. Groups will then play a picture card game to identify practices that affect growth and development in the first 1000 days, prioritize key problems in the community, and discuss local practices and beliefs related to prioritized problems. Participants are invited to prioritise the problems that they would like to address by voting using the picture cards. The Sahiya and Sahiya Sathis then help group members to discuss the causes of their prioritized problems using story-telling followed by a game in which participants are encouraged to map the causes of their prioritized problems and discuss what strategy could be used to address them. Group members, Sahiya and Sahiya Sathis then collectively assign responsibilities for each strategy, decide on indicators to measure progress and plan a community meeting to share their strategies with other community members and enlist their support. In the third phase, group members implement and review the strategies they have decided upon. At this time the Sahiya and Sahiya Sathis also introduce group members to other positive strategies for them to try, including: understanding the importance of growth promotion; how to have an adequate and diverse diet during pregnancy; exploring myths and taboos relating the maternal and child nutrition; breastfeeding practices and thermal care for infants; diets for young children aged 6-36 months; referral pathways for sick children; understanding local food resources; and planting a kitchen garden. In the fourth and final phase, group members discuss the progress of their strategies and share achievements and difficulties encountered during the meeting cycle. It is anticipated that the Sahiya and Sahiya Sathis will coordinate a full meeting cycle in the course of the study, resulting in a range of individual, household, and community-level strategies.

Intervention Type
Behavioural

Primary outcome(s)
Mean weight-for-height or length z score (WHZ) calculated using 2006 WHO growth standards among children aged 0-36 months, measured in baseline and endline (3 years) cross-sectional surveys.

Key secondary outcome(s)
Measured in baseline and endline (3 years) surveys are defined as follows:
1. % of women achieving minimum dietary diversity (MDD-W, i.e., >=5/10 food groups) Pregnant women and mothers of children aged 0-36 months
2. % of children wasted (WHZ<-2SD) Children aged 0-36 months
3. % of children concurrently wasted (WHZ<-2 SD) and stunted (HAZ<-2 SD) = WaSt Children aged 0-36 months
4. % children exclusively breastfed in the first 180 days ('lifelong recall') Children aged 6-36 months (with subsample of 6-24 m)
5. Mean child dietary diversity score – 24h recall Children aged 6-36 months (with subsample of 6-24 m)
6. % children who received the recommended number of meals as per age recommendations – 24h recall Children aged 6-36 months
7. % of children with diarrhoea in the past 14 days Children aged 0-36 months (aligned with NFHS-5)
8. % of children with fever in the past 14 days Children aged 0-36 months (aligned with NFHS-5)
9. % of children with cough in the past 14 days Children aged 0-36 months (aligned with NFHS-5)
10. % of children with SAM referred to a skilled provider in last 3 months Children aged 0-36 months with SAM
11. % of children who accessed care from a skilled provider if referred for SAM in last 3 months Children aged 0-36 months who were referred for SAM
12. % of pregnant and breastfeeding mothers who received supplementary food Take Home Rations (THR) from Anganwadi Centre (AWC) in last 3 months Pregnant women and mothers of children aged 0-6 months
13. Mean number of IFA tablets consumed in pregnancy Mothers of children aged 0-36 months
14. Mean number of calcium tablets consumed in pregnancy and the first 6 months Mothers of children aged 6-36 months
15. Mean number of ANC visits from a skilled provider (doctor, ANM, nurse or midwife) during pregnancy Mothers of children aged 0-36 months
16. % children who received supplementary food from AWC (cooked or Take Home Rations (THR)) in last 3 months children aged 6-36 months
17. % of children who received Vitamin A in the last 6 months children aged 9-36 months
18. % of children who received deworming in the last 6 months children aged 12-36 months
19. % of children who received full immunisation based on vaccination card (not recall) children aged 12-23 months (aligned with NFHS-5)
20. % of children who received care from a skilled provider for cough, fever, or diarrhoea children aged 0-36 months with symptoms of cough, fever, or diarrhoea

PROPOSED EXPLORATORY OUTCOMES
1. Mean women's dietary diversity score (WDDS) as continuous measure) Pregnant women and mothers of children aged 0-36 months
2. % achieving WDD-W (i.e., >=5/10 food groups) in pregnancy All pregnant women

3. % achieving WDD-W (i.e., >=5/10 food groups) in the postpartum period All mothers of children aged 0-36 months
4. % of women sleeping under a bed net in the previous night All mothers of children aged 0-36 months and all pregnant women
5. Decision-making score about own health, and child's health care and diet All mothers of children aged 0-36 months and all pregnant women
6. Mother's mental health - K10 scale All pregnant women and mothers of children aged 0-36 months
7. % children who were breastfed for up to 2 years Children aged 24-36 months
8. % of children with Minimum Acceptable Diet (combined DDS and minimum meal frequency) Children aged 6-36 months
9. % of children with Minimum DDS Children aged 6-36 months
10. % of children who received timely initiation of complementary feeding Children aged 6-9 months
11. % of children with fever who received a malaria diagnosis following a blood test Children aged 0-36 months who had a blood test
12. % children who slept under a bed net in the past night Children aged 0-36 months
13. % of children given ORS during diarrhoea Children aged 0-36 months who had diarrhoea
14. % of children with Severe Acute Malnutrition (WHZ<-3 SD) Children aged 0-36 months
15. % of children underweight (WAZ <-2 SD) Children aged 0-36 months
16. % of children with severe underweight (WAZ<-3 SD) Children aged 0-36 months

Completion date
30/06/2026

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. All pregnant women;
2. All mothers of children aged 0-36 months; and
3. All children aged 0-36 months (including multiple births)
residing in any of the 76 villages across 36 clusters in 9 control (non-CPAM) and 6 early CPAM intervention blocks

Healthy volunteers allowed
Yes

Age group
Mixed

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Children whose mothers have died
2. Children with severe congenital anomalies
3. Women with severe hearing or other communication impairments that may prevent them from taking part in the survey
4. Women who have not resided in the study clusters in the six months prior to the survey

Date of first enrolment
15/11/2021

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
India

Study participating centre
EKJUT
Plot no. - 556B, Potka
West Singhbhum
Chakradharpur
India
Pin - 833102

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation

Alternative Name(s)

The Children's Investment Fund Foundation, The Children's Investment Fund Foundation (UK), CIFF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the University College London publicly available repository (https://rdr.ucl.ac.uk/). A fully anonymised dataset without any names or other identifiers (i.e., with names of clusters and villages, geolocations, and names of individuals removed) will be shared. The data will become available at the time of publication of the trial findings during 2026 and will be made available indefinitely. Access criteria for sharing the data will be provided on the UCL data sharing repository. Data will be made available to researcher, policy implementers or any other individuals with a legitimate interest for using the data for the global good but not for financial gain. All types of analyses using individual and cluster-level data will be permitted but permission will need to be sought from a data sharing committee comprised of UCL and Ekjut representatives authors prior to use. Consent from participants was obtained through the following statements a) “I understand that data collected will be stored securely. It will not be possible to identify me in any publications” and b) “I agree that my data, after it has been fully anonymised, can be shared with other researchers), including outside India”. Aside from being fully anonymised there will be no other ethical restrictions.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.5	01/10/2021	10/11/2021	No	Yes
Protocol file			10/11/2021	No	No