STUDY PROTOCOL

COMMUNITY PREVENTION OF ACUTE MALNUTRITION IN JHARKHAND, INDIA:

A MIXED METHODS EVALUATION

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

A COLLABORATION BETWEEN EKJUT, UNIVERSITY COLLEGE LONDON AND THE NATIONAL HEALTH MISSION, JHARKHAND

VERSION 1.5

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ABSTRACT

BACKGROUND

There is substantial scientific agreement on the interventions needed to prevent maternal and child undernutrition, but less evidence on how to scale them up effectively through government systems. In addition, few community interventions have succeeded in effectively reducing child wasting (low weight-for-height) and stunting (low length/height-for age) in areas with the highest burden. This evidence gap is particularly great for interventions to prevent child wasting and concurrent wasting and stunting (WaSt). We aim to assess the impact, mechanisms, and cost-effectiveness of a community-led intervention to reduce wasting among children aged 0-36 months in rural Jharkhand, eastern India, where 29.5% of children under five years suffer from wasting and 48% from stunting, through a mixed methods evaluation involving a non-randomised controlled trial, process, and economic evaluations.

METHODS

The programme to be tested relies on government-incentivised community health volunteers called Accredited Social Health Activists (ASHA) and their supervisors, who are called Sahiya and Sahiya Sathi, respectively, in Jharkhand. *Sahiya* and *Sahiya Sathi* will carry out two main activities: (1) a cycle of monthly participatory women's group meetings to catalyse individual and community action for maternal and child health and nutrition; (b) home visits to pregnant women and children aged 0-36 months at risk of undernutrition to support care and diets during pregnancy, infection control, appropriate infant and young child feeding, care and treatment for sick and undernourished children, and, when necessary, linkages and referrals to improve the uptake of preventive and curative government services. In addition, the CPAM programme team will seek to improve the delivery of key health and nutrition services in the intervention areas. Further details on all intervention activities are provided below.

The intervention will be evaluated using a non-randomised controlled trial. The National Health Mission, Jharkhand, in partnership with Ekjut, has selected six blocks (i.e., administrative zones of c.100,000 people) to receive the intervention. They will also select another nine blocks that will not receive the intervention but continue to receive existing government services. Ekjut and

UCL will randomly select 48 villages in blocks that will receive the intervention and 48 in blocks that will not. Trained interviewers will then visit households in these 96 villages to identify all pregnant women and mothers of children aged 0-36 months during both baseline (2021) and endline (2025) surveys. The baseline survey will take place in 2021, during the early stages of the intervention. The endline survey will take place in 2025, after the intervention has ended. Study participants are pregnant women (n=1500 in each survey) and pairs of children aged 0-36 months and their mothers (n=4540 pairs in each survey).

The primary outcome of the trial is mean weight-for-height or length z scores among children aged 0-36 months.

BACKGROUND

Undernutrition is an underlying cause for 45% of child deaths in low- and middle-income countries.[1] Wasting (low weight-for-height) and stunting (low height/length-for-age) are markers of acute and chronic undernutrition, respectively. Considerable research has identified effective nutrition-specific (e.g. nutritional counselling and supplementation) and nutrition-sensitive interventions (e.g. Water, Sanitation and Hygiene, livelihood and social protection interventions) to prevent maternal and child undernutrition, with a focus on the peri-conceptional period and the first 1000 days of life (pregnancy and the first two years of children's lives).[2] There has been considerable research on treatment for acute malnutrition and the prevention of stunting, but less is known about what works to prevent wasting.[3]

Recent research has also highlighted the need for bring together policies, programmes and research on wasting and stunting, given these two manifestations of undernutrition share common risk factors and consequences.[4,5] In addition, children who are concurrently wasted and stunted have a risk of death comparable to children with severe wasting, making interventions that target common risk factors a priority.[6] There is therefore an urgent need for research on effective interventions to prevent child wasting, as well as concurrent wasting and stunting. This is particularly relevant in India, where an estimated 21.5% of children are wasted, 41.2% are stunted, and 7.7% are both wasted and stunted.[7]

Key questions now centre on how to increase the coverage of effective preventive interventions and access to treatment in areas with the highest burden of undernutrition, particularly in the aftermath of COVID.[8] The Government of India's Integrated Child Development Scheme (ICDS) and National Health Mission (NHM) support most globally-recommended nutrition-specific interventions, but the impact of these programmes on wasting has so far been limited.[9] From 1998 to 2015, child height-for-age improved in India, but there was little progress in weight-for-height.[10] Previous trials of community interventions that measured effects on wasting and stunting have either been conducted outside India[11], tested single interventions rather than integrated strategies, or failed to impact on children's weight-for-height and/or length-for-age.[12,13,14] (see Appendix 1 for full details). Several trials identified increases in maternal and

child dietary diversity, but very few (only three out of ten, all non-randomised) found improvements in actual maternal or child anthropometry.[15,16] In addition, no trial to date has reported effects on concurrent wasting and stunting, though many measured effects on underweight, a composite measure.

A subset of Indian trials testing a combination of group meetings using principles of Participatory Learning and Action (PLA) and home visits found mixed results. One RCT tested PLA meetings and universal home visits starting in the third trimester of pregnancy, and found some improvements in maternal and child dietary diversity as well as handwashing, but no changes in maternal or child anthropometric outcomes.[15] In another, non-randomised trial testing group meetings and home visits targeted at at-risk women in any phase of pregnancy, child wasting was reduced by 34%.[17] In both of these trials, interventions were delivered by workers specifically recruited, trained and supervised by the Indian civil society organization Ekjut. Given previous trials have had mixed results, we do not know whether home visits targeted to at-risk women and children and women's group meetings using principles of PLA can improve maternal and child nutrition outcomes, including child weight-for-height, when scaled up through the public health system.

THE CPAM PROGRAMME

From 2016 to 2021, the National Health Mission, Jharkhand has supported the scale up of PLA meetings to improve maternal and child health through Accredited Social Health Activists (ASHA, called Sahiya in Jharkhand) and their supervisors (Sahiya Sathi) across the State's 24 districts. The Mission now aims to capitalize on the Sahiya and Sahiya Sathi's existing training in PLA and their mandate to contribute to maternal and child nutrition through regular home visits for counselling during pregnancy and the first 18 months of life. From 2021 onward, the National Health Mission, Jharkhand, will support a programme for the Community Prevention of Acute Malnutrition (CPAM) in six districts of Jharkhand: West Singhbhum, Bokaro, Garhwa, Ranchi, Godda, Koderma. The programme will start in six blocks of these six districts in year 1 and be gradually scaled up to cover all of the six districts. Table 1 describes the programme's expected

year-wise coverage of Sahiya, pregnant women and children aged 0-36 months, by year. The programme will include PLA women's group meetings and home visits to at-risk women to improve maternal and child nutrition and reduce child wasting.

Years	Sahiya (n)	Pregnant women (n)	Pregnant women covered by programme (45%)	Children aged 0-36 months (n)	Children aged 0-36 months covered by programme (40%)
1	1,046	22,494	10,122	58,681	23,472
2	5,486	117,976	53,089	307,765	123,106
3	10.146	218,190	98,185	569,191	227,676
4	10,146	218,190	98,185	569,191	227,676
TOTAL		**577,570**	**259,581**	**1,504,828**	**601,930**

Table 1: Coverage of Sahiya, pregnant women and children aged 0-36 months by year in the CPAM programme

Note: Coverage was calculated using the Crude Birth Rate per 1000 population and average population size of Sahiya catchment areas (1000 population).

PROGRAMME THEORY OF CHANGE

Figure 1 is the draft programme theory of change developed by Ekjut, the National Health Mission Jharkhand, and the programme's funders, the Children's Investment Fund Foundation.

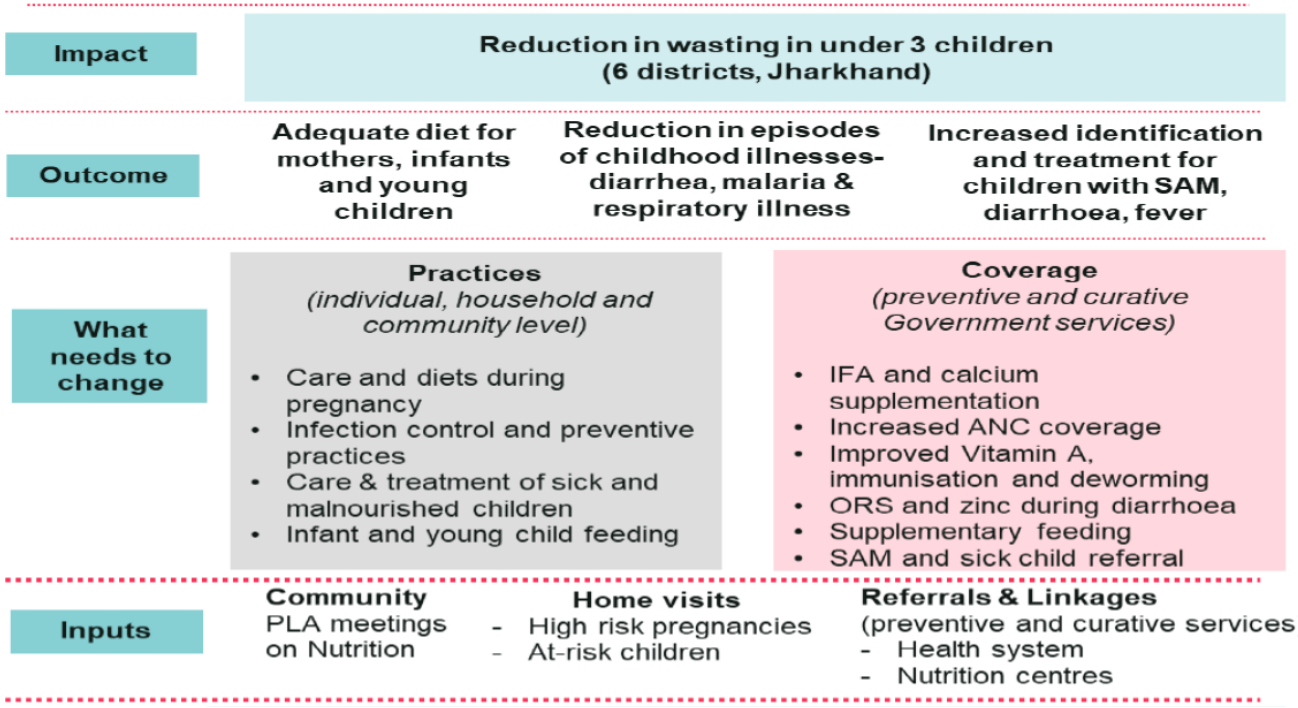


Figure 1: Draft CPAM programme theory of change

This draft theory of change will be revised during a participatory workshop in year 1, to ensure surveys, MIS and qualitative data capture the information needed to evaluate the programme. CPAM's impact, process and economic evaluations will answer one primary research question, and six secondary questions, as detailed below.

PRIMARY RESEARCH QUESTIONS

What is the effect of CPAM on mean Weight-for-Height or length *z* score (WHZ) among children aged 0-36 months?

SECONDARY RESEARCH QUESTIONS

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?

METHODS

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[18]; (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.[19,20] 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.

Service improvement

Service improvement activities will focus on improving: (a) the functioning of Village Health Sanitation and Nutrition Day (VHSND); (b) Growth monitoring by the AWW; (c) Availability of Vitamin A, Iron and Folic Acid tablets and syrup, as well as deworming tablets; and (d) referral for children with Severe Acute Malnutrition.

Current status of the intervention

As we start this evaluation, the first round of five days training of State and District training team members from six early intervention districts has been completed. The training of Sahiya Sathis in the six early blocks will be carried out in September/October 2021 and the training on Home visits for Sahiyas will happen in November 2021.

IMPACT EVALUATION

Study design

We will evaluate the impact of the CPAM intervention using a non-randomised controlled trial.[1]

Study location

The trial will take place in six purposively-selected blocks (Bero, Chakradharpur, Gobindpur, Mahagama, Manjhiaon, Markaccho) located within the six districts taking part in the early scale

[1] We will use this quasi-experimental approach to address logistical and financial constraints: an experimental design with blocks as the unit of randomisation makes it impractical to conduct a parallel cRCT, as this would require 60 blocks and over 60,000 children. A stepped-wedge trial is unfeasible given the short delay (1-1.5 years) between the introduction and scale up of CPAM in the six programme districts.

up of CPAM (West Singhbhum, Dhanbad, Garhwa, Ranchi, Godda, Koderma), and nine purposively-selected blocks (Bishrampur, Chas, Dumka, Hariharganj, Husainbad, Kasmar, Masalia, Nawadih, Shikaripara) within 3 districts (Bokaro, Dumka and Palamu) not taking part in CPAM. For the purpose of this trial, a cluster (the unit of allocation to intervention or control) is a block, i.e., an administrative unit of c.100,000 population. Jharkhand's Health Mission and Ekjut lead the purposive selection of districts and blocks for this study.

Surveys and eligibility criteria

We will carry out two cross-sectional surveys: a baseline survey in Year 1 (2021) and an endline survey in Year 4 (2025). These surveys will be conducted in the same four months of the year (c. Nov-Feb) in all intervention and control clusters, to capture data on the trial outcomes as well as exposure to PLA and home visits.

Inclusion and exclusion criteria

Eligible participants are all pregnant women; all mothers of children aged 0-36 months; all children aged 0-36 months (including multiple births).

We will exclude children whose mothers have died, those with severe congenital anomalies, women with severe hearing or other communication impairments that may prevent them from taking part in the survey, and women who have not resided in the study clusters in the six months prior to the survey.

Primary outcome

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

Secondary and exploratory outcomes

Table 2 describes secondary and exploratory outcomes for the non-randomised trial.

N	SECONDARY OUTCOMES	DENOMINATOR
	Woman	
1	% of women achieving minimum dietary diversity (MDD-W, i.e., >=5/10 food groups)[21]	Pregnant women and mothers of children aged 0-36 months
	Child	
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
	PROPOSED OUTCOMES ON THE IMPACT PATHWAY (differences between arms to be formally tested)	**DENOMINATOR**
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
N	**PROPOSED EXPLORATORY OUTCOMES (descriptive analyses only)**	**DENOMINATOR**
	Woman	
1	Mean women's dietary diversity score (WDDS) as continuous measure)[22]	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
	Child	
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

Table 2: Secondary and exploratory outcomes for the CPAM non-randomised controlled trial

Sample size

Using a range of plausible Intra-cluster Correlation Coefficient (ICC) values (0.007-0.01) for WHZ at block level from earlier studies[15,16], we estimate that sampling 4,320 children aged 0-36 months in each survey (360*6=2,160 in the intervention arm and 240*9= 2,160 in the control arm) would give the evaluation 80% power to detect a 0.15 difference in mean WHZ (from (-1.20 to -1.05) between six intervention and nine control blocks, with an auto-correlation of 0.6 between baseline and endline data. This effect size is consistent with the effect observed in an earlier study of PLA and home visits.[15] Adding 5% to the sample to account for refusals based on previous studies in the State, we will aim to approach 4,540 pairs of mothers and children aged 0-36 months in each survey, 2,270 in CPAM blocks and 2,270 in non-CPAM blocks.

Selection of blocks and villages

The overall sampling process is described in Figure 2. The unit of allocation to intervention and control is a block. Six early CPAM intervention blocks were 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.

The final sample of blocks and clusters and their respective populations are given in Table 3. The average population size per cluster (total of sampled villages) is 2,310 (range 505 to 6,686) in control and is 2,476 (range 642 to 5,208) in intervention arms and total population is 41,588 and 44,568 respectively.

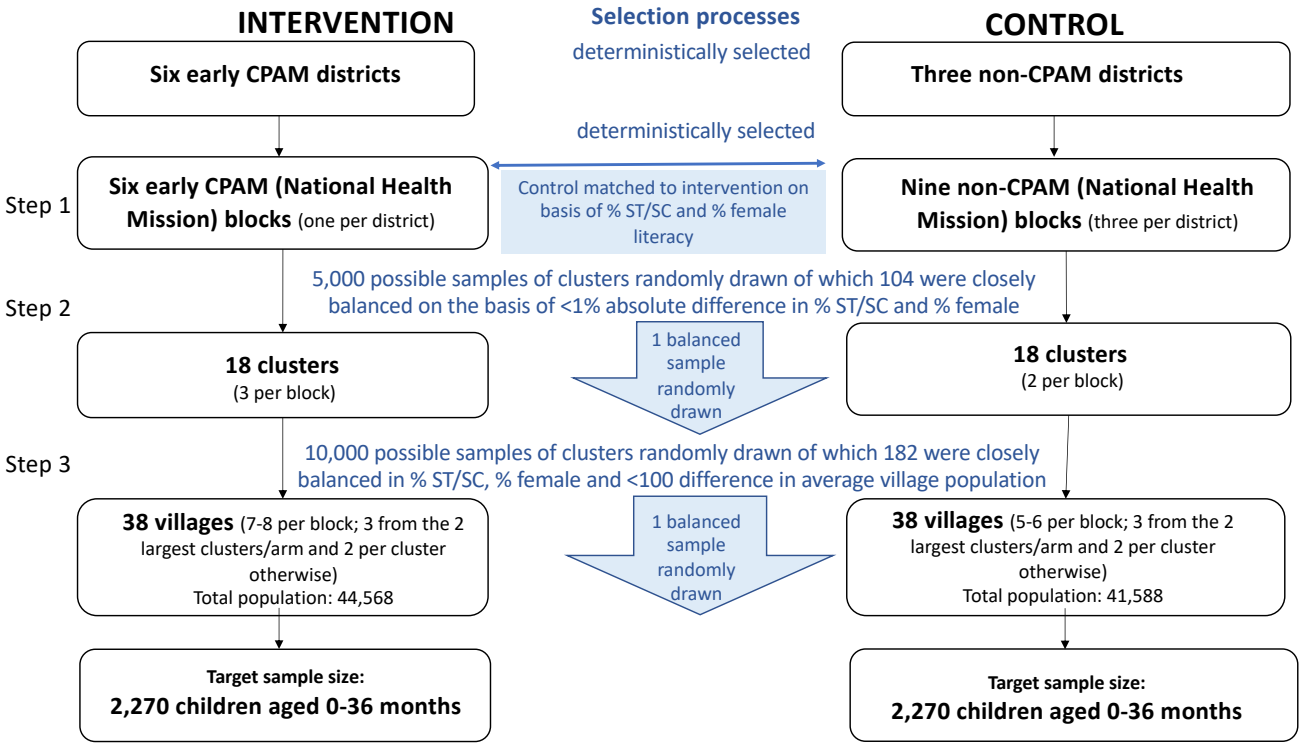


Figure 2: Sampling process

Control	NHM BLOCK									
Cluster	Berhampur	Chas	Dumka	Hariharganj	Husainbad	Kasmar	Masalia	Nawadih	Shikaripara	Total
Bishrampur	2,557									*2,557*
Tisibar	2,654									*2,654*
Olgra		4,216								*4,216*
Sardaha		1,920								*1,920*
Gadikoraia			1,195							*1,195*
Kairabani			831							*831*
Babandih				2,985						*2,985*
Tendue				585						*585*
Berepur					575					*575*
Haidarnagar					505					*505*
Khairachatar						3,910				*3,910*
Murhul Sudhi						2,669				*2,669*
Amgachhi							735			*735*
Khutojori #							1,489			*1,489*
Parasbani								5,378		*5,378*
Poplo								6,686		*6,686*
Maluti #									505	*505*
Sonadhap									2,193	*2,193*
Total	**5,211**	**6,136**	**2,026**	**3,570**	**1,080**	**6,579**	**2,224**	**12,064**	**2,698**	**41,588**

Intervention	NHM BLOCK						
Cluster	Bero	Chakradharpur	Gobindpur	Mahagama	Manjhiaon	Markaccho	Total
Bero	2,194						*2,194*
Gargaon	2,898						*2,898*
Puriyo	3,808						*3,808*
Jarjara #		1,327					*1,327*
Kendo		1,884					*1,884*
Toklo		1,540					*1,540*
Asanbani-2			4,038				*4,038*
Dhoria Mahubani			2,312				*2,312*
Tilayya			689				*689*
Kaithia				1,147			*1,147*
Kushmara				2,633			*2,633*
Jamaidih				642			*642*
Jainagra					3,025		*3,025*
Kandi #					2,315		*2,315*
Lamari Kalan					2,961		*2,961*
Dhubadih						3,367	*3,367*
Jamu						5,208	*5,208*
Naitand						2,580	*2,580*
Total	**8,900**	**4,751**	**7,039**	**4,422**	**8,301**	**11,155**	**44,568**

Table 1. Population of blocks and clusters (#: 3 villages per cluster, 2 villages per cluster otherwise.)

Survey data collection

Data collection will be led by an independent team at Ekjut, supported by UCL. A team of (preferably female) interviewers trained by Ekjut will take part in an anthropometry standardisation exercise, then pilot the survey. In each village an incentivised key informant "identifier" will be mobilised to detect pregnancies and children 0 to 36 months and inform the data collector on a regular basis. Each data collector will then conduct a household listing to identify all eligible participants in selected villages, measure the children's weight and height/length, and conduct a face-to-face interview with pregnant women and mothers using smartphones programmed with the software CommCare. All eligible pregnant women or mother/child pairs in a household will be sampled and the sampling will be exhaustive in each village. Each household with one or more eligible pregnant women or mother/child pairs would be approached up to three times in each cross-sectional study to seek their consent to participate. Data will be imported into STATA 16, anonymised, and cleaned using pre-programmed checks before being stored on secure drives at Ekjut and UCL. UCL and the Ekjut-based evaluation team will develop analysis plans and dummy tables ahead of baseline and endline analyses.

Analysis

The final analysis for the primary and secondary outcomes using endline data, supported by baseline data, will be guided by a causal model developed by Ekjut, UCL and the State Health Mission using the theory of change as well as local, national, and global data on potential confounders. We will compare outcomes between intervention and control areas using this model. The primary analysis will follow a 'difference in differences' approach in which both endline and baseline data are modelled jointly with an interaction term between time and intervention (vs. control) used to represent the intervention effect. Regression models will include random effects for cluster and for village nested within cluster, two correlated random effects for each at baseline and endline, to acknowledge the correlation structure of the data.

Extrapolating results from six early blocks to six districts in Jharkhand

Only the six CPAM early intervention blocks taking part in the evaluation will have c.36 months of exposure to interventions within the lifespan of the programme, and therefore give us the greatest chance of detecting an effect on children's WHZ. We will work with Ekjut and the Health Mission to pre-specify criteria for extrapolating effects seen on WHZ within these six early blocks to other blocks in the six scale up districts. A priori, we will expect results for the primary outcome to be transferable to scale-up districts if: (a) an impact on WHZ is detected in the six early blocks; (b) jointly agreed implementation fidelity criteria that include measures of coverage and quality are met across all CPAM implementation districts in Year 4.

PROCESS EVALUATION

The CPAM process evaluation will focus on understanding: (a) whether the intervention was implemented as planned (fidelity); (b) its pathways to impact (mechanisms); (c) and factors that enabled or hindered impact and scale up.

We will assess implementation fidelity once a year by visualising routinely collected data on:

1. Number of trainings planned versus completed
2. Number of PLA meetings planned versus completed
3. The % of meetings with at least 30% of participants who are either pregnant or mothers of children aged 0-36 months
4. The % of at-risk pregnant women and children visited at home, per month
5. The % of at-risk pregnant women & children referred to health or nutrition services, per month

We will assess pathways to impact by examining: (1) whether secondary outcomes are changing in the expected direction (i.e., increasing in relation to baseline and to control area); and (2) performing a mediation analysis using the endline survey data, to examine which of several possible pathways (changes in diets, morbidity, and care-seeking) led to any impact on the primary outcome (mean WHZ).

We will explore factors that enabled or hindered impact and scale up at health system, community, group, and individual levels, using qualitative methods. Indicative sample sizes are given below and will be refined on the basis of issues arising during implementation.

Two trained local qualitative researchers will conduct key informant interviews with district-level health mission functionaries (n=6) and senior Ekjut staff supporting the scale up (n=2). They will also review recordings (audio or note form) of district-level training and supervision meetings to understand barriers and enablers to scale up from a systems perspective. The trained qualitative researchers will conduct semi-structured interviews with approximately 12 Sahiya Sathi and 12 Sahiya, with half selected from the early intervention blocks and the other half from later scale up blocks. In these interviews, researchers will ask Sahiya and Sahiya Sathi what supported them in delivering the CPAM intervention, the community's response to it, and their perception of problems most and least addressed by CPAM.

The same researchers will also conduct focus group discussions with PLA groups in the 12 early intervention villages where the selected Sahiya and Sahiya Sathi work. We will ask about the problems and strategies prioritised by group members, why they came to group meetings, whether benefits ensued, and what challenges remained.

Finally, the researchers will conduct semi-structured interviews with 24 at-risk pregnant women (n=12) and mothers of children aged 0-36 months (n=12) purposively selected in six early intervention blocks and villages, with at least half of participants having received home visits monthly in the three months preceding the survey and the others not. These interviews will offer a more granular perspective on how at-risk pregnant women and mothers experienced the interventions, its benefits, and any limitations.

Both impact and process evaluations will enable us to understand other drivers of wasting that were not addressed by CPAM and whether these could be targeted and how. Interviews with government functionaries and Sahiyas, together with the economic evaluation described below, will help allow us to assess the sustainability of CPAM.

ECONOMIC EVALUATION

We will estimate cost-effectiveness from a provider perspective, by measuring programme and provider costs prospectively from Ekjut and State Health Mission accounts using a customised tool in MS Excel. The tool will be adapted each year to reflect the programme's changing cost structure. CPAM may increase the workload of Sahiyas or, conversely, lead to increased efficiencies. Changes in the number of referrals, and presentation for antenatal care and nutrition services will be measured in the trial surveys. The value of the change in demand for these services will be calculated using process data on the average time spent on each activity (measured through a time-use survey), and publicly available data on the salaries or incentives paid to the four main frontline workers (Accredited Social Health Activists (ASHAs, or Sahiya) and their supervisors (Sahiya Sathi), Anganwadi Workers (AWWs) and Auxiliary Nurse Midwives (ANMs), as well as available unit cost data from literature for Primary Health care Centres (PHCs), Malnutrition Treatment Centres (MTCs) and other relevant providers. The cost-effectiveness analysis will be conducted as a within-trial analysis using the intention-to-treat results. If an intervention effect is observed, incremental cost-effectiveness ratios (ICERs) will be calculated for the primary outcome (mean WHZ) and selected secondary outcome measures (including wasting WHZ<-2 and severe underweight WAZ<-3) and presented in terms of cost per unit changes in these outcomes, and if possible, cost per Disability Adjusted Life Years (DALYs) averted by modelling long-term intervention impact. ICERs are calculated as the arithmetic mean difference in cost between CPAM versus usual care, divided by the arithmetic mean difference in effect. The robustness of the results will be tested through sensitivity analyses.

ETHICAL ISSUES

Ethical approval for the study has been obtained from an independent ethics committee affiliated to Ekjut in Ranchi, Jharkhand (add number), and from University College London's Research Ethics Committee (1881/006).

We have identified six main ethical concerns arising from the proposed research:

1. **Need for consent from village leaders and caregivers of children under three years:** Study partners Ekjut have been working in the study districts for over 15 years and are familiar with its communities. We will seek consent for each village's participation in the current study from local village governance institutions and opinion leaders (Panchayati Raj Institution leaders and headmen) after explaining the study purpose and processes. All caregivers, including girls aged under 18 years who are married and have a child aged 0-36 months, will be asked to provide consent for themselves. This follows processes in previous studies conducted in the local area, where women who are married and/or have children are judged to have sufficient autonomy to consider research participation.

2. Identification and referral of children with illness and/or acute undernutrition

We will collect data on children's weight and length as part of the trial's community-based surveys. All moderately acutely malnourished children aged 6-36 months identified by the study interviewers (i.e. those with weight-for-height <-2 Standard Deviations of WHO 2006 Child Growth Standards or mid-upper arm circumference >=115 mm and <125 mm) will be referred to the local Anganwadi (Nutrition) Centre for further weighing and Take Home Rations, and to qualified primary care providers (Auxiliary Nurse Midwives of a nearby Primary Health Centre) if they have illness symptoms (cough, diarrhoea, fever). All children aged 6-36 months with severe acute malnutrition identified by the study interviewers (i.e., with weight-for-height/length <–3 Z-scores of the WHO growth standards, or mid-upper arm circumference <115 mm (2), or with bilateral oedema) will be referred to Malnutrition Treatment Centres (MTC, i.e., facility-based care) through Anganwadi workers, with follow-up by the data collection team.

3. Psychosocial distress among caregivers

There is a small risk that some of the study questions (e.g., those on mothers' mental health or children's ill-health) may be distressing to respondents, if they cause recall of negative health or social situations. To minimise the risk of psychological distress during the survey or qualitative data collection, interviewers will be trained in building rapport, maximizing comfort and security for interactions. If a participant is uncomfortable during any study procedures, they will be

reminded that they can choose not to answer any question that makes them uneasy or distressed, stop the procedure, or completely withdraw from the study at any time.

All caregivers with severe psychosocial distress as identified during the follow-up survey using the Kessler-10 item scale[2] will be offered local psychosocial support through a counsellor at Ekjut, or, if needed, telepsychiatry and a referral to the district hospital. Finally, we will establish a fund for medical emergencies to support mothers and children who need urgent referrals in the study areas in case of minor or major medical emergencies.

4. Benefits to control areas

All study participants will benefit from support with referrals in case of severe maternal psychosocial distress and child undernutrition. There are no other benefits to control areas.

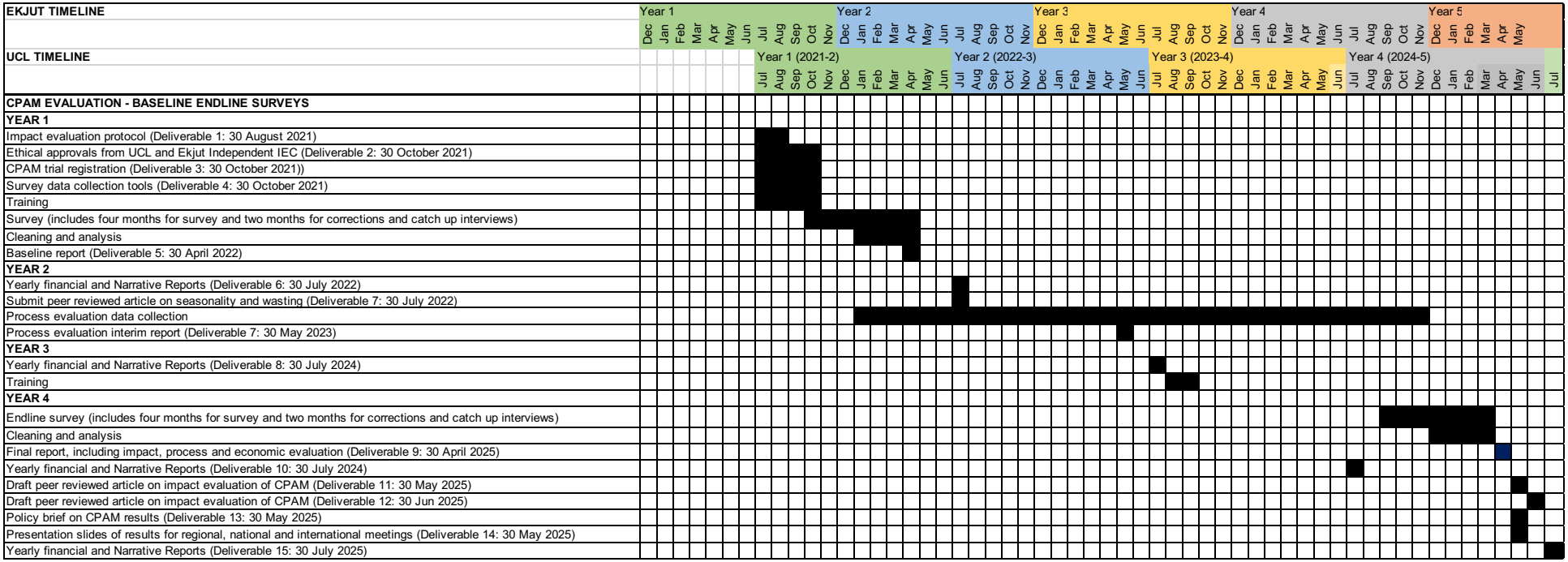
5. Contact with caregivers and children:

The study team will have regular contact with caregivers and children through data collection. Indian ethical committees do not require researchers working with children or vulnerable people to have the equivalent of a Disclosure and Barring Service (DBS) check. The UCL PI (A Prost) has undergone a DBS check. Ekjut have a child safeguarding policy.

6. COVID-related risks

Our study is currently due to start data collection in the community in November 2021. We will keep appraised of COVID case numbers using the Jharkhand State dashboard and follow local, State, and national government guidance on social distancing, mask-wearing, and travel in and out of districts. For one-to-one data collection, interviewers and participants will respect the guidance to keep six feet apart, wear masks and any tablets and anthropometry equipment will be cleaned with alcohol or disinfectant before and after use. If data collection is allowed to start but a cluster of infection appears in or near a study village, we will immediately stop data collection activities, and follow government advice at all times.

TIMELINE


EKJUT TIMELINE
Year 1
Year 2
Year 3
Year 4
Year 5
Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May
UCL TIMELINE
Year 1 (2021-2)
Year 2 (2022-3)
Year 3 (2023-4)
Year 4 (2024-5)
Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul
CPAM EVALUATION - BASELINE ENDLINE SURVEYS
YEAR 1
Impact evaluation protocol (Deliverable 1: 30 August 2021)
Ethical approvals from UCL and Ekjut Independent IEC (Deliverable 2: 30 October 2021)
CPAM trial registration (Deliverable 3: 30 October 2021))
Survey data collection tools (Deliverable 4: 30 October 2021)
Training
Survey (includes four months for survey and two months for corrections and catch up interviews)
Cleaning and analysis
Baseline report (Deliverable 5: 30 April 2022)
YEAR 2
Yearly financial and Narrative Reports (Deliverable 6: 30 July 2022)
Submit peer reviewed article on seasonality and wasting (Deliverable 7: 30 July 2022)
Process evaluation data collection
Process evaluation interim report (Deliverable 7: 30 May 2023)
YEAR 3
Yearly financial and Narrative Reports (Deliverable 8: 30 July 2024)
Training
YEAR 4
Endline survey (includes four months for survey and two months for corrections and catch up interviews)
Cleaning and analysis
Final report, including impact, process and economic evaluation (Deliverable 9: 30 April 2025)
Yearly financial and Narrative Reports (Deliverable 10: 30 July 2024)
Draft peer reviewed article on impact evaluation of CPAM (Deliverable 11: 30 May 2025)
Draft peer reviewed article on impact evaluation of CPAM (Deliverable 12: 30 Jun 2025)
Policy brief on CPAM results (Deliverable 13: 30 May 2025)
Presentation slides of results for regional, national and international meetings (Deliverable 14: 30 May 2025)
Yearly financial and Narrative Reports (Deliverable 15: 30 July 2025)

APPENDIX 1: Indian trials testing integrated community-based interventions to reduce child undernutrition[23,24,25]

	Interventions	Results	Risk of bias*
1	**Tamil Nadu Integrated Nutrition Project** Nutrition education, regular growth monitoring, primary health care, supplementary feeding for malnourished children, prophylactic vitamin A and deworming	Statistically significant improvements in weight-for-age between 1982 and 1990 for children aged 6-36 months (no control group)	Medium-high
2	**Tamil Nadu growth monitoring trial (George et al. 1993) - RCT** Growth charts to help inform mothers of their child's progress, nutritional advice, de-worming, immunisations, and monthly weighing	No difference in children's weight-for-age between intervention and control arms	Low
3	**Hyderabad RCT (Kinra et al. 2008)** ICDS services + protein supplementation for women and children	Mean birth weight higher in intervention arm. At 15 years, children in intervention arm were marginally taller.	Low
4	**Haryana RCT (Bhandari et al. 2004)** AWWs, ANMs and newly recruited worker trained to counsel mothers with locally developed feeding recommendations through home visits and group meetings	Small increase in height of infants at 6-12 months. No difference in weight.	Low
5	**INHP II – RACHNA (CARE INDIA & ICDS) 747 blocks of 78 districts in 9 states** (i) ANC; (ii) Supplementary nutrition with oil; (iii) child immunization; (iv) IYCF counselling focusing on early and exclusive breastfeeding & timely introduction of complementary feeding. AWWs encouraged to recruit community volunteers who received 6 days of training to act as 'change agents' in their communities.	Low weight-for-age reduced from 61% to 53% across programme areas between 2—1-6 (not a trial, baseline and endline survey.	Medium-high
6	**CARING RCT** Newly recruited worker offered monthly women's group meetings following principles of Participatory Learning and Action to support nutrition-specific and -sensitive interventions, and monthly home visits to women in the third trimester of pregnancy and the first 24 months to promote appropriate, IYCF, infection control and refer to health and nutrition services as required	No significant observed difference in children's length-for-height or weight-for-length between intervention and control arms.	Low
7	**Action Against Malnutrition (AAM) study** Newly recruited workers offered monthly women's group meetings following principles of Participatory Learning and Action (PLA) to support nutrition-specific and -sensitive interventions, and monthly home visits to women in the third trimester of pregnancy and the first 24 months to promote appropriate, IYCF, infection control and refer to health and nutrition services as required, and, in one arm, creches with food and referrals for children aged 6-36 months.	In areas with PLA and home visits), wasting among children under three was reduced by 34% and underweight by 25%, with no change in stunting. In areas with PLA, home visits and crèches), wasting was reduced by 27%, underweight by 40%, and stunting by 27%.	Medium-high
9	**UPAVAN RCT** Self-help group facilitators organized fortnightly women's groups meetings and household visits as three different arms: (1) nutrition-sensitive agriculture (NSA) videos (AGRI arm); (2) NSA and nutrition-specific videos (AGRI-NUT arm); or NSA videos and a nutrition-specific participatory learning and action cycle of meetings and videos (AGRI-NUT-PLA arm).	No effects on child wasting in any arm.	Low
10	**JEEViKA RCT (Gupta et al. 2019)** JEEViKA self-help group (SHG) Community Mobilizers (CMs) were trained to deliver messages on maternal and child nutrition and health, water, sanitation, and hygiene behaviours at bi-monthly SHG meetings, through the dissemination of a series of videos on health and nutrition, and targeted home visits, peer group meetings, and community events.	No effects on child weight-for-height, height-for-age, or weight-for-age.	Low

* As assessed using the Cochrane Risk of Bias tool for Randomised Controlled Trials or the ROBINS tool

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