ISRCTN81161855 https://doi.org/10.1186/ISRCTN81161855

Healthy markets and community action to improve diets in rural India

Submission date 06/11/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/11/2025	**Overall study status** Ongoing	
Last Edited 06/02/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
In Odisha, many people do not get enough healthy food. Only about 4 in 10 children and 1 in 3 women eat a diet with enough variety. Many people are also underweight. Eating more fruits, vegetables, and animal-based foods can help to improve health.

In rural communities, local markets are important places where families buy food. These markets are also social places. This study looks at how these markets can be improved to strengthen families' capabilities to eat more nutritious diets. It also aims to support women’s role in markets and increase men's involvement in family nutrition.

We are doing this study in rural areas of Keonjhar district to build capabilities of families to eat more healthy foods, by improving local markets and promoting better teamwork between men and women at home and in the community.

Who can participate?
60 markets (and a linked village area) have been selected to participate. Half will be offered the intervention; the other half will be our comparison group.

In the intervention areas, market leaseholders and managers, and all men and women living in the surrounding areas, will be invited to take part. We will also offer families with young children (aged 0-35 months when we start the study) to be sent videos on nutrition-related topics via smartphones, with accompanying home visits. Families who do not own a smartphone will be invited to join a video viewer group.

In all study areas, families with young children (aged 0-35 months when we start the study) will be invited to take part in surveys on diets, participation in markets, and household decision-making.

What does the study involve?
People living in the study areas will be invited to participate in one of two study groups.

One group will receive the following three components:
1. Market-based intervention of co-design, with monthly family days, working with weekly markets that are leased by the Gram Panchayat (GP).
We aim to support communities in co-designing these markets to make them healthier, safer, and more inclusive for everyone. Each year, when leases are renewed, we will work with market managers and vendors to improve how these spaces are used. This will include planning around five key areas: increasing the range of nutritious foods, improving food hygiene, reducing food waste, creating safer spaces for women, and encouraging people to buy healthy foods. Ideas include better stall placement, shaded areas, training on food safety, and fun ways to promote healthy foods—like short videos and wall art.
Monthly "family market days" will be held to make the market more fun and welcoming. Activities like cooking demos, games, and taste tests will help increase demand for nutritious foods. Food prices and availability will also be monitored to guide future planning. Weekly activities will include setting up kiosks in the market, where visitors can talk about their dietary needs and budgeting challenges, and get recipe tips and child feeding advice.

2. Community-level participatory groups for men and women, following a Participatory Learning and Action approach. While women's groups commonly already meet and discuss health and nutrition, men's groups do not exist for health and nutrition. For men, we will begin with topics like budgeting, then gradually move toward discussions on nutrition. These groups will promote shared responsibility in household decisions and encourage positive male involvement in food and family health.

3. Family-based interventions involving videos and home visits.
Families will also receive engaging videos each month that encourage conversation around nutrition at home. These videos are designed to be fun, relatable, and easy to share. For families without smartphones, video viewer groups will be arranged. Trained facilitators will visit homes on a monthly basis to show videos, discuss their messages, encourage participation in local groups, and refer families to health services if needed.

The control group will not receive any of these interventions.
However, community health workers and market vendors in both study groups will be offered training on nutrition, food safety, and hygiene practices.

To help us understand the impact of the intervention, we will carry out the following research activities before and after the two-year period:

Surveys, in-depth interviews, and focus group discussions:
We will speak with mothers and fathers of children (0-35 months at baseline) (or the main caregiver or decision-maker if they are unavailable). We will ask about: food consumption, willingness to pay for nutritious foods, nutrition knowledge, household cooperation, women's participation in markets, and their perceptions of market safety.

Market Stakeholder Interviews:
We will also interview vendors, markets managers, and other key market actors to understand: food hygiene practices, availability and pricing of nutritious foods, and business outcomes for vendors.

Participation Tracking:
We will record how often households visit markets, attend market events, take part in groups, watch videos, and receive home visits. We will also track video viewership, and number of home visits made by facilitators.

Experience and feedback (at endline):
Some participants will be invited to share their experiences and feedback about the interventions through interviews.

What are the possible benefits and risks of participating?
We do not know what the benefits to people participating in the study are, or if there will be any benefit at all. Participation may lead to future benefits for families in Keonjhar. If the interventions are successful, we will try to secure additional funding to deliver the intervention after the study period. In this case, priority would be given to the areas that did not receive any intervention during the study. However, we cannot be certain if this will happen or not.

We do not anticipate any adverse events, and we think that this intervention is very low risk.

Possible risks, and associated risk mitigation strategies warrant mention:
1. Alcohol consumption
The intervention includes community groups with men in rural Odisha, in an area where alcohol consumption is high. To address this, we will co-create ground rules with participants during the initial meetings, building a sense of community ownership over mutually agreed norms around alcohol use. Scheduling meetings at times that do not coincide with peak alcohol consumption—such as avoiding late afternoons or evenings, is a useful strategy. Discussions can also include the negative impact of alcohol on family wellbeing, child nutrition, and household income. It is essential to equip facilitators with the skills to recognise early signs of risky behaviour, manage challenging situations, and steer discussions back on track if alcohol becomes a dominant topic.

2. Infrastructure
Participants may choose to implement infrastructural changes in their markets, such as building toilets, water sources, or shade structures. There may be risk of injury during or after construction.
This will be entirely led and managed by the participants; the facilitators will provide support with safe architectural blueprints and support on ensuring safety of any works. Safety audits may be planned for permanent structures.

3. Sensitive questions
The evaluation includes a mental health assessment of mothers, and qualitative surveys will ask questions around intra-household family dynamics. These questions can be sensitive or difficult to answer, and the mental health questions might identify mothers at risk of self-harm.

If mothers score as high risk according to the mental health assessment, they will be provided with referral information sheet to seek care. We will follow full participant information and consent procedures. The participation sheet will be written using the local language (Odia), and use everyday language and terms as far as possible.

Enumerators will be trained to foster an environment where the study participants feel comfortable and at ease. Training of enumerators will focus on both the familiarisation with the study tools (i.e. surveys and interview scripts), and the upholding of ethical standards to ensure that they interact with study participants with sensitivity, empathy, and integrity. Further, participants will be reassured that there are no right or wrong answers, and that the interactions are taking place in a judgement-free and confidential environment.

4. Vendor conflict
Categorising foods as "healthy" or "unhealthy" may create market tensions and the risk of

stigmatising certain vendors who sell unhealthy foods. To prevent conflicts, it is essential to use sensitive, non-judgmental messaging and ensure inclusive engagement with all vendors throughout the program. We also think that the risk of this is quite low, given that diets are notoriously hard to change and so impacts on consumption of ultra-processed foods are unlikely to meaningfully affect vendors' livelihoods.

5. Prices
Infrastructure upgrades in local markets may lead to increased auction or stall fees. These costs could be transferred to consumers, disproportionately impacting low-income buyers. However, we think that this is very unlikely as the intervention is designed to include a resource mapping exercise whereby market leaseholders and designers work with their existing funds, mobilise existing grants that are available at the Gram Panchayat level for infrastructural improvements, other funds available to communities with a high proportion of Scheduled Tribe communities, as well as modest funds available by the study (on average 0.5 lakh INR (564 USD) per market, per lease renewal).

Where is the study run from?
The study will be implemented by VARRAT, a local Odisha NGO, with technical support from Ekjut (specialists of participatory approaches to improve health) and Design Jatra (participatory architecture firm). The intervention will be evaluated by London School of Hygiene & Tropical Medicine, Development Corner Ltd, and The University of Sheffield.

When is the study starting and how long is it expected to run for?
The study will start recruiting markets / villages in November 2026, with baseline surveys in Dec 2025-Jan 2026. The interventions will begin from January 2026 and run for 24 months. The endline surveys will run from Dec 2027-Jan 2028.

Who is funding the study?
The Gates Foundation and UK government (Foreign Common Development Office) have provided funds for this study.

Who is the main contact?
Dr Helen Harris-Fry
Department of Population Health
London School of Hygiene & Tropical Medicine
helen.harris-fry@lshtm.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Helen Harris-Fry

ORCID ID
https://orcid.org/0000-0003-2367-908X

Contact details
Department of Population Health, Keppel Street
London

United Kingdom
WC1E 7HT
+44 7585508822
helen.harris-fry@lshtm.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
SeHaat: Healthy market co-design and community action to improve nutritional adequacy of mothers and children: A cluster-randomised controlled trial in rural Odisha, India

Acronym
SeHaat

Study objectives
1. An integrated intervention in rural India, involving rural food markets (haats), communities, and families, increases the nutritional adequacy of mothers and children, compared with the control group that does not receive the intervention.
2. The intervention increases nutritional adequacy through improvements in nutrition knowledge and preferences of men and women, intra-household cooperation, men's involvement in nutrition-related decisions, women's participation in rural haats, and the design of the haat.
3. The intervention reaches and increases the dietary adequacy of mothers and children in households belonging to Scheduled Tribe and low socio-economic status.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 30/09/2025, LSHTM Observational / Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 7636 8636; ethics@lshtm.ac.uk), ref: 32740

2. approved 19/08/2025, Institutional Ethics Committee, National Institute of Nutrition (Ministry of Health and Family Welfare, Jamai-Osmania, Hyderabad, 500 007, India; +91 4027197200; nin@nic.in), ref: NIN/IEC/2025/8/RR/004

3. approved 27/06/2025, Ekjut Ethics Committee (Head Office Village Ichinda-Ulidih, Chakradharpur, West Singhbhum Jharkhand, 833102, India; +91 651-2243105; ekjutindia@gmail.com), ref: EC/NEW/INST/2023/3920- 06/2025

Study design

Interventional parallel observer-blind cluster-randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Maternal and child nutritional adequacy

Interventions
An integrated intervention involving rural food markets (haats), communities, and families will be tested. 60 markets and associated village clusters will be randomly allocated to two trial arms, giving 30 clusters in the intervention and 30 in the control.

The intervention: The intervention arm has three components:

1. Co-design of healthy haats that are leased by Gram Panchayats (local government), with monthly family market days, and periodic skills-building activities in the haats. The participatory co-design process will be facilitated in each haat at the intervention start (Jan-Feb 2026, and after each annual lease renewal (Apr-Aug 2026 and Apr-Aug 2027). The co-design process involves engaging leaseholders and vendors in a facilitated cycle of identifying issues, designing the haat, resource mapping, priority setting, action planing, and implementation. The process is facilitated to focus on our 5 'pillars' of a healthy haat: i) range of nutrient-dense foods (e.g. identifying additional vendors or addressing supply chain constraints), ii) food hygiene (e.g. improving food handling practices, installing a clean water source, and implementing waste disposal systems), iii) reducing food losses (e.g. creating shade structures and improved use of raised platforms), iv) gender sensitivity (e.g. creation of safe spaces for mothers to breastfeed, and provision of clean toilets), v) demand creation (e.g. use of adverts, local art, and short videos promoting nutrient-dense foods, and facilitation of kiosks to discuss food baskets, budget constraints, food price shocks, and recipe sharing).

2. Monthly community groups with men and women using a Participatory Learning and Action approach designed to boost demand for nutrient-dense foods. Groups are facilitated at a coverage of approx. 1 group per 500 population. Facilitators follow a meeting manual involving four phases: 1) learning together to identify barriers to adequate diets, 2) identifying and prioritising locally appropriate solutions to address these barriers, 3) collective action to implement strategies identified in the previous stage, 4) review of progress and planning for the next steps. While women’s groups commonly discuss health and nutrition, men’s groups for health and nutrition do not exist. For men's groups, we will begin with topics like budgeting, then gradually move toward discussions on nutrition. These groups will promote shared responsibility in household decisions and encourage positive male involvement in food and dietary choices.

3. Monthly videos shared via smartphones and home visits to mothers of children aged <5 years (0-35 months at baseline; 24-59 months by endline). The videos will form a serial-based approach designed to foster dialogue around nutritious diets within families and boost demand for nutrient-dense foods. For families without smartphones, we will create WhatsApp viewer groups. The home visits will enable facilitators to: show and share the videos if they have not already seen them, enable further dialogue around the stories conveyed in the videos (including

reflections, reiteration, or questions that arise from the videos), encourage attendance at men's and women's participatory groups and engagement in nutrition and health aspects of haats, refer any health issues to the health clinics / Anganwadi (frontline workers).

Comparator: Clusters in the control arm do not receive either component.

As a service to all trial participants, government community frontline workers in both arms are offered nutrition training, and market vendors are offered training on hygiene and food safety practices. Both arms continue to receive any existing programmes routinely provided by the Government or non-governmental organisations.

Random allocation: After obtaining consent from 60 market leaseholders and village representatives, clusters will be allocated in a 1:1 ratio (30 intervention; 30 control). Allocation will be conducted using restricted randomisation at LSHTM, with constraints to minimise risk of spillover from intervention to control areas.

Duration: The intervention will run for 24 months.

Administration: All intervention components will be led by paid facilitators, who will be employed by the lead implementing partner (non-governmental organisation, VARRAT).

Intervention Type
Behavioural

Primary outcome(s)
1. Child nutrient adequacy measured longitudinally, using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline). Children are aged 0-35 months at baseline and 24-59 months by endline. Diets are not measured at baseline if children are aged 0-5 completed months.
2. Maternal nutrient adequacy measured longitudinally, using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline). Respondents are the mother or primary female caregiver of the index child, and are aged 18-49 years.

Diets are assessed using 24-hour dietary recall, with repeat measures on 10% of the sample. Food intakes are linked to nutritive values using a compiled Food Composition Table. Repeat measures are used to account for within-person variance in diets, predicting usual nutrient intakes as the Best Linear Unbiased Predictor of observed intakes.

Mean micronutrient adequacy will be calculated for a mean of 11 priority nutrients (iron, zinc, calcium, vitamin A, vitamin C, thiamin, riboflavin, niacin, B6, folate, B12). For each nutrient, adequacy will be calculated as: intake / Recommended Nutrient Intake *100, capped at 100. The mean of these individual nutrient adequacies across the 11 nutrients will give our summary adequacy score. Nutrient adequacy scores range from 0-100.

Baseline will run from Dec 2025-Jan 2026, and endline from Dec 2027-Jan 2028.

Key secondary outcome(s))
Men's nutrient adequacy, measured longitudinally using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline). Adequacy is calculated in the same way as the primary outcomes. Respondents are the father of the index child, or another adult male decision-maker if the father is not available. Men's adequacy will not be assessed if there are no adult men living in the household.

Other outcomes of interest:
1. Mothers' consumption of perishable nutrient-dense foods (g/d) measured using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline).
2. Children's consumption of perishable nutrient-dense foods (g/d) measured using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline).
3. Global Diet Quality Score for mothers / caregivers, measured using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline).
4. Global Diet Quality Score for children, measured using 24-hour dietary recalls at endline only (24 months after baseline).
5. Women's share of total adult nutritional adequacy (women / women + men), measured using 24-hour dietary recalls at baseline (before the intervention begins) and endline (24 months after baseline).
6. Men's willingness-to-pay for nutrient-dense foods, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline). Willingness-to-pay measures are pooled and normalised across goods.
7. Women's willingness-to-pay for nutrient-dense foods, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline). Willingness-to-pay measures are pooled and normalised across goods.
8. Intra-household cooperation score, measured using a composite score (on discussion, joint decision-making, and information sharing around food choices and family budgeting) at baseline (before the intervention begins) and endline (24 months after baseline).
9. Women's nutrition knowledge score, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline).
10. Men's nutrition knowledge score, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline).
11. Proportion of men being involved in decisions around child nutrition, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline).
12. Proportion of women visiting markets in the past 3 months, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline).
13. Proportion of mothers/caregivers who perceive their local market to be a safe place, measured using a structured questionnaire at baseline (before the intervention begins) and endline (24 months after baseline).
14. Minimum cost of an adequate diet for women (INR/d), measured using market price data at baseline (before the intervention begins), midline (12 months after baseline), and endline (24 months after baseline). 'Adequate diet' defined according to dietary guidelines of the National Institute of Nutrition in India.
15. Count of healthy market features, measured using structured observations of markets at baseline (before the intervention begins), midline (12 months after baseline), and endline (24 months after baseline).
16. Proportion of markets with a functioning toilet and handwashing station (with clean water and soap), measured using structured observations of markets at baseline (before the intervention begins), midline (12 months after baseline), and endline (24 months after baseline).
17. Vendor profits (INR/month), measured using structured observations of markets at baseline (before the intervention begins), midline (12 months after baseline), and endline (24 months after baseline).
18. Mental health score of women, measured using the Self-Reported Questionnaire (SRQ-20) at baseline (before the intervention begins) and endline (24 months after baseline).

Completion date
31/01/2028

Eligibility

Key inclusion criteria
For participation in interventions:
Haat-village clusters come from four blocks (Patna, Keonjhar, Harichandanpur and Ghatgaon blocks) in Keonjhar district, Odisha. Eligible markets are those that run weekly, are leased by the government (Gram Panchayat), have a minimum of 10 vendors selling nutrient-dense foods on average over the year (minimum of 8 at any given time), and are not a block headquarter market. The village cluster associated with each market is a randomly selected village that is primarily served by the market. Residential areas (e.g. villages and surrounding hamlets) are combined to give an expected minimum of 800 population per village cluster.

In the intervention arm, all women and men are eligible to participate in the monthly participatory groups and the market activities, and all families with a child aged 0-35 months at baseline are eligible to receive videos sent via smartphones and accompanying home visits.

For primary outcomes:
1. Children (one 'index child' per household) aged 0-35 months at baseline, with a mother / female primary caregiver who is aged 18-49 years and has no discernible disability preventing them from participating in the surveys. Note that dietary recalls are not conducted for children aged 0-5 completed months, but are conducted for these children at endline.

2. Mother or primary female caregiver of the index child, aged 18-49 years, with no discernible disability preventing them from participating in the surveys.

For the secondary outcome:
1. The father of the index child, or otherwise an adult male decision-maker living in the household, aged >=18 years, with no discernible disability preventing them from participating in the surveys.

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 months

Upper age limit
49 years

Sex
All

Total final enrolment
3362

Key exclusion criteria
Clusters:
1. Markets that do not have a minimum of 10 vendors of nutrient-dense foods over the year (or fewer than 8 at any given time of year).
2. Markets that are not leased by the Gram Panchayat.
3. Markets that are located in the block headquarters.
4. Markets that are in close proximity to neighbouring markets.
5. Village clusters that are served by multiple markets.
6. Village clusters that are small (<200 households) or large (>600 households).

Trial participants (for evaluation):
1. Any primary female caregiver who does not have a child aged 0-35 months at baseline.
2. Any primary female caregiver who has a discernible disability preventing them from participating in the surveys.
3. Any primary caregiver or male respondent who is not defined as a 'household member'. That is, primary caregivers who have not resided in the household regularly at least half of the time during the past 12 months (e.g. 3-4 days of each week for 12 months, or 6 full months of past 12 months), unless they joined the household through marriage less than 12 months ago. Residing means living in the households and eating from the same pot. A married mother/father who is temporarily visiting their natal home, and so has not lived at the natal home for the past 12 months, will not be included. Household members do include servants, lodgers, and agricultural labourers currently in the household who will be staying in the household for a longer period, even if they arrived fewer than 12 months ago.
4. Any primary caregiver aged under 18 or over 49 completed years.
5. Any male respondent aged under 18 completed years.

Date of first enrolment
10/11/2025

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
India

Study participating centre
VARRAT (Voluntary Association for Rural Reconstruction and Appropriate Technology)
Boulakani Baradang
Mahakalpara
Kendrapada
Odisha
(Branch Office: Erendei, Swam Patna Keonjhar, 758030)
Kendrapada

India
754224

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

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

Location
United States of America

Funder Name
Foreign, Commonwealth and Development Office of the UK Government

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (LSHTM Data Compass).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes