ISRCTN65922679 https://doi.org/10.1186/ISRCTN65922679

# UPAVAN: Upscaling participatory action and videos for agriculture and nutrition

**Submission date**
28/10/2016

**Recruitment status**
No longer recruiting

**Registration date**
21/12/2016

**Overall study status**
Completed

**Last Edited**
13/02/2025

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Maternal and child undernutrition (the outcome of insufficient food intake and repeated infectious diseases) is one of the world's most serious health, economic and human development challenges. Child undernutrition causes an estimated 3.1 million child deaths annually, and one third of women in South Asia are underweight. There is an increasing scientific consensus that interventions to address immediate determinants of undernutrition ('nutrition-specific' interventions) are necessary but not sufficient: acceleration of progress in maternal and child nutrition will entail coupling these interventions with nutrition-sensitive programs that tackle the underlying causes of undernutrition. 'Making agriculture work for nutrition' is now a top policy priority but the evidence-base is weak, largely due to poorly designed studies that are unable to discern causal effects. In this study, three variants of a participatory agricultural intervention that use low-cost participatory videos and facilitated discussions with women's groups on maternal nutrition (body mass index) and child dietary diversity will be tested.

Who can participate?
Children aged between 0-23 months and their mothers.

What does the study involve?
The study is recruiting 148 village clusters (villages and adjoining hamlets) in rural Keonjhar district in Odisha, India. These clusters are randomly allocated to receive one of the three variants of the intervention or to a control group (no intervention). The first varient involves the circulation of locally made nutrition-sensitive agriculture videos to women's self-help groups (SHGs), with follow-up home visits to group members who are in the '1000 golden days' period, i. e. women who are pregnant or are the mother of a child under 2 years old. Frontline workers circulate two nutrition-sensitive agriculture videos each month, to 10-12 self-help groups (SHGs) per 1000 population, with each group comprising approximately 20 to 25 members. For the home visits, frontline workers visit all women in the 1000 golden day period to reinforce messages and verify the adoption of agricultural practices. The second varient is similar to the first but also contains nutrition-specific videos that focus directly on maternal and child nutrition, and related social and behaviour change. Each SHG (10-12 self-help groups (SHGs) per 1000 population) also receive two video dissemination meetings per month, with an approximately 50:50 allocation of nutrition-sensitive and nutrition-specific videos over the 36-

month intervention period. Frontline workers also conduct home visits to women in the 1000 golden day period for message reinforcement and verification of the adoption of any agricultural practices, and for knowledge recall of recommended nutrition practices. The third varient uses both nutrition-sensitive and nutrition-specific videos disseminated to SHGs (10-12 self-help groups (SHGs) per 1000 population) in a similar way to first program. In addition, an enhanced participatory approach of 'Participatory Learning and Action' (PLA) women's groups focussing on maternal and child nutrition (one PLA group per cluster) is implemented, which feeds into the nutrition-specific video development and circulation by using the discussions in the PLA group meetings to inform the prioritisation and development of video content. Home visits for women in the golden 1000 days are conducted in a similar way to the first group.

What are the possible benefits and risks of participating?
The purpose of the study is to find out if the interventions will improve agricultural practices and nutrition of children and mothers, so it is possible that these outcomes will improve, but we cannot be certain of these outcomes. In the interviews at the start and end of the study, severely undernourished women and children will be referred to the nearest health facility, so this will be some small benefit for all study groups. The participation of this village may lead to future benefits for families in Keonjhar. If the interventions prove to be successful, the trialists will try to secure additional funding to deliver one of the interventions after the 32-month study period. In this case, priority would be given to the villages that did not receive any additional intervention during the study. However, the trialists cannot be certain if this will happen or not. There are no known risks involved with participating in this study.

Where is the study run from?
The study is run by London School of Hygiene and Tropical Medicine (UK) and takes place in 148 village clusters (villages and adjoining hamlets) in rural Keonjhar district in Odisha (India)

When is the study starting and how long is it expected to run for?
December 2015 to May 2020

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Dr Suneetha Kadiyala
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
QA896

# Study information

### Scientific Title
Community-driven and digital technology-enabled agriculture intervention for nutrition: a cluster randomized controlled trial in Odisha, India

### Acronym
UPAVAN

### Study objectives
1. An agricultural intervention in rural India, involving the facilitated dissemination of locally made agricultural videos through women's groups, will improve maternal nutritional status (body mass index) and child dietary diversity, compared to the control group, through improvements in household income, agricultural development (especially the availability and accessibility of nutrient-rich foods), and women's empowerment
2. The two variants of this agricultural intervention, that embed nutrition-specific messaging and also use enhanced participatory approaches, will further enhance the impact of the intervention, compared to the control group, on maternal nutritional status and child dietary diversity

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Odisha government's Institutional Review Board, Research and Ethics Committee, Department of Health and Family Welfare, Government of Odisha, 03/09/2016, ref: 141 / SHRMU
2. London School of Hygiene and Tropical Medicine (LSHTM) Interventions Research Ethics Committee, 10/10/2016, ref: 11357

### Study design
Interventional cluster randomised trial

### Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Community

## Study type(s)
Quality of life

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Maternal and child undernutrition

## Interventions
Three variants of a participatory, video-based, agricultural intervention will be tested. 148 village clusters will be randomly allocated to four trial arms (37 clusters per trial arm), stratified by distance to nearest town (<10 km or >=10 km) and low, medium or high proportion of Scheduled Tribe or Scheduled Caste households in the cluster.

'AGRI' intervention
This involves the facilitated dissemination of locally made nutrition-sensitive agriculture videos to women's self-help groups (SHGs), with follow-up home visits to group members who are in the '1000 golden days' period, i.e. women who are pregnant or have a child under 2 years old. Frontline workers will disseminate two nutrition-sensitive agriculture videos each month, to 10-12 self-help groups (SHGs) per 1000 population, with each group comprising approximately 20 to 25 members. For the home visits, frontline workers will visit all women in the 1000 day period to reinforce messages and verify the adoption of agricultural practices.

'AGRI-NUT' intervention
This intervention is similar to the 'AGRI' intervention, but SHGs will also view and discuss nutrition-specific videos that focus on maternal and child nutrition, and related social and behaviour change. Each SHG (10-12 self-help groups (SHGs) per 1000 population) will receive two video dissemination meetings per month, with an approximate 50:50 allocation of nutrition-sensitive and nutrition-specific videos over the 32 (updated 06/08/2019, previously: 36) month intervention period. Frontline workers will also conduct home visits to women in the 1000 day period for message reinforcement and verification of the adoption of any agricultural practices, and to check participants' knowledge of recommended nutrition practices.

'AGRI-NUT+PLA' intervention
Nutrition-sensitive and nutrition-specific videos will be disseminated to SHGs (10-12 self-help groups (SHGs) per 1000 population) in a similar way to the AGRI-NUT intervention. In addition, an enhanced participatory approach of 'Participatory Learning and Action' (PLA) women's groups focussing on maternal and child nutrition (one PLA group per cluster) will be implemented. Using the PLA approach, groups discuss and prioritise problems relating to maternal and child nutrition, implement strategies at the community and/ or household level to address these problems, and informally review their strategies. The PLA component will feed into the nutrition-

specific video development and dissemination by using the discussions in the PLA group meetings to inform the prioritisation and development of video content. Home visits for women in the 1000 day period will be conducted in a similar way to the AGRI-NUT intervention.

Control group
The effect of each of the three intervention variants will be compared to a control group that will only receive any existing programs from Government or other non-governmental organisations.

The total duration of all three variants of the intervention will be 32 months. Repeat cross sectional surveys at baseline and endline (32 months after the intervention starts) will assess nutritional outcomes of index children aged 0 to 23 months, and the mothers or primary caregivers of the index children.

## Intervention Type
Behavioural

## Primary outcome measure
1. Percentage of children (aged 6 to 23 months) that consume four or more food groups per day, based on a 24-hour dietary recall, is assessed by a team of trained local data collectors, using a cross-sectional survey designed for the purpose of this study at baseline (before the interventions begin) and endline (32 months after baseline)
2. Mean maternal Body Mass Index (kg/m sq) for non-pregnant, non-postpartum women is measured by a team of trained anthropometrists, using stadiometers (Seca 213) to measure height and weighing scales to measure weight, in cross-sectional anthropometric surveys conducted at baseline and endline (32 months after baseline).

All outcomes will be measured using repeat cross-sectional surveys conducted at baseline (October to December 2016) and endline (October to December 2019).

## Secondary outcome measures
Current secondary outcome measures as of 06/08/2019:
Secondary outcomes:
1. Percentage of mothers consuming >5 out of 10 food groups per day, based on a 24-hour dietary recall is assessed by a team of trained local data collectors, using a cross-sectional survey designed for the purpose of this study at baseline (before the interventions begins) and endline (32 months after baseline)
2. Percentage of children with a weight-for-height z-score <2SD is measured by a team of trained anthropometrists, using infantometers (Seca 417) to measure child length and weighing scales to measure weight (and z-scores calculated by comparing weight-for-height against WHO standards), in cross-sectional anthropometric surveys at baseline (before the interventions begin) and endline (32 months after baseline)

Other outcomes of interest:
1. Percentage of mothers with MUAC < 23 cm is measured by a team of trained anthropometrists, using circumference tapes, in cross-sectional anthropometric surveys at baseline (before the interventions begin) and 32 months after baseline.
2. Mean haemoglobin (Hb) concentrations of mothers (g/dl) is measured by a team of trained lab technicians, using haemocue machines(model Hemocue Hb 301), in cross-sectional anthropometric surveys at baseline and 32 months after baseline
3. Mean haemoglobin (Hb) concentrations of children 6 to 23 months (g/dl) is measured by a

team of trained lab technicians, using haemocue machines, in cross-sectional anthropometric surveys at baseline and 32 months after baseline
4. Percentage of children (age 6-23 months) meeting WHO recommended Minimum Acceptable Diet is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
5. Percentage of women 'empowered' in women's decision-making in productive and health-related domains, aggregated, measured using the Women's Empowerment in Agriculture Index.
6. Percentage of women 'empowered' in the women's time use domain of the Women's Empowerment in Agriculture Index.
7. Percentage of women achieving gender parity between themselves and a male household member, defined using the Women's Empowerment in Agriculture Index
8. Mean per capita household share of food expenditures
9. Mean per capita total household expenditures
10. Mean production diversity (count of the number of crops or livestock produced)
11. Total value of agricultural production
12. Net value of agricultural production (= value of agricultural production – costs)

Previous secondary outcome measures:
Secondary outcomes:
1. Percentage of mothers consuming >5 out of 10 food groups per day, based on a 24-hour dietary recall is assessed by a team of trained local data collectors, using a cross-sectional survey designed for the purpose of this study at baseline (before the interventions begins) and endline (32 months after baseline)
2. Percentage of children with a weight-for-height z-score <2SD is measured by a team of trained anthropometrists, using infantometers (Seca 417) to measure child length and weighing scales to measure weight (and z-scores calculated by comparing weight-for-height against WHO standards), in cross-sectional anthropometric surveys at baseline (before the interventions begin) and endline (32 months after baseline)
3. Percentage of children with MUAC < 125 mm is measured by a team of trained anthropometrists, using MUAC tapes in cross-sectional anthropometric surveys, at baseline (before the interventions begin) and endline (32 months after baseline).

Other outcomes of interest:
1. Percentage of mothers with MUAC < 23 cm is measured by a team of trained anthropometrists, using head circumference tapes, in cross-sectional anthropometric surveys at baseline (before the interventions begin) and 32 months after baseline.
2. Mean haemoglobin (Hb) concentrations of mothers (g/dl) is measured by a team of trained lab technicians, using haemocue machines(model Hemocue Hb 301), in cross-sectional anthropometric surveys at baseline and 32 months after baseline
3. Mean haemoglobin (Hb) concentrations of children 6 to 23 months (g/dl) is measured by a team of trained lab technicians, using haemocue machines, in cross-sectional anthropometric surveys at baseline and 32 months after baseline
4. Percentage of children (age 6-23 months) meeting WHO recommended Minimum Acceptable Diet is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
5. Percentage of mothers receiving > 3 antenatal care visits by a qualified provider is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
6. Percentage of mothers receiving minimum iron and folic acid supplements during pregnancy is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
7. Percentage of mothers receiving tetanus injections is measured by a team of trained data

collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
8. Percentage of children (0-23 months) receiving appropriate care during illness episodes is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
9. Percentage of households using WHO-recommended handwashing practices is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
10. Mean Women's Empowerment in Agriculture Index (WEAI, measured using a modified score) (and the 5 domains of empowerment) is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
11. Mean gender parity in agriculture (also using WEAI) is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
12. Mean per capita expenditures in total, and on food, and non-food expenditures is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
13. Mean household asset ownership score is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
14. Percentage of households with number months of inadequate household food provisioning is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
15. Mean production diversity (includes produced crops, dairy, livestock and foraged non-timber forest products) is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
16. Mean total yield per crop is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
17. Mean total income and net profit from agricultural production is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
18. Percentage of households with access to credit and agricultural entitlements is measured by a team of trained data collectors, using a cross-sectional survey designed for the purpose of this study, at baseline and 32 months after baseline
19. Cost-effectiveness ratios for the primary and secondary outcomes listed above is measured using programme-related cost data provided by the implementing organisations' accounting systems and through annual structured interviews with staff, and using data on the cost-burden on participants using household expenditure data and time use surveys conducted at endline (32 months after baseline)
20. Net cost per disability-adjusted life year (DALY) averted is measured using a cross-sectional survey designed for the purpose of this study, 32 months after baseline

All outcomes will be measured using repeat cross-sectional surveys conducted at baseline (October to December 2016) and endline (October to December 2019).

## Overall study start date
01/11/2015

## Completion date
31/05/2020

# Eligibility

### Key inclusion criteria
For intervention eligibility, all women in the cluster are eligible to receive the group-based interventions and video dissemination, with intended coverage of at least one woman per household attending the SHGs. Mothers in the 1000-day period (pregnant or with a child aged up to 23 months) are eligible to receive home visits. For the trial impact evaluation eligibility, children aged 0 to 23 months (and the mothers or primary caregivers of children aged 0 to 23 months) will be interviewed measured, so the trial effects are only generalisable to this sub-population.

For participation in interventions:
1. Village clusters from four blocks (Patna, Keonjhar, Harichandanpur and Ghatgaon blocks) in Keonjhar district, Odisha, India are eligible to be randomly allocated to any of the four trial arms
2. In the intervention arms, all women are eligible to participate in the study and attend the women's SHGs
3. All pregnant women and primary caregivers of children aged 0 to 23 months are eligible to receive home visits

For primary outcomes:
1. Children (male and female) aged 6 to 23 months
2. Non-pregnant, non-postpartum (added 06/08/2019) mothers or primary caregivers of children aged 0 to 23 months

For secondary outcomes:
1. Children (male and female) aged 0 to 23 months
2. Mothers or primary caregivers of children aged 0 to 23 months

### Participant type(s)
Mixed

### Age group
Mixed

### Sex
Both

### Target number of participants
4,736 mother-child dyads (148 clusters; 32 mother-child dyads per cluster)

### Key exclusion criteria
For participation in interventions:
1. Any of the 8 clusters selected for formative research
2. Any clusters with prior exposure to programmatic work by any of the implementing partners

For primary, secondary and other outcomes:
1. Any discernible disability of children or primary caregivers that prevents them from responding to the survey, or impairs their recumbent length or standing height
2. Any primary caregiver 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

she 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 who is temporarily visiting her parental home, and so has not lived at the parental 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 less than 12 months ago.
3. Any primary caregiver not of reproductive age (that is, not aged 15 to 49 completed years)

### Date of first enrolment
19/12/2016

### Date of final enrolment
19/01/2020

## Locations

### Countries of recruitment
India

### Study participating centre
**VARRAT (Voluntary Association for Rural Reconstruction and Appropriate Technology)**
Boulakani Baradang
Mahakalpara
Kendrapada
Odisha
India
754224

### Study participating centre
**Digital Green Foundation and Trust**
Plot No N3/18, Ranjita Apartment
Flat No 401, IRC Village
Bhubaneswar
Odisha
India
751015

### Study participating centre
**Ekjut**
Amyhata
New Colony
Near Teli Samaj
Keonjhar

Odisha
India
758001

# Sponsor information

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London School of Hygiene and Tropical Medicine

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### Sponsor type
University/education

### Website
http://www.lshtm.ac.uk/

### 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, 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
UK aid Department for International Development from UK government

# Results and Publications

### Publication and dissemination plan
Trial results are planned to be published in a high-impact peer reviewed journal, within one year after the overall trial end date (before May 2021). A detailed publication and dissemination plan will be developed in year 2017.

### Intention to publish date
01/05/2021

### Individual participant data (IPD) sharing plan
The study team will make the full datasets available in anonymized form within 2 to 3 years of project completion. This embargo period is requested to allow time for additional analysis and further publication of research findings to be performed. Prior to deposit into the data repository, data outputs will be anonymized to protect participant confidentiality and converted into a file format suitable for long-term access, based on the recommendations of the UK Data Service (http://ukdataservice.ac.uk/manage-data/format/recommended-formats.aspx). Data will be submitted to LSHTM Data Compass - an institutional research data repository built upon the ePrints platform to be launched in early 2015 – for long-term curation, preservation and sharing. A metadata record will be created for each output, outlining pertinent information such as when, where and how it was created. All metadata records will be exposed via RSS, ATOM, and OAI-PMH for harvesting by 3rd party services, such as research data catalogues. A Digital Object Identifier (DOI) will also be assigned to the metadata records, enabling citation in academic papers. Access to each output will be provided through request access. It is envisaged that a request access system will be used to provide data access. An interested researcher will complete a web-based data access form in the LSHTM Research Data Repository and submit it to the primary contact for approval. If the intended use complies with consent agreement and ethical approval has been obtained, they will be asked to sign a Data Transfer Agreement indicating, among other requirements, that they will not attempt to re-identify participants.

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 09/03/2018 | | Yes | No |
| Results article | | 01/05/2021 | 06/04/2021 | Yes | No |
| Results article | Economic evaluation | 10/06/2022 | 13/06/2022 | Yes | No |

| | | | | | |
|---|---|---|---|---|---|
| Protocol article | Protocol for the cost-consequence and equity impact analyses | 27/05/2019 | 13/02/2025 | Yes | No |
| Results article | | 20/03/2020 | 13/02/2025 | Yes | No |
| Results article | Intrahousehold power inequalities and cooperation | 20/03/2023 | 13/02/2025 | Yes | No |