

# Promoting homestead gardens to improve dietary diversity in Rural India: a randomized controlled trial

<b>Submission date</b> 21/05/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/05/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/11/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many people in rural India suffer from poor nutrition because they cannot afford or otherwise do not have access to a full range of food groups. While backyard gardens could produce crops to supplement existing diets, irrigation water is often unavailable during growing seasons - a barrier that will be aggravated by climate change. This study aims to test an intervention designed to increase the consumption of a wider range of foods by promoting backyard gardens irrigated with "grey water" - relatively clean wastewater from dishwashing and bathing.

### Who can participate?

Households in 82 communities in Ganjam and Gajapati Districts of Odisha, India

### What does the study involve?

Half of the communities will be randomly assigned to receive the intervention. The intervention includes community activities designed to build awareness and capacity, as well as the provision of seeds, fencing, irrigation equipment and pest-control strategies. The intervention will be delivered by Gram Vikas, an Indian NGO. The other communities will initially serve as controls and will be offered the intervention at the end of the 12-month trial. Dietary diversity is assessed by recording the number of food groups consumed in the previous day based on a 24-hour dietary recall.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Emory University (USA)

### When is the study starting and how long is it expected to run for?

January 2024 to December 2025

Who is funding the study?

CARE USA

Who is the main contact?

Dr Sheela Sinharoy, Sheela.sinharoy@emory.edu

## Contact information

### Type(s)

Public, Scientific, Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

CARE USA US3J3/ANO5US0002/8

## Study information

**Scientific Title**

Climate Resilient Odisha Produce Study (CROPS): a randomized controlled trial in rural Odisha, India

**Acronym**

CROPS

**Study objectives**

Individuals living in households that receive the intervention will have significantly higher dietary diversity than individuals living in households that do not receive the intervention.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

1. approved 15/04/2024, Emory University IRB (1599 Clifton Rd NE, Atlanta, 30322, United States of America; +1 (0)404 727 3889; irb@emory.edu), ref: STUDY00007613

2. approved 20/05/2024, Independent Ethics Committee of XIM University (Plot No.12(A), Nijigada, Kurki, Harirajpur, Puri, Odisha, 752050, India; +91 (0)674 23777000; deansgpa@xim.edu.in), ref: XU2024520212VC

**Study design**

Non-blinded cluster-randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Dietary diversity

**Interventions**

Current interventions as of 12/09/2024:

Following enrollment and baselining of study participants, the 82 rural villages in Ganjam and Gajapati Districts in Odisha will be randomized using a random number generator either to the intervention arm (41 communities) or the control arm (41 communities).

Intervention arm:

1. Community meetings/trainings to:

1.1. Build knowledge, skills, and self-efficacy related to climate-smart agricultural techniques for year-round production of fruits and vegetables through backyard gardens

1.2. Improve knowledge of the importance of dietary diversity for all household members and

self-efficacy related to food preparation and distribution

- 1.3. Increase women's negotiating and decision-making power in the household
2. Distribution of inputs and hardware including seeds and seedlings, supplies for integrated pest management (e.g., fencing material), and hardware for greywater capture and re-use (e.g., PVC pipes, watering cans)

Control arm:

No intervention (offered the intervention at the end of the 12-month trial)

The trial will continue for a period of approximately 18 months from June 2024 to December 2025. The study protocol and ethics approvals authorize additional follow-up for up to 24 months following the completion of the trial to assess longer-term impacts.

Previous interventions:

Following enrollment and baselining of study participants, the 90 rural villages in Ganjam and Gajapati Districts in Odisha will be randomized using a random number generator either to the intervention arm (45 communities) or a control arm (45 communities).

Intervention arm:

1. Community meetings/trainings to:
  - 1.1. Build knowledge, skills, and self-efficacy related to climate-smart agricultural techniques for year-round production of fruits and vegetables through backyard gardens
  - 1.2. Improve knowledge of the importance of dietary diversity for all household members and self-efficacy related to food preparation and distribution
  - 1.3. Increase women's negotiating and decision-making power in the household
2. Distribution of inputs and hardware including seeds and seedlings, supplies for integrated pest management (e.g., fencing material), and hardware for greywater capture and re-use (e.g., PVC pipes, watering cans)

Control arm:

No intervention (offered the intervention at the end of the 12-month trial)

The trial will continue for a period of approximately 18 months from June 2024 to December 2025. The study protocol and ethics approvals authorize additional follow-up for up to 24 months following the completion of the trial to assess longer-term impacts.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Dietary diversity among adult women of reproductive age (18-49 years) is measured using a 24-hour dietary recall at baseline, 6 months, 12 months and 18 months

## **Key secondary outcome(s)**

Current secondary outcome measures as of 12/09/2024:

1. Dietary diversity among children under age 5 and other household members measured using a 24-hour dietary recall at baseline, 6 months, 12 months and 18 months
2. Food insecurity measured using the Food Insecurity Experience Scale (FIES) at baseline, 6 months, 12 months, and 18 months
3. Subjective wellbeing measured using the World Health Organization-5 (WHO-5) scale at baseline, 6 months, 12 months and 18 months

4. Self-efficacy measured using researcher-developed questions specific to self-efficacy for gardening and self-efficacy related to nutrition at baseline, 6 months, 12 months and 18 months
5. Women's empowerment measured using questions adapted from the project-level Women's Empowerment in Agriculture Index at baseline, 6 months, 12 months and 18 months

Previous secondary outcome measures:

1. Dietary diversity among children under age 5 measured using a 24-hour dietary recall at baseline, 6 months, 12 months and 18 months
2. Food insecurity measured using the Food Insecurity Experience Scale (FIES) at baseline, 6 months, 12 months, and 18 months
3. Subjective wellbeing measured using the World Health Organization-5 (WHO-5) scale at baseline, 6 months, 12 months and 18 months
4. Self-efficacy measured using researcher-developed questions specific to self-efficacy for gardening and self-efficacy related to nutrition at baseline, 6 months, 12 months and 18 months
5. Women's empowerment measured using questions adapted from the project-level Women's Empowerment in Agriculture Index at baseline, 6 months, 12 months and 18 months

### **Completion date**

31/12/2025

## **Eligibility**

### **Key inclusion criteria**

Current participant inclusion criteria as of 12/09/2024:

Intervention: Adults 18 years and older who live in the study area in Odisha, India

Evaluation: Households in 82 communities in Ganjam and Gajapati Districts of Odisha, India

Previous participant inclusion criteria:

Intervention: Adults 18 years and older who live in the study area in Odisha, India

Evaluation: Households with a child aged under 5 years (up to 25 households, one adult woman and one adult man per household) in each of the intervention and control villages

### **Participant type(s)**

Population

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Adults unable to consent
2. Individuals who do not meet age requirements
3. Prisoners
4. Cognitively impaired or individuals with Impaired Decision-Making Capacity

**Date of first enrolment**

31/05/2024

**Date of final enrolment**

31/12/2024

## **Locations**

**Countries of recruitment**

India

**Study participating centre**

**Gram Vikas, a Non-Governmental Organization registered in India under the Societies Registration Act 1860**

Plot No. 72/B

Forest Park, Bhubaneswar

Odisha

India

751009

**Study participating centre**

**Ganjam and Gajapati Districts**

Odisha

India

N/A

## **Sponsor information**

**Organisation**

CARE USA

**ROR**

<https://ror.org/038espn32>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

CARE USA

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes