

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

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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not applicable

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2024

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

2050: Up to 25 households in each of up to 82 communities (41 intervention/41 control)

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

Sponsor details

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Sponsor type

Charity

ROR

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

Funder(s)**Funder type**

Charity

Funder Name

CARE USA

Results and Publications**Publication and dissemination plan**

The results may be shared in a dissemination/consultation workshop with stakeholders, at presentations at national and international conferences, and in manuscripts published as pre-prints and in peer-reviewed journals.

Intention to publish date

31/12/2028

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