ISRCTN11819073 https://doi.org/10.1186/ISRCTN11819073

# Co-benefits of large scale organic farming on human health (BLOOM)

**Submission date**
22/03/2021

**Recruitment status**
No longer recruiting

**Registration date**
19/04/2021

**Overall study status**
Completed

**Last Edited**
06/11/2024

**Condition category**
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
The agriculture sector is the single-largest employer in India with approximately 40% of adults employed in agricultural work. In the 1960s, in order to reduce reliance on food aid, the Government of India promoted large-scale monocropping with hybrid seeds and the use of agrochemicals across the country. Whilst this Green Revolution has been credited for increases in yields of wheat and rice, agriculture in India is in crisis. Since 1995, over 250,000 farmers in India have committed suicide, many by ingestion of pesticides. Farmer debt from increasing input costs and decreasing returns has been cited as the underlying cause of this crisis.
It was in this context that Andhra Pradesh passed a pioneering government order known as Andhra Pradesh Community-managed Natural Farming (APCNF). APCNF is the world's largest chemical-free agroecology and regenerative agriculture programme. It aims to transform all 6 million farming families in Andhra Pradesh into natural farming practitioners on their 8 million hectares of land by 2034.
The primary aims of this study are to determine if the APCNF programme in Andhra Pradesh results in lower urinary pesticides and higher dietary diversity, as compared to standard agricultural practices in Andhra Pradesh.
The secondary aims are to determine whether the APCNF programme improves health in adults and in children.

Who can participate?
Adults aged 18 years and older permanently residing in an agricultural household and their children aged between 0-38 months at enrollment.

What does the study involve?
The study is recruiting 80 clusters (each cluster is ~2,000 households and is defined by the APCNF team) in Visakhapatnam, Anakapalli, Kurnool and Nandyal districts (formerly Kurnool and Visakhapatnam districts) in Andhra Pradesh, India. Following baseline assessment, clusters will be randomised to either immediately receive the APCNF programme or to receive the APCNF programme in 24 months. Participation in this training will be voluntary.
The APCNF programme will be implemented by Rythu Sadhikara Samstha (RySS), a not-for-profit established by the Government of Andhra Pradesh. Researchers at the University of Edinburgh (UoE) and Ashoka University will not implement the intervention. They will only conduct a

parallel prospective observational study of a random subset of about 2,000 farming households selected from participating clusters.
Adults 18 years and older and their children under 38 months old will be invited to take part in this study if their household is engaged in agricultural work and they permanently reside in their village. An assessment of the participant's health will be done at baseline, 12 months, and 24 months and will provide information on urinary pesticides, dietary diversity, crop yields, total household income, glycaemia, kidney function, musculoskeletal pain, headache, respiratory symptoms, dermatological symptoms, depression, malnutrition, and child growth and development.
This research study will provide evidence regarding the effectiveness of APCNF in the Indian scenario with direct generalisation to other states in India and countries in South Asia. More broadly, the results of this study will help researchers better understand the health problems caused by pesticides used in agriculture.

What are the possible benefits and risks of participating?
The participant will get results of measurements such as his/her height, weight, BMI, and blood pressure. We will explain what these measurements mean.
The potential risks from data and sample collection are minimal and include light-headedness from fasting, mild discomfort during the blood collection and slight discolouration of the area from which the blood sample will be taken. A new health problem that the participant may not know about might be identified.
The risk of spread of COVID-19 infection and current social distancing guidelines are potential challenges in conducting study activities involving study participants. However, Ashoka University has experience in conducting such procedures using all recommended precautions, such as the use of personal protective equipment (PPE), and we will do so, when needed, for this proposed study as well.

Where is the study run from?
The study is being conducted by Ashoka University and UoE, in partnership with RySS, which is a part of the Andhra Pradesh Government. The study will take place in 80 APCNF clusters divided equally between what were formerly Kurnool and Visakhapatnam districts in Andhra Pradesh (India).

When is the study starting and how long is it expected to run for?
March 2021 to March 2025

Who is funding the study?
The Medical Research Council (UK)

Who is the main contact?
Dr Lindsay Jaacks
lindsay.jaacks@ed.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Lindsay Jaacks

**ORCID ID**
https://orcid.org/0000-0002-7791-5167

**Contact details**
The University of Edinburgh
Global Academy of Agriculture and Food Security
The Roslin Institute
Easter Bush Campus
Edinburgh
United Kingdom
EH25 9RG
-
lindsay.jaacks@ed.ac.uk

**Type(s)**
Scientific

**Contact name**
Dr Poornima Prabhakaran

**ORCID ID**
https://orcid.org/0000-0003-3134-7026

**Contact details**
Centre for Health Analytics Research and Trends (CHART)
Trivedi School of Biosciences
Ashoka University
Rajiv Ganhi Education City
Sonipat
India
131029
+91 0130 230 0000
poornima.prabhakaran@ashoka.edu.in

# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Protocol serial number**
MR/T044527/1

# Study information

**Scientific Title**
Co-Benefits of Largescale Organic Farming on Human Health (BLOOM): A cluster-randomised controlled evaluation of Andhra Pradesh Community-managed Natural Farming

**Acronym**
BLOOM

## Study objectives
Current study hypothesis as of 20/07/2022:
1. The Andhra Pradesh Community-managed Natural Farming (APCNF) programme will lower urinary pesticides and increase dietary diversity, as compared to standard agricultural practices
2. The APCNF programme will improve adult (≥18 years) glycaemia (quantified as fasting blood glucose [FBG]), improve kidney function (quantified as estimated glomerular filtration rate [eGFR]), reduce malnutrition (anaemia), and reduce self-reported symptoms (musculoskeletal pain, headache, respiratory symptoms, dermatological symptoms, and depression)
3. The APCNF programme will improve child (<38 months) growth (length-for-age z-score) and cognitive development (quantified as Caregiver Reported Early Development Index [CREDI])

Previous study hypothesis:
1. The Andhra Pradesh Community-managed Natural Farming (APCNF) programme will lower urinary pesticides and increase dietary diversity, as compared to standard agricultural practices
2. The APCNF programme will achieve equivalent crop yields and total household income, as compared to standard agricultural practices
3. The APCNF programme will improve adult (>25 years) glycaemia (quantified as fasting blood glucose [FBG]), kidney function (quantified as estimated glomerular filtration rate [eGFR]), and self-reported symptoms (musculoskeletal pain, headache, respiratory symptoms, dermatological symptoms, and depression)
4. The APCNF programme will improve child (<3 years) growth (length-for-age z-score) and cognitive development (quantified as Caregiver Reported Early Development Index [CREDI])

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Approved 23/07/2021, Public Health Foundation of India (PHFI) Institutional Ethics Committee (IEC) (Delhi NCR, Plot No. 47, Sector 44, Institutional Area, Gurgaon – 122002, India; +91-11-40057500; trc-iec@phfi.org), ref: TRC-IEC 463/21
2. Approved 27/05/2022, the Government of India, Indian Council of Medical Research, Health Ministry's Screening Committee (HMSC, Health Ministry's Screening Committee, Department of Health Research, Ministry of Health & Family Welfare, Government of India, 2nd Floor, IRCS Building, 1, Red Cross Road, New Delhi - 110001, India; +91 (0)11 26588895 ext. 361; hmsc-ihd@icmr.gov.in), ref: 2021-7941
3. Approved 26/07/2021, The University of Edinburgh Royal (Dick) School of Veterinary Studies (R(D)SVS) Human Ethical Review Committee (HERC) (Royal (Dick) School of Veterinary Studies, The University of Edinburgh, Roslin, EH25 9RG; +44(0)131 651 7300; HERC.vets@ed.ac.uk), ref: HERC_703_21

Added 24/08/2023:
1. Approved 20/06/2023, Ashoka University Human Research Ethics Committee (AUHREC), (Plot No 2, Rajiv Gandhi Education City, National Capital Region, P.O Rai, Sonipat, Haryana – 131029, India; +91-130-230-0000; registrar@ashoka.edu.in), ref: UHREC/10062023/meeting2/002-6

## Study design
Community-based cluster-randomized controlled evaluation

## Primary study design
Observational

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Type 2 diabetes, chronic kidney disease, musculoskeletal pain, headache, respiratory diseases, dermatological symptoms, depression, malnutrition, cognitive development, diet quality in rural agricultural households

## Interventions
The intervention is the APCNF programme implemented by Rythu Sadhikara Samstha (RySS), a not-for-profit established by the Government of Andhra Pradesh.

Researchers at the University of Edinburgh (UoE) and Ashoka University will not implement the intervention. They will only conduct a parallel prospective observational study of a random subset of farming households from the 40 clusters randomised to receive the APCNF programme immediately ('intervention') and the 40 clusters randomised to receive the APCNF programme after 24 months ('control').

Training in APCNF practices is done by expert APCNF farmers known as Community Resource Persons (CRPs). Each cluster of 2,000 ±200 farming households (4-20 villages, depending on the size of the villages) is assigned 1-2 CRPs, who are paid by the government to live in the cluster and motivate and support farmers in adopting APCNF practices.

With regards to APCNF programme content, in addition to adhering to zero synthetic chemical inputs, the APCNF programme emphasises the following four pillars: (1) microbial seed coating with cow dung- and urine-based formulations, (2) enhancing the soil microbiome by integrating cow dung and urine, and (3) cover cropping and mulching, which together result in (4) greater soil humus, improved soil aeration, and water retention. The programme also includes: using botanical extracts for pest management, minimal tillage, using indigenous seeds, and promoting crop diversity.

At the end of the study, control clusters will receive the APCNF training such that all clusters receive the training by 2024 as originally planned by the government.

## Intervention Type
Behavioural

## Primary outcome(s)
Current primary outcome measures as of 20/07/2022:
Both primary outcomes will be measured at baseline, 12 and 24 months
1. Dialkyl phosphate (DAP) metabolites (dimethylphosphate, dimethylthiophosphate, dimethyldithiophosphate, diethylphosphate, diethylthio-phosphate, and diethyldithiophosphate) in a 15% subset of participants, measured in urine using gas chromatography-mass spectrometry (GC-MS)
2. Dietary diversity measured by 24-hour dietary recall and calculated according to FAO's Minimum Dietary Diversity for Women (MDD-W) in adults and WHO's dietary diversity score (DDS) in children

Previous primary outcome measures:
All primary outcomes will be measured at baseline, 12 and 24 months
1. Dialkyl phosphate (DAP) metabolites (dimethylphosphate, dimethylthiophosphate,

dimethyldithiophosphate, diethylphosphate, diethylthio-phosphate, and diethyldithiophosphate) measured in urine using gas chromatography-mass spectrometry (GC-MS)
2. Dietary diversity measured by 24-hour dietary recall administered using the Indian adaptation of INTAKE24 and calculated according to FAO's Minimum Dietary Diversity for Women (MDD-W)
3. Crop yield measured using a questionnaire adapted from the Agriculture Census 2015-16 (Ministry of Agriculture and Farmers' Welfare)
4. Total household income measured using a questionnaire adapted from the National Sample Survey Office's (NSS 70th Round) Situation Assessment Survey of Agricultural Households 2013 (Ministry of Statistics and Programme Implementation)

## Key secondary outcome(s))

Current secondary outcome measures as of 20/07/2022:
All secondary outcomes will be measured at baseline, 12 and 24 months
Adults:
1. Glucose measured in fasting plasma samples at a certified laboratory using the Hexokinase method
2. Creatinine and albumin measured in serum at an IDMS traceable laboratory
3. Self-reported clinical symptoms and musculoskeletal pain in the past 3 months. Symptoms will include: itchy skin, rash on skin, dry/cracking skin, blisters on the skin, chest pain, low fever, loss of appetite or body weight, extreme fatigue or weakness, headache, dizziness, eye irritation or watering, pain in the eye, redness in the eye, blurry vision, reduced hearing ability, nasal congestion or runny nose, difficulty breathing, digestive problems, urinate more than usual, and jaundice. The list of symptoms was adapted from a survey on pesticide use in Thailand (Kongtip et al. Int J Environ Res Public Health 2018)
4. Self-reported depressive symptoms measured using the Primary Health Questionnaire (PHQ, 9 items)
5. Women's empowerment measured using the abbreviated Women's Empowerment in Agriculture Index (A-WEAI) and abbreviated Women's Empowerment in Nutrition Index (A-WENI)
6. Anaemia measured in venous blood samples at a certified laboratory
7. Household crop yield will be collected via self-report using questions adapted from the Indian National Sample Survey Office's (NSSO) Situation Assessment Survey of Agricultural Households
8. Household income, expenditures, and debt will be collected via self-report using questions adapted from the NSSO Situation Assessment Survey of Agricultural Households

Children:
1. Length (≤2 years)/height (>2 years)-for-age z-score measured using a stadiometer and the WHO Child Growth Standards
2. Development measured using the Caregiver-Reported Early Development Index (CREDI)

Previous secondary outcome measures:
All secondary outcomes will be measured at baseline, 12 and 24 months
Adults:
1. Glucose measured in fasting plasma samples at a certified laboratory using the Hexokinase method
2. Creatinine and albumin measured in serum at an IDMS traceable laboratory
3. Self-reported clinical symptoms and musculoskeletal pain in the past 3 months. Symptoms will include: itchy skin, rash on skin, dry/cracking skin, blisters on the skin, chest pain, low fever, loss of appetite or body weight, extreme fatigue or weakness, headache, dizziness, eye irritation or watering, pain in the eye, redness in the eye, blurry vision, reduced hearing ability, nasal congestion or runny nose, difficulty breathing, digestive problems, urinate more than usual, and jaundice. The list of symptoms was adapted from a survey on pesticide use in Thailand (Kongtip

et al. Int J Environ Res Public Health 2018)
4. Self-reported depressive symptoms measured using the Primary Health Questionnaire (PHQ, 9 items)
5. Women's empowerment measured using the abbreviated Women's Empowerment in Agriculture Index (A-WEAI)

Children:
1. Length (≤2 years)/height (>2 years)-for-age z-score measured using a stadiometer and the WHO Child Growth Standards. The average of 2 measures with be analysed or, if measures #1 and #2 differ by >0.7 cm, a third measure will be taken and the average of the 2 closest measures analysed
2. Development measured using the Caregiver-Reported Early Development Index (CREDI)

### Completion date
01/03/2025

# Eligibility

### Key inclusion criteria
Current inclusion criteria as of 20/07/2022:
Adults:
1. Household engaged in agriculture work defined as any one or more of the following: owning land, harvesting a crop in the past month regardless of land ownership, or earning a daily wage or contract-based wage for agricultural activities. This includes farmers, farm owners, farm workers, field workers, growers, harvesters, packers, graders and sorters, as well as agricultural pesticide handlers (mixers, loaders, cleaners and sprayers)
2. Aged 18 years and older. Age will be confirmed by directly viewing a government-issued document with the individual's date of birth
3. Permanently reside in the selected household. 'Residence' will be defined as a group of people who eat from the same kitchen
4. Have a child aged <38 months who also resides in the household
5. Willing to provide informed consent

Children:
1. Aged <38 months at enrollment. Age will be confirmed by directly viewing a government-issued document with the individual's date of birth
2. Permanently reside in the selected household. 'Residence' will be defined as a group of people who eat from the same kitchen
3. Parent or legal guardian willing to provide informed consent

Previous inclusion criteria:
Adults:
1. Engaged in agriculture work defined as any one or more of the following: owning land, harvesting a crop in the past month regardless of land ownership, or earning a daily wage or contract-based wage for agricultural activities. This includes farmers, farm owners, farm workers, field workers, growers, harvesters, packers, graders and sorters, as well as agricultural pesticide handlers (mixers, loaders, cleaners and sprayers).
2. Aged >25 years. Age will be confirmed by directly viewing a government-issued document with the individual's date of birth.
3. Permanently reside in the selected household. 'Residence' will be defined as sleeping in the house on a typical weeknight.

4. Have a child aged <3 years who also resides in the household.
5. Willing to provide informed consent.

Children:
1. Aged <3 years. Age will be confirmed by directly viewing a government-issued document with the individual's date of birth.
2. Permanently reside in the selected household. 'Residence' will be defined as sleeping in the house on a typical weeknight.
3. Parent or legal guardian willing to provide informed consent.

## Participant type(s)
Healthy volunteer

## Healthy volunteers allowed
No

## Age group
Mixed

## Sex
All

## Total final enrolment
5766

## Key exclusion criteria
Current exclusion criteria as of 20/07/2022:
Adults:
1. Plan to move permanently out of the study area in the next 12 months
2. Bedridden or mentally challenged
3. Visible disabilities (e.g., physical malformations, blindness, deafness, obvious genetic syndromes)
4. Primary language other than Telugu
5. Already enrolled in a different research study
6. Unwilling to provide informed consent

Children:
1. Bedridden or mentally challenged
2. Visible disabilities (eg, physical malformations, blindness, deafness, obvious genetic syndromes)
3. Already enrolled in a different research study
4. Parent or legal guardian unwilling to provide informed consent

Previous exclusion criteria:
Adults:
1. Plan to move permanently out of the selected household in the next 12 months
2. Bedridden or mentally challenged
3. Visible disabilities (e.g., physical malformations, blindness, deafness, obvious genetic syndromes)
4. Speak a language other than Telugu
5. Females: pregnant (by self-report)

6. Already enrolled in a different research study
7. Unwilling to provide informed consent

Children:
1. Bedridden or mentally challenged
2. Visible disabilities (eg, physical malformations, blindness, deafness, obvious genetic syndromes)
3. Already enrolled in a different research study
4. Parent or legal guardian unwilling to provide informed consent

### Date of first enrolment
23/06/2022

### Date of final enrolment
30/09/2022

## Locations

### Countries of recruitment
India

### Study participating centre
**Ashoka University**
Plot No 2, Rajiv Gandhi Education City,
National Capital Region, P.O Rai
Haryana
Sonipat
India
131029

## Sponsor information

### Organisation
University of Edinburgh

### ROR
https://ror.org/01nrxwf90

## Funder(s)

### Funder type
Research council

### Funder Name
Medical Research Council

### Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
A de-identified dataset that does not contain any information that could lead to participant identification will be made publicly available on the University of Edinburgh's DataStore within 1 year of publishing the results for all primary outcomes.

### IPD sharing plan summary
Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 02/03/2023 | 03/03/2023 | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |