Community intervention to improve growth among children under two in rural India

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/12/2013		[X] Protocol		
Registration date	Overall study status Completed Condition category Nutritional, Metabolic, Endocrine	Statistical analysis plan		
13/12/2013		☐ Results		
Last Edited		Individual participant data		
11/02/2021		Record updated in last year		

Plain English summary of protocol

Background and study aims

The Government of India's Integrated Child Development Services programme has recommended the introduction of a new community-based worker focused intervention on improving the health and nutrition of mothers in pregnancy and children under two in rural, underserved areas of India, where 40% of the world's undernourished children live today. In this study, we will test a community intervention in rural eastern India in order to understand whether, how and at what cost the intervention can improve children's growth.

Who can participate?

The study aims to recruit 120 geographical clusters composed of villages and adjoining hamlets located in rural areas of Jharkhand and Odisha (eastern India). Within those clusters, the study aims to recruit 2520 pregnant women and their children.

What does the study involve?

The 120 clusters recruited to participate in the study will be randomly allocated to the community intervention group or to the control group. In the intervention group, in each cluster, a trained community worker will lead monthly counseling sessions through home visits to all mothers of children under two, and participatory meetings with women's groups. Home visits and group meetings will aim to promote nutrition and health in pregnancy and the first two years of life. Both intervention and control clusters will receive an intervention aimed at building the capacity of Village Health Sanitation and Nutrition Committees. In intervention and control clusters, every pregnant woman recruited to the study will be interviewed in the third trimester of pregnancy, and then in the first, third, sixth, ninth, twelfth and eighteenth month of her child's life, in order to monitor how the child is growing, what is the childeating, and whether the child has fallen ill. At the end of the study, we will compare length, weight, feeding practices and illnesses among children born in intervention clusters and those in control clusters.

What are the possible benefits and risks of participating?

There are three main benefits of taking part: children identified as severely acutely malnourished by the trial team will be referred for care in both intervention and control areas; the intervention may lead to greater responsiveness of local health and nutrition services; and both intervention and control clusters will receive an intervention to strengthen the capacity of

Village Health Sanitation and Nutrition Committees. If the intervention is found to improve children's growth, there may be further benefit to control clusters and similar areas if the study influences further support for a community-based worker devoted to health and nutrition in rural India. There are no known risks of participating for pregnant women and children.

Where is the study run from?

In India, the study is run by the civil society organization Ekjut (http://www.ekjutindia.org) and the Public Health Foundation of India (http://www.phfi.org). In the UK, the study is supported by University College London's Institute for Global Health (http://www.ucl.ac.uk/igh). The study is village-based. Potential respondents will be visited at home and invited to participate.

When is the study starting and how long is it expected to run for? The study started in April 2013 and is expected to run until January 2017. Recruitment of clusters began in June 2013, and recruitment of pregnant women began in October 2013. Data collection is expected to take place between October 2013 and August 2016.

Who is funding the study?

The study is funded by the Wellcome Trust, the UK Medical Research Council, and the Department for International Development (DFID) through their joint Global Health Trial scheme.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Cluster-randomised controlled trial of a community intervention to improve growth among children under two in rural India

Acronym

CARING (Community Action Research for Improved Nutrition and Growth in rural India)

Study objectives

We hypothesize that an intervention involving a community-based worker carrying out monthly participatory meetings with local women's groups and home visits to all mothers of children under two in her village with the goal of promoting appropriate nutrition along with preventive and treatment health behaviours in pregnancy and the first two years of life, will improve the growth of children under two in rural India.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. The Institutional Ethics Committee of the Public Health Foundation of India, 10/06/2013, ref: TRC-IEC-163/13
- 2. University College London's Research Ethics Committee, 11/06/2013, ref: 1881/002
- 3. Ekjut Independent Ethics Committee, 10/05/2013

Study design

Cluster randomised controlled trial, parallel design

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Improving growth and nutrition in children

Interventions

The intervention to be tested involves a community worker carrying out two activities: (a) monthly home visits to all children aged 0-24 months and their mothers in order to support appropriate feeding, infection control and caregiving; (b) a monthly participatory women's group meeting to catalyse individual and community action for maternal and child health and nutrition.

In addition, both intervention and control clusters will receive an intervention aimed at building the capacity of Village Health Sanitation and Nutrition Committees (VHSNCs) through group meetings with Committee members. In these meetings, VHSNCs will be offered information assistance with planning and monitoring their activities.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Children's length-for-age mean Z scores at 18 months

Key secondary outcome(s))

Current secondary outcome measures as of 26/07/2016:

- 1. Mean weight for height z score at 18 months
- 2. Mean weight for age z score at 18 months
- 3. Mean MUAC z score at 18 months
- 4. % of children who are stunted at 18 months
- 5. % of children who are underweight at 18 months
- 6. % of children who are wasted at 18 months
- 7. Mean birth weight (within 72h)
- 8. Change in weight from birth to 18 months
- 9. Change in height from birth to 18 months
- 10. Mean length for age z score at 72h, 3, 6, 9 and 12 months
- 11. Mean weight for height z score at 72h, 3, 6, 9 and 12 months
- 12. Mean weight for age z score at 72h, 3, 6, 9 and 12 months
- 13. Mean MUAC z score at 6, 9 and 12 months
- 14. Mean maternal MUAC in third trimester of pregnancy
- 15. Mean maternal BMI 9 months after delivery
- 16. Mean number of meals per day in pregnancy
- 17. % pregnant women with minimum dietary diversity
- 18. % infants exclusively breastfed until 6 months
- 19. % infants who started complementary foods at six months
- 20. % children given food from 4 or more groups at 9, 12 and 18 months
- 21. % children given minimum meal frequency at 6,9, 12 and 18 months
- 22. % children given iron-rich foods at 6, 9, 12 and 18 months
- 23. % children given a source of protein at 6, 9, 12 and 18 months
- 24. % children with diarrhoea, cough, fever in past 2 weeks
- 25. % children receiving appropriate care during illness episode (fluid replacement for diarrhoea and continued feeding for all illnesses)
- 26. % sick children for whom care was sought from appropriate provider
- 27. % children who received appropriate treatment from qualified provider
- 28. % children who received BCG, OPV3, DTP3, measles and Hepatitis B
- 29. Mean score in handwashing index
- 30. Infant mortality rate (per 1000 livebirths)

Previous secondary outcome measures:

- 1. Mean Z scores for weight-for-age and weight-for-height through anthropometry at birth, 3, 6,
- 9, 12 and 18 months
- 2. Prevalence of stunting, underweight, and wasting
- 3. Mean MUAC in third trimester of pregnancy
- 4. Birthweight
- 5. Growth velocity between 0 and 18 months
- 6. Infant mortality rate
- 7. 24 hour dietary recall and dietary diversity scores for mothers in the third trimester of pregnancy and at 3 and 6 months post-delivery
- 8. Birth spacing
- 9. Exclusive breastfeeding
- 10. Dietary recall and dietary diversity scores at 6, 9, 12 and 18 months
- 11. Hygienic practices in childcare and preparation of food

- 12. Uptake of preventive and care-seeking interventions for infections including: handwashing, Vitamin A supplementation, immunisation, use of oral rehydration solution
- 13. Care-seeking for childhood illnesses
- 14. Maternal BMI 9 months after delivery
- 15. Maternal empowerment
- 16. Maternal psychosocial distress
- 17. Community worker knowledge of infant and young child feeding (post-training)

Completion date

01/01/2017

Eligibility

Key inclusion criteria

- 1. All women identified in the third trimester of pregnancy between 01/10/2013 and 31/12/2015 residing in the study clusters will be invited to participate in the study in order to monitor changes in food intake and dietary diversity among pregnant women.
- 2. In addition, every woman identified as pregnant between 01/10/2013 and 31/08/2014 residing in the study clusters will be asked for permission to follow-up her live born child for a period of 18 months. Mothers and their children will be followed up at seven time points: in the third trimester of pregnancy, within 72 hours after birth, and at 3, 6, 9, 12 and 18 months after birth.

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

- 1. Stillbirths and neonatal deaths
- 2. Infants whose mothers have died
- 3. Infants with congenital abnormalities and multiple births
- 4. Mothers who migrate out of the study area permanently during the study period

Date of first enrolment

01/06/2013

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

United Kingdom

England

India

Study participating centre
UCL Institute for Global Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation

University College London (UK)

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Department for International Development

Alternative Name(s)

Department for International Development, UK, DFID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/04/2015		Yes	No
<u>Protocol article</u>	economic evaluation protocol	02/11/2016	11/02/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes