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

Submission date
09/12/2013

Recruitment status
No longer recruiting

Registration date
13/12/2013

Overall study status
Completed

Last Edited
11/02/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] 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 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 below to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
01/04/2013

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

Age group
Mixed

Sex
Both

Target number of participants
2520 mothers and children

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
England

India

United Kingdom

Study participating centre
UCL Institute for Global Health
London
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

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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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/01/2018

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
Protocol article	economic evaluation protocol	02/11/2016	11/02/2021	Yes	No