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Can crèche provision, counselling and participatory women's groups reduce undernutrition in children aged up to 3 years in eastern India?

Submission date
26/11/2018

Recruitment status
No longer recruiting

Registration date
30/01/2019

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
In India, one in five children aged under 5 years are acutely undernourished. This study aimed to understand if providing access to creches for children under 3 years, counselling through home visits and community mobilization through participatory women's groups could reduce undernutrition among children under 3 years. It was conducted in rural areas of two states in Eastern India, Jharkhand and Odisha.

Who can take part?
All mothers with children under 3 living in the areas could take part.

What does the study involve?
We will compare undernutrition among children living in areas with no intervention to those living in two areas: one with counselling and groups, and another with counselling, groups, and creches.

What are the possible benefits and risks of participating?
There are no risks to participation, and no immediate benefits to participation.

Where is the study run from?
The study is run by the Public Health Resource Network and Ekjut. Ekjut is the lead centre.

When is the study starting and how long is it expected to run for?
February 2012 to March 2017.

Who is funding the study?
Tata Trusts (India)

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
201207

Study information

Scientific Title
Effects of participatory learning and action with women’s groups, counselling through home visits and crèches on undernutrition among children under three years in eastern India: a quasi-experimental study

Acronym
AAM (Action Against Malnutrition)

Study objectives
We hypothesised that access to monthly participatory learning and action meetings with women' s groups and counselling for caregivers of children under 3 at home would reduce the prevalence of wasting among children 0-36 months by 7% (from 23% to 16%) , and that adding access to creches for children aged 6 months to 3 years to this intervention would reduce wasting by 12% (from 23% to 16%), both compared to a control area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the Public Health Resource Network (PHRN) in Delhi, 10/05 /2013, ref: IEC/EKJUT/03

Study design
Cluster-controlled non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Child undernutrition: wasting (primary outcome), stunting, underweight

Interventions
1. Participatory Learning and Action (PLA) meetings and counselling through home visits
The PLA intervention was a structured cycle of participatory women's groups meetings facilitated by a local female worker who was given an incentive of 3500 Indian rupees (INR 3500, equivalent to USD 60) per month. A cycle of meetings had four phases. In the first phase, women Identified and prioritised problems related to undernutrition among children under 3 years (e.g. lack of dietary diversity, diarrhoea, malaria) using picture cards. They then discussed the underlying medical and social causes for these prioritised problems through story-telling and discussions before identifying locally feasible strategies to address these problems. At the end of this phase, the group organised a meeting with the wider community to seek support for its chosen strategies. In the third phase, the group implemented its strategies and learned about practical actions to try at home and in the community (e.g. methods to enrich complementary foods or clearing stagnant water ponds). In the fourth phase, each group evaluated the meeting cycle.
The PLA facilitator also provided counselling to mothers of children under 3 years through home visits. Visits focused on appropriate feeding, home care practices and care during illness using

tools for the WHO's Integrated Management of Childhood Illness and Infant and Young Child Feeding counselling. The facilitator and mothers discussed early and exclusive breastfeeding, timely initiation of complementary feeding, how to enrich complementary foods, frequency of feeding, danger signs related to childhood illnesses, preventive measures (handwashing and the use of bed nets) and the importance of seeking care from trained providers. During PLA meetings, the facilitator used picture cards, story-telling, role plays, games, and demonstrations of handwashing and food enrichment. During the home visits, they used mid upper arm circumference (MUAC) tapes, a pictorial counselling tool and Mother and Child Protection (MCP) cards for age-appropriate counselling.
Each facilitator was responsible for conducting 8-10 monthly PLA meetings and visiting 25-35 mothers of children under 3 years in her cluster. Her visits were expected to cover approximately 10-15% of homes with children under 3 years in a given month. The facilitator prioritised visits to the following children under 3 years: those identified as having MUAC <10. 5cm or as severely underweight during PLA meetings; those identified as underweight by Anganwadi workers; those who recently had an illness; those who lived in hamlets; and those who had recently been discharged from a Malnutrition Treatment Centre or Nutritional Rehabilitation Centre.

2. Crèches for children aged 6 months to 3 years
Crèches offered children a protected, smoke-free environment with nutritious food, safe drinking water, handwashing stations, early childhood stimulation activities and regular growth monitoring. Children in crèches received one full meal and two snacks a day, and eggs twice a week. Meal and snack preparation was supervised with nutritional inputs to ensure caloric and protein sufficiency. The programme was available to every child in the village irrespective of their nutritional status. A special focus was given to children who did not gain weight or whose weight decreased over two consecutive months, our operational definition of growth faltering. Children whose growth faltered and those with severe underweight were given two additional calorie-dense and protein-rich meals per day. We also developed a protocol for persistent growth faltering which involved home visits and medical referrals.
Each crèche was run by two local, trained crèche workers. Like PLA facilitators, crèche workers received INR 3500 (USD 60) per month.

Intervention Type
Behavioural

Primary outcome measure
Wasting (weight-for-height) measured using infantometers (Seca 210 with 55-mm graduation) or stadiometers (Seca 213 with 1-mm graduation) and Equinox weighing scales with 100-g graduations for all children aged 0-36 months in baseline and endline surveys

Secondary outcome measures
Anthropometry:
1. Underweight (weight-for-age) measured using Equinox weighing scales with 100-g graduations for all children aged 0-36 months in baseline and endline surveys
2. Stunting (height-for-age) measured using infantometers (Seca 210 with 55-mm graduation) and stadiometers (Seca 213 with 1-mm graduation) for length/height for all children aged 0-36 months in baseline and endline surveys

Infant and toddler feeding practices:
3. Timely introduction of semi-solid and solid foods assessed through questionnaire with mothers for children aged 6-9 months at baseline and endline

4. Minimum dietary diversity (>=4 food groups) assessed through questionnaire with mothers for children aged 6-24 months at baseline and endline
5. Minimum meal frequency (breastfed children) assessed through questionnaire with mothers for children aged 6-9 months at baseline and endline
6. Minimum meal frequency assessed through questionnaire with mothers for breastfed children aged 9-24 months at baseline and endline
7. Minimum acceptable diet assessed through questionnaire with mothers for children aged 6-9 months at baseline and endline
8. Minimum acceptable diet assessed through questionnaire with mothers for children aged 9-24 months at baseline and endline
9. Consumption of iron-rich foods assessed through questionnaire with mothers for children aged 6-24 months at baseline and endline

Water, sanitation and hygiene practices:
10. Access to improved water source assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
11. Water treatment, physical or chemical assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
12. Handwashing with soap after using toilet, before preparing food and before feeding child assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline

Preventive health practices, morbidity and care-seeking:
13. Household owns a bed net assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
14. Child slept under a bed net last night assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
15. Measles immunisation received assessed through a questionnaire with mothers of children aged 12-24 months at baseline and endline
16. Vitamin A dose received in last 6 months assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
17. Deworming in last 6 months assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
18. Diarrhoea in last 14 days assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
19. Same or more breastmilk given during diarrhoea assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
20. Same or more food given during diarrhoea assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
21. Advice sought from Auxiliary Nurse Midwife (ANM), Anganwadi Worker (AWW) or Accredited Social Health Activist (ASHA) for diarrhoea assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
22. Oral rehydration solution (ORS) used during diarrhoea assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
23. Fever or cough in last 14 days assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
24. Same or more breastmilk given in case of fever or cough assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
25. Same or more food given in case of fever of cough assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
26. Advice sought for fever or cough assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline

Uptake of nutrition services:
27. Regular food received from AWW in last 3 months assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
28. Child weighed by AWW at least once in the last 3 months assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
29. Child received counselling from AWW after last weighing assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline
30. Children aged 6-36 months with severe acute malnutrition (SAM) referred to Nutrition Rehabilitation Centre assessed through questionnaire with mothers for children aged 0-36 months at baseline and endline

Overall study start date
01/02/2012

Completion date
30/03/2017

Eligibility

Key inclusion criteria
1. Children aged 0-36 months living in the study areas and their caregivers
2. Clusters are purposely selected geographic areas comprising 8-10 contiguous villages covering a population of 4000-5000.A total of 30 clusters were selected for the study, spread across five blocks (an administrative unit of around 100,000 population).

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
4668 children aged 0-36 months at baseline and 4668 at endline (total=9336) across three arms

Total final enrolment
9336

Key exclusion criteria
Did not meet inclusion criteria

Date of first enrolment
01/11/2012

Date of final enrolment
20/03/2016

Locations

Countries of recruitment
India

Study participating centre
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834002

Sponsor information

Organisation
Ekjut

Sponsor details
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Sponsor type
Charity

Website
http://www.ekjutindia.org

ROR
https://ror.org/01q3by234

Funder(s)

Funder type
Other

Funder Name
Tata Trusts

Alternative Name(s)
Sir Ratan Tata Trust, tatatrust, SRTT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
India

Results and Publications

Publication and dissemination plan
We intend to publish the results in an open access journal in 2019.

Intention to publish date
01/02/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		26/11/2018	01/02/2019	No	Yes
Results article		18/07/2019	13/09/2021	Yes	No
Dataset		18/07/2019	27/02/2023	No	No