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Evaluation of a community-based management of acute malnutrition program in urban informal settlements, Mumbai

Submission date
13/02/2017

Recruitment status
No longer recruiting

Registration date
16/02/2017

Overall study status
Completed

Last Edited
03/09/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Globally, India suffers from the greatest burden of malnourished children. Supplementing centralized inpatient models of care with community-based models can allow for a greater number of vulnerable children to be treated for acute malnutrition cost-effectively. Children living in urban informal settlements experience similarly high levels of acute malnutrition as rural children. SNEHA (Society for Nutrition, Education and Health Action), a Mumbai-based non-profit organization, aims to implement a Community-based Management of Acute Malnutrition (CMAM) program, in partnership with the Government of India (GOI) Integrated Child Development Services (ICDS) scheme. The aim is to reduce the prevalence of acute malnutrition among children under age three living in informal settlements of Mumbai, India.

Who can participate?
Children under the age of three living in informal settlements and residing in the ICDS program service areas

What does the study involve?
In the intervention areas, a minimum of 10,000 children are expected to participate in the CMAM activities with about 2,000-3,500 children and their caregivers completing surveys at the start and the end of the study. The CMAM activities include screening for acute malnutrition, growth monitoring, home-based counselling, medical screenings, vaccination updates, and referrals to public health facilities such as a municipal nutrition rehabilitation center. In the comparison areas the children receive routine ICDS services, and about 2000 children complete surveys at the start and the end of the study.

What are the possible benefits and risks of participating?
Participants in the intervention areas receive the benefit of being screened and monitored on their nutritional status. Caregivers of malnourished children receive additional benefits of home-based counselling and medical screenings. Some children experiencing malnutrition receive ready-to-use therapeutic foods; there may be some side effects such as diarrhoea which will be monitored by the SNEHA doctors.

Where is the study run from?
Society for Nutrition, Education and Health Action (SNEHA) (India)

When is the study starting and how long is it expected to run for?
November 2011 to March 2017

Who is funding the study?
1. Forbes Marshall Foundation
2. EPIC Foundation

Who is the main contact?
Dr Anuja Jayaraman

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
-

Study information

Scientific Title
In urban informal settlements, can a Community-based Management of Acute Malnutrition (CMAM) approach, integrated with public health systems, reduce prevalence of acute malnutrition rates among children under the age of three?

Study objectives
The main goal of the intervention, in partnership with the Government of India program Integrated Child Development Services (ICDS), is to reduce acute malnutrition for children under

three years of age. The study will utilize monitoring and periodic cluster-based to surveys to assess whether there has been a reduction in acute malnutrition in intervention communities for children under the age of three.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Bandra Holy Family Medical Research Society, 21/09/2015, ref: ECR/196/INST/MH/2013

Primary study design
Interventional

Study design
Interventional non-randomised study

Study type(s)
Other

Health condition(s) or problem(s) studied
Acute malnutrition

Interventions
The intervention area includes informal settlements in Mumbai covered by the Government of India (GOI) Integrated Child Development Services (ICDS). The NGO, SNEHA will coordinate integration of a Community-based Monitoring of Acute malnutrition (CMAM) approach in conjunction with ongoing ICDS services, focusing on children under the age of three. The additional activities in intervention areas include screening for acute malnutrition, growth monitoring, home-based counselling, medical screenings, vaccination updates, referrals to public health facilities such as a municipal nutrition rehabilitation center. Screening is an ongoing process of case finding and enrollment of all children under three years of age and pregnant women into the CMAM program.

The comparison area is a quasi-control area that has not been randomly allocated. The comparison area will include informal settlements in another part of Mumbai where the NGO does not provide any additional services to community, but ICDS services are being delivered. Participants for the study are selected randomly (cross-sectional cluster-based random samples) from the comparison areas.

Intervention Areas:
Pilot Phase One Areas: (population ~ 90,000) ran a full intervention from February 2012 through February 2014 and a limited intervention from March 2014 to March 2016. Follow up evaluations conducted in February 2014 and October 2015.
Pilot Phase Two Areas: (population ~60,000) ran a full intervention from February 2013 through December 2014 and a limited intervention from January 2015 to March 2016. Follow up evaluations conducted in December 2014 and October 2015.
Scale-Out Phases: (population~150,000). Baseline survey conducted from March-July 2014. Full intervention conducted until November-December 2015. Endline survey conducted November-December 2015. Limited intervention conducted from January-March 2016.

Comparison Areas:
Baseline survey conducted September - November 2014. No additional intervention and endline conducted October-December 2015.

Intervention Type
Other

Primary outcome(s)
Acute malnutrition:
For full intervention: Monthly growth monitoring of anthropometry will be conducted by intervention staff. Gender, weight in kilograms, and height in centimetres will be collected to measure acute malnutrition status based on WHO 2006 WHZ scores.
For evaluation surveys at baseline, follow-up and endline, anthropometry will be conducted by investigators. Gender, weight in kilograms, and height in centimetres will be collected to measure acute malnutrition status based on WHO 2006 WHZ scores.

Equipment used for both intervention and evaluation anthropometry include: Bubble levels (manufactured by Freemans Measures Pvt. Ltd.) to verify flat weighing locations. Children under two years of age lay or sit on an electronic baby weighing scale (manufactured by Nitiraj Engineers Pvt. Ltd.) and their lengths are measured on an infantometer (manufactured by Meditrin Instruments Pvt. Ltd.). Children over two years of age are weighed on an adult mechanical weighing scale and their heights are taken using carpenter measuring tapes. All measurements are taken by pairs of investigators.

Key secondary outcome(s)
Uptake of ICDS services by children under the age of three, assessed during the cluster-based cross-sectional evaluation surveys by asking the sampled caregiver whether her youngest child (under age 3) received services from ICDS in the previous month with further probing on what services were received. Measured at baseline, follow-up and endline.

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Boys and girls
2. Under the age of three years
3. Living in the service areas of ICDS

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Child

Upper age limit

3 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2012

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
India

Study participating centre
SNEHA (Society for Nutrition, Education and Health Action)
Behind Building no. 11
BMC Colony
Shastri Nagar
Linking Road Extension
Santa Cruz West
Mumbai
India
400054

Sponsor information

Organisation
Society for Nutrition, Education and Health Action

ROR
https://ror.org/014jj9v53

Funder(s)

Funder type
Charity

Funder Name
Forbes Marshall Foundation

Funder Name
EPIC Foundation

Funder Name
Breadsticks Foundation

Funder Name
The Impact Foundation

Funder Name
Maitri Trust

Funder Name
HDFC Bank Ltd.

Funder Name
Comic Relief

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Give Foundation

Funder Name
West Wind School

Funder Name
Blue Cross Laboratories

Funder Name
Dimension Data India Ltd.

Funder Name
Lubrizol Advanced Materials Pvt. Ltd.

Funder Name
HDB Financial Services Ltd.

Funder Name
Australian Consulate

Funder Name
Nihchal Insrani Foundation

Funder Name
Cipla Foundation

Funder Name
Care Foundation

Funder Name
Vishwanath Rao Birewar Foundation Trust

Funder Name
Jashn Jewels Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anuja Jayaraman

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/03/2018		Yes	No
Results article	results	05/04/2018		Yes	No
Results article	results	01/01/2019	03/09/2019	Yes	No
Basic results		07/04/2018	14/05/2018	No	No