

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/09/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

Dr Anuja Jayaraman

ORCID ID

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Contact details

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Linking Road Extension

Santa Cruz West

Mumbai

India

400054

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

-

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 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

Study design

Interventional non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

No participant information sheet available

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/11/2011

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

Age group

Child

Upper age limit

3 Years

Sex

Both

Target number of participants

A minimum of 10,000 children in the study intervention areas. Samples for cluster-based surveys will range from 2000-3500 children sampled per survey.

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

Sponsor details

Behind Building no. 11
BMC Colony
Shastri Nagar
Linking Road Extension
Mumbai
India
400054

Sponsor type

Charity

Website

<http://www.snehamumbai.org/>

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

Publication and dissemination plan

Dissemination of results included a consultation and sharing of results with participation from government and non-government senior officials. This took place on 16/01/017. This is a news article highlighting the event: <http://www.asianage.com/metros/mumbai/170117/wasting-in->

mumbai-slums-drops-down-to-12-per-cent-survey.html

Further plans include publication in a high-impact peer reviewed journal with intent to publish date by approximately March 2018

Link to 2016 ICUH abstract presentation: <http://icuh2016.org/wp-content/uploads/2016/03/ICUH-Abstract-Booklet.pdf> (on page 52) Title: "Reduction in Malnutrition through Implementation in Partnership with I.C.D.S"

International Conference in Urban Health, Dhaka 2015, "Use of Mobile Technology for Improving Screening of Malnutrition in a Community-based Management of Acute Malnutrition Program in Mumbai Slums."

IFPRI Together for Nutrition Conference, Delhi 2014, "Implementation of Community-based Management of Acute Malnutrition Program in an Urban Setting."

Intention to publish date

01/03/2018

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
Basic results		07/04/2018	14/05/2018	No	No
Results article	results	01/01/2019	03/09/2019	Yes	No