Clinical Trial Details (PDF Generation Date :- Wed, 10 Aug 2022 16:37:56 GMT)

CTRI Number	CTRI/2012/09/003004 [Registered on: 18/09/2012] - **Trial Registered Retrospectively**
Last Modified On	28/08/2012
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Other (Specify) [Community mobilization]
Study Design	Cluster Randomized Trial
Public Title of Study	Trial of community resource centres to improve women?s and children?s health in Mumbai slums
Scientific Title of Study	Community resource centres to improve the health of women and children in Mumbai informal settlements: a cluster randomized controlled trial of a complex intervention

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr David Osrin
Designation	Wellcome Trust Senior Research Fellow in Clinical Science
Affiliation	University College London
Address	Society for Nutrition, Education and Health Action (SNEHA), Urban Health Centre, 60 Feet Road, Shahunagar, Dharavi Mumbai MAHARASHTRA 400017 India
Phone	02224042627
Fax	
Email	d.osrin@ucl.ac.uk

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr David Osrin
Designation	Wellcome Trust Senior Research Fellow in Clinical Science
Affiliation	University College London
Address	Society for Nutrition, Education and Health Action (SNEHA), Urban Health Centre, 60 Feet Road, Shahunagar, Dharavi Mumbai MAHARASHTRA 400017 India
Phone	02224042627
Fax	
Email	d.osrin@ucl.ac.uk

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Neena Shah More
Designation	Project Director
Affiliation	SNEHA
Address	Society for Nutrition, Education and Health Action (SNEHA), Urban Health Centre, 60 Feet Road, Shahunagar, Dharavi Mumbai MAHARASHTRA 400017 India
Phone	02224042627

Fax	
Email	neena@snehamumbai.org

Source of Monetary or Material Support

Source of Monetary or Material Support
> The Wellcome Trust UK

Primary Sponsor

Primary Sponsor Details	
Name	Centre for International Health and Developoment
Address	UCL Institute of Child Health, 30 Guilford Street, London WC1N 1EH, UK
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
Dr Wasundhara Joshi	Urban Health Centre, 60 Feet Road, Shahunagar, Dharavi, Mumbai 400017, Maharashtra

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Neena Shah More	Society for Nutrition, Education and Health Action (SNEHA)	Society for Nutrition, Education and Health Action (SNEHA), Urban Health Centre ,60 Feet Road, Shahunagar, Dharavi-400017 Mumbai MAHARASHTRA	02224042627 neena@snehamumbai.org

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Multi-institutional Ethics Committee of the Anusandhan Trust	Approved	27/01/2012	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	No specific health condition

Intervention / Comparator Agent

Type	Name	Details
Intervention	Intervention: Community Resource centres will be set up in each of the 20 Intervention clusters. 20 community resource centres will be set up in 3 phases over 18 months. Each will run for 2 years, after which outcomes will be compared	The centres will: Act as bases for collection and dissemination of health in-formation. Identify families at risk and refer individuals and families to appropriate services. Coordinate health promotion events. Communicate and negotiate with health care providers. Broker interaction between communities and providers for universal health coverage. Public sector health service strengthening will be actively undertaken in intervention clusters. Information on ongoing activities will be disseminated through a

		Community Action Group.
Comparator Agent	Public sector health service strengthening	Ongoing activities to improve quality of care, in partnership with the Municipal Corporation of Greater Mumbai

Inclusion Criteria

Inclusion Criteria	
Age From	15.00 Year(s)
Age To	49.00 Year(s)
Gender	Both
Details	We will select two of Mumbai’s 24 municipal wards based on low Human Development Indices. We will identify the informal settlement areas in the chosen wards, both formally recognized and unrecognized. The minimum cluster size for inclusion will be 1000 house-holds. Where informal settlements are large we will divide them into smaller clusters along obvious geophysical bounda-ries: one large area may then provide more than one poten-tial trial cluster. We will try to avoid contiguity to minimize contamination. Using a tool for the rapid assessment of health vulnerability, each potential informal settlement cluster will be given a score. The 40 highest scoring clusters will constitute the trial frame. 20 will be allocated randomly to the intervention.

Exclusion Criteria

Exclusion Criteria	
Details	Nil

Method of Generating Random Sequence	Stratified randomization
Method of Concealment	On-site computer system
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Institutional delivery (%) Infant feeding Family planning (%) Child stunting and weight-for-height	Intervention and control arms compared after 2 years of intervention.

Secondary Outcome

Outcome	Timepoints
Consultation for domestic violence	Number of consultations for domestic violence in intervention areas tracked over 2 years.

Target Sample Size	**Total Sample Size=**20000 **Sample Size from India=**20000 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	01/02/2012
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**3 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	

Brief Summary

1. Background and study aims

Urban health is a critical but under-researched requirement for India's development. The research programme aims to develop and test a model strategy to improve women's and children's health in Mumbai slum communities.

2. Who can participate?

Key participants will be women and their families, but anyone resident in the slum communities involved can participate in activities to improve health.

3. What does the study involve?

We will set up community resource centres in urban slums. Each centre will be developed in partnership with its surrounding community and health care providers, and staffed by two community mobilizers. With support from a non-government organization hub, they will collect and disseminate health information, identify families at risk, make referrals to appropriate services and follow them up, coordinate community health promotion events, communicate with service providers, and promote interaction between communities and providers.

4. What are the possible benefits and risks of participating?

Participants will help to improve their own health, the health of their children, and the health of their communities. There are no particular risks to participating. Participants may become involved in the trial in two ways. First, in intervention areas, they may join in community efforts to improve women's and children's health in association with the resource centres. They may gain information about these efforts through community discussions, campaigns, outreach activities, or by visiting the resource centre. Second, they may participate in the evaluation by responding to a questionnaire interview in the baseline or endline phase. Information on the trial will be communicated orally by interviewers prior to consent, and potential participants will be given printed study information material in a local language. Participants will not be followed up individually over the course of the trial evaluation, since it will be based on a cross-sectional endline survey. Other information about the progress of the community resource centres will be disseminated through Community Action Groups, as and when they feel it would be appropriate.

5. Where is the study run from?

The study is run by the Society for Nutrition, Education and Health Action, a non-government organization based in Mumbai.

6. When is the study starting and how long is it expected to run for?

The study will begin in February 2012. 20 community resource centres will be set up in 3 phases over 18 months. Each will run for 2 years, after which outcomes will be compared between the 20 intervention and 20 control areas through a cross-sectional survey. The survey will run from February to July 2015.

7. How will information on the study be disseminated?

A Community Action Group will be associated with each resource centre, and will communicate study progress locally. The findings will be published in open access peer-reviewed journals.