ISRCTN96256793 https://doi.org/10.1186/ISRCTN96256793

Trial of community mobilisation in Mumbai slums to improve care during pregnancy, delivery, postnatally and for the newborn

Submission date
21/08/2007

Recruitment status
No longer recruiting

Registration date
23/08/2007

Overall study status
Completed

Last Edited
19/06/2015

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Improving maternal and newborn health in low-income settings requires both health service and community action. Previous community initiatives have generally been rural, but India is urbanizing. While working with health services to improve their quality of care, the trial tests an intervention in which slum-dweller women's groups try to improve health during pregnancy and birth, and for newborn babies in their own communities.

Who can participate?
Key participants will be women who join the community groups. We will try to involve young women and mothers, but older women may also get involved. Group members will reach out to other women and key stakeholders in their neighbourhoods. Since the aim is to improve the health of pregnant women and their newborn infants, any participant who may influence this situation may be involved. Particular examples may be older women, male community members and leaders, health workers and local opinion formers. The project outcomes will be measured by checking for all births and deaths in the project areas. All women and their newborn infants will be eligible to participate in this process, which will involve an interview as close to delivery as possible.

What does the study involve?
We will employ local community-based female facilitators to convene groups and help them to explore maternal and neonatal health issues. The groups will meet fortnightly through a seven-phase process of sharing experiences, discussion of the issues raised, discovery of potential community strengths, building of a vision for action, design and implementation of community strategies, and evaluation. The process is one of learning from each other and solving problems together. 48 slum areas have been selected randomly. 24 will have women's groups. 24 will not, but both sets of areas will benefit from health service quality improvement. We will collect information about births, healthcare and outcomes in all 48 areas and compare the two sets. We are particularly interested in seeing if the women's groups make mothers more likely to have antenatal care and safe deliveries, and improve the survival of their babies.

What are the possible benefits and risks of participating?
We don't know if the women's groups will improve mother and baby health. They have not been tested enough for us to have an opinion on whether they will be successful in a city. Since the trial is part of the City Initiative for Newborn Health, all the areas involved will benefit from improvement of provision and quality of maternal and newborn services at health posts, maternity homes, peripheral hospitals and tertiary hospitals.

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

When is the study starting and how long is it expected to run for?
The study started in October 2006 and ended in September 2009.

Who is funding the study?
The Wellcome Trust (UK).

Who is the main contact?
Neena Shah More. SNEHA, Urban Health Centre, 60 Feet Road, Dharavi, Mumbai 400 017, Maharashtra, India.
David Osrin. Institute for Global Health, UCL Institute of Child Health, 30 Guilford Street, London WC1N 1EH, UK

Contact information

Type(s)
Scientific

Contact name
Dr David Osrin

Contact details
30 Guilford Street
London
United Kingdom
WC1N 1EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06PC02

Study information

Scientific Title

Cluster-randomised controlled trial of community mobilisation in Mumbai slums to improve care during pregnancy, delivery, postpartum and for the newborn

Acronym
CINH Community Mobilisation

Study objectives
Will a community mobilisation intervention improve maternal and neonatal home care, service uptake, morbidity and mortality in slum communities of Mumbai?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval is implicit in an agreement between the implementing NGO (Society for Nutrition, Education and Health Action - SNEHA, Mumbai) and the Municipal Corporation of Greater Mumbai, which covers the activities of the City Initiative for Newborn Health, of which the trial is one component.

Specific ethics approval was gained from the Independent Ethics Committee for Research on Human Subjects (IECRHS), Mumbai, 18/06/2007, ref: 1433

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Maternal and child health

Interventions
The intervention comprises a series of meetings of community women's groups in 24 slum clusters. It is delivered by community facilitators employed by the project. Its duration in this form will be from January 2007 to January 2009. However, the aim of the intervention is to stimulate sustainable community participation, and we would hope that the intervention continues indefinitely through local efforts.

In each intervention cluster, a facilitator will convene community groups to explore maternal and neonatal health issues. Groups will meet once or twice monthly and move through action research cycles.

The programme inputs can be itemised as:
1. Recruitment, training, supervision and remuneration of facilitators. The role of the facilitator is to activate and strengthen groups, support them in identifying problems, help to plan possible solutions and support the implementation and monitoring of solution strategies in the community. Although she requires a grasp of health issues and some knowledge of potential interventions, she needs to be a facilitator rather than a teacher. As such, she may act as a broker of information and communication but her prime importance is as a catalyst for community mobilisation
2. Development of tools for conducting group meetings, process evaluation and documentation
3. Recruitment, training, supervision and remuneration of a supervisory cadre to support the community-based facilitators

The control group (24 slum clusters) do not receive an analogous intervention. Control areas benefit from the health service provision activities of the City Initiative for Newborn Health: improved maternal and newborn care at health posts, maternity homes, general hospitals and tertiary hospitals.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neonatal mortality rate.

Outcomes will be evaluated after 2 years of data collection, but are measured continuously through the same prospective registration system. Births in the 48 clusters under surveillance are identified by local women, who notify interviewers employed by the project. An interview is taken at 6 weeks postpartum for each birth. The registration system provides data on maternal survival, stillbirths and neonatal outcomes. It also provides data on care during pregnancy, delivery and postpartum, both at home and through health services.

Secondary outcome measures
Antenatal, delivery and postnatal care uptake.

Outcomes will be evaluated after 2 years of data collection, but are measured continuously through the same prospective registration system. Births in the 48 clusters under surveillance are identified by local women, who notify interviewers employed by the project. An interview is taken at 6 weeks postpartum for each birth. The registration system provides data on maternal survival, stillbirths and neonatal outcomes. It also provides data on care during pregnancy, delivery and postpartum, both at home and through health services.

Overall study start date
01/01/2007

Completion date

01/01/2010

Eligibility

Key inclusion criteria
Women who give birth in 48 vulnerable slum communities during the study period. Any woman who gives birth in the study area is potentially a participant in the data collection activities. The age range would be 12 to 49 years.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
10,000

Key exclusion criteria
Women who decline to be interviewed.

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
The Institute of Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
The Institute of Child Health (UK)

Sponsor details
University College London
30 Guilford Street
London
England
United Kingdom
WC1N 1EH

Sponsor type
University/education

Website
http://www.ich.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
ICICI Bank Ltd (India) - Social Initiatives Group

Funder Name
Wellcome Trust (UK) (grant ref: 081052)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	10/02/2008		Yes	No
Results article	community mobilisation results	01/02/2012		Yes	No
Results article	stillbirth and newborn death results	30/05/2012		Yes	No