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The effect of womens' groups facilitated by Accredited Social Health Activists (ASHAs) on birth outcomes in Eastern India

Submission date	Recruitment status	[_] Prospectively registered
28/04/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2017	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1VTP/07CH05

Study information

Scientific Title
Community mobilisation with participatory womens groups facilitated by Accredited Social Health Activists (ASHAs) to improve maternal and newborn health in underserved areas of Jharkhand and Orissa (India): a cluster randomised controlled trial

Acronym
Jharkhand Orissa Health Action Research (JOHAR)

Study objectives
The community mobilisation intervention led by ASHAs will lead to a 30% reduction in neonatal mortality in the last 24 months of the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCL Research Ethics Committee approved in March 2008, annually reviewed, ID number: 1488 /001

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Maternal and Child Health

Interventions
. Participation in learning action cycle with womens groups
2. In each intervention cluster, trained and incentivised Accredited Social Health Activists and convene womens groups
3. ASHAs are government appointed volunteers incentivised to mobilise communities for improved health outcomes, assist women to access institutional deliveries and delivery a range

of primary healthcare services
4. The participatory learning and action cycle has 4 phases
5. In the first phase, groups identify and prioritise maternal and newborn health problems, then plan strategies to address these problems
6. In the second phase, they discuss and prioritise strategies to address these problems
7. In the third and fourth phases, groups put these strategies into practice, and evaluate their progress
8. The role of the ASHA as part of the intervention being tested is to activate and strengthen groups, support them in identifying problems related to maternal and newborn health, help to plan possible solutions and support the implementation and monitoring of strategies to address identified problems in the community
9. ASHAs support group meetings alongside their other activities
10. In all clusters, control and intervention, activities are implemented to strengthen Village Health Committees
11. We do not use patient information sheets because this was a community trial of a social intervention (i.e. not a clinical trial). The intervention consists of women's groups that discuss and design their own strategies to improve newborn and maternal health. All the women in these women's groups participate voluntarily. At the start of the women's groups, there was extensive discussion of what the aims and structure of the women's groups are. By voluntarily joining a women's group, the participants consent to the intervention (i.e. women's groups). Oral consent was obtained from the respondents in the monitoring and surveillance interviews

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neonatal mortality (deaths in the first 28 complete days after birth per 1,000 live births), during the last 24 months of the study.

Secondary outcome measures
1. Early and late neonatal mortality rate
2. Stillbirth rate
3. Maternal mortality ratio
4. Pregnancy related mortality
5. Health care seeking
6. Home care practices

Overall study start date
01/09/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria

1. Women who give birth in 30 geographic clusters during the study period
2. Women and their newborn infants are included after birth, or, if a woman dies during pregnancy, at her death.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
An estimated 6000 births to women using the above inclusion/exclusion criteria, during the last 24 months of the trial, in the combined 30 study clusters.

Key exclusion criteria
1. Women who decline to be interviewed
2. Women who have migrated out of the study areas (classified as those who cannot be traced 9 months after a birth or death identification)

Date of first enrolment
01/09/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
Institute of Child Health
London
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Big Lottery Fund Strategic Grant (UK) ref: IS/2/010281409

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?
Protocol article	protocol	25/07/2011		Yes	No
Results article	results	01/02/2016		Yes	No