

Improving maternal and newborn health in rural areas of Jharkhand and Orissa through the empowerment of tribal communities

Submission date
19/11/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
05/12/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/10/2014

Condition category
Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

03PC03

Study information

Scientific Title

Study objectives

Will a community mobilisation intervention improve maternal and neonatal home care, service uptake, morbidity and mortality and maternal depression in tribal communities in Jharkhand and Orissa, India?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from an Independent Ethics Committee (chaired by Dr A.K. Debdas), 14/06/2005.

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Maternal and child health

Interventions

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, supervisions 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

There is no follow-up period after the intervention ends. The intervention is a community mobilisation intervention, which only occurs in the intervention clusters. All clusters, control and intervention, receive health system strengthening activities.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Neonatal and maternal mortality rates, measured prospectively from 01/08/2005 until the end of the trial (likely to be February 2008).

Secondary outcome measures

1. Maternal and neonatal home care practices
2. Utilisation of antenatal, delivery and postnatal services
3. Maternal depression

All outcomes measured prospectively from 1st August 2005 until the end of the trial (likely to be February 2008).

Overall study start date

01/08/2005

Completion date

01/02/2008

Eligibility**Key inclusion criteria**

Women (no defined age range) who reside in 36 predominantly tribal communities during the study period

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

9000

Key exclusion criteria

Women who decline to be interviewed or reside outside the study area

Date of first enrolment

01/08/2005

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

England

India

United Kingdom

Study participating centre

30 Guilford Street

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

The Institute of Child Health (UK)

Sponsor details

University College London (UCL)

30 Guilford Street

London

United Kingdom

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Sponsor type

Research organisation

Website

<http://www.ich.ucl.ac.uk>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

The Health Foundation (UK) (ref: 1748/3001)

Funder Name

The Department For International Development (DFID) (UK) (ref: HPD KP 14)

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 | 03/04/2010 | | Yes | No |