

Community mobilisation to increase delivery by trained health workers in Makwanpur district, Nepal

Submission date 15/09/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 28/09/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/02/2021	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In rural Nepal birth attendance by trained health workers is low. The aim of this study is to find out whether a combination of community mobilisation through women's groups and health management committee strengthening will lead to increased birth attendance by trained health workers.

Who can participate?

Village development committees in Makwanpur District, Nepal

What does the study involve?

Participating areas are randomly allocated to either receive the intervention or serve as control areas (no intervention). In the intervention areas, Female Community Health Volunteers convene monthly women's groups to identify and address problems that prevent women from delivering either in an institution or at home with a trained health worker. Health management committees also participate in three-day workshops to find ways to improve maternal and newborn health services. Follow-up meetings are conducted every three months to review progress. The number of institutional deliveries and home deliveries conducted by trained health workers, uptake of antenatal and postnatal care, death and stillbirth rates, and maternal illness are assessed and compared between the intervention and control areas.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Institute of Child Health (UK)

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

October 2010 to September 2012

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
085417/Z/08/Z

Study information

Scientific Title
Community mobilisation to increase delivery by trained health workers in Makwanpur district, Nepal: a cluster randomised controlled trial

Study objectives

A combination of community mobilisation through women's groups, and health management committee strengthening will lead to increased birth attendance by trained health workers, through increased institutional deliveries and increased attendance at home deliveries.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Nepal Health Research Council, 12/02/2009, ref: 889
2. University College London (UCL) Research Ethics Committee, 13/09/2010, ref: 2257/001

Primary study design

Interventional

Study design

Single-centre unmasked cluster randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Maternal and newborn health

Interventions

The intervention has two components, community mobilisation through women's groups, and health management committee (HMC) strengthening. Both interventions will be implemented for two years in 21 intervention clusters.

Community mobilisation through women's groups:

A government health cadre, the female community health volunteer (FCHV) runs one women's group per month. There are at least nine FCHVs running nine women's groups per cluster ($n = 189$). FCHVs are supported by seven supervisors, who provide general field support, and conduct monthly training and feedback meetings with FCHVs to discuss the upcoming women's group agenda, and monitor their progress. Women's groups work through a participatory action cycle to identify local problems preventing women from delivering in an institution, or at home with a trained health worker, and then implement and evaluate strategies to address these problems.

Health Management Committee Strengthening:

There is one health institution per cluster and each institution has a health management committee. Four Appreciative Inquiry facilitators and trained representatives from the District Public Health Office conduct three-day workshops with HMCs of each health facility ($n = 21$). Other participants such as community representatives and health workers may also join workshops. The workshops take an Appreciative Planning and Action approach, where participants are encouraged to build on their strengths to take action to improve health facilities. Facilitators will follow-up on progress at HMC meetings approximately two months after they have completed their planning workshop, and at regular intervals thereafter.

Intervention Type

Behavioural

Primary outcome(s)

1. Deliveries conducted by a trained health worker
2. Institutional deliveries

Primary and secondary outcomes will be measured through prospective identification of pregnancies. Enrolment began on 16 November 2009 and will end on 20 September 2012.

Key secondary outcome(s)

1. Neonatal deaths
2. Stillbirths
3. Maternal morbidities
4. Care behaviours

Primary and secondary outcomes will be measured through prospective identification of pregnancies. Enrolment began on 16 November 2009 and will end on 20 September 2012.

Completion date

30/09/2012

Eligibility**Key inclusion criteria**

1. Measurement of outcomes:
 - 1.1. For trained birth attendance within intervention and control clusters, women who deliver infants at gestation 28 complete weeks or greater
 - 1.2. For mortality, women of reproductive age (12 - 49 years old) who die
 - 1.3. Infants born within the study period
2. Intervention: the intervention involves community mobilisation through women's groups and health management committee (HMC) strengthening. Participation in women's groups and their activities is voluntary, and there are no pre-determined intervention inclusion criteria. Participation in HMC strengthening is also voluntary. Participants will usually be HMC members, but may also be community members whom HMCs invite to participate.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

13721

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/10/2010

Date of final enrolment

30/09/2012

Locations

Countries of recruitment

United Kingdom

England

Nepal

Study participating centre

Institute of Child Health

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Institute of Child Health, University College London (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 085417)

Results and Publications

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	06/05/2020	18/02/2021	Yes	No
Protocol article	protocol	19/05/2011		Yes	No