

Community interventions to increase child survival in Nepal

Submission date 11/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 25/06/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/12/2020	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A cluster randomised controlled trial of the impact of community women's groups and sepsis management by community volunteers on newborn survival and maternal and infant nutrition

Acronym
MIRA Dhanusha

Study objectives

1. A participatory intervention with women's groups will be associated with reductions in perinatal and neonatal mortality
2. Work by women's groups on dietary issues will be associated with improvements in maternal and infant nutrition, and possibly in perinatal and neonatal mortality
3. Training of community volunteers in the recognition and management of neonatal sepsis will be associated with increases in identification and treatment of neonatal sepsis, and improvements in neonatal mortality

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Nepal Health Research Council Ethics Committee (Nepal) gave approval on the 25th November 2004
2. Ethics Committee of the Institute of Child Health and Great Ormond Street Hospital for Children (UK) gave approval on the 14th March 2005

Study design

Factorial cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Neonatal mortality; neonatal sepsis

Interventions

This is a factorial cluster randomised controlled trial involving 60 village development committee clusters.

Female Community Health Volunteers will be supported in convening monthly women's groups. The groups will work through an action research cycle in which they:

1. Identify local issues around maternity, newborn health and nutrition
2. Prioritise key problems
3. Develop strategies to address them
4. Implement the strategies
5. Evaluate their success

Female Community Health Volunteers will be trained to care for vulnerable newborn infants. They will:

1. Identify local births
2. Identify low birth weight infants
3. Identify possible newborn infection
4. Manage the process of treatment and referral
5. Follow up infants and support families

Total duration of treatment: 2 years. Total duration of follow-up: 3 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Neonatal mortality rates. Outcome measures are collected prospectively on an ongoing basis, so no specific timepoints for measurement. However, for the purposes of analysis of the trial, we will look at both primary and secondary outcome measures annually for 3 years.

Key secondary outcome(s)

1. Community groups:
 - 1.1. Care practices and health care seeking behaviour
2. Stillbirth rates
3. Maternal mortality ratios
2. Sepsis management:
 - 2.1. Identification and treatment of neonatal sepsis by community health volunteers
 - 2.2. Causes of death assessed by community verbal autopsy

Outcome measures are collected prospectively on an ongoing basis, so no specific timepoints for measurement. However, for the purposes of analysis of the trial, we will look at both primary and secondary outcome measures annually for 3 years.

Completion date

01/01/2010

Eligibility**Key inclusion criteria**

Main target population:

1. Women of reproductive age, of whom there are 140,000
2. Infants under a year of age, of whom there are 19,000
3. 26,000 pregnancies expected annually in the district

Key participants:

Women who either join community groups or have a pregnancy. The women's group intervention involves social mobilisation and group membership and activities will not be restricted to women of reproductive age. Since the aim is to improve the situation of pregnant women and their newborn infants, any participant who may affect this situation may be involved. Particular stakeholders may be older women, male community members, health workers and local opinion formers. All women and their newborn infants will be eligible to participate in the data collection exercise, for which enrolment will occur either during pregnancy or in the post-natal period.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2010

Locations**Countries of recruitment**

United Kingdom

England

Nepal

Study participating centre

UCL Centre for International Health and Development

London

United Kingdom

WC1N 1EH

Sponsor information**Organisation**

University College London (UCL) Centre for International Health and Development (UK)

ROR

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

Funder(s)**Funder type**

Research organisation

Funder Name

UBS Optimus Foundation (Switzerland)

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 on prevalence of Caesarean section	30/12/2014	30/12/2020	Yes	No
Protocol article	protocol	03/06/2011		Yes	No