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Community interventions to increase child survival in Nepal

Submission date	Recruitment status	[_] Prospectively registered
11/03/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/06/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2008

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

Age group
Adult

Sex
Female

Target number of participants
100 births per cluster per year, giving 200 births in 2 years and 12000 births in total.

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
England

Nepal

United Kingdom

Study participating centre

UCL Centre for International Health and Development
London
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Sponsor information

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

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Sponsor type
University/education

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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
UBS Optimus Foundation (Switzerland)

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