

Impact of a community-based participatory intervention to improve essential newborn care (ENC) in rural Nepal: a randomised controlled trial

Submission date 04/06/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/07/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/09/2007	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.ich.ucl.ac.uk/ich/academicunits/International_perinatal_care_unit

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

98-CH-06

Study information

Scientific Title

Acronym

MIRA (Mother and Infant Research Activities - a Nepali non-governmental organisation [NGO])
Makwanpur Study

Study objectives

Neonatal deaths in developing countries make the largest contribution to global mortality in children younger than 5 years. 90% of deliveries in the poorest quintile of households happen at home. We postulated that a community-based participatory intervention could significantly reduce neonatal mortality rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Nepal Health Research Council and the ethics committee of the Institute of Child Health and Great Ormond Street Hospital for Children.

Study design

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

Neonatal mortality

Interventions

12 local female facilitators work within VDCs in the Makwanpur District in Nepal to explore perinatal health issues, with one in each of the 12 intervention VDCs. Their role is to act as a

change agent rather than a teacher, to activate and strengthen existing mothers' groups, support them in identifying and prioritising maternal and neonatal problems, help to identify possible solutions and support the planning, implementation and monitoring of the solution strategies in the community. Each women's group moves through a participatory planning cycle of assessment, sharing experiences, planning, action and reassessment with the aim of improving essential maternal and newborn care. We have also trained women identified by local community groups as baby monitors to spot high risk newborn infants soon after birth.

The study will compare outcomes including neonatal and perinatal mortality rates, perinatal care practices and health service utilisation in 12 village development committee areas (8,000 people per VDC), compared with 12 matched areas where the intervention is not implemented.

Married women of reproductive age (15-49 years) within the study area have been identified and are visited monthly by study personnel. All pregnancies occurring within the cohort will be followed until at least six weeks after delivery to determine the outcome of birth.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Neonatal mortality rate

Secondary outcome measures

1. Stillbirths and maternal deaths
2. Uptake of antenatal and delivery services
3. Home care practices
4. Infant morbidity
5. Health-care seeking

Overall study start date

01/09/1999

Completion date

01/11/2000

Eligibility

Key inclusion criteria

Married women aged 15 to 49 in 24 rural Village Development Committees (VDCs) in Makwanpur District, Nepal

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

24 village development committees

Key exclusion criteria

No exclusion criteria

Date of first enrolment

01/09/1999

Date of final enrolment

01/11/2000

Locations**Countries of recruitment**

England

Nepal

United Kingdom

Study participating centre

30 Guilford Street

London

United Kingdom

WC1N 1EH

Sponsor information**Organisation**

Institute of Child Health (UK)

Sponsor details

30 Guilford Street

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Sponsor type

Research organisation

Website

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

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Department for International Development (DFID)

Funder Name

The Department of Child and Adolescent Health and Development (CAH)/World Health Organization (WHO) (Switzerland)

Funder Name

United Nations Children's Fund (UNICEF)

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		11/09/2004		Yes	No
Other publications		15/06/2006		Yes	No