

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

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>04/06/2004   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>02/07/2004 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>10/09/2007       | <b>Condition category</b><br>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

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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.

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Quality of life

**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(s)**

Neonatal mortality rate

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

No exclusion criteria

**Date of first enrolment**

01/09/1999

**Date of final enrolment**

01/11/2000

## **Locations**

**Countries of recruitment**

United Kingdom

England

Nepal

**Study participating centre**

**30 Guilford Street**

London

United Kingdom

WC1N 1EH

## **Sponsor information**

**Organisation**

Institute of Child Health (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**

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? |
|------------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>    | Study website | 11/09/2004   |            | Yes            | No              |
| <a href="#">Other publications</a> |               | 15/06/2006   |            | Yes            | No              |
| <a href="#">Study website</a>      |               | 11/11/2025   | 11/11/2025 | No             | Yes             |