Improving essential maternal and newborn care in poor rural communities in Malawi

Submission date	Recruitment status	Prospectively registered		
13/08/2008	No longer recruiting	[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
29/08/2008		[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/05/2013	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Guler Eroglu

Contact details

Centre for International Health and Development
University College London (UCL) Institute of Child Health
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)20 7905 2261
g.eroglu@ich.ucl.ac.uk

Additional identifiers

Protocol serial number

Sub-grant no. 231

Study information

Scientific Title

Improving essential maternal and newborn care in poor rural communities in Malawi: two randomised controlled trials of community-based health promotion interventions to reduce maternal and neonatal mortality and morbidity

Acronym

MaiMwana

Study objectives

1. Community mobilisation through women's groups will reduce neonatal and maternal mortality rates through changes in care practices and health seeking behaviour 2. Infant care and feeding counselling for pregnant and breastfeeding mothers will change knowledge and practice relating to exclusive breastfeeding and family planning which will in turn reduce mortality rates and mother to child transmission of HIV

Please note that as of 04/06/10 this record has been updated. All updates may be found in the relevant field with the above update date. Please also note that anticipated end date has been extended from 28/02/2008 to 31/01/2009 following a Data Safety and Monitoring Board meeting on 21st October 2008. At this meeting it was also recommended that the follow up period be extended from 2 years to 3 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Health Sciences of Malawi. Date of approval: 29/01/2003 (ref: MED/4/36/I/167)

Study design

2 x 2 cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Maternal, neonatal and child health

Interventions

Please note that as of 04/06/10, the data collection for this trial ended on 31/01/2009

Women's groups intervention trial: Community-based participatory women's groups to mobilise communities around mother and newborn health

Infant feeding care intervention trial: Community-based volunteer infant-feeding and care counsellors to support mothers in exclusive breastfeeding and family-planning

The two trials are part of a factorial design, where the same participants are enrolled in the control or intervention arms of each trial, producing four different groupings of intervention combinations: 12 clusters with both interventions, 12 clusters with women's groups intervention only, 12 clusters with infant feeding care intervention only and 12 clusters with no interventions.

Total duration of interventions: 3 years (A period of 9 months of data collection preceded the interventions)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Current information as of 04/06/10:

For the women's groups trial:

Maternal, infant, neonatal and perinatal mortality, assessed by monthly visits for 3 years. Pregnant women are followed up until at least 6 months after birth. Any mothers or infants who have died were followed up with a verbal autopsy interview to establish the cause of death.

For the infant feeding care trial:

- 1. Exclusive breastfeeding rates, determined through 1-month and 6-month post-partum interviews using a structured questionnaire
- 2. Infant mortality assessed by monthly visits for 3 years

(Please note that at the time of registration, the total duration of follow up was 2 years)

Key secondary outcome(s))

The following were determined through 1-month and 6-month post-partum interviews using a structured questionnaire:

For the women's groups trial:

- 1. Changes in care taker practices and care-seeking behaviour, recognition of danger signs
- 2. Maternal and neonatal morbidity

For the infant feeding care trial:

- 1. Changes in care taker practices and care-seeking behaviour
- 2. Neonatal and infant morbidity

Completion date

31/01/2009

Eligibility

Key inclusion criteria

All women aged 10-49 who agree to take part.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Female

Key exclusion criteria

Women who have no possibility of conceiving during the study period (women who have had hysterectomy or permanent sterilisation).

Date of first enrolment

01/07/2005

Date of final enrolment

31/01/2009

Locations

Countries of recruitment

United Kingdom

England

Malawi

Study participating centre

Centre for International Health and Development

London United Kingdom WC1N 1EH

Sponsor information

Organisation

University College London (UK)

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name

Current information as of 04/06/10:

Funder Name

Wellcome Trust (UK) - (ref: WT085417)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Initial information at time of registration:

Funder Name

Save the Children, Saving Newborn Lives Programme (Sub-grant no. 231)

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	18/05/2013		Yes	No
Protocol article	protocol	17/09/2010		Yes	No

Data obtained from the women's group intervention

Other publications

30/09/2006

Yes

No