ISRCTN06477126 https://doi.org/10.1186/ISRCTN06477126

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**	[_] Statistical analysis plan
29/08/2008	Completed	[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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Not Specified

Participant information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
01/07/2005

Completion date
31/01/2009

Eligibility

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

Participant type(s)
Patient

Age group
Other

Sex
Female

Target number of participants
As of 04/06/10: 17,280 (at time of registration 11,520)

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
England

Malawi

United Kingdom

Study participating centre
Centre for International Health and Development
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ich.ucl.ac.uk/ich

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

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?
Other publications	Data obtained from the women's group intervention	30/09/2006		Yes	No
Protocol article	protocol	17/09/2010		Yes	No
Results article	results	18/05/2013		Yes	No