

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

<b>Submission date</b> 13/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/05/2013	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

**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)

**Sponsor details**

c/o Prof Anthony Costello  
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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?
<a href="#">Other publications</a>	Data obtained from the women's group intervention	30/09/2006		Yes	No
<a href="#">Protocol article</a>	protocol	17/09/2010		Yes	No
<a href="#">Results article</a>	results	18/05/2013		Yes	No