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Investigation of the effect of emergency obstetric care training interventions on the knowledge and skills of final year midwifery students in Kenya

Submission date
02/12/2017

Recruitment status
No longer recruiting

Registration date
05/12/2017

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
An estimated 289,000 maternal deaths, 2.6 million stillbirths and 2.4 million newborn deaths occur globally each year, with most occurring around the time of childbirth. Kenya continues to have a high level of maternal and newborn death; maternal mortality was estimated at 510 per 100,000 live births in 2015 and child mortality to be 52 per 1,000 live births. This means that an estimated 6,000 to 8,000 pregnant women die in Kenya every year. The medical and surgical interventions to prevent these deaths are known, and most maternal and newborn deaths are in principle preventable. Providing emergency obstetric and newborn care (EmONC) by skilled birth attendants is known to reduce maternal and newborn mortality. The Kenyan government has included emergency obstetric and newborn care as a priority in their National Health Strategy. In 2012, the Ministry of Health in Kenya adapted the Liverpool School of Tropical Medicine (LSTM) EmONC training package and produced national curriculum/guidelines in 2014 for implementation nationally. However, the focus has been on in-service EmONC capacity building. To improve the effectiveness of periodic in-service EmONC training programmes, EmONC must be adequately covered within pre-service midwifery and medical curriculum and adequately taught in training institutions. LSTM has previously supported several midwifery training institutions in Kenya to improve the content and quality of EmONC training within their curriculum. However, the effect of these interventions has not been determined. Although there have been two studies evaluating the effectiveness of EmONC training for pre-service students but generalising the results is limited by the type of participants included (medical students and interns) and weak study designs. The aim of this study is to examine the effectiveness of EmONC training and to see if it improves the skills and knowledge of participants.

Who can participate?
Final year midwifery students in Kenya medical training institutions.

What does the study involve?
Participating medical training institutions are randomly allocated to one of three groups. Those

in the first group receive no EmONC programmes. Those in the second group receive it partially. Those in the last group receive the full EmONC programme. Participants are followed up with questionnaires and skill assessments to measure their knowledge, skills and confidence. The knowledge and skills of 60 students in each of the KMTCs in each group will be assessed and compared.

What are the possible benefits and risks of participating?
There are no risks or immediate benefits for participation in the study. The lectures in the participating institutions will not be involved in student assessments and the investigators will not disclose individual participant assessment results to the lecturers or administrative authorities of these institutions. The results from the study will improve the understanding of the effect of EmONC training interventions on the knowledge and skills of final year midwifery students compared with the standard curriculum, potentially resulting in improvements to the standard curriculum.

Where is the study run from?
1. Centre for Maternal and Newborn Health Liverpool School of Tropical Medicine (UK)
2. Liverpool School of Tropical Medicine Kenya (Kenya)

When is the study starting and how long is it expected to run for?
July 2017 to June 2018

Who is funding the study?
United Kingdom Department for International Development (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LSTM 17-059

Study information

Scientific Title
A cluster randomised controlled trial of an intervention to improve the emergency obstetric care knowledge and skills of midwifery students prior to graduation in Kenya

Acronym
Kenya PETI study (Kenya Pre-service Emergency obstetric care Training Interventions Study)

Study objectives
Emergency obstetric care training interventions results in better knowledge and skills amongst final year midwifery students compared to their standard training curriculum. The specific research questions are:
1. What is the effect of EmONC capacity building interventions on knowledge and skills of pre-service midwifery students?
2. What is the effect of EmONC capacity building interventions on self-reported confidence to provide EmONC?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Liverpool School of Tropical Medicine Research and Ethics Committee, 01/12/2017, ref: No.: 17-059RS
2. Kenyatta National Hospital Research and Ethics Committee Nairobi Kenya

Study design
Cluster randomised control trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Emergency obstetric care capacity building/training interventions

Interventions
The four emergency obstetric and newborn care (EmONC) capacity building interventions are:
a. EmONC training for midwifery teachers: Midwifery teachers/lecturers are trained in the LSTM 5-day EmONC course.
b. Training of EmONC trainers for midwifery teachers: Midwifery teachers/lecturers are trained to use evidence based EmONC training methods and content. Training in EmONC (a-above) is a pre-requisite to this training.
c. Supply of EmONC training equipment for skills laboratory: Supply of EmONC training equipment and technical support to set-up and use the skills labs.

d. Supportive supervision/mentorship: 3-monthly visits to supported KMTCs to facilitate the use of evidence based EmONC training methods and content.

Intervention and control groups:
There are two intervention (partial or full EmONC capacity building interventions) and one control group (no EmONC capacity building intervention):
1. No EmONC intervention: Training colleges that have received NO previous EmONC capacity building interventions between 2014 and 2017.
2. Partial EmONC intervention: Training colleges that have SOME EmONC capacity building training interventions between 2014 and 2017.
3. Full EmONC intervention: Training colleges that have received ALL the EmONC capacity building interventions between 2014 and 2017.

Based on the Kenya National EmONC guidelines, intervention 'a' is a pre-requisite for b and d. Intervention 'a' is mandatory for Colleges in the partial intervention group.

The sampling frame includes all eight regions in the country to ensure a large enough sample is obtained. Including training colleges from different areas across the country also help ensure the generalisability of the findings.
To determine the sample frame in each group of the study from which 4 Kenya Medical Training College (KMTCs) are drawn, the research team based in Nairobi work with the headquarters of KMTC and principals of all colleges in the country to map out all Colleges in each group based on the predefined group characteristic (see EmOC training interventions above). Information that is collected are:
1. Availability of a 2018 midwifery final year cohort. If available number of students
2. External support for EmOC training since January 1st 2014 and defining the type of support (training of teaching and clinical supervision staff, supply of EmOC mannequins for training, supportive supervision after EmOC training of clinical staff)

After excluding KMTCs without final midwifery cohort, the Colleges are grouped into three, and given unique numbers by the PI. Four colleges are then be randomly selected in each group. The PI is responsible for randomisation and concealment of the study arms. The training colleges in each of the groups are randomly allocated, using computer generated random numbers until the group size is achieved. The group characteristic will only be revealed to the rest of the research team after analysis. These groups are based on predefined study characteristics (see intervention and control groups section above).

The data collectors are blinded from the trial characteristic of each institution. Each data collection team collects data from 4 institutions with different trial characteristic. All data collectors are from a different county to where the institution is located and midwifery educators/teachers in that institution are not involved in data collection. Finally, the statistician performing the analysis are blinded from the trial characteristic of each study arm. Prior to interpreting the data, the PI reveal the concealment. The PI is not be involved in data collection but train the data collectors.

Intervention Type
Other

Primary outcome(s)
Student knowledge and skills are measured for all groups using the multiple-choice questions and skill assessment score within 2 weeks across all assessment sites.

Key secondary outcome(s))
Student self-reported confidence in performing EmONC skills is measured using Casey-Fink Readiness for Practice Survey and the Likert scale questionnaire are administered after the knowledge and skills assessments for all groups during the data collection period of 2 weeks.

Completion date
01/06/2018

Eligibility

Key inclusion criteria
Individual participant:
Final year midwifery students in Kenya medical training institutions.

Participating institutions:
All Kenya medical training colleges with a final year cohort in 2018 including institutions that have received external interventions to improve emergency obstetric training.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
381

Key exclusion criteria
Kenya medical training colleges without final year midwifery students in 2018.

Date of first enrolment
01/03/2018

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Kenya

Study participating centre
Centre for Maternal and Newborn Health
Liverpool School of Tropical Medicine
Liverpool
United Kingdom
L3 5QA

Study participating centre
Liverpool School of Tropical Medicine Kenya
Nairobi
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P.O. Box 24672-00100

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
United Kingdom Department for International Development

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Charles Ameh, Principal Investigator Charles.Ameh@lstmed.ac.uk.

Added 22/03/2021:
Written informed consent from the participating colleges was obtained from the college principal, 4 weeks before data collection. Participants received the study information sheet 1 week before the data collection and written informed consent was obtained on the day of assessment. Before the start of each knowledge and skills assessment, the participants were asked if they had read the information sheet and were given an opportunity to ask any questions they may have had. They were then asked to indicate their willingness to participate and sign two copies of the consent form (one for the participant and one for the study records). At registration prior to the assessment, each study participant was given a unique identification number that consisted of the institutional code and the participant number for participants' confidentiality.
Individual participant testing results were only known to the research team and the individual participants and not with faculty members at the institution. Anonymised, summarized results were shared with each KMTC. Colleges included in the control arm were provided with EmONC training after the completion of the research study. Hard copies of all data were kept in locked cupboards and soft copies on password-protected computers only accessible to authorised research team members.
All data were managed in strict confidence in accordance with the LSTM internal data management policy and protocols. Besides, data collected will be anonymised for this study and handled in accordance with Kenya Data Protection Act 2019 and UK Data Protection Act 2018.

De-identified personal information may be shared with other researchers on request for research purposes. The study team may share the results or part of the results with the groups named below:
1. The National Bioethics Committee
2. The Institutional Review and Ethics Committee
3. Ministry of Health – Kenya, related government departments/organisations and representatives of Liverpool School of Tropical Medicine

The results of this research may be published as blogs, conference abstracts and in peer-review scientific journals but participants will not be identified in any report or publication. After the study has been published (approximately by 31/12/2021 after data analysis and reporting), we will make our dataset available on request electronically. The study results will be retained in the research record for at least 6 years after the study is completed. Full anonymised research information entered into the record will be kept indefinitely.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		12/10/2018	18/10/2022	No	No