

Training for life: emergency obstetric simulation-based training in a low-income country

Submission date 23/07/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 10/08/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/02/2021	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Despite great efforts of the United Nations, globally perinatal (during pregnancy) and maternal mortality rates remain unacceptably high. Over the past decades, obstetric simulation training (simulation of pregnancy and birth related emergencies) has increasingly been used for teaching medical skills. In high-resource countries, there have been many studies on the effectiveness of obstetric simulation-based training, with increasing evidence that it is associated with improvement in outcomes, particularly for the newborn child. Much less research into this has been carried out for low-income countries.

The aim of this study is to investigate the effectiveness of an emergency obstetric simulation-based training program with medical technical skills and teamwork skills on maternal and perinatal mortality in a medium- to high-risk labour ward in Mulago Hospital, Kampala, Uganda.

Who can participate?

Senior house officers working in the medium- to high-risk labour ward in Mulago Hospital, Kampala, Uganda

What does the study involve?

Senior house officers will be receive a 1 day, 8 hour main training session, with simulated scenarios based on the main local causes of maternal and perinatal mortality. This will then be followed by repetition training sessions.

Where is the study run from?

Mulago Hospital, Kampala, Uganda

When is the study starting and how long is it expected to run for?

October 2014 to January 2019

Who is funding the study?

1. Máxima Medical Center, Veldhoven (The Netherlands)
2. Rotary Club Eindhoven-Welschap (The Netherlands)

3. Rotary Club Son (The Netherlands)
4. Rotary Club Kyambogo-Kampala (Uganda)

Who is the main contact?

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Contact information

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Additional identifiers

Protocol serial number

Trainingforlife

Study information

Scientific Title

Training for life: evaluation of a stepped wedge cluster randomised trial about emergency obstetric simulation-based training in a low-income country

Study objectives

Simulation-based obstetric training in a low-income country will decrease the composite of maternal and perinatal mortality ratios

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dr. Nakwagala Frederick Nelson, chairman Mulago Research & Ethics Committee, 14/01/2015, Protocol MREC 674

Hellen N. Opolot, Executive Secretary Uganda National Council for Science and Technology, 21/09/2015, SS 3927

Primary study design

Interventional

Study design

Interventional stepped-wedge cluster randomised trial

Study type(s)

Other

Health condition(s) or problem(s) studied

Emergency obstetric health care

Interventions

This is a stepped-wedge trial with 7 study groups, which will be cluster-randomised to receive the intervention by a computer-generated random sequential roll-out of the training sessions over time.

The training will be performed using a train-the-trainers model in which training is cascaded down from master trainer to local facilitators to learners. Local facilitators will be trained during a four-day train-the-trainers course with an annual repetition and will train all senior house officers (residents). The senior house officers will be naturally divided in seven clusters and randomized for the moment of training. The training consists of a one-day, monodisciplinary, simulation-based training followed by repetition training sessions. Scenarios are based on the main local causes of maternal and neonatal mortality.

Full body simulators (Noelle® and Pedi® Blue neonate, Gaumard) are used for all training sessions. Other training materials (e.g. disposables, balloon ventilators) will be obtained from Mulago Hospital labour ward and reused as much as possible. Course content (e.g. syllabus, instructor manual, slides, observation forms) was developed in cooperation with staff members of the obstetrics and gynaecology department in Mulago Hospital and Medsim, a medical simulation centre in Eindhoven, The Netherlands. All materials are written in English. The instructional design features described by Issenberg et al. and Cook et al. were used to design the training program.

All training sessions will take place at the skills lab of the Makerere University College of Health Sciences, situated at Mulago hospital. The first step will be the train-the-trainers course for the local facilitators provided by a Dutch team, consisting of two obstetricians, a communication expert and a simulation technician. They are all certified simulation educators. The train-the-trainers course will take four days. During the first day, principles of simulation-based education (e.g. learning theories, crew resource management, debriefing techniques) and the training program for the SHOs will be discussed and registered. Additionally, local protocols for obstetric emergencies will be restructured during the first day and the local trainers will be introduced to the full body simulators. From the second day on, the local facilitators will start practicing during obstetric simulated scenarios on each other. This includes preparing, leading and debriefing a simulated scenario, including technical set-up (simulators, audio-video equipment, presentation equipment). On the last day the trainers will educate junior house officers (intern doctors) in

simulation-based obstetric training as a final test. The Dutch team of master trainers will provide the local trainers feedback. Afterwards, the local trainers will facilitate simulation-based training sessions for all SHOs without supervision of the master trainers in the above mentioned training scheme. Each training session will be organised by two local trainers (main and repetition training). Finally, the master trainers will provide an annual one-day train-the-trainers repetition course.

The main training of the SHOs will comprise a one-day (8-hour), simulation-based, obstetric training, focusing on both medical technical skills and crew resource management skills (i.e. teamwork skills).

The training scenarios will be postpartum haemorrhage, eclampsia, fetal distress with a vacuum-assisted vaginal delivery and resuscitation of the newborn, breech delivery, and a repetition scenario of postpartum haemorrhage. These scenarios relate to local leading causes of perinatal and maternal mortality and obstetric healthcare problems. Learning goals and learning objectives are defined for the scenarios in collaboration with the local trainers.

The main training will start with a general introduction and a knowledge test. Afterwards, the concept of simulation-based training will be explained and the SHOs will set their individual learning goals. Subsequently, the five scenarios will be covered. Every scenario will start with a short introduction of the scenario, followed with performing the scenarios by two to three trainees. The trainers and remaining SHOs observe the trainees via synchronised video broadcast. Every trainee will participate in at least two scenarios. After each scenario a debriefing by means of the video recordings will be provided by the trainers. The debriefing contains three different phases; reaction, analysis and take home phase. The instructors will provide feedback on both medical technical skills and crew resource management skills. When all five scenarios are completed, the predefined learning goals will be evaluated. Finally, all SHOs undergo the same knowledge test and they are asked to fill in an evaluation questionnaire on course perception.

After the main training, SHOs will be invited to take part in repetition training sessions. Each repetition training session will comprise half a day. During a repetition training, one clinical scenario will be executed (and repeated). New scenarios will be designed for these sessions based on the same emergency obstetric situations in the main training. However, expectations for the level of performance will be raised and some extra elements such as hand hygiene will be added to keep it challenging. Each repetition training will start with an introduction, in which learning goals will be defined. At the end of every training, learning goals will be evaluated and summarized.

Intervention Type

Other

Primary outcome(s)

Combined mortality proportion (CMP), measured using Mulago Hospital registration books, measured repeatedly during periods of 7 weeks from the start of the trial (with the exception of holiday and exam periods):

1. Maternal mortality ratio (MMR) - the number of maternal deaths per 100,000 live births
2. Perinatal mortality (PMR) - the number of stillbirths and deaths in the first week of life per 1000 live births

In Mulago hospital only deliveries with a gestational age of 28 weeks or more or a birth weight of more than one kilogram are registered. These deliveries will be included in the analysis.

Key secondary outcome(s)

The following were measured repeatedly during periods of 7 weeks from the start of the trial (with the exception of holiday and exam periods):

1. Perception of trainees in the training program, assessed using a 42-item questionnaire about ten instructional design features of the training program including feedback, repetition, curriculum integration, difficulty range, learning strategies, clinical variation, controlled environment, individualization, defined outcomes, and simulator validity (the ID-SIM). The data will be treated as ordinal data at the item level. Suggestions for improvement can be made in an open remark. Participants are asked to complete this at the end of the full-day main training
2. Knowledge of SHOs about technical and non-technical emergency obstetric skills, assessed using 30-item multiple choice knowledge test at the onset and end of the full day of training
3. Clinical performance in the simulated postpartum haemorrhage scenarios, assessed by independent Dutch simulation instructors through reviewing the videotaped training sessions of the full-day main training. A skills checklist based on literature and clinical experience will be used and assessors will be blind to the day of training and whether the scenario was the first or last of the day. The mean score of the clinical performance of the first and last scenario of the SHOs' main training will be compared.
4. Team performance, assessed by independent Dutch simulation instructors through reviewing the videotaped training sessions of the full-day main training. The Clinical Teamwork Scale (CTS) will be used, which contains questions about communication, situational awareness, decision-making, role responsibility, and patient friendliness. Assessors will be blind to the day of training and whether the scenario was the first or last of the day. The mean score of the clinical performance of the first and last scenario of the main training will be compared
5. Percentage of deliveries by vacuum extraction and caesarean sections, prospectively collected from Mulago Hospital's patient registration book
6. The following were measured using the Weighted Adverse Outcome Score (WAOS):
 - 6.1. Maternal death
 - 6.2. Intrapartum or perinatal death
 - 6.3. Uterine rupture
 - 6.4. Apgar score less than 7 after 5 minutes
7. Maternal and perinatal mortality ratios, evaluated separately (these ratios are not independent in the combined mortality proportion). This data will be prospectively registered using the delivery and patient registration books in Mulago Hospital.
8. Ratio of maternal and perinatal mortality per total number of deliveries. This data will be prospectively registered using the delivery and patient registration books in Mulago Hospital.

Completion date

13/01/2019

Eligibility

Key inclusion criteria

1. Senior house officer (resident)
2. Work at the medium to high-risk maternity ward of the Mulago hospital
3. Aged 18 years or older
4. Fluent in English

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

None

Date of first enrolment

14/01/2015

Date of final enrolment

20/04/2016

Locations

Countries of recruitment

Uganda

Study participating centre

Mulago Hospital

P.O. Box 7051

Kampala

Uganda

P.O. Box 7051

Sponsor information

Organisation

Mulago National Referral Hospital

ROR

<https://ror.org/02rhp5f96>

Funder(s)

Funder type

Not defined

Funder Name

Máxima Medical Centre Veldhoven, the Netherlands

Funder Name

Rotary Club Eindhoven-Welschap

Funder Name

Rotary Club Kyambogo-Kampala

Funder Name

Rotary Club Son

Results and Publications

Individual participant data (IPD) sharing plan

Prof. Dr. Byamugisha is in charge of the dataset (byamugisha2001@yahoo.com). We asked consent from participants to collect data and analyse these data by the researchers involved in the training for life team. However, we did not ask permission to share this with other people not involved in the training for life program. If anyone does want to have/see our dataset, we have to discuss this with the ethical board of Mulago Hospital.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/02/2021	08/02/2021	Yes	No
Protocol article	protocol	28/07/2020	31/07/2020	Yes	No