ISRCTN98617255 https://doi.org/10.1186/ISRCTN98617255

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

Submission date
23/07/2018

Recruitment status
No longer recruiting

Registration date
10/08/2018

Overall study status
Completed

Last Edited
08/02/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
AAC van Tetering
anne_van_tetering@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Miss Anne van Tetering

Contact details
P. Debyelaan 25
Maastricht
Netherlands
6229 HX

Type(s)
Scientific

Contact name
Prof Swan Guid Oei

Contact details
De Run 4600
Veldhoven
Netherlands
5504 DB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Interventional stepped-wedge cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not applicable in web format, contact details to request participant information sheet: anne_van_tetering@hotmail.com

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 measure
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.

Secondary outcome measures
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 dayThe 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 rapture
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.

Overall study start date
16/10/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Power calculation was carried out as described in both Hussey et al. and Woertman et al. First the sample size calculation for a standard randomised clinical trial (RCT) was calculated. To show a reduction in combined mortality proportion of 20% with an alpha of 0.05 and a power of 80%, a total of 6,398 deliveries would be needed for a simple RCT design. The design effect was calculated assuming an intracluster correlation (ICC) of 0.05, a cluster size of 3,343 deliveries per year, and seven clusters. Considering the design effect, we need 2,367 deliveries per measurement period. To achieve this number we need at least 5 weeks for each period. However, to obtain logistical possibilities, the duration of each step will be seven weeks with a total study duration of 56 weeks.

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

Sponsor details
P.O. Box 7051
Kampala
Uganda
P.O. Box 7051

Sponsor type
Hospital/treatment centre

Website
Not applicable

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

Publication and dissemination plan
We intend to publish our:
1. Study protocol to BMC Pregnancy and Childbirth in 2018
2. "Evaluating Training for Life: acceptability of acute obstetric simulation-based training and the effect on knowledge, teamwork, and medical-technical skills in Uganda" in IJGO in 2018.
3. "The effects of the Training for Life program on the percentage of ventouse deliveries, percentage of caesarean sections, the Weighted Adverse Outcome Score and maternal and neonatal mortality ratios" in 2019.
4. "Training for life: evaluation of a stepped wedge cluster randomised trial about emergency obstetric simulation-based training in a low-income country" in 2019

Intention to publish date
01/08/2018

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?
Protocol article	protocol	28/07/2020	31/07/2020	Yes	No
Results article	results	05/02/2021	08/02/2021	Yes	No