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Learning clinical breast exam skills with high fidelity versus low fidelity simulators in Rwanda

Submission date
16/08/2018

Recruitment status
No longer recruiting

Registration date
05/09/2018

Overall study status
Completed

Last Edited
04/04/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Breast cancer is the most common cancer discovered in women globally. Although great strides in detecting and treating patients with breast cancer have been made, these developments have not reached women in low and middle-income countries (LMICs), such as Rwanda. Simulation training is one solution, where screening and diagnostic techniques can be taught to healthcare providers. Simulation training involves teaching and practising techniques on models prior to performing skills on live patients.
We developed a simulation-based training program for health care providers in clinical breast examination (CBE). This study aims to look at whether low cost, locally available models, which are less realistic (low fidelity) are as effective for CBE teaching as high fidelity models. High fidelity models are made of realistic materials that look and feel similar to patients and anatomic structures, whereas low fidelity models sacrifice realism for increased affordability and availability. Low fidelity models can be especially important in LMICs, where resources and costs are strained.

Who can participate?
Adult medical students or residents rotating at CHUK hospital in Kigali, Rwanda

What does the study involve?
All participants will receive clinical breast examination (CBE) training, which will involve lectures and hands-on training, along with 4 examinations of these skills throughout the training day. Participants will be randomly allocated to perform this on either a high fidelity or low fidelity model. The examinations will be recorded on video for evaluation; however, their faces will not be recorded.

What are the possible benefits and risks of participating?
The possible benefit to participants taking part in this study is that they will learn the skills required for effective clinical breast examination. There are no known risks to participants taking part in this study.

Where is the study run from?
CHUK Hospital Kigali (Rwanda)

When is the study starting and how long is it expected to run for?
May 2014 to May 2017

Who is funding the study?
Center for Surgery and Public Health - Brigham and Women's Hospital (USA)

Who is the main contact?
1. Dr Shilpa Murthy (shilpamurthy83@gmail.com)
2. Dr Robert Riviello (robertriviello@gmail.com)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Clinical breast exam skill acquisition using high fidelity versus low fidelity simulation models in Rwanda: a randomised crossover trial

Study objectives
We used a randomized cross-over trial study design focused on clinical breast exam skill acquisition using high fidelity versus low fidelity models to determine whether training on low fidelity models confers similar skill acquisition as training on high fidelity models.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Rwanda National Health Research Committee, 10/09/2014, NHRC/2014/PROT/0182
CHUK Ethics Committee, 08/08/2014, EC/CHUK/2014/14

Study design
Interventional single-centre randomised crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Participants were randomised using a computerised random number generator in blocks of two. For every two participants, one was randomised to the high fidelity simulation (HF) group and one to the low fidelity simulation (LF) group. Participants received their fidelity group in a sealed envelope. Participants were not blinded to the models, as both types of models were present in the classroom. The video recordings were coded with unique identifiers so that the video rater was blinded to the level of trainee (medical student versus resident), and the exam attempt (exam 1, 2, 3, versus 4).
A one day four-hour simulation-based session designed to teach clinical breast examination (CBE) was implemented for both groups. This educational course was developed using standardized materials and lesson plans adapted for Rwanda based off primary literature, medical textbooks, the American College of Surgeons (ACS) student simulation-based surgical skills curriculum, surgical council on resident education (SCORE), and breast objective structured clinical exam (OSCE). Participants performed a baseline CBE on the model they were randomised

to prior to any teaching sessions. Following this pre-test (Exam 1), participants engaged in a two-hour didactic lecture series on breast anatomy, breast pathology, and CBE. Didactic teaching sessions between HF and LF groups were identical. All lectures were taught by investigator Murthy, SS, with the exception of breast anatomy lecture, which was taught by investigator Ingabire, A when his clinical duties permitted. Following the lectures, students performed a clinical breast examination on the model they were randomised to (Exam 2). After this second exam, students had 90 minutes of hands-on training and practice with the simulator model by investigator (Murthy, SS). Trainees had the opportunity to undergo repeated practice of CBE with immediate feedback from study investigator (Murthy, SS). After lectures, hands-on simulation teaching and practice, participants took a third CBE exam (Exam 3), and then participated in a fourth CBE exam (Exam 4) where they crossed over to the other model they were not originally randomised to. A video analysis technique was used to evaluate the CBE technical skills of participants at each point of the exam. The participants had their entire attempt anonymously recorded using a video recording device. In order to maintain confidentiality, the individual's face was not recorded, and a unique study number was used in all videos.
Consent was obtained from all participants in the study.

Intervention Type
Other

Primary outcome measure
Our primary outcome was to determine mean difference in CBE exam scores between HF and LF groups. The evaluation tool used to score clinical breast exams was published in a study by Schubart et. al and we obtained permission from the authors to use their tool. We expanded and adapted the tool to fit it to the Rwandan cultural context with a similar scoring system as the original research paper.
This was assessed at exams 1-4 and 1 month after the intervention.

Secondary outcome measures
The following are assessed at exams 1-4 and 1 month after the intervention:
1. Overall improvement in CBE exam scores after the education intervention was implemented
2. Whether addition of simulation to lectures improved the mean difference in CBE exam scores
3. Provider level traits that may affect the mean difference in exam scores

Overall study start date
01/05/2014

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. Consenting medical students or residents rotating at CHUK hospital in Kigali, Rwanda
2. Aged 18 years or older

Participant type(s)
Health professional

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
N/A

Date of first enrolment
01/07/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Rwanda

United States of America

Study participating centre
University Teaching Hospital Kigali
KN 4 Ave
Kigali
Rwanda
N/A

Study participating centre
Center For Surgery and Public Health
1620 Tremont St
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Sponsor information

Organisation
Center for Surgery and Public Health, Brigham and Women's Hospital

Sponsor details
1620 Tremont St
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02120

Sponsor type
University/education

ROR
https://ror.org/03vek6s52

Funder(s)

Funder type
Not defined

Funder Name
Center for Surgery and Public Health, Brigham and Women's Hospital

Results and Publications

Publication and dissemination plan
We are hoping to publish the results by 2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
Datasets will not be available unless we get permission from our Rwandan co-investigators, as this is a collaborative multi-institutional international study

IPD sharing plan summary
Not expected to be made available