ISRCTN17048881 https://doi.org/10.1186/ISRCTN17048881

A randomized cross-over trial focused on breast core needle biopsy skill acquisition and confidence using high fidelity versus low fidelity simulation models in Rwanda

Submission date
23/05/2018

Recruitment status
No longer recruiting

Registration date
08/06/2018

Overall study status
Completed

Last Edited
18/09/2018

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 (BC) is the most common cancer diagnosed in low and middle-income countries (LMICs). It is a leading cause of cancer related death for women worldwide. It is the most common type of cancer diagnosed in women at Rwanda's national referral hospitals. As community awareness of BC increases, the number of patients seeking care for breast complaints, including cancer, has risen. It is critical to increase the number of health care providers who are skilled in diagnosing and treating breast disease in order to provide quality care to patients. As medical education changes from traditional apprenticeship models towards competency-based education, simulation has become increasingly important. Concerns of teaching novice physicians on live patients, patient safety, quality, and operating room time and costs are addressed by training novice physicians on simulators before examining real patients. These simulation models are described in terms of fidelity, which is determined by the extent of their realism to human patients or anatomic structures through visual and tactile features. Low fidelity (LF) simulators sacrifice realism for cost whereas high fidelity (HF) simulators are costly but appear very similar to a patient or anatomic structure. Studies demonstrate that training on LF models confers the same benefit as training on HF models. Breast core needle biopsy (BCNB) is a procedure to remove a small amount of suspicious tissue from the breast with a hollow needle. A BCNB simulation training course has been developed using low (LF) and high fidelity (HF) models. The aim of this study is to find out whether training residents on LF models confers similar BCNB skill acquisition and confidence as training on HF models.

Who can participate?

Residents training in either surgery or obstetrics and gynecology (OB/GYN) in any post-graduate year at the University of Rwanda, rotating at University Teaching Hospital (CHUK) in Kigali, Rwanda

What does the study involve?

Participating residents are randomly allocated to use either an LF or HF model. Residents

perform a BCNB exam on the model to which they are allocated (Exam 1). After the exam, participants listen to a four-hour lecture session and they have 60 minutes of hands-on training with an attending physician with the simulator model to which were originally allocated. After the lectures and hands-on simulation practice, participants take a second BCNB exam (Exam 2) and then participate in a third BCNB exam where they cross over to the other model (Exam 3). At the end of the course, participants take a confidence survey.

What are the possible benefits and risks of participating?
The benefits to participants are that they will gain skills in ultrasound guided BCNB techniques. There are no real risks to participating in the study.

Where is the study run from?
1. University Teaching Hospital, Kigali (CHUK) (Rwanda)
2. Center For Surgery and Public Health (USA)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Shilpa Murthy
2. Dr Robert Riviello

Contact information

Type(s)
Scientific

Contact name
Dr Shilpa Murthy

Contact details
401 N. Senate Ave
Indianapolis
United States of America
46204

Type(s)
Scientific

Contact name
Dr Robert Riviello

Contact details
1620 Tremont St
Boston
United States of America
02120

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized cross-over trial focused on breast core needle biopsy skill acquisition and confidence using high fidelity versus low fidelity simulation models in Rwanda

Study objectives
A randomized cross-over trial focused on breast core needle biopsy (BCNB) skill acquisition using high fidelity (HF) versus low fidelity (LF) simulation models to determine whether training on LF models for post-graduate residents confers similar breast BCNB skill acquisition and confidence as training on HF models.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at University Teaching Hospital, Kigali (CHUK), 18/07/2014, ref: NHRC/2014 /PROT/0182, and the Ministry of Health of Rwanda (MOH). It was granted exempt study status by the institutional review board at Partners Healthcare in Boston at Brigham and Women's Hospital.

Study design
Single-center randomized education cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Benign or malignant breast disease

Interventions
A one-day, five-hour BCNB educational training course for surgical residents was implemented after baseline assessment. Similar sessions were conducted for OB/GYN residents on different days. During the first course for surgical residents, instructors included two fellowship trained Rwandan and United States (USA) breast surgeons, one radiologist, and one emergency department physician with fellowship training in ultrasound. The OB/GYN training sessions were identical in lecture and evaluation content except only one USA fellowship trained breast surgeon and one USA trained radiologist were available as instructors and evaluators.

Residents performed a baseline BCNB exam prior to any educational intervention on the model to which they were randomized (Exam 1). After the baseline exam, participants listened to a four-hour lecture session. Subsequently they had 60 minutes of hands-on training by an attending physician with the simulator model to which they were originally randomized. After the lectures and hands-on simulation practice, participants took a second BCNB exam (Exam 2) and then participated in a third BCNB exam where they crossed over to the other model (Exam 3). At the end of the course, participants took a confidence survey.

Prior to the course, the instructors were trained on how to evaluate participants in a similar manner using the US guided BCNB evaluation tool.

Intervention Type
Other

Primary outcome measure
The mean difference in BCNB exam scores between HF and LF groups, measured on the day the education intervention was implemented (exam 1, 2 and 3)

Secondary outcome measures
1. Provider level traits that may affect mean difference in exam scores
2. Participant confidence assessed using survey at the end of the course

Overall study start date
01/05/2014

Completion date
20/05/2017

Eligibility

Key inclusion criteria
Residents training in either surgery or obstetrics and gynecology (OB/GYN) in any postgraduate year (PGY) at the University of Rwanda, rotating at CHUK hospital in Kigali, Rwanda

Participant type(s)
Health professional

Age group

Adult

Sex
Both

Target number of participants
15 individuals were required in each arm

Key exclusion criteria
Medical students and anyone who was not a postgraduate Rwandan resident in surgery or OB-GYN rotating at University Teaching Hospital, in Kigali, Rwanda

Date of first enrolment
01/10/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Rwanda

United States of America

Study participating centre
University Teaching Hospital, Kigali (CHUK)
Department of Surgery
Kigali
Rwanda
-

Study participating centre
Center For Surgery and Public Health
1620 Tremont St
Boston
United States of America
02120

Sponsor information

Organisation
Center for Surgery and Public Health

Sponsor details
1620 Tremont St
Boston
United States of America
02120

Sponsor type
University/education

ROR
https://ror.org/03vek6s52

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The trialists will publish their results shortly within the next month or two. They will submit their paper this upcoming month.

Intention to publish date
31/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Shilpa Murthy. The data will be readily available only on a case by case basis if it is approved in collaboration with their Rwandan colleagues.

IPD sharing plan summary
Available on request