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The influence of a virtual simulator on the acquisition of trainees ultrasound skills

Submission date
18/02/2013

Recruitment status
No longer recruiting

Registration date
22/03/2013

Overall study status
Completed

Last Edited
29/06/2016

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Simulation training in transvaginal ultrasound (TVUS) leads to skill acquisition and opens up a new era for learning ultrasound skills. The limited opportunities of training offered to trainees lead to insufficient practice in scanning. Several studies have suggested that simulation training provides facilities to trainees to practice and learn freely. In order to improve patient safely and comfort in addition to enhancing trainee confidence, learning ultrasound skills through theory-based, structured-systematic approaches to training on the simulator will shorten the length of training time and enhance the individuals learning. Therefore, the introduction of simulation training will help to build on the trainees sonographic knowledge base and develop important ultrasound skills before they work with real patients. Thus this additional simulation training in a clinical environment would improve trainees competency in obstetrics and gynaecology ultrasound scanning.

Who can participate?
The study subjects are recruited primarily from specialist trainees (ST1- ST7 level) in Obstetrics and Gynaecology in the Welsh Deanery, other NHS staff and students of the MSc programme in Cardiff University who fulfil the inclusion criteria.

What does the study involve?
Subjects are randomly allocated into control and intervention (simulation-supported) learning groups. For the simulation group: trainees are undertaking and completing all tutorials on the simulator and are provided with simulator feedback and continued access during the trial duration. For the non-simulation (control) group: trainees are permitted to accessing the unassessed tutorial/tasks mode before monthly assessment to familiarise themselves with the simulator. At the baseline phase of trial, the simulator is used to assess baseline skills of each subject to test their eligibility to participate. After that, subjects skills are re-assessed every month for evaluating acquisition during the trial (within 6 months). During the trial, the intervention group receive structured, self-directed simulation training while the control group are allowed to access (unassessed practice) modules on the simulator with no feedback provided. Both groups are permitted to receive conventional training in the normal way.

What are the possible benefits and risks of participating?
Study subjects will receive a detailed report and feedback about their skill assessment. They would be made aware of the skill areas that need further training as well as recognising how their skills have been gradually improved by the simulator (for intervention/simulator group). In the control group, they would be able to access ultrasound-learning material throughout the study and gain access to lectures to build up their basic knowledge of ultrasound. At the end of the trial they would be able to have access to the simulator if required to do so. This research is risk-free as it is a practical training but without involving patients. However, study subjects are advised to observe the general and professional guidelines related to avoidance of repetitive stress and injury during conventional scanning in their clinical settings or while using the simulator.

Where is the study run from?
The study runs from three training hospitals in Wales, UK
University Hospital of Wales, Cardiff
Singleton Hospital, Swansea
Wrexham Maelor Hospital, Wrexham.
Sampling selected from different Welsh Deanery training hospitals across North and South Wales, UK.

When is study starting and how long is it expected to run for?
The study started in May 2011 and will run until the required number of 60 trainees have been recruited and assessed.

Who is funding the study?
The research is organised and supervised by the Department of Obstetrics and Gynaecology, Cardiff School of Medicine, University Hospital of Wales. The study is funded by a scholarship from Saudi Arabia government.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SPON896-10

Study information

Scientific Title
Validation and determination of the influence of a virtual simulator on the acquisition of ultrasound skills and comparison of learning curves of those using simulation-supported training with a conventional training approach

Study objectives
Simulation-based learning plays a significant role in the enhancement of the educational process and provides a more efficient learning environment. Recently, new devices have become available to enhance ultrasound training, ranging from physical fetal or gynaecological mannequins to the virtual reality computer-based ultrasound simulator (ScanTrainer, MedaPhor Ltd., Cardiff, UK) developed at Cardiff, UK. This Ultrasound Simulator aims to shorten the length of training time through a series of simulation tutorials encompassing a number of objectives, tasks and assessments with computer-generated individualised student feedback. It is hypothesised that such an approach to training will lead to improved technical performance in the real-life scanning environment.

The studys primary aim is to compare the learning curves for the acquisition of core ultrasound scanning skills among research subjects (trainees) undergoing conventional ultrasound training only with those undergoing conventional training supported by structured simulation training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Ethics Research Committee Panel B. Cardiff, UK, REC Reference Number 10AA /SE02/75, 14 December 2010

Study design
Parallel randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Improving ultrasound skills and training competency for trainees

Interventions
The intervention group were instructed to use the simulator to practice ultrasound skills in addition to receiving clinical training arranged by their hospital, whereas the control group received conventional training alone.

Number of simulation training is unlimited as the simulator is always free to access and use. However, six skill assessment sessions are booked for each participant. Duration of intervention is 6 months, starts from first day of participation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in ultrasound scan performance (OSATS) in obstetrics and gynaecology between simulation- supported trained and untrained subjects

Secondary outcome measures
1. Determine factors that have affected engagement in the project and acquisition of relevant skills. This will provide information on barriers and limitations of simulation training in a clinical environment.
2. Evaluate the validity of task performance sheet for assessing relevant skills in comparison to the simulators task metrics.
3. Overall subjective ultrasound skills acquisition with/out simulation training
4. Differences in skills scores at each assessment session

Overall study start date
15/05/2011

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Subjects (aged 18- 50+) should have (none or limited) ultrasound experience of any kind
2. None or limited previous access to transvaginal ultrasound experience
3. Motivated to learn transvaginal ultrasound skills

4. Intends to complete the requirements of the Royal College of Obstetricians and Gynaecologists (RCOG) ultrasound training curriculum or a similar structured programme
5. Based within Wales or within a very short distance of travel to Cardiff

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60-80

Key exclusion criteria
1. Individuals who have already completed any structured ultrasound training programme and certified accordingly
2. Individuals at consultant level in obstetrics and gynaecology or radiology even if they have no ultrasound experience
3. Radiographers on the ultrasound MSc programme with previous experience in transvaginal ultrasound scanning

Date of first enrolment
15/05/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
University Hospital of Wales
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Cardiff University Registry and Academic Services
30 - 36 Newport Road
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Sponsor type
University/education

Website
http://www.cf.ac.uk

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Saudi Arabia Government - Scholarship funding, PhD project undertaken at Cardiff University

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration