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# Can we make arthritis surgery better and safer for patients by training surgeons using cadaveric simulation?

**Submission date**
14/08/2014

**Recruitment status**
No longer recruiting

**Registration date**
03/09/2014

**Overall study status**
Completed

**Last Edited**
28/10/2022

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
Due to changes in working regulations, todays trainee surgeons will have had far fewer hours of experience in the operating theatre by the time they become consultants than in the past. There has been a change in the training culture in the modern NHS and it is rightly now considered unacceptable to allow young surgeons to practice (perform) operations for the first time on real patients. The government has urged that there is a need to look at additional ways of training surgeons that provide realistic yet safe training. This will help to ensure that future orthopaedic (bone and joint) surgeons are trained to the highest possible standard to perform safe operations for their patients. One way of overcoming this problem is by using simulated surgery. Much in the same way as pilots learn to fly aeroplanes using a flight simulator before doing it for real, surgeons can first learn to do operations using simulation. One of the most promising simulation opportunities for learning surgery is found in using donated dead human bodies (cadavers). This is a very valuable learning resource for young surgeons as cadavers have the correct arrangement of all parts of the body that is found in the living patient, and it replicates the experience of surgery in an accurate and sophisticated way. A recent change in the law has allowed human cadavers to be used for training surgeons in the UK for the first time in history. It is not yet known whether this type of training will help young surgeons to learn operations more quickly and to a higher standard. The aim of this study is to see whether there are any benefits to the learning curve of the trainee surgeons.

Who can participate?
Junior surgeons in their fourth and fifth years of clinical practice after medical school, on a training programme in the West Midlands area

What does the study involve?
Participants are randomly allocated into one of two groups. One group attends a cadaveric simulation training course in September 2014. The other group attends the exact same course in July 2015. Between September 2014 and July 2015, all participants in both groups have their performance measured during certain operations they perform on real patients during the year. As during this time period some of the participants have received the training (the September

group) and some have not yet (the July group), the research team is able to see what effect, if any, the new type of training has had on the participants real-life operations.

What are the possible benefits and risks of participating?
This study offers three major potential benefits for arthritis patients:
1. Young surgeons could learn to do arthritis surgery using cadaveric simulation and achieve a high level of skill before operating on live patients
2. More experienced surgeons-in-training learn to perform increasingly complex operations for arthritis such as joint replacement surgery. There are many surgeon-related factors that can affect the outcome of these operations. Key skills could be learnt using cadaveric simulation, therefore helping to ensure the best outcome for the patients.
3. This research will also help develop tools for assessing surgeons' technical skill and could, with further work in the future, be used to help assess if surgeons are competent to proceed to the next stage of their training.
There are no risks to patients from their surgeons participating in this study. The training cannot make them worse surgeons. The surgeons themselves will need to make a time commitment to attend the training course, and will be asked to complete some additional assessments during the year, in addition to those which are already a standard feature of training. We also need to talk to the surgeons who are taking part to find out about their view and experiences of the new training.

Where is the study run from?
University Hospital Coventry & Warwickshire, West Midlands Surgical Training Centre, Warwick Medical School (UK)

When is the study starting and how long is it expected to run for?
September 2014 to August 2015

Who is funding the study?
1. Arthritis Research UK
2. Health Education West Midlands (UK)

Who is the main contact?
Dr Hannah James
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### Study website
http://www.cadtrauma.co.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Hannah James

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
Arthritis Research UK Grant reference number 20485

# Study information

### Scientific Title
Does learning to perform surgery on cadavers lead to better surgeons and safer patients?

### Acronym
cad:trauma study

### Study objectives
The study hypothesis is that provision of a cadaveric simulation training (CST) course to junior orthopaedic surgeons-in-training will improve their real world operative performance.

The following objectives will be addressed in the study:
1. Measurement of the early surgical skill acquisition trajectory of CST-trained and standard-trained participants using an objective, validated outcome measure
2. Characterize skill retention and transfer to live surgery following a CST intervention
3. Determine trainee and trainers perspectives on the experience of CST

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. University of Warwick's Biomedical and Scientific Research Ethics Committee, 29/05/2014, ref. REGO-2014-718
2. National research ethics approval (15/WM/0464) (added 28/01/2020)
3. Confidentiality Advisory Group approval (16/CAG/0125) (added 28/01/2020)

### Study design
Randomised multi-centre controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled 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 participant information sheet

## Health condition(s) or problem(s) studied
Education and training of surgeons

## Interventions
Participants will be randomised to two groups:

The CST intervention is a two-day course and will take place on 25/09/2014 at the West Midlands Surgical Training Centre (WMSTC) at the University Hospital Coventry & Warwickshire. Faculty and participants will be briefed on the study at the start of the day.
Demographic data on participants and their subjective skills rating will be measured at the beginning of the day using a surgical self-efficacy questionnaire. Participant performance of the taught procedures during the course will be assessed by the supervising faculty surgeons, using both the Objective Structured Assessment of Technical Skills in Surgery (OSATS) and the Generic Operative Supervised Learning Event (GOSLE) measures. All participants will also have Procedure Based Assessments (PBAs) completed for each procedure, which is standard current educational practice.

Control group: Self-efficacy questionnaires (SEQs) will be administered to the control participants on 25/09/2014. Control participants and their trainers will be briefed about the study outcome measures at this time (OSATS/GOSLE/PBA), and from the 25/09/14 onwards they will be asked to complete these during every live surgical procedure they perform.

After the training intervention, participants in the intervention group will disperse to their respective host hospitals and continue to be exposed to a variety of trauma surgery as per standard training.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
1. Objective Structured Assessment of Technical Skill in Surgery (OSATS). This is a validated tool for assessing technical skill in surgeons. It is completed by a senior surgeon immediately after supervising a trainee performing a procedure. It is generic to all operations and assesses learners across six domains; respect for tissue, time and motion, knowledge and instrument handling, flow of operation, use of assistants and knowledge of this procedure. Each domain is scored on a Likert scale of one to five, with one being the worst and five the best.
2. Generic Operative Supervised Learning Event (GOSLE). This is a new tool developed for

assessing technical skill in Trauma & Orthopaedic surgeons, which is undergoing validation (which this trial will contribute towards). The GOSLE is similarly generic to all surgical procedures and completed by a senior surgeon immediately after supervising a trainee. The GOSLE measures the percentage of the procedure performed (in 5% increments), description of the steps performed by the trainee and a global rating assessment of their performance on this occasion. The global rating is on an eight-point scale with attached descriptors and guidance notes, ranging from able to assist, with guidance to able to anticipate, avoid and/or resolve common problems'.
3. Procedure Based Assessment (PBA). This is the current gold standard tool used for assessing surgeons-in-training performance. It is procedure-specific, thus the fields on the assessment are different between procedures. The PBA consists of a checklist tool against which performance is scored for different steps of the operation as on not observed, unsatisfactory or satisfactory. The checklist is different for each procedure. There is a global rating scale assessment ranging from zero  insufficient evidence to support a summary judgment, to four  competent to perform the procedure unsupervised (could deal with complications that arose). There is also space for reflective comments to be made by both the trainer and trainee.

Both the intervention and control group participants will be instructed to arrange completion of the study outcome assessment measures at every subsequent index case they perform on a real patient during the study follow-up period. All outcome data will be collected centrally on the trial website and will be accessed centrally to anonymise and extract it for analysis.

### Secondary outcome measures
Surgical self-efficacy questionnaire (SEQ) scores. Participants in the intervention group will be assessed at baseline during the cadaveric simulation training course (25-26th September 2014). Participants in both the intervention and control courses will be assessed during the September 2014-August 2015 training year on each occasion that they perform one of the index study procedures (dynamic hip screw fixation of a femoral neck fracture, hemi-arthroplasty for femoral neck fracture, open reduction-internal fixation of an ankle fracture and lower limb compartment releases). The precise timing of these measurements will vary due to the irregular nature of trauma surgery.

### Overall study start date
25/09/2014

### Completion date
31/07/2020

## Eligibility

### Key inclusion criteria
Trainee Trauma & Orthopaedic Surgeons in the West Midlands Area who are in their fourth ('Core Training Year 2') or fifth ('Speciality Training Year 3') post-graduate year of clinical practice

### Participant type(s)
Patient

### Age group
Adult

### Sex

Both

**Target number of participants**
32

**Key exclusion criteria**
Refusal of consent

**Date of first enrolment**
25/09/2014

**Date of final enrolment**
04/08/2015

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University Hospitals Coventry & Warwickshire**
Coventry
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CV2 2DX

# Sponsor information

**Organisation**
Arthritis Research UK (UK)

**Sponsor details**
Copeman House
St Mary's Gate
Chesterfield
Derbyshire
United Kingdom
S41 7TD

**Sponsor type**
Charity

**Website**
http://www.arthritisresearchuk.org/

**ROR**
https://ror.org/02jkpm469

# Funder(s)

**Funder type**
Charity

**Funder Name**
Arthritis Research UK; Grant Number 20485

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

**Funder Name**
Health Education West Midlands (UK)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 25/09/2020 | 28/09/2020 | Yes | No |
| Other publications | | 24/09/2020 | 28/10/2022 | Yes | No |

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|---|---|---|---|
| HRA research summary | 28/06/2023 | No | No |