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Simulation-based arthroscopic surgery study

Submission date	Recruitment status	[_] Prospectively registered
09/05/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2019	Surgery	

Plain English summary of protocol

Background and study aims
Surgeons in training are taught a range of skills, including technical skills, communication, clinical knowledge and anatomy, and decision making. On a background of decreasing working time available, less independent operating, and greater public expectations of the medical profession, simulation is seen as an important support to routine surgical training. However, there is little evidence to say it improves surgical performance, and these studies are not based on factual measurements but rather opinions. The aim of this study is to use motion analysis to specifically assess the technical skills aspects of surgical training, and in order to find out whether simulation training can improve performance.

Who can participate?
Adults enrolled in Health Education Thames Valley/Oxford Deanery Training Programme in junior surgical training posts.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in normal clinical training alone. Those in the second group take part in one hour additional simulation training a week for thirteen weeks. The simulation sessions themselves involve self-directed practice on bench-top simulators, which monitor performance using wireless elbow mounted motion sensors recording hand movements, smoothness of hand movements and time taken.

What are the possible benefits and risks of participating?
The main benefits of participating are the additional training opportunities given. These will also be offered to those who take part in usual training alone at the end of the study. There are no notable risks involved with participating.

Where is the study run from?
Nuffield Orthopaedic Centre (UK)

When is the study starting and how long is it expected to run for?
March 2015 to January 2017

Who is funding the study?
Royal College of Surgeons of England (UK)

Who is the main contact?
Mr Patrick Garfjeld Roberts

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02777333

Secondary identifying numbers
MSD-IDREC-C1-2014-152

Study information

Scientific Title
Does simulation training improve intra-operative arthroscopic technical skills performance in junior orthopaedic trainees?

Study objectives
That the addition of simulation training improves arthroscopic technical skills performance of junior orthopaedic trainees during knee arthroscopy in the operating theatre compared to usual clinical training programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Sciences Interdivisional Research Ethics Committee, University of Oxford, 12/09/2014, ref: MSD-IDREC-C1-2014-152

Study design
Single blinded randomised 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 below to request a patient information sheet.

Health condition(s) or problem(s) studied
Arthroscopic surgery training

Interventions
Participants are randomly allocated to one of two groups using a blocked randomisation with random block sizes and a 1:1 allocation ratio.

Control/Non-simulation study arm: Participants will receive no additional treatment/training beyond their usual day to day clinical work as a senior house officer level trainee (including but not limited to: ward work, attending theatre, clinics, out-of-hours/'on-call') for the 13 weeks of the study.

Intervention/simulation study arm: Participants will receive weekly 1 hour simulation sessions over 13 weeks at the skills lab at the Nuffield Orthopaedic Centre, arranged on an individual basis to fit around clinical commitments. The simulation sessions will involve self directed practice on non-anatomical and anatomic arthroscopic bench-top simulators (#1711-1 and #1517-29-11 available from SawBones, Malmo, SE), during which they can monitor their performance using wireless elbow mounted motion sensors recording hand movements, smoothness of hand movements and time taken.

Total duration is 13 weeks in both groups.

Both groups will be followed up at 13 weeks, with no planned further follow up.

Intervention Type

Behavioural

Primary outcome measure
Motion analysis parameters ('hand movements', 'minor hand movements', 'smoothness of movements', 'time taken', 'maximum hand acceleration', 'stationary time', 'idle time' and 'hand dominance') are measured using wireless elbow mounted motion sensors during diagnostic knee arthroscopy at 3 months.

Secondary outcome measures
1. Performance during diagnostic knee arthroscopy is measured using the Global rating scale at 3 months
2. Motion analysis parameters as a function of 'ideal' motion analysis parameters are judged by a supervising clinician during the same case at 3 months
3. Change in simulator performance using motion analysis parameters at baseline and 3 months
4. Structural and functional changes on fMRI using resting state networks, voxel based morphometry, diffusion tractography and quantitative magnetisation transfer is measured at 3 month follow up by comparison to baseline fMRI
5. Feasibility of simulation training during usual clinical training is measured using a qualitative survey designer for this study at 3 month follow up

Overall study start date
03/03/2015

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Healthy adults, Male or Female, aged 18 years or above
3. Enrolled in Health Education Thames Valley/Oxford Deanery Training Programme in junior surgical training posts

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria

1. Unwilling or unable to provide informed consent
2. Previously completed higher surgical training programme

Date of first enrolment
01/01/2016

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
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Sponsor information

Organisation
University of Oxford

Sponsor details
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University of Oxford
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Other

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this study will contribute to a DPhil thesis, and will be submitted to academic peer reviewed journals and conferences, likely with an orthopaedic, arthroscopic or medical education focus.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019	09/08/2019	Yes	No