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Virtual reality training for hip surgery

Submission date
21/11/2018

Recruitment status
No longer recruiting

Registration date
23/11/2018

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Surgical procedures are becoming increasingly complex, but there are fewer training opportunities for junior doctors. This is due to restrictions in working hours, as well as an improved focus on patient safety. Novel methods of training surgeons to perform complex procedures are required to safely and effectively educate the next generation.
Total hip replacement (THR) was heralded as the operation of the 20th Century, but is a complex skill. Errors during this surgery are a result of technical mistakes and failures in decision-making, communication and behaviours (non-technical skills). Currently, training surgeons learn to perform hip replacement initially from lectures, textbooks and workshops on sawbone materials, before learning on real patients in surgery. Practicing on human donors may also contribute to education, but this is expensive and thus poorly accessible. For over twenty years, keyhole surgery has been practiced by surgeons on simulators – computers with controllers which can train for the technical and non-technical skills. However, simulators have been unable to simulate open procedures, such as total hip replacement.
Our group has developed a cognitive training tool and a novel virtual reality (VR) simulator to train for total hip replacement surgery with the latest commercially-available technology. We aim to see if surgical trainees are able to prepare for surgery using cognitive training tools, as compared to conventional videos and texts. We aim to then see if they can learn technical and non-technical skills for this performing hip replacement from VR as effectively as from current training methods from expert surgeons.

Who can participate?
Junior surgeons with no independent experience of performing hip replacement

What does the study involve?
Participants will be randomly selected to receive cognitive training and then VR or conventional training in a syllabus. They will be assessed in a written exam as well as during performing a real total hip replacement procedure on a human donor.

What are the possible benefits and risks of participating?
The possible benefits of participating are threefold. Junior surgeons will receive structured training and practice regarding an important and common procedure (THR), half will be exposed to new forms of training (cognitive and virtual), and thirdly they will contribute towards research to improve the next generation of surgical education. There are no significant risks from

participating, and a full risk-analysis has been performed to mitigate all risks during performing hip replacement on the human donors.

Where is the study run from?
1. Imperial College London (UK)
2. Chelsea & Westminster Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2018 to October 2019

Who is funding the study?
1. Royal College of Surgeons of England (UK)
2. The Michael Uren Foundation (UK)
3. Johnson & Johnson (USA)
4. CW+ Trust (UK)

Who is the main contact?
Kartik Logishetty
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
237607

Study information

Scientific Title
The THRiVR study: a randomized controlled trial comparing Virtual Reality to conventional training for surgeons learning Total Hip Replacement

Acronym
THRiVR

Study objectives
The primary hypothesis is:
1. Surgical trainees learning with virtual reality (VR) can perform simulated total hip arthroplasty to the higher technical levels than those trained with conventional training

The secondary hypotheses are:
2. Compared to the control, VR-trained surgeons develop higher levels of non-technical skills
3. The skills developed in VR training for hip arthroplasty are gained over time on a learning curve
4. VR is an acceptable form of surgical training
5. Cognitive training enhances development of knowledge related to total hip replacement, prior to conventional and VR training

Ethics approval required
Old ethics approval format

Ethics approval(s)
Imperial College London and Imperial College Healthcare Health Research Authority, 10/04/2018, In18/HRA/2085

Study design
Interventional single-blinded two-stage paralle design 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Total hip replacement

Interventions
Participants will be randomly allocated to either the intervention or the control group through stratified block randomisation, using blocks of equal size with stratification to balance surgical experience of total hip arthroplasty through any approach.
For stage 1, participants in the intervention group will undergo cognitive-task based training, and participants in the control group will undergo video and text-based training.
For stage 2, participants in the intervention group will receive a fully-immersive virtual reality total hip arthroplasty training program over 5 60 minute sessions administed by a technician. Participants in the control group will undergo conventional surgical training, involving 1-to-1 dry-bone and anatomical practicals with expert hip surgeons for 5 60 minute sessions.

Intervention Type
Mixed

Primary outcome measure
Technical and non-technical skills in total hip replacement, assessed using the ISCP Total Hip Arthroplasty Procedure Based Assessment from cadaveric total hip arthroplasty at the end of the 6 week program.

Secondary outcome measures
1. Behavioural related to safety and teamwork, assessed using the NOTECHS score at the cadaveric assessment (after the end of the 6 week program)
2. Knowledge of basic science and procedural steps related to THR, assessed using a postgraduate level exam in the 5 weekly VR sessions
3. Time-to-complete VR THR, measured in the 5 weekly VR sessions by the virtual reality platform from the point when the surgeon begins the first step of the procedure
4. Errors in task performance, measured in the 5 weekly VR sessions by the virtual reality platform by recording the number of errors in instrument selection
5. Accuracy in implant orientation in dry-bone, cadaver and VR sessions, measured in the 5 weekly VR sessions by the virtual reality platform by recording degrees of deviation from an assigned target, in cup inclination, cup anteversion, height of femoral neck osteotomy in millimetres from the less trochanter, and angle of femoral neck osteotomy in degrees
6. Feasibility and usability, assessed using Technology Acceptance Model-based and Realism surveys after the end of the 6 week program

Overall study start date
01/02/2018

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Surgeons in training
2. Aged 18 years or older
3. Able to read and speak English
4. Able to provide informed consent

Participant type(s)

Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Total final enrolment
24

Key exclusion criteria
1. Unable to speak or read English at a sufficient level to give informed consent
2. Retired from surgical practice
3. Suffers from a psychiatric illness that limits informed consent
4. Unwilling or unable to receive or access emails for study questionnaires
5. Medical history of headaches or epilepsy
6. Registered as partial sighted
7. Injuries or deformity preventing full function of both upper limbs
8. Performed more than 25 THRs under supervision or independently

Date of first enrolment
22/11/2018

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
Canada

England

United Kingdom

Study participating centre
MSk Lab, Imperial College London
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
University of Ottawa Orthopaedics
The Ottawa Hospital - General Campus
501 Smyth Rd, Ottawa, ON
Ottawa
United Kingdom
K1H 8L6

Sponsor information

Organisation
Imperial College London

Sponsor details
South Kensington Campus
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

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

Funder Name
Chelsea and Westminster Health Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The research outputs from this project will be disseminated in peer-reviewed scientific journals, in internal reports to Imperial College and funding bodies, by presentation at conferences, and by publication of results on public-access websites.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The data will be stored on a secure lab server at Imperial College London, and we do not plan to share individual data sets, video-recordings or analyses unless directly contacted by another academic researcher or institution for their non-commercial use.

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		01/12/2019	10/09/2021	Yes	No