**Study Title:** A prospective randomised controlled study assessing the impact of simulation training in primary total hip replacement (THR).

**Internal Reference Number / Short title:** THR Performance & Assessment
**Ethics Ref:** 19/SC/0492
**IRAS Project ID: 270167**
**Date and Version No:** 6th August 2019, Version 1.0


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| **Chief Investigator:** | **Professor Jonathan Rees**<br>Professor of Orthopaedic Surgery and Musculoskeletal Science<br>Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS).<br>Honorary Consultant Orthopaedic Surgeon<br>Nuffield Orthopaedic Centre (NOC)<br>Oxford University Hospitals NHS Foundation Trust |
| **Investigators:** | **Mr Daniel Howgate**<br>Honorary Specialty Registrar in Trauma & Orthopaedic Surgery<br>Oxford University Hospitals NHS Foundation Trust.<br>Royal College of Surgeons (RCS) of England and Dinwoodie Charitable Company Research Fellow<br>Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS). Botnar Research Centre<br><br>**Mr Ben Kendrick**<br>Consultant Orthopaedic Surgeon<br>Nuffield Orthopaedic Centre (NOC)<br>Oxford University Hospitals NHS Foundation Trust |
| **Sponsor:** | University of Oxford/Clinical Trials and Research Governance<br>Joint Research Office,<br>1st Floor Boundary Brook House,<br>Churchill Drive,<br>Headington,<br>OX3 7GB |
| **Funder:** | **Dinwoodie Charitable Company** |


**Chief Investigator Signature:**

**Statistician Signature:** We do not require a dedicated statistician for data analysis of this particular study. However, if required we have access to many statisticians in the Centre for Statistics in Medicine (CSM) and our Trials Unit within the Botnar Research Centre.

The investigators have no potential conflicts of interest to declare.

**Confidentiality Statement**
This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee,

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## 1. KEY CONTACTS

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|---|---|
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| **Sponsor** | University of Oxford/Clinical Trials and Research Governance<br>Joint Research Office,<br>1st Floor Boundary Brook House,<br>Churchill Drive,<br>Headington,<br>OX3 7GB |
| **Funder(s)** | **Dinwoodie Charitable Company**<br>4 Tytherington Green, Macclesfield, SK10 2FA<br>E-mail: dinwoodie@irwinmitchell.com<br>Tel: 01625610549<br>Charity no. 1151139<br>Company no. 08391977 |
| **Statistician** | N/A |
| **Committees** | N/A |

## 2. LAY SUMMARY

This research study is focused upon assessing and optimising surgeon's performance during, and patient outcomes following, total hip replacement (THR) surgery. The primary research question is to determine if additional simulation training can improve the intra-operative performance of surgical trainees (Specialty Registrars) during a THR, or the outcome of patients after their THR. We will also aim to define an 'expert' standard in performing a primary elective THR, which may be used as a benchmark when assessing surgical trainee performance; and also determine if operative surgeon performance metrics during a THR are correlated with surgical experience, or patient outcomes.

The surgeon participants in this study will be divided into 2 groups depending upon their position and seniority. The 'Expert' group will be composed of Consultant Orthopaedic Surgeons and Senior Fellows, and the 'Trainee' group will be composed of Trauma & Orthopaedic Specialty Registrars (StR's) on Deanery clinical placements. The intervention to be tested is the simulation-based training and cognitive learning package. This will be delivered for 1-2 hours per week over a 4-week period in a supervised non-clinical setting to a randomised sub-group of 50% of the Specialty Registrars enrolled into this study. Surgeon participants within the Expert group will not undergo any interventions.

The outcome measures will be surgeon-specific and patient-specific. These outcome measures for the 'Trainee' group will commence following completion of the simulation training (if applicable), whereas they can commence immediately following study approval for the 'Expert' group. The surgeon-specific outcome measures will be the objective motion-analysis metrics generated by validated and extensively used wireless sensors placed on the elbows of surgeons under their sterile gowns during the operation; and subjective assessments of surgical trainee performance using validated and reliable forms of structured human grading. Patient-specific outcome measures will be collected for a pre-determined number of patients who have undergone a primary elective THR by any of the surgeon participants in this study. All patient-specific outcome measures (with the exception of a post-operative questionnaire) are routinely collected as part of the patients NHS clinical care, and no other additional investigations are required for conducting this research. All patients will be asked to provide their written informed consent for the use of their data in this study. The patient-specific outcome measures include: pre- and post-operative blood tests and radiograph (X-ray) analysis; the incidence of blood transfusions and any other peri-operative complications; the in-patient length of stay; and two patient-reported outcome measure (PROMs) questionnaires.

Statistical analysis will then be performed on the data collected, specifically aiming to identify any significant differences in either surgeon performance metrics, or patient outcome measures between:

1) The StR's who have undertaken additional simulation training versus those who have routine Deanery training.
2) The 'Trainee' group and the 'Expert' group. A sub-group analysis may be performed within the 'Expert' group also to determine any differences between the Consultants and Fellows.

In summary, this novel research will use validated methodology and routinely collected patient outcome measures in order to determine the impact of simulation training on surgical trainee performance and patient outcomes following a primary elective THR, and also help to benchmark an expert level of performance in this commonly performed and highly effective operation. The results of this study will hopefully help in shaping the future of orthopaedic surgical training and assessment within the United Kingdom.

## 3. SYNOPSIS

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|---|---|
| Study Title | A prospective randomised controlled study assessing the impact of simulation training in primary total hip replacement (THR). |
| Short title | THR Performance & Assessment |
| Study registration | IRAS Project ID: 270167<br>6th August 2019 |
| Sponsor | University of Oxford/Clinical Trials and Research Governance<br>Joint Research Office,<br>1st Floor Boundary Brook House,<br>Churchill Drive,<br>Headington,<br>OX3 7GB |

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| Funder | Dinwoodie Charitable Company | | |
| Study Design | Prospective randomised controlled study, with an additional comparator group. | | |
| Study Participants | Trauma & Orthopaedic Specialty Registrars (intervention and control groups), Consultant Orthopaedic Surgeons, and Arthroplasty Fellows.<br>Patients undergoing elective primary THR at the 2 named NHS Hospitals in this study, when their lead surgeon is enrolled as a participant in this study. | | |
| Participant Sample Size | Surgeon participant Group 1 a: Interventional group ('StR's'): Thames Valley Deanery Trauma & Orthopaedic Specialty Registrars on Arthroplasty clinical placements (n=8) receiving additional training<br><br>Surgeon participant Group 1 b: control group (StR's): Thames Valley Deanery Trauma & Orthopaedic Specialty Registrars on Arthroplasty clinical placements receiving routine and normal Deanery training only (n=8).<br><br>Surgeon participant Group 2: ('Experts & Fellows'): Consultant Orthopaedic Surgeons (n=5), and nationally appointed Arthroplasty Fellows (n=8).<br><br>Patient Participants: Estimated total n= 193, calculated on the basis of outcomes data following THR to be collected for:<br>8 patients per Specialty Registrar (n = 128)<br>5 patients per Fellow (n = 40)<br>5 patients per Consultant (n = 25) | | |
| Planned Study Period | Total length of project = 18-24 months<br>Length of individual participants involvement = 6 months | | |
| Planned Recruitment period | Start date for recruitment = August 2019<br>End date for recruitment = February 2021 (with possible extension to August 2021) | | |
| | Objectives | Outcome Measures | Timepoint(s) |
| Primary | To assess the impact of simulation training on surgical trainee performance and patient outcomes following THR. | **Participants:**<br>• Wireless motion data metrics from elbow worn sensors (hand movements, path length and time taken).<br>• Global Rating Scales (GRS).<br>• Objective Structured Assessment of Technical Skills (OSATS).<br>• Surgical checklists.<br><br>**Patients:**<br>• X-ray analysis of THR.[4]<br>• Blood loss and transfusion rates. | Intra-operative assessments to be performed at a minimum of 8 separate THR operations for each participant in Group 1 (StR'S) over a 6-month period.<br><br>Outcome measures data will be collected for all patients who have had a THR performed by any participant as the |

| | | | |
|---|---|---|---|
| | | • Peri-operative patient morbidity<br>• In-patient length of stay.<br>• PROMs: EQ-5D and OHS. | lead surgeon in this study. |
| Secondary | To define an expert standard when performing a primary elective THR.<br><br>To determine if operative surgeon performance metrics during a THR relate to surgical experience, or patient outcomes. | **Participants:**<br>• Wireless motion data metrics from elbow worn sensors (hand movements, path length and time taken).<br><br>**Patients:**<br>• X-ray analysis of THR.[4]<br>• Blood loss and transfusion rates.<br>• Peri-operative patient morbidity<br>• In-patient length of stay.<br>• PROMs: EQ-5D and OHS. | Intra-operative assessments at a minimum of 5 separate THR operations for each participant in Group 2 (Experts & Fellows).<br><br>Outcome measures data will be collected for all patients who have had a THR performed by any participant as the lead surgeon. |
| Intervention(s) | The intervention to be tested is the simulation-based training and cognitive learning package. This will be delivered in a supervised non-clinical laboratory setting to a randomised sub-group of 50% of the participants within the 'StR' group. | | |

## 4. ABBREVIATIONS

| | |
|---|---|
| AF's | Arthroplasty Fellows |
| CCT | Certificate of Completion of Training |
| CI | Chief Investigator |
| CTRG | Clinical Trials & Research Governance, University of Oxford |
| CUREC | Central University Research Ethics Committee |
| DGH | District General Hospital |
| EPR | Electronic Patient Record |
| EQ-5D | EuroQol-5D |
| GCP | Good Clinical Practice |
| GDPR | General Data Protection Regulation |
| GRS | Global Rating Scales |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| LOS | Length of stay |
| MS-IDREC | Medical Sciences Inter-Divisional Research Ethics Committee |

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|---|---|
| NDORMS | Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences |
| NHS | National Health Service |
| NICE | National Institute for Health and Clinical Excellence |
| NJR | National Joint Registry |
| NOC | Nuffield Orthopaedic Centre |
| OHS | Oxford Hip Score |
| OOSEC | Oxford Orthopaedic Simulation & Education Centre |
| OPD | Out-Patient Department |
| OUH | Oxford University Hospitals |
| PACS | Picture Archiving and Communication System |
| PI | Principal Investigator |
| PIC | Participant Informed Consent |
| PIS | Participant Information Sheet |
| POAC | Pre-operative assessment clinic |
| PROMs | Patient-Reported Outcome Measures |
| PSA | Procedure-Specific Assessments |
| QALY | Quality-Adjusted Life Year |
| R&D | NHS Trust R&D Department |
| REC | Research Ethics Committee |
| RES | Research Ethics Service |
| SOP | Standard Operating Procedure |
| StR | Specialty Registrar |
| TMS | Theatre Management System |
| T&O | Trauma & Orthopaedic |
| THR | Total Hip Replacement |
| TSC | Training & Standards Committee |
| UTH | University Teaching Hospital |
| WGH | Wycombe General Hospital |
| WHO | World Health Organisation |
| W/L | Waiting Lists |

## 5. BACKGROUND AND RATIONALE

THR is one of the most commonly performed, cost-effective, and successful orthopaedic operations of the 21st century. Since 2002, the NJR of England and Wales has recorded information on all patients and

implants used in arthroplasty (joint replacement) surgery, including THR, and report these figures annually (http://www.njrcentre.org.uk). According to the 15th annual NJR report in 2018, 91,698 primary (first time) THR's were performed in the year up to 31st December 2017. Furthermore, a total of 992,218 primary THR have been recorded on the NJR following its inception in 2002, which reflects the huge demand for this operation. According to the latest NJR annual report data, the mean age for a patient undergoing a primary THR is 68.0 (SD 11.4), with 59.8% females and 40.2% males. The most common indication for a patient to have a THR in the NHS is primary osteoarthritis of the hip joint, which accounted for 90% (n=86,994) of all THR cases recorded in the 15th annual NJR report.

This study builds upon previous research from our group, which has demonstrated the value of simulation training in arthroscopic orthopaedic surgery, and mini-open partial (uni-compartmental) knee replacement. This research proposal aims to utilise similar proven methodology and validated technology to evaluate and determine the effectiveness of simulation training in THR surgery, with the aim of improving training and patient outcomes. Defining an 'expert' surgeon standard in primary THR has never been attempted using motion analysis data. However, previous research from our group has used this technology and methodology to differentiate surgeons of various levels of training based upon their intra-operative performance metrics as measured by the wireless motion sensors. The accuracy, validity, and safety of these motion sensors has been proven in these previous research projects, and we now plan on utilising them in a commonly performed 'open' orthopaedic operation.

The reasons for undertaking this study are to improve training in THR surgery, and to make recommendations to the national orthopaedic training and standards committee. By delivering the above aims, we will be able to:

1) Determine if additional simulation-based training for surgical trainees leads to improved intra-operative performance, or patient outcomes following THR.
2) Define an expert standard when performing a primary elective THR. This information will be a useful 'benchmark' against which Surgical Trainees performance and competence can be measured.
3) Determine if operative surgeon performance metrics during a THR relate to surgical experience, or patient outcomes.

The justification for including an 'Expert' comparator group within our study is to establish a benchmark standard of the optimal surgical performance metrics for a primary THR, against which we can assess StR performance. Within this study we have combined the 'Experts' and 'Fellows' into a single group as all the participants within this group are post-CCT (certificate of completion of training) in Trauma & Orthopaedic Surgery, and will undertake the same assessments at the same time points. The 'Fellows' are eligible to apply for Consultant posts, and will therefore represent a sub-Consultant level of performance, which we anticipate to be higher than that of StR's, but potentially below that of an established Consultant. The reason we are recording performance data for both 'Experts' and 'Fellows', is that this will allow further sub-group analysis, which may identify differences in performance metrics or patient outcomes between these surgeons.

The simulation-based training (intervention) to be tested in this study has been granted ethical approval by the University of Oxford Medical Sciences Interdivisional Research Ethics Committee (Reference MS-IDREC R57808/RE001).

## 6. OBJECTIVES AND OUTCOME MEASURES

| Objectives | Outcome Measures | Timepoints of evaluation |
|---|---|---|
| **Primary**<br><br>To assess the impact of simulation training on surgical trainee performance and patient outcomes following THR. | **Participants:**<br>• Wireless motion data metrics from elbow worn sensors (hand movements, path length and time taken)<br>• Global Rating Scales (GRS).<br>• Objective Structured Assessment of Technical Skills (OSATS).<br>• Surgical checklists.<br><br>**Patients:**<br>• X-ray analysis of THR.[4]<br>• Blood loss and transfusion rates.<br>• Peri-operative patient morbidity<br>• In-patient length of stay.<br>• PROMs: EQ-5D and OHS. | Intra-operative assessments to be performed at a minimum of 8 separate THR operations for each participant in Group 1 (StR'S) over a 6-month period.<br><br>Outcome measures data will be collected for all patients who have had a THR performed by any participant as the lead surgeon in this study. |
| **Secondary**<br><br>To define an expert standard when performing a primary elective THR.<br><br>To determine if operative surgeon performance metrics during a THR relate to surgical experience, or patient outcomes. | **Participants:**<br>• Wireless motion data metrics from elbow worn sensors (hand movements, path length and time taken)<br>**Patients:**<br>• X-ray analysis of THR.[4]<br>• Blood loss and transfusion rates.<br>• Peri-operative patient morbidity<br>• In-patient length of stay.<br>• PROMs: EQ-5D and OHS. | Intra-operative assessments at a minimum of 5 separate THR operations for each participant in Group 2 (Experts & Fellows).<br><br>Outcome measures data will be collected for all patients who have had a THR performed by any participant as the lead surgeon. |

## 7. STUDY DESIGN

Please see Appendix A for study flow diagram.

This is a prospective randomised controlled study designed to assess the impact of specific training interventions on surgical trainee's operative performance and patient outcomes following primary elective THR. We will also study the performance and patient outcomes of both 'Experts' and 'Fellows' in an additional comparator group, which will allow a potential expert standard in THR to be defined.

All study participants will be recruited from 2 Hospitals within the Thames Valley (Oxford) Post-graduate Medical Deanery, and will be composed of: Trauma & Orthopaedic Specialty Registrars ('StRs') holding national training numbers; Consultant Orthopaedic Surgeons ('Experts'); and Orthopaedic Arthroplasty Fellows ('Fellows'). Over the 18-24 month anticipated study period we aim on recruiting a total of up to 16 StR's, 8 Fellows, and 5 Experts. See section 9 for further details on participant recruitment.

StR's will be randomised in a 1:1 ratio to receive either: routine normal Deanery training (the control group, n=8); or routine normal Deanery training with additional simulation-based and cognitive learning (the intervention group, n=8). The intervention group will receive this training for 1-2 hours per week over a 4 to 6-week period. The 'Experts' and 'Fellows' will not be eligible for any intervention, and will act as a separate comparator group.

All participants will be assessed intra-operatively at set timepoints when performing elective primary THR surgery on patients within the named NHS Hospitals. The timepoints will vary depending upon each group. Each StR enrolled into this study will be assessed at a minimum of 8 separate THR operations over a 6-month period, commencing at 6 weeks in to their 6-month clinical placement. Both the 'Fellows' and 'Experts' will be assessed at a minimum of 5 separate THR operations depending upon the reliability of their performance data.

All patients in this study will have been listed for routine elective primary THR surgery under a named Orthopaedic Consultant on the NHS. There will be no interventions or deviations from routine clinical practise regarding the pre-operative investigations or work-up, the operation itself, the peri-operative care, or post-discharge follow-up.

## 8. PARTICIPANT & PATIENT IDENTIFICATION

### 8.1. Consultants, Fellows, and Specialty Registrars

**Group 1** ('StR's'): Trauma & Orthopaedic Specialty Registrars on Arthroplasty clinical placements.

**Group 2** ('Experts' and 'Fellows'): Consultant Orthopaedic Surgeons, and nationally appointed Orthopaedic Arthroplasty Fellows.

**Inclusion Criteria**

**Group 1** ('StR's'): All Specialty Registrars holding a National Training Numbers (NTN) in Trauma & Orthopaedic Surgery within the Thames Valley (Oxford) Deanery and who are or will be working on arthroplasty clinical placements at either the NOC, Oxford University Hospitals NHS Foundation Trust, or WGH, Buckinghamshire Healthcare NHS Trust over the specified recruitment period will be eligible for participation in this study. We anticipate recruiting 2 StR's from each recruitment centre every 6 months, over an 18 to 24-month period (total n = 12-16).

**Group 2** ('Experts' and 'Fellows'): All Consultant Orthopaedic Surgeons with a sub-specialty practise in adult reconstructive (arthroplasty) surgery holding substantive posts at the NOC are eligible for participation in this study. The Consultant Orthopaedic Surgeons at WGH will not be required for the intra-operative assessment within this study, as we will gather sufficient motion data from the NOC Consultants to be able to benchmark an 'expert' performance. Nationally appointed Orthopaedic AF's working at either at either the NOC, Oxford University Hospitals NHS Foundation Trust, or WGH, Buckinghamshire Healthcare NHS Trust over the specified recruitment period will be eligible for participation in this study. We anticipate recruiting 2 AF's every 6-months over an 18 to 24-month period (total n = 6-8)

**Exclusion Criteria**

- Inability to comply with study procedures or timetable

- Moving outside of the area, relinquishing their position, or National Training Number.

### 8.2. Patients

Adult patients (aged 18 years or above) diagnosed with primary hip osteoarthritis who have been listed for elective primary THR in the NHS.

**Inclusion Criteria**

- Adult patients (aged 18 years or above) diagnosed with primary hip osteoarthritis who have been listed for elective primary THR in the NHS.
- THR operation performed by a surgeon participant as lead surgeon.

**Exclusion Criteria**

Patients may not enter the study if ANY of the following apply:

- Patients with complex hip pathology (e.g. previous trauma, hip dysplasia, infection).
- Patients who have had previous surgery on their affected hip.

## 9. PROTOCOL PROCEDURES

### 9.1. Recruitment

#### 9.1.1 Consultant, Fellow and Specialty Registrar recruitment

**Group 1:** Specialty Registrars ('StR's').
StR's will be identified within the Oxford Deanery's T&O Higher Surgical Training Programme. The current Training Programme Director (TPD), Miss Jane Webber (Consultant Orthopaedic Surgeon at Milton Keynes University Hospital) has overall responsibility for allocating clinical placements to StR's. With the agreement and assistance of the TPD, we will identify the StR's who have been allocated clinical placements within the named recruitment centres over the upcoming 18 to 24-month recruitment period starting from September 2019, and contact them directly via e-mail to ask if they would be interested in participating in this study. There is a regional T&O StR group e-mail list, which will be used to inform all StR's of this study. Furthermore, the lead researcher will attend the weekly T&O StR Teaching Programme in advance of the start of this study to hand out PIS in person, and any questions can be directly addressed.

**Group 2:** Consultant Orthopaedic Surgeons ('Experts'), and nationally appointed Orthopaedic Arthroplasty Fellows ('Fellows').

The Experts and Fellows at the NOC and WGH will be approached in person to ask if they would be interested in participating in this study. A PIS outlining the study, including their role, will be provided for their attention, and any questions can be directly addressed.

#### 9.1.2 Patient Recruitment

Following screening and identification of patients using waiting lists within the Orthopaedic Department at the 2 named NHS Hospitals, the PI (DJH), or a suitably qualified deputy, will attend the patient's routine

POAC appointment in order to highlight with the direct clinical care team that the patient may be eligible for participation in this study. The patients direct clinical care team will then approach the patient to enquire about participation in this study, and only if interest to participate is expressed, they will then be referred onto the PI. The PI will then proceed to confirm eligibility, and outline the purpose of the study. A patient information sheet and verbal information will be provided on: what data we will be collecting and specifically how it will be used; and any risks and benefits to taking part.

### 9.2. Informed Consent

The PI (DJH), or a suitably qualified deputy, will take informed consent from every participant involved in this study. This will be taken at their visit before any study specific procedures are performed.

Each participant must personally sign and date the latest approved version of the Informed Consent form at this visit. Written and verbal versions of the PIS and Informed Consent form (ICF) will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason, and with no obligation to give the reason for withdrawal. The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, or other independent parties in order to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. A copy of the signed Informed Consent will be offered to the participant. The original signed form will be retained by the PI (DJH) at the study site

Visit 1 - **Group 1 (**'StR's'):

Following enrolment for participation in this study, the StR's will be randomly allocated to receive either routine normal Deanery training (the 'control' group), or routine normal Deanery training plus additional simulation training (the 'intervention' group). Following randomisation all StR participants will undergo a baseline written and practical skills assessment within the OOSEC.

### 9.3. Subsequent Visits

**Group 1a (**'StR's') - Intervention group:
StR's randomised to the 'intervention group' will be required to complete the 4-week period of additional training outlined in section 9.3. Following completion of this additional training, participants within this group will undertake approximately 2 intra-operative assessments every 6 weeks over the duration of their 6-month clinical placements (total 8 assessments). The StR's will also undertake a final Technical Skills assessment in OOSEC Laboratory at 3 months into their placement (See Appendix A for Study Flow Diagram).

**Group 1b (**'StR's') – control group:

Participants within this group will undertake approximately 2 intra-operative assessments every 6 weeks over the duration of their 6-month clinical placements (total 8 assessments). The StR's will also undertake a final Technical Skills assessment in OOSEC Laboratory at 3 months into their placement (See Appendix A for Study Flow Diagram).

**Group 2:** 'Experts' and 'Fellows':

Following enrolment for participation in this study, all participants within this group will undergo a baseline practical skills assessment within the OOSEC. Participants within this group will then undertake a minimum of 5 separate intra-operative assessments each.

**Patients:**
Following enrolment for participation in this study, all patients will be asked to complete the pre-operative PROMs questionnaires (EQ-5D and OHS). These are part of routine clinical care, and are a mandatory for all patients undergoing THR in the NHS. The patients will not be asked to undertake any further assessments outside of their routine clinical care until the time of their scheduled post-operative out-patient department (OPD) clinic review appointment. All patients will only be followed up routinely following discharge by their named Consultant in an OPD clinic. This OPD appointment normally takes place 6 to 8 weeks following discharge. No additional clinic appointments or investigations will be required outside of the patients expected routine clinical care. At this visit the patients will be asked to complete the post-operative validated PROMs questionnaires (EQ-5D and OHS). This takes a few minutes and is the only extra outcome measure the patients are asked to complete.

### 9.4 Randomisation

Randomisation will be performed via a blinded sealed envelope containing information regarding which arm of the study they will participate in. As we only anticipate recruiting 2 StR's from each recruitment centre every 6 months, a more complex allocation/randomisation procedure will not be required. Over the 18 to 24-month study period we aim to recruit and randomise 6-8 StR's to the 'intervention' group, and randomise 6-8 StR's to the 'control' (routine training) group, with an even distribution of these StR's in both groups across the two recruiting hospital sites.

### 9.5 Blinding and code-breaking

Standard surgical practise will be followed. Patients are not formally blinded to which Surgeon (Consultant, Fellow, or StR) performs their operation, and are informed if requested. In line with standard surgical practise and training within the NHS, patients will provide informed consent that they understand no guarantees can be given that a particular person will perform the procedure. The person will, however, have appropriate experience.

Due to the nature of this study the StR's cannot be blinded to their allocations into either the 'control' or 'intervention' groups, however the assessment methods and any assessors will be blinded.

### 9.6 Description of study intervention(s),

The intervention to be tested is the simulation-based and cognitive learning package, which will be delivered to a randomised sub-group of 50% of the StR's recruited into this study. This will be delivered in a supervised setting within the OOSEC over a 4-week period for between 1 to 2 hours per week, over 3 to 4 consecutive but separate six-month placements (please see Appendix A for Study Flow Diagram). This will take place on a Wednesday afternoon, which is when all the Regional StR's are due to attend teaching in Oxford at the NOC.

The OOSEC is a secure enclosed laboratory space within the NOC, which contains all the necessary equipment required to run the simulation-based and cognitive learning training. The simulation training in general may include:

1) Focussed workshops on saw-bone models (simulated bones)
2) Digital and computer-based cognitive learning packages
3) Virtual reality platforms.

All participants within group 1 (StR's) will be asked to attend and complete baseline and final assessments within the OOSEC, which will consist of a multiple-choice questionnaire (MCQ) and a simulated procedure. Participants within group 2 (Consultants and Fellows) will only be required to complete a baseline simulated procedure.

### 9.7 Intra-operative surgeon performance data collection

The following protocol will apply to all episodes of intra-operative performance data collection for StR's and Fellows. The intra-operative data collection for Consultant performed operations will differ slightly in that they require no supervision, and no surgeon will 'take over' the operation. However, the methods for recording the intra-operative data will remain the same.

A maximum of two study participants (excluding Consultants) will attend any given list. The PI (DJH) will attend the World Health Organisation (WHO) briefing in theatre on the morning of the list, introduce themselves and explain their role during the list. If recording an StR, neither the participant or PI will disclose which arm of the study the participants are in (routine training, or additional simulation training). The supervising Consultant will confirm the cases on the list the StR or AF's will be performing under supervision and training.

**Operative protocol**

After anaesthesia and patient set-up, the supervising Consultant and participant will scrub in up in the usual manner with the motion sensors in position on the lead surgeon's elbows under their sterile gown (see Appendix C). The procedure will then continue routinely and normally, but with the PI collecting motion data via the wireless Bluetooth sensors. The PI will also manually record the timings of each stage of the THR operation. This process will allow synchronisation of motion data to the participants progression throughout the stages of the operation. Data collection will stop when the dressing has been applied to the surgical wound.

Following completion of the operation, the participants in conjunction with the supervising Consultant will be asked to complete short written assessments of the lead surgeons' intra-operative performance. These assessments may include: Global Rating Scales (GRS), Objective Structured Assessment of Technical Skills (OSATS), and surgical checklists.

**Intra-operative deviations or interruptions**

Sometimes the supervising Consultant needs to take over part or all of an operation if it proves particularly difficult. In the event that a procedure has to be taken over completely by the Consultant then data recording will stop. If minor adjustments only are made by the Consultant during the operation then these will be noted and time marked against the motion data.

### 9.8 Protocol Early Discontinuation/Withdrawal of Participants

During the course of this study a participant or patient may choose to voluntarily withdraw early at any time. This may happen for several reasons, including but not limited to:

- Inability to comply with study procedures or timetable.
- Participant or patient decision.
- Moving outside of the area.

Patients or participants may choose to stop study assessments. Patients or participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. Patients who withdraw from this study will continue to receive routine clinical care under their named Consultant on the NHS.

According to the design of the study, the Investigator may discontinue a patient or participant from the study treatment at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening).
- Significant protocol deviation.
- Significant non-compliance with intervention (simulation training) or study requirements.
- Clinical care decision.

### 9.9 Definition of End of Study

The end of study will be the date of the last visit of the last patient at follow-up, at which point all of the study data has been entered and queries resolved. We anticipate that this will be by December 2021.

## 10 SAFETY REPORTING

Patients will not be placed at any additional risk during this study.

The participants in the 'simulation-training sub-group' of this study will be expected to participate in low-risk simulated surgical activities within the OOSEC. The low risk to participants will also be highlighted as part of the informed consent process, which will take place before any study-specific procedures or training are performed. Such activities will be those normally encountered in their training, such as the use of orthopaedic power tools, saws, and sharp instruments. As part of the baseline visit, the lead investigator, or suitably qualified deputy, will outline the materials and tasks involved in each training session to the participants. The training sessions will be delivered in a supervised setting to StR's within the OOSEC, which is part of the University of Oxfords premises (NDORMs). As specified previously the OOSEC is a secure enclosed laboratory space, which contains all the necessary equipment required to run the simulation-based and cognitive learning training.

In the unlikely event that any participant sustains an injury, we will follow the OOSEC safety policy. Any significant incidents will be recorded in a logbook within the OOSEC, and reported directly to the Health & Safety Manager within the Medical Sciences Division of the University of Oxford.

### 10.4 Definition of Serious Adverse Events

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation

- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect.

As outlined in section 10 above, we do not anticipate any serious adverse events whilst conducting our intervention simulation training. In the extra-ordinary event that any were to occur we would follow the OOSEC Health & Safety Policy.

This study does not add any additions to the usual inherent risks associated with THR surgery. If any patient were to experience a serious adverse event during the operation, peri- or post-operative period, these would be as a consequence of their normal care, and not this study. These would therefore be investigated in line with NHS protocols. We will also report on patient's peri-operative morbidity (30 day) as part of the secondary objectives outlined in section 6 of this study.

### 10.5 Reporting Procedures for Serious Adverse Events

A serious adverse event occurring to a participant will be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was 'related' (resulted from administration of any of the research procedures), and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs will be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form (see HRA website).

## 11 STATISTICS AND ANALYSIS

**Analysis of motion data.**

Motion data from the wireless sensors produces performance surrogate markers such as: the number of movements (major & minor); total path length; and smoothness/economy of movement. Data distributions will be assessed for normality using the Shapiro-Wilk test. Previous studies show such data are not normally distributed, and we would expect to use non-parametric tests, such as the Mann-Whitney U test to compare the performance metrics between the 2 groups of participants (StR's against Experts & Fellows). The Mann-Whitney U test will also be used to compare performance metrics between the two sub-groups of StR's (control and intervention), and also within the intervention sub-group in order to compare performance before and after training.

Performance metrics within all groups of participants will be reported using descriptive statistics to outline the central tendency (mean, median, and mode) and variation (range, variance, and standard deviation) in readings obtained. The Kruskal-Wallis one-way analysis of variance (ANOVA) test will be used to test for differences in the mean values obtained for all performance metrics between the two groups of participants. The Wilcoxon signed-rank test will be used to determine any differences in performance metric between the two groups.

**Analysis of other routinely obtained data**

**X-ray (radiograph) analysis:**

X-rays will be reviewed by two independent Consultant Orthopaedic Surgeons who will be blinded to the patient and lead surgeon's identity in order to reduce bias. There are several important parameters to be evaluated when reviewing a pelvic x-ray, therefore we will ask each reviewer to allocate a categorical global rating (see below) for both the pre- and post-operative x-rays. [5] The Chi-squared test will be used

to determine if there are any significant differences between each group, and also intra-group differences (for example StR's before and after additional training).

*Pre-operative x-ray*
1: Hip osteoarthritis without significant bone loss.
2a: Hip osteoarthritis with significant bone loss on acetabular side.
2b: Hip osteoarthritis with significant bone loss on femoral side.
3: Hip osteoarthritis with significant bone loss on both acetabular and femoral sides.

*Post-operative x-ray*
1: Excellent implant position and restoration of hip anatomy.
2a): Good overall with minor imperfections on acetabular side.
2b): Good overall with minor imperfections on femoral side.
3: Moderate concerns but does not require revision surgery.
4: Significant concerns requiring revision surgery.

Every patients post-operative x-ray will also be reviewed by the PI (DJH) for acetabular component positioning (inclination and version) using the methodology described by Bachhal [4]. This continuous data will be assessed for normality of distribution, and analysed using similar methodology as described above for the motion data. We will be looking for any statistically significant differences between the 2 groups of participants, within the two sub-groups of StR's (control and intervention), and also within the intervention sub-group in order to compare performance before and after additional training.

**Other outcomes data:**
Following collection of the outcome measures listed below, the normality of the data distribution will be checked with the Shapiro-Wilk test. Descriptive statistics will be used to outline the central tendency and variation of these data sets. Statistical analyses between each group of participants will be performed using either the parametric unpaired t-test or a non-parametric Mann-Whitney U test depending on the distribution of the data. Subsequent analysis of the outcomes data using a paired t-test, or Mann-Whitney U test will also be performed within the two sub-groups of the StR's (control and intervention), and also within the intervention sub-group in order to compare outcomes before and after additional training.

- Theatre time usage.
- Blood loss (pre-/post-op haemoglobin levels)
- In-patient length of stay.
- PROMs: EQ-5D and OHS.

The Chi-squared test (or Fishers exact test if the sample is <5) will be used to determine any significant differences between the groups regarding the incidence of blood transfusions or peri-operative morbidity.

All of these tests will be performed using the SPSS statistical package, which is available for any registered student on the University of Oxford current Licencing agreement.

## 12 DATA MANAGEMENT

Within this study both patients and participants will have all of their personal data anonymised via the use of Unique Patient or Participant Identifiers (UPI's). A master list of key linking identifiers for both patients

and participants will be kept on a password protected file on the OUH secure Trust Network Server. Only completely anonymised data will be used outside of OUH Trust property, which will be kept on a password-protected University owned laptop or hard-drive. We plan on keeping study data for a period of 5 years following completion on the study (up to December 2026), before securely disposing of it. We believe that this storage is appropriate as the core content is scientific research data and is therefore in the public interest. Furthermore, we will require access to this data in the case of individuals wishing to scrutinise the scientific methodology, results, or conclusions of our study.

**Intra-Operative Data**
Raw data will be produced from the wireless sensors. Please see section 12.3 for further details regarding the recording, transfer, and storage of this data.

**Other 'personal data'**

**1) Electronic Patient Record Data**

The following data will be obtained from the NHS Electronic Patient Records (EPR), which includes the Insignia Picture Archiving and Communication System (PACS), and the Theatre Management System (TMS):

- X-ray (radiograph) analysis.
- Theatre time usage.
- Blood test & transfusion rate analysis.
- Peri-operative morbidity (30 day).
- In-patient length of stay.
- Patient demographics (age, gender, BMI)

**2) Questionnaire Data**

**Patient Questionnaire Data**
The patient questionnaires consist of the following components:

- Patient Reported Outcome Measures: The OHS and EQ-5D.

**Participant (Medical Health Professionals) Questionnaire Data**

Written assessments of intra-operative performance will be conducted shortly after completion of a recorded THR. These assessments may include: Global Rating Scales (GRS), Objective Structured Assessment of Technical Skills (OSATS), and surgical checklists. The data collected from these will be anonymised as it will be linked with the UPI, and not provide any names or other personal information. The hard copies will be transcribed into digital format as soon as possible, which will be stored onto a password protected encrypted file on a University owned computer/hard-drive. The hard copies of the forms will then be disposed of.

### 12.4 Source Data

Please see section 12 on Data management for further details. In general, the source data is as follows:

**Intra-Operative Data**

- Wireless motion data.
- Global rating scales and checklists.

**Hospital Records Data**

- NHS EPR for laboratory and clinical data.

- Insignia PACS for radiograph (x-ray) analysis.
- TMS for theatre lists, workflow, and productivity information.

**Questionnaire Data**

- PROMs questionnaire forms to be completed pre- and post-op (as detailed above).
- Participant performance assessment tools and feedback forms.

All confidential data will be stored securely. On all study-specific documents, other than the signed consent, the participant and patients will be referred to by the study UPI, and not by name.

### 12.5 Access to Data

OOSEC research team members will have access to the raw motion data. This can be matched to other metrics during the THR surgery through the use of Unique Participant Identifiers (UPI).

Direct access to the data generated from this study will be granted to authorised representatives (for example the Data Protection Officer, Caldicott Guardian, or Information Governance Team) from the sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

### 12.6 Data Recording and Record Keeping

**Intra-operative data**

**Motion Data**

Anonymised non-personal raw motion data from the motion sensors will be wirelessly uploaded to secure off-site servers using SSL/TLS using strong cipher suites that support perfect forward secrecy. This prevents decoding of captured data, even if the secret long-term key itself is compromised. Every instance has a built-in firewall that is configured using a least privilege basis and will only accept https (port 443) connections from the internet. The data centres are staffed 24x7 by trained security guards and access is authorised strictly on a least privileged basis. Usable output motion analysis metrics will be downloaded from the secure server and stored locally on an Excel spreadsheet (.xlsx) or similar software. These data may be opened in other programmes or copied to other formats for certain analyses e.g. SPSS data files (.sav). Where study data are generated in a proprietary file type, these will be transposed to Excel format or similar.

**Electronic Patient Record Data**

The routine patient data will be accessed via their unique Hospital/NHS number on the recruiting NHS Trusts computer system. Following identification, the minimum dataset required (outlined previously) will be extracted by manually transcribing it directly onto a password protected encrypted file on a University owned computer/hard-drive. The data within this file will be anonymised using the UPI, and cannot be linked to any patient directly. No patient identifiable data will be directly transferred or saved from the recruiting NHS Trusts computer system.

**Patient & Participant Questionnaire Data**

Data from the hard copies of each questionnaire (detailed above) will be transcribed into digital format as soon as possible, which will be stored onto a password protected encrypted file on a University owned computer/hard-drive. The hard copies of the forms will then be disposed of. As they will not contain any personal data they will not have to be securely disposed of (confidential waste bins/shredding).

## 13 QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

### 13.4 Risk assessment

Please see section 10 on safety reporting.

### 13.5 Study monitoring

Not applicable.

### 13.6 Study Committees

There will be no oversight committees for this study.

## 14 PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

## 15 SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or
(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

## 16 ETHICAL AND REGULATORY CONSIDERATIONS

### 16.4 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

### 16.5 Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

### 16.6 Approvals

Following Sponsor approval, the protocol, informed consent form, and participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

### 16.7 Other Ethical Considerations

One potential ethical consideration in relation to this study will be what the researcher should do if a senior participant (Consultant or Fellow) is found to be underperforming in comparison to their peers. After much consideration, and consultation with the University of Oxfords Medical Sciences Interdivisional Research Ethics Committee (MS-IDREC), we have adopted the following approach to this situation, however we would welcome any additional advice or guidance from the NHS REC: 'The data generated within this study will be anonymised using Unique Participant Identifiers (UPI's), and all participants will be exempt from individual disclosure or reporting of their study data to regulatory bodies (such as the Joint Committee on Surgical Training (JCST), Royal Colleges of Surgeons (RCS), or General Medical Council (GMC). It is not the purpose or role of this study to assess the clinical competence of surgeons, as this is undertaken through a prolonged and rigorous series of post-graduate professional assessments and examinations conducted by the above-named regulatory bodies. In the event of a senior colleague performing consistently and substantially below the level seen within their peer group, then this will be anonymously highlighted within the results section of the study report, which will be openly available for review. Furthermore, all participants will be individually informed of their performance results, which will be supplied in the context of their respective peer groups. It will be up to the professional judgement of the individual participant to reflect and decide how to act upon their results'.

### 16.8 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee HRA (where required) host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties. Following completion of this study, all participants will be informed of the results of their individual performances, which will be anonymously reported in comparison to the average group level results of participants of other training levels. Patients will be offered the opportunity to be sent a newsletter containing the summary results following completion of this study.

### 16.9 Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

### 16.10 Expenses and Benefits

No additional expenses will be made for either the patient's or participants involvement in this study.

The direct benefits to participants may include:

- The opportunity to practice and develop their surgical skills under supervision in the simulation laboratory.
- The opportunity to objectively assess their surgical skills using the wireless motion sensors, which may in turn highlight areas for improvement.
- The opportunity to complete work-based assessments as part of the study (for example the PBA form), which are currently an integral part of surgical training requirements.

## 17 FINANCE AND INSURANCE

### 17.4 Funding

This study is being kindly funded through a research grant from the Dinwoodie Charitable Company.

### 17.5 Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

### 17.6 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

## 18 PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the Dinwoodie Charitable Company. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

## 19 DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Not applicable

## 20 ARCHIVING

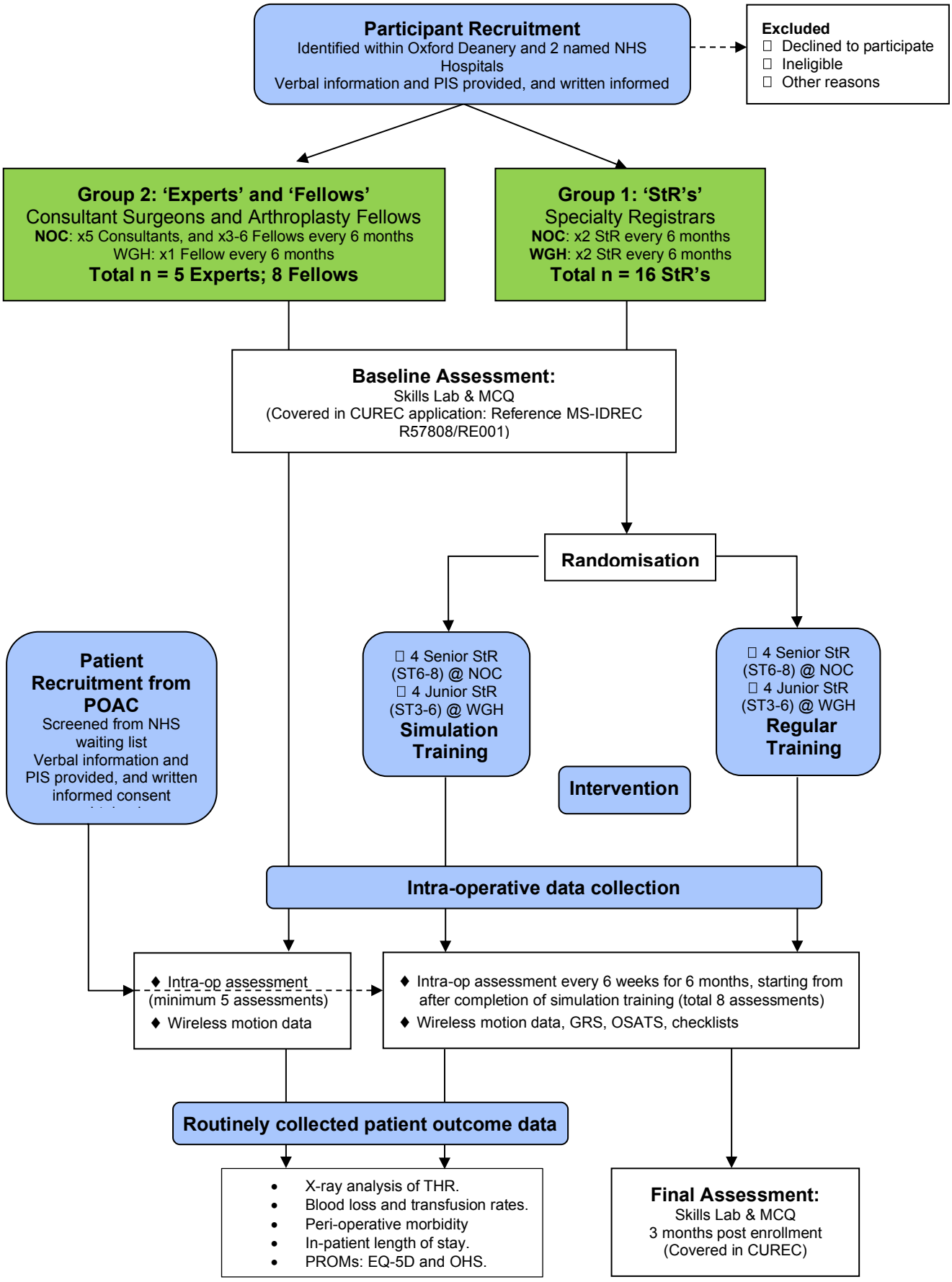
The results of this study will form part of a Thesis submitted in support of an application for the Degree Doctor of Philosophy in Musculoskeletal Sciences (DPhil) by the PI (DJH) at the University of Oxford.

## 21 REFERENCES

1. Reiley, C.E., et al., *Review of methods for objective surgical skill evaluation.* Surg Endosc, 2011. **25**(2): p. 356-66.
2. Martin, J.A., et al., *Objective structured assessment of technical skill (OSATS) for surgical residents.* Br J Surg, 1997. **84**(2): p. 273-8.

3. Garfjeld Roberts, P., et al., *Objectively Assessing Intraoperative Arthroscopic Skills Performance and the Transfer of Simulation Training in Knee Arthroscopy: A Randomized Controlled Trial.* Arthroscopy, 2019. **35**(4): p. 1197-1209 e1.
4. Bachhal, V., et al., *A new method of measuring acetabular cup anteversion on simulated radiographs.* Int Orthop, 2012. **36**(9): p. 1813-8.
5. Vanrusselt, J., et al., *Postoperative radiograph of the hip arthroplasty: what the radiologist should know.* Insights Imaging, 2015. **6**(6): p. 591-600.

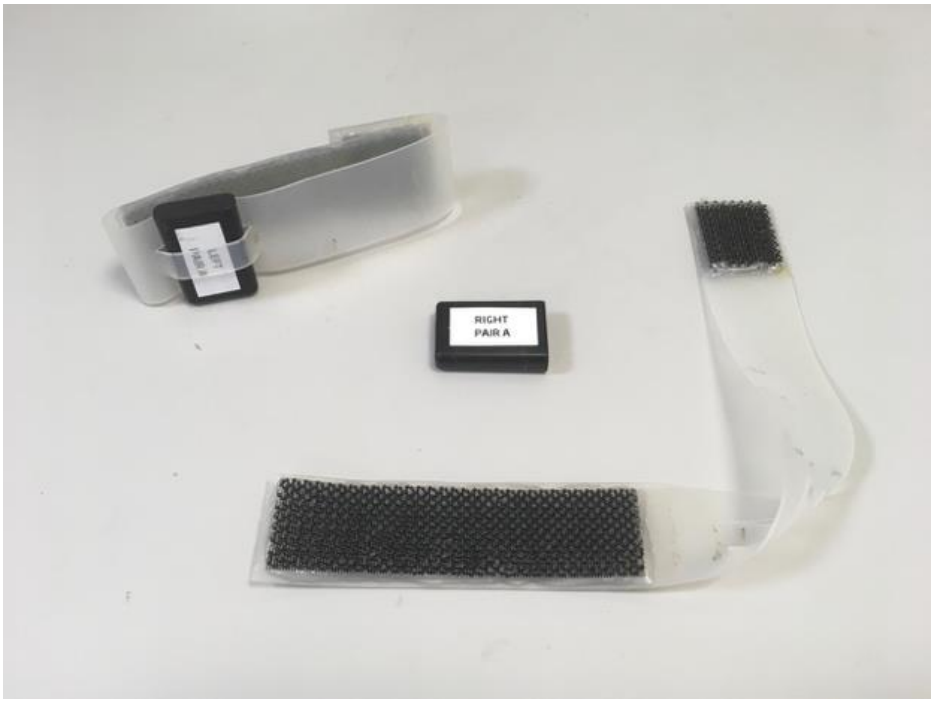
## 22 APPENDIX A: STUDY FLOW CHART



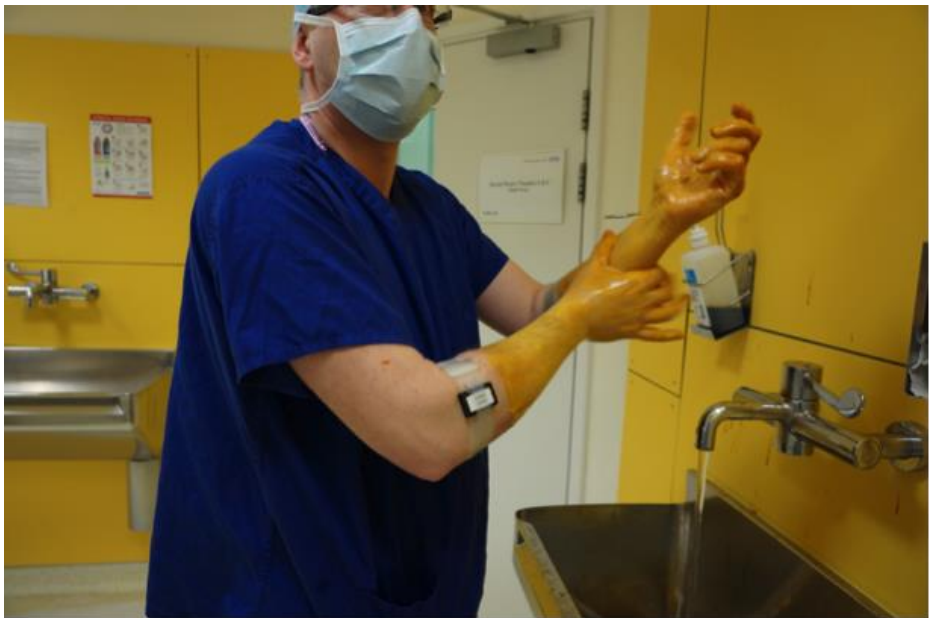
## 23 APPENDIX B: SCHEDULE OF STUDY PROCEDURES FOR PATIENTS

| **Procedures** | **Routine Visits (3): pre-operative; in-patient; post-operative.** | | | | |
|---|---|---|---|---|---|
| | **NHS Waiting list review** | **Pre-operative clinic** | **In-patient admission** | **In-patient admission** | **Out-patient review** |
| | **Screening** | **Baseline** | **Intra-operative** | **Post-operative In-patient** | **6-8 weeks Post-operative Out-patient** |
| Informed consent | ✗ | ✓ | ✗ | ✗ | ✗ |
| Demographics | ✓ | ✗ | ✗ | ✗ | ✗ |
| Laboratory tests (Blood) | ✗ | ✓ | ✗ | ✓ | ✗ |
| Radiology | ✗ | ✓ | ✗ | ✓ | ✗ |
| Eligibility assessment | ✓ | ✓ | ✗ | ✗ | ✗ |
| Randomisation | ✗ | ✗ | ✗ | ✗ | ✗ |
| Electronic Patient Record Data | ✗ | ✓ | ✓ | ✓ | ✓ |
| Patient Questionnaire Data | ✗ | ✓ | ✗ | ✗ | ✓ |

## 24 APPENDIX C: Wireless Motion Sensors




**Wireless sensors**



**Wireless sensors worn in theatre scrub room**
(Surgeon would put on sterile gown &
gloves as standard prior to operation)

## 25 APPENDIX D: AMENDMENT HISTORY

| Amendment No. | Protocol Version No. | Date issued | Author(s) of changes | Details of Changes made |
|---|---|---|---|---|
| | | | | |

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee and HRA (where required).