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Cadaveric simulation vs standard training for postgraduate trauma & orthopaedic surgical trainees: protocol for the CAD:TRAUMA study multi-centre randomised controlled educational trial

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3 **Cadaveric simulation vs standard training for postgraduate trauma & orthopaedic surgical**
4 **trainees: protocol for the CAD:TRAUMA study multi-centre randomised controlled**
5 **educational trial**
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34 Education, Training, Simulation

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39 Abstract

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44 **Introduction**

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49 The quantity and quality of surgical training in the UK has been negatively affected by
50
51 reduced working hours and NHS financial pressures. Traditionally surgical training has
52
53 occurred by the master-apprentice model involving a process of graduated responsibility, but
54
55 a modern alternative is to use simulation for the early stages of training. It is not known if
56
57 simulation training for junior trainees can safeguard patients and improve clinical outcomes.
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3 This paper details the protocol for a multicentre randomised controlled educational trial of a
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6 cadaveric simulation training intervention versus standard training for junior postgraduate
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9 orthopaedic surgeons-in-training. This is the first study to assess the effect of cadaveric
10
11 simulation training on patient outcome.
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14 15 **Methods and Analysis**

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20 We will recruit postgraduate orthopaedic surgeons-in-training in the first three years (of
21
22
23 eight) of the specialist training programme. Participants will be block randomised and
24
25
26 allocated to either cadaveric simulation or standard 'on-the-job' training, learning three
27
28
29 common orthopaedic procedures, each of which is a sub-study within the trial. The
30
31
32 procedures are 1) Dynamic Hip Screw(DHS), 2) hemiarthroplasty and 3) ankle fracture
33
34
35 fixation. These procedures have been selected as they are very common procedures which
36
37
38 are routinely performed by junior surgeons-in-training. A pragmatic approach to sample size
39
40
41 is taken in lieu of a formal power calculation as this is novel exploratory work with no a priori
42
43
44 estimate of effect size to reference. The primary outcome measure is the technical success
45
46
47 of the surgery performed on patients by the participating surgeons-in-training during the
48
49
50 follow-up period for the three sub-study procedures, as measured by the implant position on
51
52
53 the post-operative radiograph. The secondary outcome measures are procedure time, post-
54
55
56 operative complication rate and patient health state at 4 months post-operation (EQ-5D –
57
58
59 substudies 1 and 2 only).
60

61 62 63 **Ethics, registration and dissemination**

1
2
3 National research ethics approval was granted for this study (15/WM/0464). Confidentiality
4
5
6 Advisory Group approval was granted for accessing radiographic and outcome data without
7
8 patient consent on 27 February 2017 (16/CAG/0125). The results of this trial will be
9
10 submitted to a peer-reviewed journal and will inform educational and clinical practice.
11
12
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14

15 **Trial registration number**

16
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20 ISRCTN20431944; Pre-results

21
22
23 Protocol version V_P_1.1
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30 Article Summary

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34
35 Strengths and limitations of this study:

- 36
37 • Surgeons-in-training should not be doing operations for the first time on living
38 patients.
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43
- 44 • Simulation using deceased human bodies may be a good way to train novice
45 surgeons at the early stages of learning, until they are competent enough to operate
46 on real patients.
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- 50
51 • This is the first randomised trial assessing the impact of a cadaveric simulation
52 intervention on patient outcomes
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- We cannot do a power calculation as this is novel work and we do not know what the effect size is likely to be
- Sample size is limited by the capacity of the surgical training centre

Introduction

It is imperative that surgeons are trained to a high standard, so they can perform safe and effective operations for patients. The quality and quantity of surgical training in the UK is currently under threat from a 'perfect storm' of factors(1). These include reduced working hours(2, 3), shift based working patterns(4) with the loss of the traditional surgical firm, and a move to expedite training and shorten specialist programmes(5, 6). This is set within a climate of unprecedented financial austerity in the NHS and ever increasing service pressures.

Simulation offers a solution to some of these challenges by moving the early part of the surgical learning curve away from patients into a controlled environment, where skills can be rapidly acquired and competency can be assessed before trainees are released into clinical practice(7). Simulation is also potentially a very efficient way of training, as large numbers of

1
2
3 trainees can be trained simultaneously, at an intensity not feasible in the clinical environment
4
5
6 due to competing service demands.
7
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9

10 Cadaveric simulation - training using deceased, preserved or fresh human bodies - is a
11 particularly promising modality for training. It offers a highly realistic 'high fidelity' simulation
12 where surgical anatomy is represented as in life, including soft tissues and neurovascular
13 relationships(8, 9). This allows for a much more realistic simulated operation than would be
14 possible on a plastic model or virtual reality simulator. In addition to the superior anatomic
15 and tactile (haptic) properties of cadavers, the whole operating theatre environment can be
16 simulated, including (but not limited to) surgical dress, draping, instrumentation and
17 multidisciplinary team. This 'whole dress rehearsal' for surgery may enhance development of
18 non-technical skills in addition to the technical operative surgical skills(10).
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There is abundant low quality evidence showing cadaveric simulation may induce short term
skill improvement as measured by subjective and behavioural metrics, but there is a lack of
high quality, quantitative evidence that skills learnt in cadaveric simulation can transfer to the
workplace, leading to improved outcomes for patients(8).

Our trial attempts to address this evidence deficit, and is both topical and timely.

Good Clinical Practice

1
2
3 This trial will be undertaken in compliance with Good Practice Guidelines, complying with the
4
5 Declaration of Helsinki and UK Legislation. Warwick standard operating procedures (SOPs)
6
7
8 will be followed.
9

10 11 12 13 Consolidated Standards of Reporting Trials 14

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17
18 The results of the trial will be reported in line with the Consolidated Standard of Reporting
19
20 (CONSORT) statement(11). This protocol has been written according to the SPIRIT
21
22 reporting guidelines(12).
23
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26 27 Aim 28

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32 The aim is to determine which of the two surgical training strategies for junior orthopaedic
33
34 surgeons-in-training leads to the best patient outcomes for three common procedures.
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44 Objectives 45

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49 1. To assess the impact of a cadaveric simulation training intervention on the patient
50
51 outcome of operations performed by junior orthopaedic surgeons-in-training
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- 53
54 2. To define the early learning curve of DHS, Hemiarthroplasty and ankle fracture
55
56 fixation
57
- 58
59 3. To explore the feasibility of using post-operative x-rays to assess technical skill
60

Methods and Analysis

Study design

This is a UK multicentre, two-arm, group parallel randomised controlled educational trial

Sample size

This trial is the first attempt to objectively measure transfer of open operative skills from cadaveric simulation into the workplace using patient-based outcome measures. There is no available estimate of effect size to reference against a priori in determining sample size, therefore a pragmatic approach to sample size will be taken in lieu of a formal power calculation. The surgical training centre can accommodate 16 delegates at one time and financial resources permitted one iteration of the cadaveric training course. Our maximum sample size is therefore 16 participants in each arm of the study

Outcome measures

A) Radiographic outcomes

1
2
3 The radiographs will be obtained electronically from hospital servers and the implant position
4
5 measured manually using computer software. The operations will be identified
6
7 retrospectively by access to the participating surgeons' electronic logbooks. The
8
9 measurements vary by operation type and are defined as follows.
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11
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14

15 **Sub-study 1: Dynamic Hip Screw**

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17
18
19
20 1. Primary Outcome
- 21
22 ▪ Tip-Apex distance (in mm)
- 23
24 2. Secondary Outcomes (in order of importance)
- 25
26 ▪ Lag screw position in the femoral head (defined by Cleveland Zones)
 - 27
28 ▪ Plate flush to lateral femoral cortex (binary Y/N)
 - 29
30 ▪ 8 cortex hold for plate screws (binary Y/N)
- 31
32
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36

37 **Sub- study 2: Hemiarthroplasty**

- 38
39
40
41 1. Primary Outcome
- 42
43 ▪ Leg length discrepancy (mm)
- 44
45 2. Secondary Outcomes (in order of importance)
- 46
47 ▪ Femoral stem alignment (degrees off neutral)
 - 48
49 ▪ Cement mantle quality (Barrack grade score)
 - 50
51 ▪ Femoral offset change relative to native hip (mm)
- 52
53
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58 **Sub- study 3: Ankle fracture fixation**

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6 1. Primary Outcome
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- 8 ▪ Medial clear space (mm)
9

10 2. Secondary Outcomes
11

- 12 ▪ Lateral malleolar displacement (mm)
13
14 ▪ Tibiofibular clear space (mm)
15
16 ▪ Talocrural angle (degrees)
17
18 ▪ Medial malleolar displacement (mm)
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28 B) Clinical Outcomes
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32 The clinical outcome measures for sub-studies 1-3 are;
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37 1) Procedure Time
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42 Defined as knife-to-skin/surgical start time to wound closure/surgical stop time. These will be
43 obtained from hospital theatre management systems. Procedure time has been chosen as
44 an outcome measure as there is evidence in the literature that procedure time is inversely
45 related to experience, and so can be used as a surrogate measure of technical
46 proficiency(13)
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53 2) Intra-operative radiation dose to patient
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3 Defined as time under fluoroscopy (seconds) and radiation dose (mGym2). There is
4
5 evidence that with increasing experience and skill, surgeons use less intra-operative x-rays
6
7 to adjust the position of the fracture and implant(13). Hemiarthroplasty does not require
8
9 fluoroscopy so this will not be used as an outcome measure for sub-study 2.
10
11
12
13
14

15 3) Post-operative complication rate

16
17
18
19
20 The complications of interest are the acute post-operative complications during the inpatient
21
22 admission. These will be sub-categorised as acute medical complications (hospital acquired
23
24 pneumonia, renal complications, cardiac complications, DVT/PE) and surgical complications
25
26 (wound infection, wound dehiscence, metalwork failure, deep infection).
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32 4) Health state at 4 months post-operation (EQ-5D)

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37 Health state at 4-months post-operation will be measured using EQ-5D, which is a
38
39 standardized instrument measuring generic health status, which has been widely validated
40
41 in clinical trials. This data is being collected separately as part of the WHiTE comprehensive
42
43 cohort study of hip fracture patients (ISRCTN63982700) and reported elsewhere(14). EQ-5D
44
45 will be used for sub-studies 1 and 2 only as these involve hip fractures.
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53 Screening and eligibility

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3 Orthopaedic surgeons-in-training in their first, second or third specialist training year in the
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5 West Midlands Workforce Deanery will be eligible to participate in the trial. Eligible trainees
6
7 will be identified by liaison with the training programme directors for Trauma & Orthopaedic
8
9 surgery in the three West Midlands schools; Warwick, Birmingham and Oswestry. An
10
11 invitation email will be sent to all eligible trainees by programme administrators at the
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13 deanery.
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23 Inclusion criteria

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27 1) Trauma & Orthopaedic surgeon-in-training in West Midlands school
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29 (Warwick/Birmingham/Oswestry)
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31
32 2) In specialty training year 1-3
33
34
35 3) Willing and able to attend a two-day cadaveric simulation training course at the West
36
37 Midlands Surgical Training Centre, Coventry
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40

41 Exclusion criteria

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46 1) Unavailable on course dates
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53 Consent

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58 Surgeon participants:
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6 Potential study participants will be provided with written and verbal information about the
7
8 study. Consent will be obtained by the trial team. The right to refuse participation without
9
10 giving reasons will be fully respected, and enrolled participants will be free to withdraw from
11
12 the study at any time without reason, and without prejudice to their training. All participants
13
14 will be provided with the contact information of a team member who can provide further
15
16 information about the study. All participants who are allocated to the control group will have
17
18 the opportunity to undertake the cadaveric simulation training intervention at the end of the
19
20 study follow-up. This provision is being offered so that the control group are not
21
22 disadvantaged in their access to educational opportunity by virtue of being randomised to
23
24 the control group.
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32 Patients whose operations are assessed:
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37 Patients who undergo an operation by a surgeon who is participating in the study will not be
38
39 separately consented to allow access to radiographs to assess their implant position or
40
41 clinical outcome data. Permission to access this information for the purposes of this study
42
43 without patient consent has been granted from the confidentiality advisory group
44
45 (16/CAG/0125). It is recognised that seeking consent from a group of primarily elderly, frail
46
47 patients to assess low risk, routine clinical data in a secure manner for a trial they are not
48
49 directly participating in would be unduly burdensome for the patients. All patient data will be
50
51 fully anonymised and handled securely in line with university data regulations.
52
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58 Randomisation
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6 Participants will be randomised at the point of recruitment using block randomisation (block
7
8 size 4) to generate a random sequence list, to which participants will be assigned in the
9
10 order that they enter the study. The allocation sequence will be generated by a senior
11
12 medical statistician, participants will be enrolled by the trial team.
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20 Postrandomisation withdrawals

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25 Withdrawn participants will not be replaced.
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30 Study setting

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34 The study participants will be on training rotations within the regional hospitals of the West
35
36 Midlands during the study follow-up. The hospitals where trainees have been working, and
37
38 performing operations, during the study follow up will be identified from the participants
39
40 electronic surgical logbook records.
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49 Interventions

50 51 52 53 Control group

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3 The control group will undertake normal clinical training 'on-the-job' according to the master-
4
5 apprentice model, which is the current standard training practice.
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10 Intervention group (cadaveric simulation trained)

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15 Participants allocated to the intervention group will receive an intensive, 2-day cadaveric
16
17 simulation training course at the start of the training year, where 4 common orthopaedic
18
19 surgical procedures will be taught (DHS, hemiarthroplasty, ankle fracture fixation and lower
20
21 limb fasciotomy). All intervention participants will receive training on all 4 procedures, which
22
23 will be considered separately in the analysis as individual sub-studies (as they have different
24
25 radiographic outcome measures). The fasciotomy procedure is included as a 'filler' to make
26
27 the course structure work, and chosen because it is an important high-stakes, anatomically
28
29 critical operation that is rarely performed by trainees. Outcomes related to the fasciotomy
30
31 procedure will not be collected or included in the analysis.
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42 The cadaveric simulation training course

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45
46 The course will be delivered in September at the start of the surgical training year (which
47
48 runs August to August). The course will take place at the West Midlands Surgical Training
49
50 Centre (WMSTC) at the University Hospital Coventry & Warwickshire (UHCW). The WMSTC
51
52 is a specialized wet-laboratory facility for delivering cadaveric training, and has an
53
54 experienced dedicated faculty to facilitate training delivery.
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4 The course will consist of two full days of teaching, with expert consultant faculty teaching on
5
6 fresh-frozen hemi-cadavers (waist-to-toe-tip). The participant:faculty ratio will be 2:1, and
7
8 participant:cadaver ratio will be 2:1. Each participant will undertake each of the four
9
10 procedures in their entirety as primary surgeon('skin-to-skin'), and will act as assistant when
11
12 their partner is the primary surgeon four times. Hence is participant is exposed to eight
13
14 procedures during the course:
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23 The environment and psychological fidelity of the simulation will be maximised by providing;
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26

- 27 • Full surgical dress including masks, gloves, gowns and lead x-ray aprons
- 28 • The usual disposable surgical drapes
- 29 • Skin preparation (iodine solution) to prepare the surgical site, and participants and
30
31 faculty will be asked to observe the usual sterile field precautions as in real theatre
32
33 • Full surgical instrument trays, surgical implants and cement (for hemiarthroplasty) of
34
35 the same type as in real theatre will be used
36
37 • Image intensifier (mobile x-ray) will be available for intra-operative use
38
39 • Background noise levels and room temperature were maintained at what would
40
41 usually be expected in the operating theatre
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51 The simulated operating theatres will be set up within the WMSTC as two parallel
52
53 round-robin circuits. The two stations requiring x-ray use (DHS and ankle ORIF) will be set
54
55 up at the far end of the room to create a radiation zone and where appropriate, standard
56
57 precautions will be used. Careful consideration will be given to the optimum sequential use
58
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1
2
3 of the cadaveric specimens in planning the course structure. For example, it is necessary
4 that the DHS station precedes the hemiarthroplasty station as it would obviously not be
5 possible to perform a DHS operation when the femoral head had been removed. Similarly,
6 the fasciotomy incisions would compromise the soft tissue envelope of the lower limb to a
7 sufficient degree that the fidelity of the ankle ORIF station would be compromised. It is
8 important to make the best and most efficient use of the cadaveric material, for both ethical
9 and financial reasons.
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25 Blinding

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29 The participants cannot be blinded to the type of training they receive, neither can the trial
30 team in organising the cadaveric simulation training. The trial team will take no part in the
31 training of participants. The assessment of radiographic images will be made blinded to
32 group allocation.
33
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42 Adverse event management

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45
46 In the unlikely event of a serious adverse event (SAE), the chief investigator will report to the
47 sponsor (University of Warwick), ethics committee and project supervisors.
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54 Patient and public involvement

1
2
3 There was no direct patient or public involvement in the design of the study, although clearly
4 training competent surgeons is in the public interest. There is qualitative work to be done
5
6 around this trial to better understand patient expectations of surgical training.
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9

10 11 12 13 End of trial 14

15
16
17 The trial will end when data collection is complete. The trial will be stopped prematurely if
18 required by the ethics committee, following recommendations from the sponsor, or if funding
19
20 for the study is withdrawn. The research ethics committee and confidentiality advisory group
21
22 will be notified in writing once the trial is complete.
23
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28

29 30 Trial Oversight 31

32
33
34 This trial is being undertaken as part of a doctoral research project (HKJ), and supervised by
35
36 three senior supervisors (DG, JF, GTRP). The supervisors will act as the trial management
37
38 group and steering committee. The trial is being conducted within a registered Clinical Trials
39
40 Unit, and will follow the CTU standard operating procedures.
41
42
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44
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46 47 Data Collection Plan 48

49
50
51 The operations performed by the participants will be identified by the surgeons' electronic
52
53 logbook. These will be extracted and anonymised to study identifier by the electronic
54
55 logbook data team, before being sent to the trial team. The data will include operation type,
56
57 date, hospital, hospital ID, patient age, American Society of Anaesthesiologists Grade and
58
59
60

1
2
3 supervision code. The radiographs and clinical outcome data relating to these procedures
4
5 will then be obtained from the study sites via liaison with the respective Research &
6
7 Development Departments. Data will be entered into a secure trial database on a
8
9 professionally encrypted trial-specific computer, fully anonymised with only study identifiers.
10
11 Once data collection is complete, and prior to analysis, range checks for data values will be
12
13 undertaken, and data will be double checked on entry to the statistical software package.
14
15 The project supervisors will act as the data monitoring committee. No interim analysis will be
16
17 undertaken. The trial team and statistician will have access to the final trial dataset.
18
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25 Statistical Analysis Plan

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27
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29
30 Baseline data will be summarised and compared between the two arms of the study. A
31
32 CONSORT chart showing the flow of participants through the study will be produced.
33

34 The three taught procedures (substudies 1-3) will be analysed and reported individually.
35
36
37

38
39 The main analysis will investigate and report differences between the two groups with
40
41 respect to the implant positions (as measured from radiographs), the procedure times, the
42
43 intra-operative radiation dose to the patient, and patient outcomes, as measured by post-
44
45 operative complications and health state at 4 months post-operation (hip fractures only).
46
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50
51 Statistical tests will be two-sided and considered to demonstrate a significant difference
52
53 when $p < 0.05$. Temporal trends by group for implant position, procedure time and radiation
54
55 dose will be presented. Linear mixed effects models will be fitted to allow for within-surgeon
56
57 correlation between repeated observations (surgeon clustering as a random effect), and to
58
59
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1
2
3 adjust for important co-variables such as patient condition, age and surgeon experience.

4
5
6 These will be summarised by plotting individual learning curves, and then modelled to
7
8 estimate the overall learning curves for the two arms of the study.
9

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11
12
13 Descriptive statistical analyses of between-group comparisons will be presented for
14
15 complication rate and health state, with temporal analysis of the latter being reported if
16
17 appropriate and feasible. The statistical analysis will be supervised and checked by a senior
18
19 medical statistician at Warwick University.
20
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25 In the event of missing data, statistician advice will be sought on multiple imputation.
26
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30 Ethics and dissemination

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34 Master-apprentice 'on-the-job' training for surgeons is the current training standard in the
35
36 UK(15, 16), and therefore the control arm of the study reflects usual practice. The cadaveric
37
38 simulation training intervention is a novel experimental intervention, but as it is an
39
40 educational intervention it does not expose trial participants to any substantial risks of harm.
41
42 The trial results will be reported in accordance with the CONSORT statement, and
43
44 disseminated through publication in peer reviewed journals and conferences. The results of
45
46 the trial will be presented to Health Education England and the Royal Surgical College. The
47
48 dataset, statistical code and technical appendices will be made available on request to the
49
50 corresponding author.
51
52
53
54

55 Funding

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6 This work was supported by Versus Arthritis grant number 20845
7
8
9

10 Sponsor Contact Information
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29 Declaration/Conflict of Interests
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31

32 None to declare
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10 Author Statement/Contributions
11

12
13 HKJ designed the study and wrote the manuscript

14 GTRP co-designed the study and the intervention and edited the manuscript

15
16 JDF edited the manuscript, made a substantial contribution to the design and is lead
17 supervisor for the qualitative part of the project

18
19 DG co-designed the study, edited draft protocols and is lead supervisor for the
20 quantitative part of the project
21
22

23
24 Acknowledgements
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27 None
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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	#3	Date and version identifier	3
Funding	#4	Sources and types of financial, material, and other support	15
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1

1	Roles and	#5b	Name and contact information for the trial sponsor	15
2	responsibilities:			
3	sponsor contact			
4	information			
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8	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	14
9	responsibilities:		collection, management, analysis, and interpretation of data;	
10	sponsor and funder		writing of the report; and the decision to submit the report for	
11			publication, including whether they will have ultimate	
12			authority over any of these activities	
13				
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16	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	14
17	responsibilities:		centre, steering committee, endpoint adjudication committee,	
18	committees		data management team, and other individuals or groups	
19			overseeing the trial, if applicable (see Item 21a for data	
20			monitoring committee)	
21				
22				
23				
24	Introduction			
25				
26				
27	Background and	#6a	Description of research question and justification for	1
28	rationale		undertaking the trial, including summary of relevant studies	
29			(published and unpublished) examining benefits and harms	
30			for each intervention	
31				
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34	Background and	#6b	Explanation for choice of comparators	11
35	rationale: choice of			
36	comparators			
37				
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39	Objectives	#7	Specific objectives or hypotheses	5-6
40				
41	Trial design	#8	Description of trial design including type of trial (eg, parallel	5
42			group, crossover, factorial, single group), allocation ratio, and	
43			framework (eg, superiority, equivalence, non-inferiority,	
44			exploratory)	
45				
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47				
48	Methods:			
49	Participants,			
50	interventions, and			
51	outcomes			
52				
53				
54				
55	Study setting	#9	Description of study settings (eg, community clinic, academic	10
56			hospital) and list of countries where data will be collected.	
57			Reference to where list of study sites can be obtained	
58				
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1	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
2				
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5				
6	Interventions:	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-13
7	description			
8				
9				
10				
11	Interventions:	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A – educational trial
12	modifications			
13				
14				
15				
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18	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A – educational trial
19	adherence			
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24	Interventions:	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A – educational trial
25	concomitant care			
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29	Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	6-7
30				
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40	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
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47	Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
48				
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54	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
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1 **Methods:**

2 **Assignment of**
3 **interventions (for**
4 **controlled trials)**
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6

7	Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
17	Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
24	Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
28	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
34	Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A - educational trial

39 **Methods: Data**
40 **collection,**
41 **management, and**
42 **analysis**
43
44

46	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
57	Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for	14

participants who discontinue or deviate from intervention protocols

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4	Data management	#19	Plans for data entry, coding, security, and storage, including 14
5			any related processes to promote data quality (eg, double data
6			entry; range checks for data values). Reference to where
7			details of data management procedures can be found, if not in
8			the protocol
9			
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11			
12	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary 14-15
13			outcomes. Reference to where other details of the statistical
14			analysis plan can be found, if not in the protocol
15			
16			
17	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and 14-15
18	analyses		adjusted analyses)
19			
20			
21	Statistics: analysis	#20c	Definition of analysis population relating to protocol non- 15
22	population and		adherence (eg, as randomised analysis), and any statistical
23	missing data		methods to handle missing data (eg, multiple imputation)
24			
25			
26			
27	Methods: Monitoring		
28			
29	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary 14
30	formal committee		of its role and reporting structure; statement of whether it is
31			independent from the sponsor and competing interests; and
32			reference to where further details about its charter can be
33			found, if not in the protocol. Alternatively, an explanation of
34			why a DMC is not needed
35			
36			
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39	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines, 14
40	interim analysis		including who will have access to these interim results and
41			make the final decision to terminate the trial
42			
43			
44	Harms	#22	Plans for collecting, assessing, reporting, and managing N/A –
45			solicited and spontaneously reported adverse events and other educational
46			unintended effects of trial interventions or trial conduct trial
47			
48			
49	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, N/A –
50			and whether the process will be independent from educational
51			investigators and the sponsor trial
52			
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55	Ethics and		
56	dissemination		
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1	Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3
2				
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4	Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A – educational trial
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11	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
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17	Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A – educational trial
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22	Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
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27	Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
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31	Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
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37	Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A – educational trial
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42	Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15
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50	Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15
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54	Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
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Appendices

1	Informed consent	#32	Model consent form and other related documentation given to	Appendix
2	materials		participants and authorised surrogates	
3				
4				
5	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	N/A –
6			biological specimens for genetic or molecular analysis in the	educational
7			current trial and for future use in ancillary studies, if	trial
8			applicable	
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12 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the
13 [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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For peer review only

BMJ Open

Cadaveric simulation vs standard training for postgraduate trauma & orthopaedic surgical trainees: protocol for the CAD:TRAUMA study multi-centre randomised controlled educational trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-037319.R1
Article Type:	Protocol
Date Submitted by the Author:	04-May-2020
Complete List of Authors:	James, Hannah; University of Warwick Warwick Medical School, Clinical Trials Unit; University Hospitals Coventry and Warwickshire NHS Trust, Trauma & Orthopaedic Surgery Pattison, Giles; University Hospitals Coventry and Warwickshire NHS Trust, Trauma & Orthopaedic Surgery Fisher, Joanne; University of Warwick Warwick Medical School, Clinical Trials Unit Griffin, Damian; University of Warwick, Warwick Medical School
Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Surgery
Keywords:	MEDICAL EDUCATION & TRAINING, ORTHOPAEDIC & TRAUMA SURGERY, Trauma management < ORTHOPAEDIC & TRAUMA SURGERY

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3 **Cadaveric simulation vs standard training for postgraduate trauma & orthopaedic surgical**
4 **trainees: protocol for the CAD:TRAUMA study multi-centre randomised controlled**
5 **educational trial**
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25 Word Count 3,420

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29 Keywords

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31
32
33
34 Education, Training, Simulation

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39 Abstract

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44 **Introduction**

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49 The quantity and quality of surgical training in the UK has been negatively affected by
50
51 reduced working hours and NHS financial pressures. Traditionally surgical training has
52
53 occurred by the master-apprentice model involving a process of graduated responsibility, but
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55 a modern alternative is to use simulation for the early stages of training. It is not known if
56
57 simulation training for junior trainees can safeguard patients and improve clinical outcomes.
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3 This paper details the protocol for a multicentre randomised controlled educational trial of a
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6 cadaveric simulation training intervention versus standard training for junior postgraduate
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8 orthopaedic surgeons-in-training. This is the first study to assess the effect of cadaveric
9
10 simulation training for open surgery on patient outcome. The feasibility of delivering
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12 cadaveric training, use of radiographic and clinical outcome measures to assess impact and
13
14 the challenges of upscaling provision will be explored.
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20 **Methods and Analysis**

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24
25 We will recruit postgraduate orthopaedic surgeons-in-training in the first three years (of
26
27 eight) of the specialist training programme. Participants will be block randomised and
28
29 allocated to either cadaveric simulation or standard 'on-the-job' training, learning three
30
31 common orthopaedic procedures, each of which is a sub-study within the trial. The
32
33 procedures are 1) Dynamic Hip Screw(DHS), 2) hemiarthroplasty and 3) ankle fracture
34
35 fixation. These procedures have been selected as they are very common procedures which
36
37 are routinely performed by junior surgeons-in-training. A pragmatic approach to sample size
38
39 is taken in lieu of a formal power calculation as this is novel exploratory work with no a priori
40
41 estimate of effect size to reference. The primary outcome measure is the technical success
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43 of the surgery performed on patients by the participating surgeons-in-training during the
44
45 follow-up period for the three sub-study procedures, as measured by the implant position on
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47 the post-operative radiograph. The secondary outcome measures are procedure time, post-
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49 operative complication rate and patient health state at 4 months post-operation (EQ-5D –
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51 substudies 1 and 2 only).
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Ethics, registration and dissemination

National research ethics approval was granted for this study by the NHS Research Authority South Birmingham Research Ethics Committee (15/WM/0464). Confidentiality Advisory Group approval was granted for accessing radiographic and outcome data without patient consent on 27 February 2017 (16/CAG/0125). The results of this trial will be submitted to a peer-reviewed journal and will inform educational and clinical practice.

Trial registration number

ISRCTN20431944; Pre-results

Protocol version V_P_1.1

Article Summary

Strengths and limitations of this study:

- This is the first randomised controlled trial assessing the impact of cadaveric simulation training on clinical outcomes
- Patient-centred outcome measures are used to measure an educational intervention for surgeons

- Multicentre study to maximize external validity of the results
- The training dose is small as cadaveric training is expensive to deliver
- Pragmatic approach to sample size which is limited by the capacity of the surgical training centre

Introduction

It is imperative that surgeons are trained to a high standard, so they can perform safe and effective operations for patients. The quality and quantity of surgical training in the UK is currently under threat from a 'perfect storm' of factors(1). These include reduced working hours(2, 3), shift based working patterns(4) with the loss of the traditional surgical firm, and a move to expedite training and shorten specialist programmes(5, 6). This is set within a climate of unprecedented financial austerity in the NHS and ever increasing service pressures.

Simulation offers a solution to some of these challenges by moving the early part of the surgical learning curve away from patients into a controlled environment(7), where skills may be more rapidly acquired as compared to the clinical environment. Simulation is also

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2
3 potentially a very efficient way of training, as large numbers of trainees can be trained
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5 simultaneously, at an intensity not feasible in the clinical environment due to competing
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7 service demands.
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13 Cadaveric simulation - training using deceased, preserved or fresh human bodies - is a
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15 particularly promising modality for training. Fresh-frozen cadavers retain many of the soft
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17 tissue handling characteristics seen in live patients, and in combination with presenting the
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19 correct anatomy, particularly complex neurovascular relationships, may offer a more realistic
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21 simulated operation than would be possible on a plastic model or virtual reality simulator(8,
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23 9). Cadaveric material does not bleed(10) and hence may be less useful for simulating
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25 procedures where haemorrhage control is an important feature.
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32 The operating theatre environment can be simulated, including (but not limited to) surgical
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34 dress, draping, instrumentation and multidisciplinary team. This 'whole dress rehearsal' for
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36 surgery may enhance development of non-technical skills in addition to the technical
37
38 operative surgical skills(11).
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44
45 There are several challenges in delivering cadaveric simulation training. It is expensive to
46
47 provide(9), particularly when cadaveric material has to be purchased under license where
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49 there is not a local body donation programme. It requires considerable infrastructure to
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51 deliver, including specialist wet laboratory facilities with the appropriately trained staff. These
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53 challenges become particularly pressing when provision of cadaveric training on a large
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55 scale is considered, and are an important driver in the development of high quality evidence
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3 of educational impact. This evidence is necessary before considerable financial investment
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6 can be recommended in providing cadaveric simulation training on a larger scale.
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10 There is abundant low quality evidence showing cadaveric simulation may induce short term
11
12 skill improvement as measured by subjective and behavioural metrics, but there is a lack of
13
14 high quality, quantitative evidence that skills learnt in cadaveric simulation can transfer to the
15
16 workplace, leading to improved outcomes for patients(8).
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22 Our trial attempts to address this evidence deficit, and is both topical and timely.
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30 Good Clinical Practice

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33 This trial will be undertaken in compliance with Good Practice Guidelines, complying with the
34
35 Declaration of Helsinki and UK Legislation. Warwick standard operating procedures (SOPs)
36
37 will be followed.
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43

44 Consolidated Standards of Reporting Trials

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46
47 The results of the trial will be reported in line with the Consolidated Standard of Reporting
48
49 (CONSORT) statement(12). This protocol has been written according to the SPIRIT
50
51 reporting guidelines(13).
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58 Aim

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6 The aim is to determine which of the two surgical training strategies for junior orthopaedic
7
8 surgeons-in-training leads to the best patient outcomes for three common procedures.
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18 Objectives

- 22 1. To assess the impact of a cadaveric simulation training intervention on the patient
23
24 outcome of operations performed by junior orthopaedic surgeons-in-training
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26
- 27 2. To define the early learning curve of DHS, Hemiarthroplasty and ankle fracture
28
29 fixation
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31
- 32 3. To explore the feasibility of using post-operative x-rays to assess technical skill
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40 Methods and Analysis

41 42 43 44 Study design

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48 This is a UK multicentre, two-arm, group parallel randomised controlled educational trial
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53 54 Sample size

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3 This trial is the first attempt to objectively measure transfer of open operative skills from
4
5
6 cadaveric simulation into the workplace using patient-based outcome measures. There is no
7
8
9 available estimate of effect size to reference against a priori in determining sample size,
10
11 therefore a pragmatic approach to sample size will be taken in lieu of a formal power
12
13 calculation. The surgical training centre can accommodate 16 delegates at one time and
14
15 financial resources permitted one iteration of the cadaveric training course. Our maximum
16
17 sample size is therefore 16 participants in each arm of the study
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25 Outcome measures

26 27 28 29 A) Radiographic outcomes

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32
33
34 The radiographs will be obtained electronically from hospital servers and the implant position
35
36 measured manually using computer software. The operations will be identified
37
38 retrospectively by access to the participating surgeons' electronic logbooks. The
39
40 measurements vary by operation type and are defined as follows.
41
42
43
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46

47 **Sub-study 1: Dynamic Hip Screw**

48 49 50 51 1. Primary Outcome

- 52
53
54 ▪ Tip-Apex distance (in mm)

55 56 2. Secondary Outcomes (in order of importance)

- 57
58
59 ▪ Lag screw position in the femoral head (defined by Cleveland Zones)

- Plate flush to lateral femoral cortex (binary Y/N)
- 8 cortex hold for plate screws (binary Y/N)

Sub- study 2: Hemiarthroplasty

1. Primary Outcome

- Leg length discrepancy (mm)

2. Secondary Outcomes (in order of importance)

- Femoral stem alignment (degrees off neutral)
- Cement mantle quality (Barrack grade score)
- Femoral offset change relative to native hip (mm)

Sub- study 3: Ankle fracture fixation

1. Primary Outcome

- Medial clear space (mm)

2. Secondary Outcomes

- Lateral malleolar displacement (mm)
- Tibiofibular clear space (mm)
- Talocrural angle (degrees)
- Medial malleolar displacement (mm)

B) Clinical Outcomes

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6 The clinical outcome measures for sub-studies 1-3 are;
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10 1) Procedure Time
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15 Defined as knife-to-skin/surgical start time to wound closure/surgical stop time. These will be
16 obtained from hospital theatre management systems. Procedure time has been chosen as
17 an outcome measure as there is evidence in the literature that procedure time is inversely
18 related to experience, and so can be used as a surrogate measure of technical
19 proficiency(14)
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30 2) Intra-operative radiation dose to patient
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35 Defined as time under fluoroscopy (seconds) and radiation dose (mGym²). There is
36 evidence that with increasing experience and skill, surgeons use less intra-operative x-rays
37 to adjust the position of the fracture and implant(14). Hemiarthroplasty does not require
38 fluoroscopy so this will not be used as an outcome measure for sub-study 2.
39
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47 3) Post-operative complication rate
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49
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51 The complications of interest are the acute post-operative complications during the inpatient
52 admission. These will be sub-categorised as acute medical complications (hospital acquired
53 pneumonia, renal complications, cardiac complications, DVT/PE) and surgical complications
54 (wound infection, wound dehiscence, metalwork failure, deep infection).
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6 4) Health state at 4 months post-operation (EQ-5D)
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10 Health state at 4-months post-operation will be measured using EQ-5D, which is a
11
12 standardized instrument measuring generic health status, which has been widely validated
13
14 in clinical trials. This data is being collected separately as part of the WHiTE comprehensive
15
16 cohort study of hip fracture patients (ISRCTN63982700) and reported elsewhere(15). EQ-5D
17
18 will be used for sub-studies 1 and 2 only as these involve hip fractures.
19
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27 Screening and eligibility
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32 Orthopaedic surgeons-in-training in their first, second or third specialist training year in the
33
34 West Midlands Workforce Deanery will be eligible to participate in the trial. Eligible trainees
35
36 will be identified by liaison with the training programme directors for Trauma & Orthopaedic
37
38 surgery in the three West Midlands schools; Warwick, Birmingham and Oswestry. An
39
40 invitation email will be sent to all eligible trainees by programme administrators at the
41
42 deanery.
43
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51 Inclusion criteria
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- 56 1) Trauma & Orthopaedic surgeon-in-training in West Midlands school
57
58 (Warwick/Birmingham/Oswestry)
59
60

- 1
- 2
- 3
- 4 2) In specialty training year 1-3
- 5
- 6 3) Willing and able to attend a two-day cadaveric simulation training course at the West
- 7
- 8 Midlands Surgical Training Centre, Coventry
- 9
- 10
- 11
- 12

13 Exclusion criteria

14

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- 18 1) Unavailable on course dates
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- 24

25 Consent

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30 Surgeon participants:

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35 Potential study participants will be provided with written and verbal information about the
36 study. Consent will be obtained by the trial team. The right to refuse participation without
37 giving reasons will be fully respected, and enrolled participants will be free to withdraw from
38 the study at any time without reason, and without prejudice to their training. All participants
39 will be provided with the contact information of a team member who can provide further
40 information about the study. All participants who are allocated to the control group will have
41 the opportunity to undertake the cadaveric simulation training intervention at the end of the
42 study follow-up. This provision is being offered so that the control group are not
43 disadvantaged in their access to educational opportunity by virtue of being randomised to
44 the control group.
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3 Patients whose operations are assessed:
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8 Patients who undergo an operation by a surgeon who is participating in the study will not be
9
10 separately consented to allow access to radiographs to assess their implant position or
11
12 clinical outcome data. Permission to access this information for the purposes of this study
13
14 without patient consent has been granted from the confidentiality advisory group
15
16 (16/CAG/0125). It is recognised that seeking consent from a group of primarily elderly, frail
17
18 patients to assess low risk, routine clinical data in a secure manner for a trial they are not
19
20 directly participating in would be unduly burdensome for the patients. All patient data will be
21
22 fully anonymised and handled securely in line with university data regulations.
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30 Randomisation

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34 Participants will be randomised at the point of recruitment using block randomisation (block
35
36 size 4) to generate a random sequence list, to which participants will be assigned in the
37
38 order that they enter the study. The allocation sequence will be generated by a senior
39
40 medical statistician, participants will be enrolled by the trial team.
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49 Postrandomisation withdrawals

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53 Withdrawn participants will not be replaced.
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58 Study setting

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6 The study participants will be on training rotations within the regional hospitals of the West
7
8 Midlands during the study follow-up. The hospitals where trainees have been working, and
9
10 performing operations, during the study follow up will be identified from the participants
11
12 electronic surgical logbook records.
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20 Interventions

21 22 23 24 25 Control group

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29 The control group will undertake standard residency training according to the master-
30
31 apprentice model, which is the current standard practice in UK. No additional training or
32
33 access to learning materials will be provided beyond the fortnightly didactic teaching
34
35 sessions which are delivered as a part of routine training.
36
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39

40 41 42 Intervention group (cadaveric simulation trained)

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45
46 Participants allocated to the intervention group will receive an intensive, 2-day cadaveric
47
48 simulation training course at the start of the training year, where 4 common orthopaedic
49
50 surgical procedures will be taught (DHS, hemiarthroplasty, ankle fracture fixation and lower
51
52 limb fasciotomy). All intervention participants will receive training on all 4 procedures, which
53
54 will be considered separately in the analysis as individual sub-studies (as they have different
55
56 radiographic outcome measures). The fasciotomy procedure is included as a 'filler' to make
57
58
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1
2
3 the course structure work, and chosen because it is an important high-stakes, anatomically
4
5 critical operation that is rarely performed by trainees. Outcomes related to the fasciotomy
6
7 procedure will not be collected or included in the analysis.
8
9

10 11 12 13 14 15 The cadaveric simulation training course 16

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18
19
20 The course will be delivered in September at the start of the surgical training year (which
21
22 runs August to August). The course will take place at the West Midlands Surgical Training
23
24 Centre (WMSTC) at the University Hospital Coventry & Warwickshire (UHCW). The WMSTC
25
26 is a specialized wet-laboratory facility for delivering cadaveric training, and has an
27
28 experienced dedicated faculty to facilitate training delivery.
29
30
31

32
33
34 The course will consist of two full days of teaching, with expert consultant faculty teaching on
35
36 fresh-frozen hemi-cadavers (waist-to-toe-tip). The participant:faculty ratio will be 2:1, and
37
38 participant:cadaver ratio will be 2:1. Each participant will undertake each of the four
39
40 procedures in their entirety as primary surgeon('skin-to-skin'), and will act as assistant when
41
42 their partner is the primary surgeon four times. Hence each participant is exposed to eight
43
44 procedures during the course:
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53 The environment and psychological fidelity of the simulation will be maximised by providing;
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55

- 56
57
58 • Full surgical dress including masks, gloves, gowns and lead x-ray aprons
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60

- The usual disposable surgical drapes
- Skin preparation (iodine solution) to prepare the surgical site, and participants and faculty will be asked to observe the usual sterile field precautions as in real theatre
- Full surgical instrument trays, surgical implants and cement (for hemiarthroplasty) of the same type as in real theatre will be used
- Image intensifier (mobile x-ray) will be available for intra-operative use
- Background noise levels and room temperature were maintained at what would usually be expected in the operating theatre

The simulated operating theatres will be set up within the WMSTC as two parallel round-robin circuits. The two stations requiring x-ray use (DHS and ankle ORIF) will be set up at the far end of the room to create a radiation zone and where appropriate, standard precautions will be used. Careful consideration will be given to the optimum sequential use of the cadaveric specimens in planning the course structure. For example, it is necessary that the DHS station precedes the hemiarthroplasty station as it would obviously not be possible to perform a DHS operation when the femoral head had been removed. Similarly, the fasciotomy incisions would compromise the soft tissue envelope of the lower limb to a sufficient degree that the fidelity of the ankle ORIF station would be compromised. It is important to make the best and most efficient use of the cadaveric material, for both ethical and financial reasons.

Blinding

1
2
3 The participants cannot be blinded to the type of training they receive, neither can the trial
4
5 team in organising the cadaveric simulation training. The trial team will take no part in the
6
7 training of participants. The assessment of radiographic images will be made blinded to
8
9 group allocation.
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15 Adverse event management

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20 In the unlikely event of a serious adverse event (SAE), the chief investigator will report to the
21
22 sponsor (University of Warwick), ethics committee and project supervisors.
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27 Patient and public involvement

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32 There was no direct patient or public involvement in the design of the study, although clearly
33
34 training competent surgeons is in the public interest. There is qualitative work to be done
35
36 around this trial to better understand patient expectations of surgical training.
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41 End of trial

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46 The trial will end when all the radiographic and clinical outcome data has been collected
47
48 from the participating sites. The trial will be stopped prematurely if required by the ethics
49
50 committee, following recommendations from the sponsor, or if funding for the study is
51
52 withdrawn. The research ethics committee and confidentiality advisory group will be notified
53
54 in writing once the trial is complete.
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Trial Oversight

This trial is being undertaken as part of a doctoral research project (HKJ), and supervised by three senior supervisors (DG, JF, GTRP). The supervisors will act as the trial management group and steering committee. The trial is being conducted within a registered Clinical Trials Unit, and will follow the CTU standard operating procedures.

Data Collection Plan

Data on the numbers of procedures performed by the participating surgeons at baseline will be collected. The operations performed by the participants during study follow-up will be identified by the surgeons' electronic logbook. Only procedures coded as 'S-TS: supervised-trainer scrubbed' or 'STU: supervised trainer unscrubbed' will be included in the analysis.

This is to ensure that only procedures where the trainee has performed the key parts (S-TS) or the entire procedure (STU) are included. If further information on supervisor input/takeover is required this can be obtained by accessing the corresponding procedure based assessment (PBA) record for the operation. PBAs are routinely collected as part of training.

Procedure data will be extracted and anonymised to study identifier by the electronic logbook data team, before being sent to the trial team. The data will include operation type, date, hospital, hospital ID, patient age, American Society of Anaesthesiologists Grade and supervision code. The radiographs and clinical outcome data relating to these procedures will then be obtained from the study sites via liaison with the respective Research &

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2
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4 Development Departments. Data will be entered into a secure trial database on a
5
6 professionally encrypted trial-specific computer, fully anonymised with only study identifiers.
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9 Once data collection is complete, and prior to analysis, range checks for data values will be
10
11 undertaken, and data will be double checked on entry to the statistical software package.
12

13
14 The project supervisors will act as the data monitoring committee. No interim analysis will be
15
16 undertaken. The trial team and statistician will have access to the final trial dataset.
17

18 19 20 Statistical Analysis Plan 21

22
23
24
25 Baseline data including completed months of training and number of prior procedures
26
27 performed will be summarised and compared between the two arms of the study. A
28

29
30 CONSORT chart showing the flow of participants through the study will be produced.
31

32
33 The three taught procedures (substudies 1-3) will be analysed and reported individually.
34
35

36
37 The main analysis will investigate and report differences between the two groups with
38
39 respect to the implant positions (as measured from radiographs), the procedure times, the
40
41 intra-operative radiation dose to the patient, and patient outcomes, as measured by post-
42
43 operative complications and health state at 4 months post-operation (hip fractures only).
44
45

46
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48
49 Statistical tests will be two-sided and considered to demonstrate a significant difference
50
51 when $p < 0.05$. Temporal trends by group for implant position, procedure time and radiation
52
53 dose will be presented. Linear mixed effects models will be fitted to allow for within-surgeon
54
55 correlation between repeated observations (surgeon clustering as a random effect), and to
56
57 adjust for important co-variables such as patient condition, age and surgeon experience.
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3 These will be summarised by plotting individual learning curves, and then modelled to
4
5
6 estimate the overall learning curves for the two arms of the study.
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10 Descriptive statistical analyses of between-group comparisons will be presented for
11
12 complication rate and health state, with temporal analysis of the latter being reported if
13
14 appropriate and feasible. The statistical analysis will be supervised and checked by a senior
15
16 medical statistician at Warwick University.
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19

20
21
22 In the event of missing data, statistician advice will be sought on multiple imputation.
23
24
25

26 27 Ethics and dissemination 28 29 30

31
32 Master-apprentice 'on-the-job' training for surgeons is the current training standard in the
33
34 UK(10, 16), and therefore the control arm of the study reflects usual practice. The cadaveric
35
36 simulation training intervention is an experimental educational intervention and does not
37
38 expose trial participants to any substantial risks of harm. The trial results will be reported in
39
40 accordance with the CONSORT statement, and disseminated through publication in peer
41
42 reviewed journals and conferences. The results of the trial will be presented to Health
43
44 Education England and the Royal Surgical College. The dataset, statistical code and
45
46 technical appendices will be made available on request to the corresponding author.
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52 53 Funding 54 55 56

57
58 This work was supported by Versus Arthritis grant number 20845
59
60

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5
6 Sponsor Contact Information
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8
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24 Declaration/Conflict of Interests
25
26

27 None to declare
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Author Statement/Contributions

HKJ designed the study and wrote the manuscript

GTRP co-designed the study and the intervention and edited the manuscript

JDF edited the manuscript, made a substantial contribution to the design and is lead supervisor for the qualitative part of the project

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DG co-designed the study, edited draft protocols and is lead supervisor for the quantitative part of the project

Acknowledgements

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For peer review only



CONSENT FORM

(Biomedical and Scientific Research Ethics Committee) Study Number: REGO-2014-718

Title of Project: cad:trauma study

Name of Researcher(s): Mrs Hannah James, Professor Damian Griffin, Mr Giles Pattison, Dr Jane Kidd

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **April 2014 (version 1)** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my education or legal rights being affected.
3. I understand that relevant sections of data collected during the study, may be looked at by individuals from The University of Warwick or from regulatory authorities where it is relevant. I give permission for these individuals to have access to this data.
4. I agree to take part in the above study.

Name of Participant	Date	Signature

Name of Person taking consent	Date	Signature

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	#3	Date and version identifier	3
Funding	#4	Sources and types of financial, material, and other support	15
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1

1	Roles and	#5b	Name and contact information for the trial sponsor	15
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7				
8	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	14
9	responsibilities:		collection, management, analysis, and interpretation of data;	
10	sponsor and funder		writing of the report; and the decision to submit the report for	
11			publication, including whether they will have ultimate	
12			authority over any of these activities	
13				
14				
15				
16	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	14
17	responsibilities:		centre, steering committee, endpoint adjudication committee,	
18	committees		data management team, and other individuals or groups	
19			overseeing the trial, if applicable (see Item 21a for data	
20			monitoring committee)	
21				
22				
23				
24	Introduction			
25				
26				
27	Background and	#6a	Description of research question and justification for	1
28	rationale		undertaking the trial, including summary of relevant studies	
29			(published and unpublished) examining benefits and harms	
30			for each intervention	
31				
32				
33				
34	Background and	#6b	Explanation for choice of comparators	11
35	rationale: choice of			
36	comparators			
37				
38				
39	Objectives	#7	Specific objectives or hypotheses	5-6
40				
41	Trial design	#8	Description of trial design including type of trial (eg, parallel	5
42			group, crossover, factorial, single group), allocation ratio, and	
43			framework (eg, superiority, equivalence, non-inferiority,	
44			exploratory)	
45				
46				
47				
48	Methods:			
49	Participants,			
50	interventions, and			
51	outcomes			
52				
53				
54				
55	Study setting	#9	Description of study settings (eg, community clinic, academic	10
56			hospital) and list of countries where data will be collected.	
57			Reference to where list of study sites can be obtained	
58				
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1	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
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5				
6	Interventions:	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-13
7	description			
8				
9				
10				
11	Interventions:	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A – educational trial
12	modifications			
13				
14				
15				
16				
17				
18	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A – educational trial
19	adherence			
20				
21				
22				
23				
24	Interventions:	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A – educational trial
25	concomitant care			
26				
27				
28				
29	Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	6-7
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40	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
41				
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47	Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
48				
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54	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
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1 **Methods:**

2 **Assignment of**
3 **interventions (for**
4 **controlled trials)**
5
6

7	Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
17	Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
24	Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
28	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
34	Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A - educational trial

39 **Methods: Data**
40 **collection,**
41 **management, and**
42 **analysis**
43
44

46	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
57	Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for	14

participants who discontinue or deviate from intervention protocols

1			
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3			
4	Data management	#19	Plans for data entry, coding, security, and storage, including 14
5			any related processes to promote data quality (eg, double data
6			entry; range checks for data values). Reference to where
7			details of data management procedures can be found, if not in
8			the protocol
9			
10			
11			
12	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary 14-15
13			outcomes. Reference to where other details of the statistical
14			analysis plan can be found, if not in the protocol
15			
16			
17	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and 14-15
18	analyses		adjusted analyses)
19			
20			
21	Statistics: analysis	#20c	Definition of analysis population relating to protocol non- 15
22	population and		adherence (eg, as randomised analysis), and any statistical
23	missing data		methods to handle missing data (eg, multiple imputation)
24			
25			
26			
27	Methods: Monitoring		
28			
29	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary 14
30	formal committee		of its role and reporting structure; statement of whether it is
31			independent from the sponsor and competing interests; and
32			reference to where further details about its charter can be
33			found, if not in the protocol. Alternatively, an explanation of
34			why a DMC is not needed
35			
36			
37			
38			
39	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines, 14
40	interim analysis		including who will have access to these interim results and
41			make the final decision to terminate the trial
42			
43			
44	Harms	#22	Plans for collecting, assessing, reporting, and managing N/A –
45			solicited and spontaneously reported adverse events and other educational
46			unintended effects of trial interventions or trial conduct trial
47			
48			
49	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, N/A –
50			and whether the process will be independent from educational
51			investigators and the sponsor trial
52			
53			
54			
55	Ethics and		
56	dissemination		
57			
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1	Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3
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3				
4				
5	Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	N/A – educational trial
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11	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
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16				
17	Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A – educational trial
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22	Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
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27	Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
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31	Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
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37	Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A – educational trial
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42	Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15
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50	Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	15
51				
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54	Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
55				
56				
57				

Appendices

1	Informed consent	#32	Model consent form and other related documentation given to	Appendix
2	materials		participants and authorised surrogates	
3				
4	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	N/A –
5			biological specimens for genetic or molecular analysis in the	educational
6			current trial and for future use in ancillary studies, if	trial
7			applicable	
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10				

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12 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the
13 [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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For peer review only

BMJ Open

Cadaveric simulation vs standard training for postgraduate trauma & orthopaedic surgical trainees: protocol for the CAD:TRAUMA study multi-centre randomised controlled educational trial

Journal:	<i>BMJ Open</i>
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Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Surgery
Keywords:	MEDICAL EDUCATION & TRAINING, ORTHOPAEDIC & TRAUMA SURGERY, Trauma management < ORTHOPAEDIC & TRAUMA SURGERY

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3 **Cadaveric simulation vs standard training for postgraduate trauma & orthopaedic surgical**
4 **trainees: protocol for the CAD:TRAUMA study multi-centre randomised controlled**
5 **educational trial**
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34 Education, Training, Simulation

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39 Abstract

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44 **Introduction**

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49 The quantity and quality of surgical training in the UK has been negatively affected by
50
51 reduced working hours and NHS financial pressures. Traditionally surgical training has
52
53 occurred by the master-apprentice model involving a process of graduated responsibility, but
54
55 a modern alternative is to use simulation for the early stages of training. It is not known if
56
57 simulation training for junior trainees can safeguard patients and improve clinical outcomes.
58
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3 This paper details the protocol for a multicentre randomised controlled educational trial of a
4
5
6 cadaveric simulation training intervention versus standard training for junior postgraduate
7
8 orthopaedic surgeons-in-training. This is the first study to assess the effect of cadaveric
9
10 simulation training for open surgery on patient outcome. The feasibility of delivering
11
12 cadaveric training, use of radiographic and clinical outcome measures to assess impact and
13
14 the challenges of upscaling provision will be explored.
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19

20 **Methods and Analysis**

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22
23
24 We will recruit postgraduate orthopaedic surgeons-in-training in the first three years (of
25
26 eight) of the specialist training programme. Participants will be block randomised and
27
28 allocated to either cadaveric simulation or standard 'on-the-job' training, learning three
29
30 common orthopaedic procedures, each of which is a sub-study within the trial. The
31
32 procedures are 1) Dynamic Hip Screw(DHS), 2) hemiarthroplasty and 3) ankle fracture
33
34 fixation. These procedures have been selected as they are very common procedures which
35
36 are routinely performed by junior surgeons-in-training. A pragmatic approach to sample size
37
38 is taken in lieu of a formal power calculation as this is novel exploratory work with no a priori
39
40 estimate of effect size to reference. The primary outcome measure is the technical success
41
42 of the surgery performed on patients by the participating surgeons-in-training during the
43
44 follow-up period for the three sub-study procedures, as measured by the implant position on
45
46 the post-operative radiograph. The secondary outcome measures are procedure time, post-
47
48 operative complication rate and patient health state at 4 months post-operation (EQ-5D –
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50 substudies 1 and 2 only).
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Ethics, registration and dissemination

National research ethics approval was granted for this study by the NHS Research Authority South Birmingham Research Ethics Committee (15/WM/0464). Confidentiality Advisory Group approval was granted for accessing radiographic and outcome data without patient consent on 27 February 2017 (16/CAG/0125). The results of this trial will be submitted to a peer-reviewed journal and will inform educational and clinical practice.

Trial registration number

ISRCTN20431944; Pre-results

Protocol version V_P_1.1

Article Summary

Strengths and limitations of this study:

- This is the first randomised controlled trial assessing the impact of cadaveric simulation training on clinical outcomes
- Patient-centred outcome measures are used to measure an educational intervention for surgeons

- Multicentre study to maximize external validity of the results
- The training dose is small as cadaveric training is expensive to deliver
- Pragmatic approach to sample size which is limited by the capacity of the surgical training centre

Introduction

It is imperative that surgeons are trained to a high standard, so they can perform safe and effective operations for patients. The quality and quantity of surgical training in the UK is currently under threat from a 'perfect storm' of factors(1). These include reduced working hours(2, 3), shift based working patterns(4) with the loss of the traditional surgical firm, and a move to expedite training and shorten specialist programmes(5, 6). This is set within a climate of unprecedented financial austerity in the NHS and ever increasing service pressures.

Simulation offers a solution to some of these challenges by moving the early part of the surgical learning curve away from patients into a controlled environment(7), where skills may be more rapidly acquired as compared to the clinical environment. Simulation is also

1
2
3 potentially a very efficient way of training, as large numbers of trainees can be trained
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5 simultaneously, at an intensity not feasible in the clinical environment due to competing
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7 service demands.
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11
12 Cadaveric simulation - training using deceased, preserved or fresh human bodies - is a
13
14 particularly promising modality for training. Fresh-frozen cadavers retain many of the soft
15
16 tissue handling characteristics seen in live patients, and in combination with presenting the
17
18 correct anatomy, particularly complex neurovascular relationships, may offer a more realistic
19
20 simulated operation than would be possible on a plastic model or virtual reality simulator(8,
21
22 9). Cadaveric material does not bleed(10) and hence may be less useful for simulating
23
24 procedures where haemorrhage control is an important feature.
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32 The operating theatre environment can be simulated, including (but not limited to) surgical
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34 dress, draping, instrumentation and multidisciplinary team. This 'whole dress rehearsal' for
35
36 surgery may enhance development of non-technical skills in addition to the technical
37
38 operative surgical skills(11).
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44 There are several challenges in delivering cadaveric simulation training. It is expensive to
45
46 provide(9), particularly when cadaveric material has to be purchased under license where
47
48 there is not a local body donation programme. It requires considerable infrastructure to
49
50 deliver, including specialist wet laboratory facilities with the appropriately trained staff. These
51
52 challenges become particularly pressing when provision of cadaveric training on a large
53
54 scale is considered, and are an important driver in the development of high quality evidence
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3 of educational impact. This evidence is necessary before considerable financial investment
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5
6 can be recommended in providing cadaveric simulation training on a larger scale.
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9

10 There is abundant low quality evidence showing cadaveric simulation may induce short term
11
12 skill improvement as measured by subjective and behavioural metrics, but there is a lack of
13
14 high quality, quantitative evidence that skills learnt in cadaveric simulation can transfer to the
15
16 workplace, leading to improved outcomes for patients(8).
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22 Our trial attempts to address this evidence deficit, and is both topical and timely.
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30 Good Clinical Practice

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33 This trial will be undertaken in compliance with Good Practice Guidelines, complying with the
34
35 Declaration of Helsinki and UK Legislation. Warwick standard operating procedures (SOPs)
36
37 will be followed.
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44 Consolidated Standards of Reporting Trials

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48 The results of the trial will be reported in line with the Consolidated Standard of Reporting
49
50 (CONSORT) statement(12). This protocol has been written according to the SPIRIT
51
52 reporting guidelines(13).
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58 Aim

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6 The aim is to determine which of the two surgical training strategies for junior orthopaedic
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8 surgeons-in-training leads to the best patient outcomes for three common procedures.
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18 Objectives

- 22 1. To assess the impact of a cadaveric simulation training intervention on the patient
23
24 outcome of operations performed by junior orthopaedic surgeons-in-training
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- 27 2. To define the early learning curve of DHS, Hemiarthroplasty and ankle fracture
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29 fixation
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- 32 3. To explore the feasibility of using post-operative x-rays to assess technical skill
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40 Methods and Analysis

41 42 43 44 Study design

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48 This is a UK multicentre, two-arm, group parallel randomised controlled educational trial
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53 54 Sample size

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3 This trial is the first attempt to objectively measure transfer of open operative skills from
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5
6 cadaveric simulation into the workplace using patient-based outcome measures. There is no
7
8
9 available estimate of effect size to reference against a priori in determining sample size,
10
11 therefore a pragmatic approach to sample size will be taken in lieu of a formal power
12
13 calculation. The surgical training centre can accommodate 16 delegates at one time and
14
15 financial resources permitted one iteration of the cadaveric training course. Our maximum
16
17 sample size is therefore 16 participants in each arm of the study
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24

25 Outcome measures

26 27 28 29 A) Radiographic outcomes

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34 The radiographs will be obtained electronically from hospital servers and the implant position
35
36 measured manually using computer software. The operations will be identified
37
38 retrospectively by access to the participating surgeons' electronic logbooks. The
39
40 measurements vary by operation type and are defined as follows.
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42
43
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48 **Sub-study 1: Dynamic Hip Screw**

49 50 51 1. Primary Outcome

- 52
53 ▪ Tip-Apex distance (in mm)

54 55 56 2. Secondary Outcomes (in order of importance)

- 57
58 ▪ Lag screw position in the femoral head (defined by Cleveland Zones)

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- Plate flush to lateral femoral cortex (binary Y/N)
 - 8 cortex hold for plate screws (binary Y/N)

Sub- study 2: Hemiarthroplasty

1. Primary Outcome
 - Leg length discrepancy (mm)
2. Secondary Outcomes (in order of importance)
 - Femoral stem alignment (degrees off neutral)
 - Cement mantle quality (Barrack grade score)
 - Femoral offset change relative to native hip (mm)

Sub- study 3: Ankle fracture fixation

1. Primary Outcome
 - Medial clear space (mm)
2. Secondary Outcomes
 - Lateral malleolar displacement (mm)
 - Tibiofibular clear space (mm)
 - Talocrural angle (degrees)
 - Medial malleolar displacement (mm)

B) Clinical Outcomes

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6 The clinical outcome measures for sub-studies 1-3 are;
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10 1) Procedure Time
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15 Defined as knife-to-skin/surgical start time to wound closure/surgical stop time. These will be
16
17 obtained from hospital theatre management systems. Procedure time has been chosen as
18
19 an outcome measure as there is evidence in the literature that procedure time is inversely
20
21 related to experience, and so can be used as a surrogate measure of technical
22
23 proficiency(14)
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30 2) Intra-operative radiation dose to patient
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35 Defined as time under fluoroscopy (seconds) and radiation dose (mGym²). There is
36
37 evidence that with increasing experience and skill, surgeons use less intra-operative x-rays
38
39 to adjust the position of the fracture and implant(14). Hemiarthroplasty does not require
40
41 fluoroscopy so this will not be used as an outcome measure for sub-study 2.
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43
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47 3) Post-operative complication rate
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51 The complications of interest are the acute post-operative complications during the inpatient
52
53 admission. These will be sub-categorised as acute medical complications (hospital acquired
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55 pneumonia, renal complications, cardiac complications, DVT/PE) and surgical complications
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57 (wound infection, wound dehiscence, metalwork failure, deep infection).
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6 4) Health state at 4 months post-operation (EQ-5D)
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10 Health state at 4-months post-operation will be measured using EQ-5D, which is a
11
12 standardized instrument measuring generic health status, which has been widely validated
13
14 in clinical trials. This data is being collected separately as part of the WHiTE comprehensive
15
16 cohort study of hip fracture patients (ISRCTN63982700) and reported elsewhere(15). EQ-5D
17
18 will be used for sub-studies 1 and 2 only as these involve hip fractures.
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27 Screening and eligibility
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32 Orthopaedic surgeons-in-training in their first, second or third specialist training year in the
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34 West Midlands Workforce Deanery will be eligible to participate in the trial. Eligible trainees
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36 will be identified by liaison with the training programme directors for Trauma & Orthopaedic
37
38 surgery in the three West Midlands schools; Warwick, Birmingham and Oswestry. An
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40 invitation email will be sent to all eligible trainees by programme administrators at the
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42 deanery.
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51 Inclusion criteria
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- 56 1) Trauma & Orthopaedic surgeon-in-training in West Midlands school
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58 (Warwick/Birmingham/Oswestry)
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- 3
- 4 2) In specialty training year 1-3
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- 6 3) Willing and able to attend a two-day cadaveric simulation training course at the West
- 7
- 8 Midlands Surgical Training Centre, Coventry
- 9

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13 Exclusion criteria

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- 18 1) Unavailable on course dates
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25 Consent

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30 Surgeon participants:

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35 Potential study participants will be provided with written and verbal information about the
36 study. Consent will be obtained by the trial team. The right to refuse participation without
37 giving reasons will be fully respected, and enrolled participants will be free to withdraw from
38 the study at any time without reason, and without prejudice to their training. All participants
39 will be provided with the contact information of a team member who can provide further
40 information about the study. All participants who are allocated to the control group will have
41 the opportunity to undertake the cadaveric simulation training intervention at the end of the
42 study follow-up. This provision is being offered so that the control group are not
43 disadvantaged in their access to educational opportunity by virtue of being randomised to
44 the control group.
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3 Patients whose operations are assessed:
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8 Patients who undergo an operation by a surgeon who is participating in the study will not be
9
10 separately consented to allow access to radiographs to assess their implant position or
11
12 clinical outcome data. Permission to access this information for the purposes of this study
13
14 without patient consent has been granted from the confidentiality advisory group
15
16 (16/CAG/0125). It is recognised that seeking consent from a group of primarily elderly, frail
17
18 patients to assess low risk, routine clinical data in a secure manner for a trial they are not
19
20 directly participating in would be unduly burdensome for the patients. All patient data will be
21
22 fully anonymised and handled securely in line with university data regulations.
23
24
25
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29

30 Randomisation

31
32
33

34 Participants will be randomised at the point of recruitment using block randomisation (block
35
36 size 4) to generate a random sequence list, to which participants will be assigned in the
37
38 order that they enter the study. The allocation sequence will be generated by a senior
39
40 medical statistician, participants will be enrolled by the trial team.
41
42
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49 Postrandomisation withdrawals

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53 Withdrawn participants will not be replaced.
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57

58 Study setting

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6 The study participants will be on training rotations within the regional hospitals of the West
7
8 Midlands during the study follow-up. The hospitals where trainees have been working, and
9
10 performing operations, during the study follow up will be identified from the participants
11
12 electronic surgical logbook records.
13
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20 Interventions

21 22 23 24 25 Control group

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29
30 The control group will undertake standard residency training according to the master-
31
32 apprentice model, which is the current standard practice in UK. No additional training or
33
34 access to learning materials will be provided beyond the fortnightly didactic teaching
35
36 sessions which are delivered as a part of routine training.
37
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39
40

41 42 Intervention group (cadaveric simulation trained)

43
44
45
46 Participants allocated to the intervention group will receive an intensive, 2-day cadaveric
47
48 simulation training course at the start of the training year, where 4 common orthopaedic
49
50 surgical procedures will be taught (DHS, hemiarthroplasty, ankle fracture fixation and lower
51
52 limb fasciotomy). All intervention participants will receive training on all 4 procedures, which
53
54 will be considered separately in the analysis as individual sub-studies (as they have different
55
56 radiographic outcome measures). The fasciotomy procedure is included as a 'filler' to make
57
58
59
60

1
2
3 the course structure work, and chosen because it is an important high-stakes, anatomically
4
5
6 critical operation that is rarely performed by trainees. Outcomes related to the fasciotomy
7
8 procedure will not be collected or included in the analysis.
9

10 11 12 13 14 15 The cadaveric simulation training course 16

17
18
19
20 The course will be delivered in September at the start of the surgical training year (which
21
22 runs August to August). The course will take place at the West Midlands Surgical Training
23
24 Centre (WMSTC) at the University Hospital Coventry & Warwickshire (UHCW). The WMSTC
25
26 is a specialized wet-laboratory facility for delivering cadaveric training, and has an
27
28 experienced dedicated faculty to facilitate training delivery.
29
30
31

32
33
34 The course will consist of two full days of teaching, with expert consultant faculty teaching on
35
36 fresh-frozen hemi-cadavers (waist-to-toe-tip). The participant:faculty ratio will be 2:1, and
37
38 participant:cadaver ratio will be 2:1. Each participant will undertake each of the four
39
40 procedures in their entirety as primary surgeon('skin-to-skin'), and will act as assistant when
41
42 their partner is the primary surgeon four times. Hence each participant is exposed to eight
43
44 procedures during the course:
45
46
47
48
49
50
51

52
53 The environment and psychological fidelity of the simulation will be maximised by providing;
54
55

- 56
57
58 • Full surgical dress including masks, gloves, gowns and lead x-ray aprons
59
60

- The usual disposable surgical drapes
- Skin preparation (iodine solution) to prepare the surgical site, and participants and faculty will be asked to observe the usual sterile field precautions as in real theatre
- Full surgical instrument trays, surgical implants and cement (for hemiarthroplasty) of the same type as in real theatre will be used
- Image intensifier (mobile x-ray) will be available for intra-operative use
- Background noise levels and room temperature were maintained at what would usually be expected in the operating theatre

The simulated operating theatres will be set up within the WMSTC as two parallel round-robin circuits. The two stations requiring x-ray use (DHS and ankle ORIF) will be set up at the far end of the room to create a radiation zone and where appropriate, standard precautions will be used. Careful consideration will be given to the optimum sequential use of the cadaveric specimens in planning the course structure. For example, it is necessary that the DHS station precedes the hemiarthroplasty station as it would obviously not be possible to perform a DHS operation when the femoral head had been removed. Similarly, the fasciotomy incisions would compromise the soft tissue envelope of the lower limb to a sufficient degree that the fidelity of the ankle ORIF station would be compromised. It is important to make the best and most efficient use of the cadaveric material, for both ethical and financial reasons.

Blinding

1
2
3 The participants cannot be blinded to the type of training they receive, neither can the trial
4
5 team in organising the cadaveric simulation training. The trial team will take no part in the
6
7 training of participants. The assessment of radiographic images will be made blinded to
8
9 group allocation.
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14

15 Adverse event management

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19
20 In the unlikely event of a serious adverse event (SAE), the chief investigator will report to the
21
22 sponsor (University of Warwick), ethics committee and project supervisors.
23
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26

27 Patient and public involvement

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31
32 There was no direct patient or public involvement in the design of the study, although clearly
33
34 training competent surgeons is in the public interest. There is qualitative work to be done
35
36 around this trial to better understand patient expectations of surgical training.
37
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39
40

41 End of trial

42
43
44
45
46 The trial will end when all the radiographic and clinical outcome data has been collected
47
48 from the participating sites. The trial will be stopped prematurely if required by the ethics
49
50 committee, following recommendations from the sponsor, or if funding for the study is
51
52 withdrawn. The research ethics committee and confidentiality advisory group will be notified
53
54 in writing once the trial is complete.
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Trial Oversight

This trial is being undertaken as part of a doctoral research project (HKJ), and supervised by three senior supervisors (DG, JF, GTRP). The supervisors will act as the trial management group and steering committee. The trial is being conducted within a registered Clinical Trials Unit, and will follow the CTU standard operating procedures.

Data Collection Plan

Data on the numbers of procedures performed by the participating surgeons at baseline will be collected. The operations performed by the participants during study follow-up will be identified by the surgeons' electronic logbook. Only procedures coded as 'S-TS: supervised-trainer scrubbed' or 'STU: supervised trainer unscrubbed' will be included in the analysis.

This is to ensure that only procedures where the trainee has performed the key parts (S-TS) or the entire procedure (STU) are included. If further information on supervisor input/takeover is required this can be obtained by accessing the corresponding procedure based assessment (PBA) record for the operation. PBAs are routinely collected as part of training.

Procedure data will be extracted and anonymised to study identifier by the electronic logbook data team, before being sent to the trial team. The data will include operation type, date, hospital, hospital ID, patient age, American Society of Anaesthesiologists Grade and supervision code. The radiographs and clinical outcome data relating to these procedures will then be obtained from the study sites via liaison with the respective Research &

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3
4 Development Departments. Data will be entered into a secure trial database on a
5
6 professionally encrypted trial-specific computer, fully anonymised with only study identifiers.
7

8
9 Once data collection is complete, and prior to analysis, range checks for data values will be
10
11 undertaken, and data will be double checked on entry to the statistical software package.
12

13
14 The project supervisors will act as the data monitoring committee. No interim analysis will be
15
16 undertaken. The trial team and statistician will have access to the final trial dataset.
17

18 19 20 Statistical Analysis Plan 21

22
23
24
25 Baseline data including completed months of training and number of prior procedures
26
27 performed will be summarised and compared between the two arms of the study. A
28
29 CONSORT chart showing the flow of participants through the study will be produced.
30

31
32 The three taught procedures (substudies 1-3) will be analysed and reported individually.
33
34

35
36
37 The main analysis will investigate and report differences between the two groups with
38
39 respect to the implant positions (as measured from radiographs), the procedure times, the
40
41 intra-operative radiation dose to the patient, and patient outcomes, as measured by post-
42
43 operative complications and health state at 4 months post-operation (hip fractures only).
44
45

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47
48
49 Statistical tests will be two-sided and considered to demonstrate a significant difference
50
51 when $p < 0.05$. Temporal trends by group for implant position, procedure time and radiation
52
53 dose will be presented. Linear mixed effects models will be fitted to allow for within-surgeon
54
55 correlation between repeated observations (surgeon clustering as a random effect), and to
56
57 adjust for important co-variables such as patient condition, age and surgeon experience.
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3 These will be summarised by plotting individual learning curves, and then modelled to
4
5
6 estimate the overall learning curves for the two arms of the study.
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10 Descriptive statistical analyses of between-group comparisons will be presented for
11
12 complication rate and health state, with temporal analysis of the latter being reported if
13
14 appropriate and feasible. The statistical analysis will be supervised and checked by a senior
15
16 medical statistician at Warwick University.
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21
22 In the event of missing data, statistician advice will be sought on multiple imputation.
23
24
25

26 27 Ethics and dissemination 28 29 30

31
32 Master-apprentice 'on-the-job' training for surgeons is the current training standard in the
33
34 UK(10, 16), and therefore the control arm of the study reflects usual practice. The cadaveric
35
36 simulation training intervention is an experimental educational intervention and does not
37
38 expose trial participants to any substantial risks of harm. The trial results will be reported in
39
40 accordance with the CONSORT statement, and disseminated through publication in peer
41
42 reviewed journals and conferences. The results of the trial will be presented to Health
43
44 Education England and the Royal Surgical College. The dataset, statistical code and
45
46 technical appendices will be made available on request to the corresponding author. The
47
48 study was approved by the NHS Research Authority South Birmingham Research Ethics
49
50 Committee (15/WM/0464).
51
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58 Funding 59 60

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5
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7
8
9

10 Sponsor Contact Information
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29 Declaration/Conflict of Interests
30
31

32 None to declare
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59 References:
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Author Statement/Contributions

HKJ designed the study and wrote the manuscript

GTRP co-designed the study and the intervention and edited the manuscript

1
2
3 JDF edited the manuscript, made a substantial contribution to the design and is lead
4 supervisor for the qualitative part of the project
5
6 DG co-designed the study, edited draft protocols and is lead supervisor for the
7 quantitative part of the project
8
9

10
11 Acknowledgements
12

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14 None
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For peer review only

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	#3	Date and version identifier	3
Funding	#4	Sources and types of financial, material, and other support	15
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1

1	Roles and	#5b	Name and contact information for the trial sponsor	15
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7				
8	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	14
9	responsibilities:		collection, management, analysis, and interpretation of data;	
10	sponsor and funder		writing of the report; and the decision to submit the report for	
11			publication, including whether they will have ultimate	
12			authority over any of these activities	
13				
14				
15				
16	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	14
17	responsibilities:		centre, steering committee, endpoint adjudication committee,	
18	committees		data management team, and other individuals or groups	
19			overseeing the trial, if applicable (see Item 21a for data	
20			monitoring committee)	
21				
22				
23				
24	Introduction			
25				
26				
27	Background and	#6a	Description of research question and justification for	1
28	rationale		undertaking the trial, including summary of relevant studies	
29			(published and unpublished) examining benefits and harms	
30			for each intervention	
31				
32				
33				
34	Background and	#6b	Explanation for choice of comparators	11
35	rationale: choice of			
36	comparators			
37				
38				
39	Objectives	#7	Specific objectives or hypotheses	5-6
40				
41	Trial design	#8	Description of trial design including type of trial (eg, parallel	5
42			group, crossover, factorial, single group), allocation ratio, and	
43			framework (eg, superiority, equivalence, non-inferiority,	
44			exploratory)	
45				
46				
47				
48	Methods:			
49	Participants,			
50	interventions, and			
51	outcomes			
52				
53				
54				
55	Study setting	#9	Description of study settings (eg, community clinic, academic	10
56			hospital) and list of countries where data will be collected.	
57			Reference to where list of study sites can be obtained	
58				
59				
60				

1	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
2				
3				
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5				
6	Interventions:	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-13
7	description			
8				
9				
10				
11	Interventions:	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A – educational trial
12	modifications			
13				
14				
15				
16				
17				
18	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A – educational trial
19	adherence			
20				
21				
22				
23				
24	Interventions:	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A – educational trial
25	concomitant care			
26				
27				
28				
29	Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	6-7
30				
31				
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40	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
41				
42				
43				
44				
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46				
47	Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
48				
49				
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54	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
55				
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Methods:**Assignment of interventions (for controlled trials)**

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A - educational trial

Methods: Data collection, management, and analysis

Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for	14

participants who discontinue or deviate from intervention protocols

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2			
3			
4	Data management	#19	Plans for data entry, coding, security, and storage, including 14
5			any related processes to promote data quality (eg, double data
6			entry; range checks for data values). Reference to where
7			details of data management procedures can be found, if not in
8			the protocol
9			
10			
11			
12	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary 14-15
13			outcomes. Reference to where other details of the statistical
14			analysis plan can be found, if not in the protocol
15			
16			
17	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and 14-15
18	analyses		adjusted analyses)
19			
20			
21	Statistics: analysis	#20c	Definition of analysis population relating to protocol non- 15
22	population and		adherence (eg, as randomised analysis), and any statistical
23	missing data		methods to handle missing data (eg, multiple imputation)
24			
25			
26			
27	Methods: Monitoring		
28			
29	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary 14
30	formal committee		of its role and reporting structure; statement of whether it is
31			independent from the sponsor and competing interests; and
32			reference to where further details about its charter can be
33			found, if not in the protocol. Alternatively, an explanation of
34			why a DMC is not needed
35			
36			
37			
38			
39	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines, 14
40	interim analysis		including who will have access to these interim results and
41			make the final decision to terminate the trial
42			
43			
44	Harms	#22	Plans for collecting, assessing, reporting, and managing N/A –
45			solicited and spontaneously reported adverse events and other educational
46			unintended effects of trial interventions or trial conduct trial
47			
48			
49	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, N/A –
50			and whether the process will be independent from educational
51			investigators and the sponsor trial
52			
53			
54			
55	Ethics and		
56	dissemination		
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1	Research ethics	#24	Plans for seeking research ethics committee / institutional	3
2	approval		review board (REC / IRB) approval	
3				
4				
5	Protocol amendments	#25	Plans for communicating important protocol modifications	N/A –
6			(eg, changes to eligibility criteria, outcomes, analyses) to	educational
7			relevant parties (eg, investigators, REC / IRBs, trial	trial
8			participants, trial registries, journals, regulators)	
9				
10				
11	Consent or assent	#26a	Who will obtain informed consent or assent from potential	9
12			trial participants or authorised surrogates, and how (see Item	
13			32)	
14				
15				
16				
17	Consent or assent:	#26b	Additional consent provisions for collection and use of	N/A –
18	ancillary studies		participant data and biological specimens in ancillary studies,	educational
19			if applicable	trial
20				
21				
22	Confidentiality	#27	How personal information about potential and enrolled	14
23			participants will be collected, shared, and maintained in order	
24			to protect confidentiality before, during, and after the trial	
25				
26				
27	Declaration of	#28	Financial and other competing interests for principal	16
28	interests		investigators for the overall trial and each study site	
29				
30				
31	Data access	#29	Statement of who will have access to the final trial dataset,	14
32			and disclosure of contractual agreements that limit such	
33			access for investigators	
34				
35				
36				
37	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	N/A –
38	trial care		compensation to those who suffer harm from trial	educational
39			participation	trial
40				
41				
42	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	15
43	trial results		results to participants, healthcare professionals, the public,	
44			and other relevant groups (eg, via publication, reporting in	
45			results databases, or other data sharing arrangements),	
46			including any publication restrictions	
47				
48				
49				
50	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	15
51	authorship		professional writers	
52				
53				
54	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	N/A
55	reproducible research		participant-level dataset, and statistical code	
56				
57				

Appendices

1	Informed consent	#32	Model consent form and other related documentation given to	Appendix
2	materials		participants and authorised surrogates	
3				
4	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	N/A –
5			biological specimens for genetic or molecular analysis in the	educational
6			current trial and for future use in ancillary studies, if	trial
7			applicable	
8				
9				
10				

11 None The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-
12 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made by the
13 [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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15