TRIAL PROTOCOL

Full title: Suture fixation versus tension band wiring for simple olecranon fracture fixation: a multi-centre randomised controlled trial (Simple Olecranon Fracture Fixation Trial – SOFFT)

Short title: Simple Olecranon Fracture Fixation Trial – SOFFT

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Sponsor: Wrightington, Wigan and Leigh NHS Foundation trust

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Abbreviations and Glossary

AE	Adverse event
API	Associate Principal Investigator
APR	Annual Progress Report
CF	Consent form
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials statement
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
DASH	Disabilities of the Arm Shoulder and Hand
DCF	Data Clarification Form
DMC	Data Monitoring Committee
EQ5D-5L	EuroQol 5 Dimensions (5L) Score
EUDRACT	European Union Drug Regulatory Agency Clinical Trial
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
HTA	Health Technology Assessment
ICH	International Conference on Harmonisation
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site Files
ISRCTN	International Standard Randomised Controlled Trial Number
MHRA	Medicines and Healthcare Regulatory Authority
NHS	National Health Service
NIHR	National Institute for Health Research
PAG	Patient Advisory Group
PI	Principal Investigator
PIS	Patient Information Sheet
QoL	Quality of life
PSS	Personal Social Service
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWAT	Study Within a Trial
TMF	Trial Master File
TSC	Trial Steering Committee
UAR	Unexpected adverse reaction
VAS	Visual Analogue Scale
YTU	York Trials Unit

Contents

Amendment History/Changes from previouss version

Amendment Number	Revised Protocol Version Number and date	Details of changes made (including justification if required)
NA (Change from Detailed Project Description)	1 (04.03.2020)	Section 4.4.2: Addition of participant exclusion criteria of previous study entry and bilateral olecranon fractures based on DMC recommendation. Section 4.6: Surgeon training. Sawbone training has been added as an alternative to cadaveric training. Section 4.9.2: Addition of Net Promoter Score as a measure of patient satisfaction.
NA (Changes requested during REC review)	1.1 (21.05.2020)	Section 4.6: Surgeon training. Text added to clarify training requirements for all participating surgeons. Other minor corrections to ensure consistency made throughout.

Trial Synopsis

Acronym	SOFFT
Long title	Simple Olecranon Fracture Fixation Trial (SOFFT): Suture fixation versus tension band wiring for simple olecranon fracture fixation: a multi-centre randomised controlled trial
Type of Trial	Non-CTIMP
Study design	A large pragmatic, two-arm, parallel group, individually randomised, controlled trial.
Setting	Participating secondary care centres with UK Major Trauma Centres and Trauma Units within the UK treating olecranon fractures and with facilities to support research activity.
Target population	Patients aged 16 years and over with a clinical diagnosis of a Mayo Grade IIA acute olecranon fracture requiring surgical fixation.
Intervention	Tension suture repair
Control	Standard tension band wiring
Primary outcome	The primary outcome is the Disabilities of the Arm Shoulder and Hand (DASH) score at 4 months follow-up.
Secondary outcomes	DASH (at 12, 18, and 24 months), re-operations related to the injury or to remove metalwork, pain score, EuroQol 5 Dimensions (5L) Score (EQ5D-5L), radiological union, complications, elbow range of movement, resource use and work impact.
Estimated recruitment period	24 months (target date of first enrolment 01/05/2020)
Duration per patient	18 to 24 months approximately.
Estimated total trial duration	54 months duration (1 November 2019 to 30 April 2024)
Planned trial sites	Up to 35
Planned sample size	280 (140 in the intervention group and 140 in the control group)
Main eligibility	**Inclusion criteria**

criteria	• Patients aged ≥ 16years • Mayo Grade IIA acute olecranon fracture within 3 weeks of injury • Closed or Gustillo and Anderson grade 1 open injury • The surgeon believes the patient will benefit from surgical intervention • Ability to give informed consent **Exclusion criteria** • Surgery contra-indicated • Gustillo and Anderson grade 2 or 3 open injury • Associated upper limb injuries or prior upper limb pathology adversely affecting function • Evidence of fracture comminution (Mayo Grade IIB) or instability around the elbow and/or forearm (Mayo Grade III) • Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires • Previous entry into SOFFT • Concurrent olecranon fracture in the opposite limb

Simple Olecranon Fracture Fixation Trial (SOFFT) Study Flow chart:

Set up, months 1-6; internal pilot, months 7-15

Main Study: Recruitment, months 16-30; 18 month follow-up, months 31-48

Analysis and reporting; 49-54 months

Patients with Olecranon fractures

Inclusion Criteria:

- ≥16 years old
- Acute olecranon fracture (Mayo Grade IIA) within 3 weeks of injury
- Closed injury or Gustillo and Anderson grade 1
- The surgeon believes the patient will benefit from surgical intervention
- Ability to give informed consent

Exclusion Criteria:

- Surgery contra-indicated
- Gustillo and Anderson grade 2 and 3 open injuries
- Associated upper limb injuries or prior upper limb pathology adversely affecting function
- Evidence of fracture comminution (Mayo Grade IIB) or instability around the elbow and/or forearm (Mayo Grade III)
- Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires
- Previous entry into SOFFT
- Concurrent olecranon fracture in the opposite limb

Baseline

- DASH
- VAS (Pain)
- EQ5D-5L
- X-ray

Randomise
280 patients

Tension Suture Repair (n = 140)

Novel technique using no 2 synthetic braided suture as described by Das and Watts[34]

- Perioperative data collected

Tension Band Wiring (n = 140)

AO OTA technique with 2 x 1.6mm K-wires and cerclage wire

- Perioperative data collected

4 Months follow-up (clinic)

- DASH ***(primary outcome)***, pain (VAS), EQ5D-5L
- Reoperation
- Elbow range of movement
- Fracture union using radiographic assessment
- Complications
- Return to work and normal activities

12 and 18 Months follow-up

- DASH, pain (VAS), EQ5D-5L
- Reoperation
- Complications
- Return to work and normal activities

24 Months follow-up (for those that reach this timepoint by month 48)

- DASH, pain (VAS), EQ5D-5L
- Reoperation
- Complications

Analysis

Draft HTA Report; dissemination

Internal pilot

- Number of sites open
- Number of eligible participants
- Number recruited
- Number randomised
- Number of crossovers
- Fidelity of intervention

Abbreviations

DASH – Disabilities of the Arm, Shoulder and Hand Questionnaire

EQ5D- 5L - EuroQoL 5 dimension 5 level

VAS – Visual Analogue Scale

Study Assessment Schedule

Assessment (M=month)	**Baseline[1] (Clinic)**	**Randomisation**	**Intervention**	**M4 (Clinic)**	**M12 (Postal Questionnaire)**	**M18 (Postal Questionnaire)**	**M24[2] (Postal Questionnaire)**
Allowed variation in days				+/- 14			
Eligibility screen	x						
Informed consent	x						
Randomisation		x					
Assessments							
DASH	X[3]			x	x	x	x
VAS (pain)	x			x	x	x	x
Net Promotor Score				x	x	x	x
Euroqol EQ-5D-5L	X[3]			x	x	x	x
X-ray	x			x			
Perioperative data			X[4]	x			
Elbow range of Movement				x			
Fracture union using radiographic assessment				x			
Patient & Surgeon preferences	x						
Treatment Information				x			
Reoperation				x	x	x	x
Complications				x	x	x	x
Resource Use				x	x	x	x
Return to work and normal activities				x	x	x	x

[1]Baseline measures will be collected prior to randomisation
[2]For those participants who reach this timepoint by month 48
[3]Collected pre- and post-injury
[4]Intra-operative fluoroscopy images will be obtained

1. Background and rationale

1.1. General Introduction

The olecranon is the bony point positioned at the back of the elbow when the elbow is bent. Olecranon fractures are usually caused by a fall directly onto the olecranon or indirectly following a fall onto an outstretched arm (e.g. when trying to break a fall) (1). Direct trauma forces the olecranon into the distal end of the humerus causing the olecranon to break. With indirect trauma, more often seen in older people due to poor bone quality, the fracture is caused by the sudden contraction of the triceps on the semi-flexed elbow of the outstretched arm, which leads to a piece of the bone being pulled away (avulsion fracture) (1). The estimated UK incidence of olecranon fractures is 12 per 100,000 population (2). Approximately three quarters of all olecranon fractures are displaced (i.e. the fractured pieces of bone are incorrectly aligned with ≥ 2mm separation of bone fragments), simple (two fragments) fractures with a stable ulnohumeral joint, classified as Mayo Type IIA and require surgery (2).

The purpose of surgical management is to realign the bone fragments, internal fixation methods keep the bone fracture stable and allow healing, early mobilisation and rehabilitation (1). Currently, displaced fractures of the olecranon with a stable ulnohumeral joint are commonly managed by open reduction and internal fixation (open surgery to realign the fractured bone fragments and maintain that position), using internal fixation methods to keep the bone fracture stable to allow healing, early mobilisation and rehabilitation. The traditional approach which is the current predominant method of management, both in the UK and internationally, is a low-cost technique using tension band wiring with two parallel/ longitudinal Kirschner wires (k-wires) and a cerclage wire in a ‘figure of 8 loop’. Whilst surgical outcome with tension band wiring for Mayo IIA olecranon fractures is good with high rates of satisfaction and fracture union, (3, 4) there are risks of improper wire placement, joint penetration, nerve or blood vessel injury, restriction of movement, wire migration that can threaten the skin, and non-union of the bone. Furthermore, due to the prominence of the metal work under the skin, a common complication after fixation with tension band wiring is that the metal work causes pain when leaning on the elbow, or can break the skin. Thus, patients may require a second

surgery to remove the wires, with the associated surgical risks and delayed recovery for patients and costs for the NHS.

The need to undergo surgery to remove the hardware used for internal fixation exposes a patient to the risk of surgery and undergoing general anaesthesia for a second time. This is of concern to all patients but particularly for elderly patients who are more likely to have co-morbidities which may expose them to greater risk from general anaesthesia. The surgery to remove hardware is usually done as a day case but may require one night in hospital. Evidence suggests that there is variation across the country in re-operation for prominent metalwork: some centres routinely ask patients at their final follow up visit (around 12-16 weeks) whether they would like the metalwork removed whereas others only offer removal if the patient raises concerns. A Cochrane review estimated removal rates of tension band wiring in four RCTs ranged from 16% to 100% (5). Based on data provided by two Trusts for the grant application (34% and 24%) and a recent UK publication (50%) the mean removal rate in the NHS is estimated as 36% (6).

There are a number of alternative techniques for treating olecranon fractures; plate fixation is used for multi-fragmentary fractures and can produce good outcomes in simple fractures but re-operation rates are still approximately 30% and the plates are costly (7-9). Other devices have also been employed such as intramedullary nails, lag screws and tension plates (10-17).

Suture or suture anchor techniques have been described with the aim of reducing the hardware related complications and re-operation (18-21). From the suture anchor technique described by Ravenscroft (22), an all suture technique has been developed by Watts et al. to fix the fracture using strong synthetic sutures alone (21) which has been found to be promising. Development was aided by training ten senior Upper Limb Orthopaedic Fellows in the technique with no significant changes in the technique over this period required to achieve success. An initial cohort study of 10 patients found good outcomes with a mean Oxford Elbow Score of 41/48 and QuickDASH score of 9 at a minimum of 14 months for a mixture of simple olecranon fractures and osteotomies (18). A comparative multi-centre study of a consecutive series of patients with surgical treatment of

olecranon fractures has shown that the technique is safe and effective and may have advantages over traditional tension band wiring (23). A retrospective review of tension band wiring (89 patients) and tension suture repair using Watts' technique (28 patients) of simple olecranon fractures reported significantly fewer re-operations in the tension suture group (3.5%) compared to the tension band wiring group (34%) (p=0.0037). Fixation failure rates were similar between groups (1/28 patients in the tension suture group against 2/89 in the tension band wire group)(23).

Tension suture repair is considered less likely to require a second surgery to remove the fixation material, thereby reducing risk and inconvenience for the patient and saving the NHS money, without compromising the outcome. This approach involves neutralizing the deforming forces of triceps by passing strong synthetic sutures through the tendon to the bone distal to the fracture site, thereby transmitting this deforming force to the other side of the fracture and neutralizing the effect. A number of techniques have been described to achieve this tension suture repair but the technique described by Das and Watts will be studied as it is safe, simple, reproducible and easy to learn.

In addition to the risks of surgery, there is the inconvenience to patients of impaired ability to undertake usual activities for up to 2 weeks, including work for those in employment. Therefore, an intervention that was not inferior to the current method in terms of patient function, but that reduced the need for a second surgical procedure would have substantial patient benefit. In addition to reducing patient discomfort and the need for re-operation this research has the potential to save the NHS money as the suture surgery is likely to be less expensive to perform and less expensive in the long term if re-operation rates are reduced.

In a survey of ten orthopaedic surgeons participating in a cadaveric training course for the suture technique in 2018, nine reported that they would consider moving to the tension suture repair technique from tension band wiring, with the tenth surgeon already using it. All reported the technique to be reproducible and that no specific modifications were required. Surgeons are currently being trained in this technique through cadaveric courses

and 80 UK surgeons were taught the technique at a British Shoulder and Elbow Society (BESS) training course in October 2018.

A survey of BESS members conducted by the project team in July 2018, demonstrated that the technique is being adopted by an increasing number of surgeons in the UK supported by cadaveric training courses, larger cadaveric demonstrations and online learning tools.

1.2. Rationale and Justification for the Study

There are numerous studies looking at alternative ways to apply the tension band wiring technique to try to improve outcomes and reduce complications (7, 24-32). However, at present there is no high quality evidence from a randomised controlled trial (RCT) comparing the clinical and cost effectiveness of the tension suture repair compared to the traditional tension band wiring currently offered on the NHS for the internal surgical fixation of displaced fractures of the olecranon. This study will determine whether the functional outcome of the tension suture repair is non-inferior to the traditional approach of tension band wiring in restoring patient function and will provide sufficient benefit to patients and the NHS in terms of reduced second surgeries (5).

The rationale for potential cost savings for the NHS is based on costs obtained from the Finance Department of the sponsoring Trust. Suture for fixation is less expensive (£14) than tension band wiring (£31.21 based on a cost of £7 for two Kirschner wires plus £12 for one cerclage wire loop and £12.21 for kit sterilisation) and the theatre time for the surgical procedure is usually 20 minutes shorter for the suture repair.

A second operation to remove either type of hardware is costly (£3,082). Reducing the need for a second surgery to remove hardware with suture fixation would lead to substantially reduced costs for the NHS and society (i.e. £3,082 for surgery, reduced analgesia requirements and reduced societal costs from lost work days for secondary surgery). Based on the estimated incidence of 12 per 100,000 olecranon fractures of which 73% are Type IIA Mayo, there are approximately 3,800 such fractures in England in the 16+ years population. The initial cost saving for the primary surgery would be approximately £65,000/year due to lower material costs. Reducing the number of second surgeries from approximately 36% (n=1,368) to 4% (n=152) per year would save the NHS approximately £3.73 million per

annum (£4.2milllion to £0.47 million)(23). It is anticipated that there would also be societal cost savings with less time off work for the patient and fewer hospital attendances. These estimates are based on assumptions (e.g. that all other costs remain the same between the two interventions): the proposed study will provide robust evidence in this regard.

Therefore, the conduct of a randomised controlled trial to assess clinical and patient rated outcomes and cost effectiveness is timely, before this technique is more widely adopted without sufficient scientific or cost justification.

1.3. Risks and Benefits

Both procedures will have the general surgical risks of wound infection, haematoma, bleeding, wound healing problems, seroma, heart attack, stroke, venous thromboembolism and death.

Risks to participants from the intervention or control treatments are not increased through trial participation. Measures, such as our emphasis on good practice and standardised protocols/care pathways throughout, are likely to reduce risk and could bring additional benefits.

In the unlikely event that new information arises during the trial that may affect participants' willingness to take part, the TSC will review this information to determine whether changes are required to the patient information leaflet. A revised consent form will also be produced if necessary.

1.3.1. Risks of Tension Band Wiring

The specific risks associated with this technique include wire migration, wire breakage, bone tunnel fracture, loss of fracture reduction, ulnar nerve injury, median nerve injury, radial nerve injury, radioulnar synostosis, joint penetration by metalwork, heterotopic ossification and stiffness of the elbow.

Complications of infection (2-7%), nerve and blood vessel injury, joint penetration, scar tenderness, prominent metalwork, malunion, non-union (3%) and metalwork migration, heterotopic ossification and osteoarthritis have been reported (4, 33, 34). Rates of re-

operation vary between 16-100% for tension band wiring of olecranon fractures (4, 5, 34). The range of movement at the elbow is generally good following surgery but loss of extension has been reported and the Disabilities of the Arm Shoulder and Hand (DASH) score has been reported to be 18/100 at an average of four years after surgery.

1.3.2. Risks of Tension Suture Repair

The specific risks associated with this technique include suture failure, bone tunnel fracture, loss of fracture reduction and ulnar nerve injury, heterotopic ossification and stiffness of the elbow.

A reoperation rate of 3% was observed in a retrospective series of tension suture repair of olecranon fractures (23).

1.3.3. Potential Benefits

Within the trial, participants allocated to receive tension suture repair may experience benefit through avoiding repeat surgery and the associated complications of this.

Tension suture repair may be less likely to require a second surgery to remove the fixation material, thereby reducing the risks associated with surgery and the inconvenience for the patient, though the purpose of the study is to provide evidence regarding this.

2. Aims and Objectives

2.1. Aim

To investigate the clinical and cost-effectiveness of tension suture repair versus traditional tension band wiring for the surgical fixation of Mayo Grade IIA fractures of the olecranon.

2.1.1. Primary Hypothesis

The functional outcome, measured by the DASH score at 4 months, for the tension suture repair technique will not be inferior to traditional tension band wiring for the internal surgical fixation of Mayo Grade IIA fractures of the olecranon in adult patients over the age of 16 years.

2.2. Primary Objective

To undertake a multi-centre parallel group RCT to determine whether tension suture repair is not inferior to traditional tension band wiring for the internal surgical fixation of Mayo Grade IIA fractures of the olecranon in adult patients over the age of 16 years.

2.3. Secondary Objectives

- Undertake a 9-month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility.
- To undertake an analysis of the rate of re-operation.
- To investigate the cost-effectiveness of the two interventions from the NHS perspective in order to identify the most efficient provision of future NHS care and to describe the resource impact on the NHS for the two treatment options.

3. Trial Design

The trial objectives will be addressed using a multi-centre, parallel group, non-inferiority RCT within UK Major Trauma Centres and Trauma Units. There will be a 9-month internal pilot to assess assumptions about recruitment and fidelity of implementation of the tension suture technique. A report will be provided to the funder and subject to approval from the funder (assuming feasibility has been established) we will proceed to the main trial.

The study has a total 24-month recruitment period, including an internal pilot phase of 9 months at the start followed by the main recruitment period. Following baseline, randomisation and treatment, all participants will be followed up for 18 months including a follow up visits at 4 months post treatment then postal questionnaire to be completed by the participant at 12 months and 18 months as per the patient flow diagram. Those patients that reach 24 months within the planned follow-up period will be asked to complete an additional postal questionnaire at 24 months.

3.1. Pilot Study

We will undertake a 9-month internal pilot study to test our assumptions about recruitment and intervention fidelity to confirm whether the trial is feasible. Specifically, the ability to set up 24 study sites, the ability to recruit trial participants at an acceptable rate and achieve a goal of at least 80% follow-up of recruited patients for the primary outcome at the 4 month follow-up point. A recruitment rate, defined as the proportion of eligible patients recruited, of between 50% and 70% would indicate a green light for progression to the main trial; a recruitment rate between 45% and 49% would be an amber light with adjustments such as an increase in the number of recruiting sites to mitigate against the lower recruitment rate. A recruitment rate less than 45% would suggest the trial was not feasible.

Secondary reasons for undertaking the pilot will be to closely monitor operational aspects of the trial including surgeon training, participant eligibility and consent procedures, study activity and patient adherence.

The fidelity of tension suture repair will be a monitored using a surgeon-completed checklist, which has been developed to address surgeon adherence to the mandatory, prohibited and optional elements of the intervention. Reasons for use of prohibited elements will be recorded. Photographs will be obtained intra-operatively to enable independent assessment of fidelity of technique. There is some uncertainty about the feasibility of using intra-operative photography for this purpose and the internal pilot will be used to trial this method. If it is found to be feasible it will continue to be used throughout the whole trial. The use of photography to assess fidelity will be discontinued beyond the pilot phase if compliance rates are below 70% or if the quality of the images obtained do not allow adequate assessment of fidelity in more than 30% of images received.

Surgeons will complete the checklist at the end of each procedure and the checklist and intra-operative photographs will be assessed by the CI or a second clinical co-investigator for repeated variation from technique. In addition, intra-operative lateral radiographs of the elbow in flexion and extension, captured as part of routine care, will be assessed by two independent radiologists to assess adequacy of reduction and maintenance of reduction under stress.

The internal pilot will be reviewed by the Data Monitoring Committee (DMC) who will review the pilot data and make a recommendation to the Trial Steering Committee and Trial Management Group regarding any changes required and also to the funding body who will determine whether the study progresses to the full trial.

4. Methods

4.1. Participants

Adults ≥16yrs of age who have sustained a Mayo Grade IIA fracture of the olecranon requiring surgical fixation.

4.2. Study Setting

Patients will be recruited from Trauma and Orthopaedic Departments of NHS Major Trauma Centres and Trauma Units within the UK treating olecranon fractures and with facilities to support research activity. A list of all study sites will be maintained by the trial management team and held in the trial master file.

4.3. Selection of Patients

The flow of patients through this trial is illustrated in the study flow chart (Page 12). Participants will be identified by orthopaedic surgeons and research staff who will be responsible for recording and reporting information in the case report forms (CRFs).

4.4. Eligibility Criteria

We will include all adult patients (16 years or older) with Mayo Grade IIA acute olecranon fractures who meet the eligibility criteria below.

Any questions raised about eligibility will be addressed prior to entering the participant into the study. There will be no exceptions (waivers) to eligibility criteria prior to participant inclusion into the study.

4.4.1. Participant Inclusion Criteria

- Patients aged ≥ 16years
- Mayo Grade IIA acute fracture within 3 weeks of injury
- Closed or Gustillo and Anderson grade 1 open injury
- The surgeon believes the patient will benefit from surgical intervention
- Ability to give informed consent

4.4.2. Participant Exclusion Criteria

- Surgery contra-indicated
- Gustillo and Anderson grade 2 or 3 open injury
- Associated upper limb injuries or prior upper limb pathology adversely affecting function
- Evidence of fracture comminution (Mayo Grade IIB) or instability around the elbow and/or forearm (Mayo Grade III)
- Evidence that the patient would be unable to adhere to trial procedures or complete questionnaires
- Previous entry into SOFFT
- Concurrent olecranon fracture in the opposite limb

4.5. Interventions

Eligible and consenting patients will be randomly allocated to either tension suture repair or standard tension band wiring.

Participants will undergo treatment as per the randomisation allocation under the care of one of the participating surgeons.

Study treatments should be given as soon as practical following recruitment. The timing of treatment is determined by local service pressures, however NICE guidelines recommend surgical treatment within 72 hours of a decision to operate for other low energy trauma (https://www.nice.org.uk/guidance/NG38/chapter/Recommendations#ongoing-orthopaedic-management).

Postoperative management will be as per routine practice at participating sites.

4.5.1. Standard Tension Band Wiring

This will be undertaken according to standard AO technique using two longitudinal K-wires and one or two steel cerclage wires in a figure of eight configuration to provide compression through a transverse 2.5mm drill hole in the ulna distal to the fracture site. All participating surgeons will be invited to a training course to revise the standard AO technique of tension band wiring of the olecranon and the ten criteria established by Schneider for optimal technique (35).

4.5.2. Tension Suture Repair

The mandatory, prohibited and optional elements of the tension suture repair intervention are defined as the following; accurate fracture reduction, compression with a clamp, a transverse 2.5mm drill hole placed in the ulna distal to the fracture site (no less than 2mm, no more than 3.5mm), repair with two lengths of Number 2 synthetic braided suture passed through the drill hole and the insertion of triceps to the olecranon (no less than 2 sutures, more than two sutures can be use up to a maximum of 4, suture material should be Orthocord, Fibrewire or Fibretape (Vicryl, Ticron or Ethibond should not be used), suture size not less a No.2 and not greater than No.5), a minimum of two sutures should be configured according to technique of Das, Jariwala and Watts (18), sutures must be passed through the triceps tendon at the insertion to the olecranon, suture knots should be buried under Anconeus muscle and no supplementary k-wires should be used.

A video of the technique is available to support surgeons (refer to section 4.6 for further details on training). Surgeons will be advised of mandatory, prohibited and optional elements of the procedure. All technical aspects of the procedure will be recorded prospectively using a checklist and image capture as described in section 3.1.

4.6. Surgeon Training

In order to standardise delivery of interventions across all participating sites, all Principal Investigator (PI) surgeons will be required to attend a training course to learn the correct suture technique and to revise the standard AO technique of tension band wiring of the olecranon and the ten criteria established by Schneider (35) for optimal technique.

Surgeon training events will be held using cadaveric or sawbone models. Assessments of understanding will be undertaken with a structured questionnaire.

Training will be cascaded by the PI to other participating surgeons at a site in keeping with GCP to ensure all those providing the surgery are adequately trained in the technique.

Videos of the technique are available already. Trial specific videos will be produced to have available as a further online training tool.

A record of all trial specific training undertaken by all participating surgeons will be maintained at their site. Information on prior experience of using each procedure will be recorded.

Fidelity will monitored using a checklist and image capture as described in section 3.1.

4.7. Rehabilitation/Physiotherapy

All trial participants will receive standardised, written physiotherapy information detailing the types of exercises they may perform for rehabilitation following their injury. In this pragmatic trial, any rehabilitation input (such as formal referral to physiotherapy) will be left to the discretion of the treating clinicians.

Physiotherapy will be delivered as per usual practice at individual centres. This may include a short period of immobilisation, and 6-7 out-patient physiotherapy attendances. Physiotherapy sessions may include passive mobilisation, active exercises, stretches, manual therapy, massage and hydrotherapy, and will commonly include equipment such as balls, theraband, tubigrip, and mirrors.

A record of any additional rehabilitation input (type of input and number of additional appointments) together with any other required investigations/interventions will be self-reported by trial participants as part of the 4, 12, 18 and 24 month follow ups.

4.8. Assessments and Follow-Up

The trial assessment schedule is provided at the beginning of the protocol (see: Study Assessment Schedule). All participants will be followed up at 4 months, 12 months, 18

months. Follow up assessments will be completed at 24 months post-randomisation only for participants who reach that follow-up point within the trial recruitment and follow-up window of up to month 48 of the study.

Trial participants should also attend any routine clinical appointments that may be scheduled outside of trial visits, in line with the routine care pathway at the participating site.

4.9. Outcomes

4.9.1. Primary outcome

The primary outcome will be the Disabilities of the Arm Shoulder and Hand (DASH) score, at 4-months, the point at which the patient should have recovered from the initial intervention and bony union should be complete (6).

Fracture of the olecranon affects the ability to bend and straighten the arm as well as to turn the hand up and down, thereby affecting a range of everyday activities. The DASH has been chosen as the primary outcome measure because it captures the range of ways in which patients are likely to be affected by the fracture including activities of daily living, pain, social activities and sleep (http://www.dash.iwh.on.ca/). The 30-item PROM was designed for use in people with musculoskeletal disorders of the upper limb and is a reliable and valid instrument (36).

Baseline assessment will ask participants about their functioning before their injury and before their surgery. Baseline assessment will be completed prior to randomisation.

4.9.2. Secondary outcomes

Secondary outcomes will be collected at 4, 12 and 18 months post-randomisation for the whole population, and at 24 months post-randomisation only for those who reach that follow-up point within the trial recruitment and follow-up window of up to month 48 of the study (unless stated otherwise). These time points will enable identification of early complications and later re-operations and gather data to inform resource use and work impact.

- DASH (at 12, 18, and 24 months).

- Pain using a Numeric Rating Scale: a unidimensional measure of pain intensity in adults (37). The scale is an 11-point numeric scale with 0 representing 'no pain' and 10 representing 'worst imaginable pain', measuring average pain over the past week (38).

- Net Promotor Score (Patient Satisfaction): an overarching measure of patient satisfaction. The score assesses the likelihood of the patient recommending the healthcare received to friends or relatives using an 11-point numeric scale with 0 representing 'not at all likely' and 10 representing 'extremely likely' (39, 40).

- EuroQol 5 Dimensions (5L) Score (EQ5D-5L): measures health-related quality of life in terms of 5 dimensions: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, anxiety and depression. The EQ-5D-5L will be scored according to the User Guide (41). EQ-5D-5L data will be collected twice at baseline: i.e. once to assess patient health related quality of life on the day (after the injury) and once with regard to the week before injury.

- Radiological union: union will be defined as the presence of bridging trabeculae seen on anterior-posterior and lateral x-rays of the elbow at 4 months. The assessment of union will be undertaken by assessors independent of the trial. The 4-month x-ray is part of routine practice.

- Complications: Information on all complications will be collected. Expected complications that will be recorded will include (but not be limited to) deep wound infection, (using Centres for Disease Control (CDC) and Prevention definition (42) superficial infection (using CDC definition), rehospitalisation, nerve and skin problems.

- Elbow range of movement: Elbow range of flexion, extension, pronation and supination will be assessed at 4 months by a suitably trained independent observer using a hand-held goniometer following trial specific instructions.

- Re-operations related to the injury or to remove metalwork; reason for reoperation will be recorded. The decision to have further surgery will be made by the patient and their

treating clinician. There are no protocols restricting the decision to re-operate but data will be collected on the reasons for re-operation e.g. discomfort, stiffness, prominent fixation device, infection, patient choice, surgeon choice.

- Resource use and work impact: An accurate record of procedures at hospital level will be put in place in order to record the cost of each type of surgery and related complications via a surgical form specifically designed for this trial. Patient-reported questionnaires and hospital forms will be designed to collect information on hospital stay (initial and subsequent inpatient episodes, outpatient hospital visits and A&E admissions); primary care consultations (e.g. GP, nurse and physiotherapy); work impact of both interventions; and return to work and return to normal activities.

4.10. Imaging Assessments

The routine imaging performed on admission will be used to confirm eligibility.

Intra-operative fluoroscopy images will be obtained. This is part of routine care but instructions will be provided in an attempt to standardise the images obtained.

X-rays will be taken at 4-months as is part of routine care.

Although there are no x-rays additional to standard care, under Ionising Radiation (Medical Exposure) Regulations (2017), appropriate approvals will be obtained to ensure risk is minimised.

If a patient has not had radiological union at 4 months any additional imaging performed as part of routine NHS care will be obtained. Additional imaging will be reviewed by the independent radiological observers.

4.11. Participant Recruitment

The research team will work closely with the clinicians at each centre to optimise the screening and recruitment procedures for their local circumstances.

All members of staff involved in eligibility sign-off and informed consent process (including surgeons) must have training in Good Clinical Practice (GCP).

An Associate Principal Investigator (API) scheme will be utilised at participating centres to involve aspiring researchers to coordinate study recruitment. The APIs will be trained in study processes and will be supervised by the PI at the site. Participating centres will be encouraged to involve local Trauma Co-ordinators and Specialty Trainees in Trauma and Orthopaedic Surgery, particularly "out of hours" (evenings and weekends) when Research Nurses or APIs may not be available.

Potential participants will be provided with information about the study including a patient information sheet at the earliest possible opportunity, either at fracture clinic or by post. Information may also be made available online e.g. infographics, videos.

4.11.1. Recruitment Strategy

We have based our recruitment strategy on an audit of a prospective trauma database of 6872 fractures at the Edinburgh Orthopaedic Trauma Unit for the period July 2007 to June 2008 (2). The audit identified 64 olecranon fractures, 47 of which were Type IIA, 9/100,000 population. Our recruitment plan is based on an average site catchment population of 300,000, therefore on average we expect 27 potentially eligible participants with a Mayo Type IIA olecranon fracture per site per year. We have assumed that 50% of these will meet the eligibility criteria, an average of 13.5 per site per year. Because we are investigating two surgical interventions of similar intensity, a recruitment rate of 70% is possible (eg. DRAFFT, HTA 08/116/97; FixDT, HTA 11/136/04) which would provide an average of 0.75 patients recruited per site per month meaning the target sample size of 280 participants could be recruited ahead of schedule using 25 sites. Using a more conservative recruitment rate of 50% the full sample could be recruited within the planned 24-month recruitment period using 30 sites.

4.12. Screening and Recruitment Procedures

Screening by the research team or treating clinician will take place to identify potentially eligible patients for the trial. This will occur in A&E, fracture clinics and /or the orthopaedic trauma meeting of participating NHS hospitals, following patient referral from A&E. A routine x-ray to confirm a Mayo Type IIA fracture will be taken as part of routine care and

used for eligibility assessment. A surgeon delegated to perform this task, will confirm eligibility and they, or a member of the research team, will invite the patient to consider joining the study. The patient will be provided with an information sheet either in person or via post or email and have the opportunity to ask questions of the surgeon and the local research team before making a decision on participation.

Screening logs will be kept by all participating sites to capture numbers of ineligible or non-consenting patients at each site. We can therefore identify potential areas to target to improve recruitment rates. All olecranon fracture cases treated during the recruitment period will be recorded on the screening log and it will be noted whether the patient has been recruited into the trial or not. If the patient has not been recruited to the trial, the reason for this will be recorded e.g. ineligible (reason for ineligibility), unwilling to consent.

4.13. Informed Consent

Patients will be provided with a detailed participant information sheet (PIS), outlining the study and clearly explaining the risks and benefits of trial participation. Potential participants will be given a contact phone number, so they have the opportunity to ask questions of clinical staff and to discuss the trial with friends/family prior to agreement to take part. Participants will be given the opportunity to discuss the trial with research staff or the treating surgeon prior to their treatment. The patient may be asked at the time of approach whether they have had sufficient time to consider participation and whether they agree to consent at that time; if required, they will be given further time to reach a decision on whether to take part.

Depending on local circumstances consent will be obtained in advance of, or on the day of admission for the procedure. Patients will have the opportunity to ask questions of the clinical and local research team before written consent for the study is obtained. Appropriately delegated research staff or surgeons will obtain written informed consent.

Participants will have the right to withdraw from the study at any time. The reason for withdrawal will be recorded in the case report form.

Specific consent will be sought to enable the sharing of identifiable data with York Trials Unit (YTU) as part of the study in order to facilitate the collection of outcome data.

In the unlikely event that new information arises during the trial that may affect participants' willingness to take part, this will be reviewed by the Trial Steering and Data Monitoring Committee for addition to the participant information sheet. A revised consent form will also be completed if necessary.

All consent forms will be stored in accordance with local requirements. A copy of the consent form will be given to the participant, a further copy filed in the patient medical records and the original signed copy kept in the Investigator Site File (ISF). A copy will be sent through an agreed secure method to YTU for central monitoring purposes.

Responsibility for recording written informed consent will be with the site PI, or persons designated by the Investigator, who conducted the informed consent discussion. Designated responsibility should be recorded on the site delegation log. Permission will be sought to inform the patient's GP of their participation in the study.

4.14. Randomisation and Enrolment Procedure

Randomisation will be undertaken by York Trials Unit (YTU). When patients have given written informed consent and all the baseline forms have been completed, the authorised site research staff will contact YTU either by accessing a secure, internet-based randomisation service website hosted by York Trials Unit (https://ytu.york.ac.uk/YorkRand/) or via telephone to obtain the patient's treatment allocation and enrol the patient into the study. Research staff will be required to provide the patient's trial identification number and other details to confirm patient eligibility in order to avoid inappropriate entry of patients into the trial. Web- or telephone-based randomisation will ensure allocation concealment and immediate unbiased allocation.

Patients will be randomised in a 1:1 ratio to receive either tension suture repair technique or traditional tension band wiring for simple olecranon fracture fixation (refer to section 5.5.1). Across the study each participant will have an equal probability of allocation to either group.

4.14.1. Blinding

The operating surgeon will be informed of the allocation and will not be blind to the intervention.

Participants will not be informed which treatment they have received and the surgical wound is the same.

Outcome assessments will be performed wherever possible by assessors unaware of treatment allocation. However, as with many surgical trials, it is not feasible to completely blind outcome assessors to the intervention because it may also be apparent to physiotherapists and other research staff assessing outcomes which intervention the participant has received. In addition, if the wire protrudes or becomes uncomfortable, or the participant has sight of the x-ray, it may become apparent to the participant which intervention they have received.

It is not possible to blind the x-ray assessment, due to the wire from the tension band wiring procedure being apparent but these will be reviewed by independent radiologists.

The primary outcome is a patient-reported measure (PROM), helping mitigate surgeon or outcome assessor influence.

Data on patient preferences will be collected at baseline. All staff involved in checking, entering, and analysing questionnaire responses will be blind to patients' treatment allocation where possible. All recruiting centres will have surgeons who are familiar with the treatments for both trial arms.

Procedures for breaking codes/un-blinding are not required.

5. Data Management

5.1. Data collection methods

Data will be collected at baseline, 4, 12 and 18 months post-randomisation (with additional postal follow-up of those patients who reach the 24 month follow-up point by month 48 of the study). Baseline data will be collected at recruiting sites by a member of clinical and/or

research staff. Follow-up data collection at 4 months will take place in clinic as most centres have a routine 4-month patient follow-up in clinic. A postal copy of the patient questionnaire will be sent to the participant at this timepoint. 12 and 18 months follow up will be conducted by postal questionnaire and supplemented by information collected from patients' medical records by research staff. This will be supplemented by additional postal, email and telephone follow-up where necessary.

YTU will manage the postal, email and telephone data collection, and the scanning and processing of all data collection forms. All reporting of data collection will be undertaken in line with the Consolidated Standards of Reporting Trials (CONSORT) statement. To minimise attrition, we will use multiple methods to keep in touch with patients. We will ask patients, for full contact details (including mobile phone number and email address if available).

A pre-notification letter will be sent 2 weeks before the follow-up questionnaire is due at 4, 12, 18 and 24 months, to help prime participants and find out if they are no longer at that address. A text message reminder will also be sent on the day patients are expected to receive the postal questionnaire at 4, 12, 18 and 24 months. This has been shown to significantly reduce time to questionnaire response (43). We will also send 2 and 4 week postal reminders where required. Where these methods fail there will be a final attempt to obtain data via telephone, prioritising the primary outcome measure.

The SOFFT trial will act as a host trial for an embedded study within a trial (SWAT) which aims to look at an intervention to improve retention. The protocol for this SWAT can be found in Appendix 1

We will also write newsletters during the trial to keep the participants informed and engaged with the trial, which can enhance response rates (44).

Imaging data is likely to be stored initially by participating centres using the Picture Archive and Communication System (PACS). All patient identifiable details will be removed from the imaging, before being saved either onto compact discs in a format such as Digital Imaging and Communications in Medicine (DICOM) or if necessary, securely transferred by email or other agreed secure NHS electronic imaging transfer method.

Compact discs containing the images will be sent to the coordinating centre by post using a free-post envelope and will be securely made available to the independent reviewers (radiologists) to assess the images.

A management system will be used to track participant recruitment and study status as well as Case Report Form (CRF) returns. Data from CRFs will be processed by administrative personnel. Data will be verified through cross checking of the data against the hard copy of the CRF. The trial coordinator and statistician will write a Validation Plan for the CRFs in consultation with the YTU Data Manager. The Plan will include detailed coding for the CRFs and data query resolution rules/procedures. Quality Control will be applied at each stage of data handling to ensure that all data are reliable and have been processed correctly.

Study data will be recorded in a number of files for both the administration of the study and collection of patient data.

All data will be completely anonymised for the purposes of analysis and any subsequent reports or publications. For the purposes of ongoing data management, once randomised, individual patients will only be identified by participant identification numbers.

5.2. Data Entry

The data collected by sites using paper CRFs, will be mailed (original paper CRFs) to YTU to be entered/scanned into a secure web-based interface, specifically developed for this study. When necessary, a site can securely return the CRF electronically.

All data will be stored and transferred following YTU standard operating procedures. The staff involved in the trial (both at the sites and YTU) will receive training on data protection. The staff will be monitored to ensure compliance with privacy standards.

Data will be checked according to procedures detailed in the trial specific Data Management Plan.

5.3. Data Storage

Each site will hold data according to the General Data Protection Regulation (Great Britain, 2018) and data will be collated in CRFs identified by a unique identification number (i.e. the

participant identification number) only. A Trial Enrolment Log at the sites will list the participant identification numbers. YTU will maintain a list of participant identification numbers for all trial patients at each site.

All YTU data recorded electronically will be held in a secure environment at the University of York, with permissions for access as detailed in the delegation log. The Department of Health Sciences, in which YTU is based at the University of York, has a backup procedure approved by auditors for disaster recovery. Full data backups are performed nightly using rotational tapes, to provide five years' worth of recoverable data. The tapes are encrypted and password protected and stored in a locked fire-proof safe in a separate secured and alarmed location. All study files will be stored in accordance with Good Clinical Practice guidelines. Study documents (paper and electronic) held at the YTU will be retained in a secure (kept locked when not in use) location for the duration of the trial. All essential documents, including source documents, will be retained for a minimum period of 10 years after study completion. The separate archival of electronic data will be performed at the end of the trial, to safeguard the data for the period(s) established by relevant regulatory requirements. All work will be conducted following the University of York's data protection policy which is publically available (University of York, 2017).

5.4. Data Quality Assurance and Quality Control

Wrightington, Wigan and Leigh Hospitals NHS Foundation Trust has agreed to be the lead sponsor for this project and take overall responsibility for the quality of study conduct. This study will be fully compliant with the Research Governance Framework (Health Research Authority, 2017b) and MRC Good Clinical Practice Guidance (Medical Research Council, 2012). A trial specific data management plan agreed by the Chief Investigator, Sponsor, YTU and other study investigators will be drafted to provide detailed instructions and guidance relevant to database set up, data entry, validation, review, query generation and resolution, quality control processes involving data access and transfer of data to the Sponsor at the end of the study, and archiving.

A rigorous programme of quality control will be undertaken. The day-to-day management of the trial will be the responsibility of the Trial Coordinator based at York Trials Unit. Regular

meetings with the Trial Management Group will be held and will monitor adherence to the trial protocols at the trial sites. Quality assurance checks will be undertaken by York Trials Unit to ensure integrity of randomisation, study entry procedures and data collection.

5.4.1. Direct Access to Source Data/Documents

A statement of permission to access source data by study staff and for regulatory and audit purposes will be included within the participant consent form with explicit explanation as part of the consent process and participant information sheet.

Once YTU has completed the analysis and published in all intended scientific journals, the anonymised data will be made available for other researchers if requested.

In principle, anonymised data will be made available for meta-analysis and where requested by other authorised researchers and journals for publication purposes. Requests for access to data will be reviewed by the Chief Investigator, study Sponsor and trial team.

The Investigator(s)/Institutions will permit monitoring, audits, and REC review (as applicable) and provide direct access to source data and documents.

5.5. Statistical Considerations

5.5.1. Method of Randomisation

Participants will be randomly allocated in a 1:1 ratio to suture fixation or tension band wiring, using computer generated permuted blocks of random sizes, stratified by centre Randomisation will be carried out using YTU's online randomisation service (https://ytu.york.ac.uk/YorkRand/) independently of the trial team.

5.5.2. Determination of Sample Size

There will be a 24-month recruitment period for the SOFFT trial. The total target sample size will be 280 participants. This was calculated using the standard deviation values for the DASH which range from 16 to 28 depending on the population under study (6, 45-49). To be conservative a SD of 23 was assumed. Minimal clinical important differences for the DASH are around 10 points from individual studies using anchor-based methods (36, 47). We

estimate that a 10 point difference on the DASH at 4 months represents the threshold at which differences become important, and which would represent an appropriate non-inferiority margin. For 90% statistical power, 224 participants are required to establish non-inferiority of suture fixation compared with tension band wiring technique within a margin of 10 points on the DASH (SD=23), based on the lower limit of a 95% two-sided confidence interval (equivalent to a one-sided 97.5% confidence interval). Assuming 20% attrition at 4 months follow-up, gives the total target sample size 280.

5.5.3. Pilot Phase Analysis

The recruitment rate and 95% confidence interval (CI) will be estimated from the data collected. A CONSORT diagram will be produced to show the flow of participants through the study and the following outcomes calculated: number of eligible patients; proportion of eligible patients approached for consent; proportion of eligible patients not approached and reasons why; proportion of patients approached who provide consent; proportion of patients approached who do not provide consent; proportion of patients providing consent who are randomised; proportion of patients randomised who do not receive the randomly allocated treatment; proportion of patients dropping out between randomisation and follow-up.

Data will be summarised on the reasons why eligible patients were not approached, reasons for patients declining to participate in the study; reasons why randomised patients did not receive their allocated treatment and reasons for drop-out, if available.
Results will be compared against the study's recruitment assumptions and progression targets, and continuation of the trial or relevant modifications will be decided by the funding body.

5.5.4. Statistical Analysis Plan

Full analyses will be detailed in a statistical analysis plan (SAP), which will be finalised prior to the end of data collection and which will be reviewed and approved by the independent data monitoring committee. Any exploratory analyses of sub-groups that are of clinical interest will be pre-specified in the SAP. This trial will be reported according to the

CONSORT guidelines for clinical trials (Consolidated Standards of Reporting Trials, 2010), and the flow of participants through the trial will be detailed in a CONSORT flow diagram.

Statistical analyses will be on intention to treat (ITT) basis with patients being analysed in the groups to which they were randomised. Statistical significance will be at the 5% level (unless otherwise stated in the SAP), and analyses will be conducted in the latest available version of Stata or similar statistical software.

Baseline characteristics will be presented by trial arm. All trial outcomes will be reported descriptively by group at all time points at which they were collected. Continuous data will be summarised as means, standard deviations, medians and ranges, whereas data on further procedures and complications will be summarised as frequencies and percentages. Outcomes will be illustrated graphically over time where appropriate, including confidence intervals.

The primary analysis model will be a mixed effects regression analysis, with DASH scores at 4, 12 and 18 months follow-up as the dependent variable, adjusting for baseline DASH, randomised group and other pertinent baseline characteristics as fixed effects and including treating centre as random effects. The model will account for similarities of scores by the same person by means of an appropriate covariance structure. The estimated treatment group differences at 4 months will be reported as the primary endpoint and associated 97.5% confidence interval and p-value. Non-inferiority will be accepted if the lower bound of the two-sided 95% CI (equivalent to a one sided 97.5% CI) for the treatment difference at 4 months lies within the non-inferiority margin of 10 points. Secondary analyses will include an estimate of treatment group differences at 12 and 18 months from the same model. A secondary analysis model will include the 24 months time point in the primary model for those participants who would have reached that time point. Per-protocol and complier average causal effect (CACE) analyses will also be undertaken. The amount of missing data will be mitigated by including all data in the primary analysis model, which allows the inclusion of any patient with complete baseline data and valid outcome data at one or more follow-up points. The nature of missingness for outcome data will be explored and multiple

imputation considered if appropriate. Secondary continuous outcomes will be analysed by similar mixed effects regression analyses.

5.5.5. Health Economic Analysis

The economic evaluation will assess the impact of available treatments for the treatment of Mayo Grade IIA fractures of the olecranon on the health of the patient and the costs to the NHS and personal social services (PSS), both in the short and the long term. The short-term cost-effectiveness of tension suture repair compared to tension band wiring for surgical fixation for will be estimated using direct results of the trial up to 18 months of follow-up (and 24 months where data are available). As non-union of the fracture has potentially life long implications, we will consider an extrapolation analysis to estimate the health and cost implications beyond the duration of the SOFFT trial. Individual patient data from the trial will be used to evaluate resource use, costs and health outcomes associated with the surgical procedures and will be collected over the follow-up period of the trial.

The primary economic outcome will be the additional cost per quality-adjusted life year (QALY) gained by undergoing tension suture repair using an intention-to-treat approach. Costs and health outcome data for the economic analysis will be collected prospectively during the trial at baseline, 4, 12 and 18 months (and 24 months for those participants that reach this timepoint during the trial).

Health care resource use will be presented for both arms in terms of mean value, standard deviation and mean difference (with 95% CI) between the groups. The cost of each type of surgery and related complications will be essential for the analysis. Hence an accurate record of procedures at hospital level (e.g. centres in the trial) will be put in place in order to record per patient information (e.g. surgical procedures, complications related to the procedures, other medical complications). Costs relating to surgical procedures will be micro-estimated based on time in theatre, staff time, consumables and devices, and nights in hospital after the procedure. Unit costs will be derived from established national costing sources such as NHS Reference Costs and PSSRU Unit costs of health and social care. Unit costs will be multiplied by resource use to obtain a total cost for each patient. QALYs will be estimated by means of the EQ-5D as recommended by the NICE appraisal guidance (50).

Patients will complete the EQ-5D-5L (https://www.nice.org.uk/about/what-we-do/our-programmes/nice guidance/technology-appraisal-guidance/eq-5d-5l) and descriptive statistics will be summarised by trial arm for each time point (51).

Regression methods will be used for the incremental analysis as this allows differences in prognostic variables. Patterns of missing data will be summarised and the impact of missingness assessed using multiple imputation techniques if necessary. A range of sensitivity analysis will be conducted to test the robustness of the results under different scenarios, including probabilistic sensitivity analysis (51). An extrapolated model will be used to estimate cost-effectiveness over a lifetime.

A literature review will be conducted to explore whether previous economic evaluations have assessed the cost-effectiveness of tension suture repair versus tension band wiring for the SOFFT population, in case previous models exist these could be adapted to estimate the long-term cost-effectiveness. If no previous models are retrieved a de novo model will be developed. The extrapolation analysis will be conducted in accordance with the NICE Guide to the Methods of Technological Appraisal (50) and Decision Modelling for Health Economic Evaluation (52).

5.6. Project Management and Data Monitoring

5.6.1. Project Management

The project will be sponsored by Wrightington, Wigan & Leigh NHS Foundation Trust. Each site will have a site PI who will be responsible locally for the study and where possible an Associate PI (API) who will be a trainee surgeon or another appropriate member of the research team. APIs will be encouraged to register with the NIHR API scheme.

YTU is undertaking the duties formally delegated by the trial Sponsor.

The Trial Manager at YTU will be responsible for all aspects of trial management. They will be supported by a Trial Co-ordinator(s), who will be responsible for the day-to-day support of trial sites, coordinate recruitment, data handling, and the management of the administrative trial team. The team at YTU will meet on a regular basis during the study and will work closely with the Chief Investigator (CI), particularly at the start of the project and

during the internal pilot of the study, including regular teleconferences to ensure that all aspects of preparation of study material, study site setup and the start of recruitment progress smoothly. We will keep in close contact via email and telephone throughout.

The primary responsibility for monitoring the safety of participants in clinical trials lies with the trial Sponsor. Data monitoring will be undertaken by the Trial Management Group (TMG), Trial Steering Committee (TSC) and a Data Monitoring and Ethics Committee (DMEC), on behalf of the Sponsor and Funder. The project will also be monitored by the Sponsor for whom a representative will be invited to attend the Trial Management Group and Trial Steering Committee meetings. The minutes/records of these meetings will be stored at YTU and will be shared with the sponsor on a routine basis.

Regular progress reports will be submitted to the Funding Body.

5.6.2. Trial Management Group (TMG)

A Trial Management Group (TMG) has been established to monitor the day-to-day management (e.g. protocol and ethics approvals, set-up, recruitment, data collection, data management) of the study. Chaired by the Chief Investigator, membership will include the co-applicants, coinvestigators, members of YTU (trial manager, statistician) and other research staff on the project. Throughout the project there will be regular teleconference contact supplemented by face-to-face meetings where required (at least annually). Frequency of meetings will vary depending on the stage of the trial but at least monthly during the early stages and pilot.

5.6.3. Trial Steering Committee (TSC)

Independent oversight of the study will be conducted by the Trial Steering Committee (TSC) which will provide overall supervision for SOFFT on behalf of the Sponsor and Project Funder and ensure that the project is conducted to the rigorous standards set out in the UK Policy Framework for Health and Social Care Research and the Guidelines for Good Clinical Practice. The TSC will monitor the progress of the trial and provide independent advice. This committee comprises of an Independent Chair, a public contributor, and the Chief Investigator. A Sponsor representative will also be invited to attend the TSC meetings. Other

study collaborators may also attend the meeting with the agreement of the Chair. The TSC will meet at least annually and will work to a Charter which has been agreed.

5.6.4. Data Monitoring Committee (DMC)

The study will be regularly reviewed by the independent Data Monitoring Committee (DMC) comprising of independent clinicians and health service researchers with appropriate expertise. The role of the DMC is to review accumulating trial data and advise the sponsor (directly or indirectly) on the future management of the trial.

The DMC will meet at least annually or more frequently if the committee requests, to provide project oversight to the trial. The DMC will review safety and efficacy data as well as quality and compliance data. The DMC will review all serious adverse events which are thought to be treatment related and unexpected. The independent members of the DMC committee will be allowed to see unblinded data.

The DMC will adopt a DAMOCLES charter (53) which will define its terms of reference and responsibilities in relation to oversight of the trial.

6. Safety Monitoring

6.1. Definitions

An adverse event (AE) will be defined as the following: any untoward medical occurrence in a trial participant to whom a research treatment or procedure has been administered (intervention or control) and which does not necessarily have a causal relationship with the treatment. For the purposes of SOFFT, we will only collect AE data for events that are related to the original elbow injury and unexpected.

Complications, which might be expected with this condition and treatments, are detailed in Table 1 (section 6.2) should **not** be reported as an adverse event. These are well known complications of surgery of which the specialist clinical care teams will be experienced in managing. These complications however will be recorded in the SOFFT CRFs.

Where repeated adverse events of similar type are observed, these will be discussed with the DMC and will be onward reported to Sponsor and REC should concerns be raised in relation to the type of event and/or frequency observed.

A serious adverse event (SAE) will be defined as any untoward occurrence that:

- Results in death.
- Is a life-threatening event (that is it places the participant, in the view of the Investigator, at immediate risk of death).
- Requires unplanned hospitalisation or prolongation of existing hospitalisation (unplanned refers to emergency hospitalisations resulting in an inpatient stay; prolonged hospitalisation is deemed to be where a patient's stay is longer than expected).
- Results in persistent or significant disability or incapacity (substantial disruption of one's ability to conduct normal life functions).
- Is another important medical condition.

Important medical events that may not be immediately life-threatening, result in death or hospitalisation but may jeopardise the participant or may require intervention to prevent one of the outcomes listed in the definition of an SAE will also be considered serious.
In the context of this study, SAEs will only be reported to YTU if they appear to be related to the original injury or an aspect of taking part in the study.

Other than for fatalities, this procedure does not apply to any other SAEs which may occur during the trial which are unrelated to original injury or the trial procedures.

6.2. Collection, Recording and Reporting of Adverse Events

An appropriate member of the research team will record all directly observed AEs and all AEs reported by the trial patient up to 12 months following their trial treatment.

In addition, sites should follow their own local procedures for the reporting of any adverse events linked to clinical care.

All AEs requiring reporting will be recorded on an AE or SAE form and will be reported to York Trials Unit according to the agreed timelines.

The severity and likely relationship to study treatments of any adverse events will be documented by the designated site clinician.

An event is defined as 'related' if the event was due to the administration of any research procedure. Whereas an 'unexpected event' is defined as a type of event not listed in the protocol as an expected occurrence.

All non-serious AEs whether expected or not, should be recorded in the patient's medical notes.

Related and unexpected AEs will be recorded on the study AE form by the research staff and sent to YTU within an agreed timescale (usually five days). SAEs should be notified to the Principal Investigator and to YTU within 24 hours of the research staff or clinical team becoming aware of the event.

At the time of reporting, the PI or delegated clinician will be asked to record an assessment of causality (to trial treatment) selecting an option from the list below:

- Definitely related — there is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
- Probably related — there is evidence to suggest a causal relationship, and the influence of other factors is unlikely.
- Possibly related — there is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the trial procedures). However, the influence of other factors may have contributed to the event (i.e. the patient's clinical condition, other concomitant events).
- Unlikely to be related — there is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial procedures). There is another reasonable explanation for the event (e.g. the participant's clinical condition, or other concomitant treatments).
- Unrelated — there is no evidence of any causal relationship.

Once received, causality and expectedness will be confirmed by the Chief Investigator. SAEs that are deemed to be unexpected and related to the trial will be notified to the Research Ethics Committee (REC) and sponsor within 15 days.

All such events will be reported to the Trial Steering Committee and Data Monitoring Committee at their next meetings. All participants experiencing SAEs will be followed up as per protocol until the end of the trial.

Table 1 - Expected complications associated with olecranon fracture fixation surgery.

General surgical complications	
Infection at surgical site	Complex regional pain syndrome (CRPS)
Bleeding/haematoma	Wound healing problems
Stiffness	Seroma
Heterotopic ossification	Neurological complications
Rehospitalisation	Skin problems
Granuloma / suture abscess	Sinus
Cutaneous nerve injury / neuroma / numbness / altered sensation	Unexplained pain
Anaesthetic related complications	
Myocardial infarction (MI)	Cerebrovascular accident (CVA)
Venous thromboembolism (VTE)	Block related nerve lesion
Complications specific to olecranon fracture surgery	
Non-union	Delayed union
Mal-union	Fracture displacement
Hardware prominence	Hardware migration
Hardware failure	Fixation failure
Ulna nerve lesion	Median nerve lesion
Radial nerve lesion	Radioulnar synostosis
Vascular injury	Ulnohumeral instability

7. Research Governance

7.1. Ethical Considerations and Approval

The study will be conducted to protect the human rights and dignity of the patient as reflected in the Declaration of Helsinki (54).

Formal NHS Research Ethics Committee (REC) approval will be sought via the Health Research Authority (HRA). Local R&D approvals (confirmation of capacity and capability) will be obtained for participating sites. Any further amendments to the trial protocol will be submitted and approved by the HRA and REC where required.

7.2. Competent Authority Approvals (Proposed action to comply with the Medicines for Human Use (Clinical Trials) Regulations 2004)

The techniques under investigation are well-recognized and international accepted surgical procedures using CE-marked implants and medical devices. We do not therefore require prior authorisation by the UK Competent Authority, the MHRA, under The Medical Devices Regulations (Great Britain, 2002).

7.3. Regulatory Compliance

The trial will comply with the principles of the Declaration of Helsinki (54). It will also be conducted in compliance with the approved protocol, and the principles of GCP. An agreement will be in place between the site PI and the Sponsor, setting out respective roles and responsibilities.

All deviations from the protocol or GCP will be reported by PIs or designated site staff to YTU. The site must inform the PI as soon as they are aware of a possible serious breach of compliance, so that the sites can report this breach to the trial Sponsor (via YTU) with onward reporting to ethics and regulatory bodies as necessary. For the purposes of this regulation, a 'serious breach' is one that is likely to affect to a significant degree:

- The safety, physical or mental integrity of the participants in the trial, or
- The scientific value of the trial.

Processing of all trial data will comply with the General Data Protection Regulation (Great Britain, 2018).

7.4. Patient Confidentiality

The researchers and clinical care teams must ensure that patients' anonymity will be maintained and that their identities are protected from unauthorised parties. Patients will be assigned a unique participant identification number and this will be used on CRFs; patients will not be identified by their name. Sites will keep securely and maintain the patient Enrolment Log showing participant identification numbers and names of the patients. This unique participant number will identify all CRFs and other records and no names will be used, in order to maintain confidentiality.

All records will be kept in locked locations. All consent forms will be secured safely in a separate compartment of a locked cabinet. Clinical information will not be released without written permission, except as necessary for monitoring by the trial monitors.

At the end of the study, data will be securely archived by participating sites and the University of York for a minimum of ten years.

7.5. Trial Closure

The end of the trial will be defined as the last patient last contact which will occur at approximately 18 months after the end of the recruitment period (end of follow-up for the last patient) and after all the data are entered and queries resolved.

An end of study declaration form will be submitted to the Research Ethics Committee (REC) and Sponsor within 90 days of trial completion and within 15 days if the trial is discontinued prematurely. A summary of the trial report and/or publication will be submitted to the REC, Sponsor and Funders within one year of the end of the trial.

7.6. Annual Progress Reports

An Annual Progress Report (APR) will be submitted to the REC which gave the favourable ethics opinion 12 months after the date on which the favourable opinion was given and thereafter until the end of the study (if applicable).

7.7. Urgent Safety Measures

The site PI may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. These safety measures should be taken immediately and may be taken without prior authorisation from the REC.

7.8. Access to Data

The Investigator(s)/institution(s) will permit authorised representatives of the Sponsor and applicable regulatory agencies direct access to source data/documents to conduct trial-related monitoring, audits and regulatory inspection. Trial participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical notes.

Essential trial documentation (i.e. the documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced) will be kept with the Trial Master File (TMF) and Investigator Site Files (ISF). The Sponsor will ensure that this documentation will be retained for a minimum of ten years after the conclusion of the trial to comply with standards of Good Clinical Practice. The CRF data will be stored for a minimum of ten years after the conclusion of the trial as paper records; and a minimum of 20 years in electronic format in accordance with guidelines on Good Research Practice (55) . All paper records will be stored in a secure storage facility or off-site by York Trials Unit. All electronic records will be stored on a password protected server.

The PI at any participating site will archive the trial essential documents generated at the site for the agreed archiving period in accordance with the signed Clinical Trial Site agreement or Organisational Information Document.

7.8.1. Source Data List

Table 2: Source Data

Type of Data	Source Document
Informed consent	Informed Consent Form
Relevant Medical History and Current Medical Conditions	Patient Medical Records
Fulfilment of eligibility criteria	Patient Medical Records
Demographics	Patient Medical Records / Patient Self-report

DASH	Patient Completed Questionnaire (at baseline and months 4, 8 and 12)
EQ-5D-5L	Patient Completed Questionnaire
Health Economic Data	Patient Completed Questionnaire
Treatment and rehabilitation data	Patient Medical Records

7.9. Indemnity

This study will be sponsored by Wrightington, Wigan and Leigh Hospitals NHS Foundation Trust. If there is negligent harm during the trial, when the NHS Trust owes a duty of care to the person harmed, NHS Indemnity covers NHS staff and medical academic staff with honorary contracts only when the feasibility trial has been approved by the R&D department. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.

8. Patient and Public Involvement

At the outset of planning the project Adam Watts met with Wrightington, Wigan & Leigh Musculoskeletal Patient and Public Involvement (PPI) group in a meeting facilitated by the Trust PPI Co-ordinator.

The PPI group have already contributed to study design and would very keen to continue with this. They felt that face to face meetings were the best way to do this rather than by e-mail and they were happy to convene as necessary. They have contributed to patient facing study material such as patient information sheets, consent forms, patient rehabilitation leaflet and patient questionnaires.

They do not wish to sit on the steering group and are happy to delegate to the lay representative co-applicant but would be willing to form a lay advisory group for monitoring of the study if requested. They would like to meet to discuss the research data summary on completion of the trial and felt it was particularly important for them to get involved in dissemination of the findings.

The PPI group have been given additional training by Adam Watts in the surgical techniques being studied and by YTU to include how the study will be set up and 'run', research

methodologies, auditing to meet governance requirements. This provided an opportunity to meet other members of the team and engage with members of the research community they would not routinely have had the opportunity to meet.

The lay co-applicant will be the link between the research team and the PPI group and will represent the views of the PPI group at meetings of the TMG and will facilitate input from the PPI group during any ongoing development of patient facing materials, data analysis and during dissemination. He will be supported in this role by Dr Jane Martindale, physiotherapist and PPI co-ordinator at the Trust and Liz Cook from the research team.

Key time points for consultation will be when the study is being set up, at the end of the pilot and when the study is being written up and disseminated. There will be an update newsletter on a quarterly basis and the group are happy to be contacted between meetings where necessary if anything arises needing their input.

The plan for PPI during the study is as follows:

- Following discussion, the patient co-applicant plans to attend the monthly Trial Management Group meetings a minimum of every three months, but will be included in correspondence relating to all of the meetings. This will be kept under review to minimise time burden but ensure he is able to engage with the trial team.
- An independent patient/public representative is a member of the Combined Trial Steering and Data Monitoring Committee.

Table 3: Patient and Public Involvement Schedule

Time Point	Meeting / Duties	Activity	PPI members
Ethics and trial set up	• Review ethics of trial processes. • Review patient information documents.	• Panel meeting. • Email of documents for comment.	All.
Mid-way through recruitment stage	• Review of any recruitment issues. • Review of any other trial issues.	• Discussion with panel members on individual basis.	All.
Study closure/set up of full trial	• Final evaluation of any recruitment or patient issues during	• Panel meeting.	All.

	trial. • Forward planning to improve upon full trial design.		
Monthly Trial Management Meetings	• Provide patient perspective on any issues or changes proposed during the course of the trial. • Feedback to other panel members at panel meetings.	• Either meeting attendance or via email update.	Patient Co-Applicant.
Note: Panel members may also be invited to review changes in patient information documents on an ad hoc basis via email, should changes be required prior to meeting.			

9. Finance

This research is funded by the NIHR HTA programme (Ref: NIHR127739).

The financial arrangements for the study will be as contractually agreed between the funder (HTA), and the Sponsor (Wrightington, Wigan and Leigh NHS Foundation Trust). Separate collaboration agreements will be put in place between the Sponsor and each of the collaborating organisations.

10. Dissemination and Publication Policy

A dissemination and publication policy will be developed with an agreement between partners including ownership and exploitation of intellectual property, and publication rights. The publication policy and the agreement will ensure that any intellectual property generated during the project is protected and that the publication process is organised in a fair, balanced and transparent manner. The TMG will be responsible for overseeing these arrangements. The creation and signature of the agreements will be the responsibility of the coordinating centre (University of York). It will be ensured that all partners have input into the document.

Targets for dissemination will include NICE, Clinical Commissioning Groups, the Department of Health and the Speciality Advisory Committees (SAC) for the curriculum for clinicians who will undertake treatment of olecranon fractures. The study protocol and results will be

presented orally and will be made publicly available in appropriate publications and a summary of the study will be made available in plain English for patient-focused outlets.

The executive summary and copy of the trial report will be sent to NICE and other relevant bodies, including Clinical Commissioning Groups, so that the study findings can inform their deliberations and be translated into clinical practice nationally. We will also work with the relevant National Clinical Director in the Department of Health to help ensure the findings of the trial are considered when implementing policy and will work with the Speciality Advisory Committees (SAC) to incorporate the findings into the training curriculum for clinicians who will undertake treatment of olecranon fractures. The British Elbow and Shoulder Society are willing to adopt the trial for inclusion in their research portfolio which will facilitate dissemination of findings to relevant stakeholders. A number of dissemination channels will be used to inform clinicians, patients and the public about the results of the study. The projected outputs are listed below.

We will seek to raise the profile of the trial via social media including a dedicated Twitter account. This will be aimed at participating site staff and focus on trial progress, trial related events, and publicising research outputs.

The study protocol will be published in a peer-reviewed, open access journal, after the study commences.

An HTA monograph will be produced.

On completion of the study, the findings of the HTA report will be presented at national and international meetings of organisations such as the British Orthopaedic Association Annual Congress, UK Orthopaedic Trauma Society, the British Shoulder and Elbow Society, North American Orthopaedic Trauma Association, European Federation of National Associations of Orthopaedics and Traumatology (EFORT), European Shoulder and Elbow Society (SECEC) and American Academy of Orthopaedic Surgeons.

The study report will be published in peer reviewed high impact general medical and orthopaedic journals; such as Lancet, the BMJ, the Journal of Bone and Joint Surgery or similar.

An updated video of the surgical technique and including study outcomes will be submitted to Bone and Joint Essential Surgical Techniques for peer-review publication.
The study results will be shared with relevant evidence synthesis teams (including within the Cochrane Collaboration) in order to ensure that results are incorporated in future systematic reviews.

A summary of the study report, written in lay language will be produced and made available to participants, members of our user group and relevant patient-focused websites.
As part of the trial an information booklet on the condition, the likely recovery process and physiotherapy exercises will be produced. We will explore making this more widely available to patients following the trial.

The findings of the SWATs will be disseminated in a relevant journal read by trialists such as BMC Trials or BMJ Open and disseminated at relevant conferences such as the International Clinical Trials Methodology Conference. Data will be made available to allow for inclusion in future meta-analyses with studies of the same intervention in other trials.

11. Department of Health disclaimer

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

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13. Appendices

13.1. Appendix 1 – SWAT protocol

Social Incentive Retention Cover Letter SWAT (Study within a Trial)

An embedded, randomised controlled trial to investigate whether the inclusion of a social incentive text cover letter with the 12 month postal questionnaire improves response rates.

Name and title of SWAT lead applicant

Mrs Elizabeth Cook

Names and titles of SWAT Co-applicants

Dr Catriona McDaid, Mrs Sophie James, statistician (tbc).

Applicant affiliations

York Trials Unit, Department of Health Sciences, Faculty of Sciences, ARRC Building, University of York, Heslington, YO10 5DD

SWAT Registration

Host trial Registration

ISRCTN: 87904264; IRAS ID:

Background:

Fundamental to health research is the testing of interventions through RCTs. Achieving high participation, and retention of participants in RCTs has traditionally been difficult. Published data show that a minority of RCTs recruit successfully [2,3]. Problems with trial recruitment can limit the internal and external validity of a study and the overall sample size and statistical power. Poor return of questionnaires in randomised controlled trials (RCTs) affects retention rates. This can introduce bias and thus affect generalisability and validity, with an associated reduction in statistical power.

There is therefore a need to develop and test interventions to improve recruitment and retention of participants. A robust method of testing interventions is to embed 'Studies Within A Trial' (SWATs) of recruitment and retention strategies in ongoing randomised trials [4].

There is some evidence that using a pen as a nonmonetary incentive increases response rates and time to response for trial follow-up questionnaires (5, 6). The theoretical basis underlying the use of pen incentives is that of *reciprocation*, where people feel obligated to respond with positive behaviour received, with positive behaviour in return (7-10). In the context of trial recruitment, offering a potential participant a gift such as a pen may make the person more likely to take up the trial invitation to enrol. It is also possible that the convenience of having a pen to hand upon receipt of the invitation may increase the likelihood of the forms being completed. One trial in the U.S. embedded in an observational study, showed that including a pen with the study logo to a questionnaire mailed to women who had previously not responded significantly improved recruitment rates (11).

Personalisation of letters accompanying postal questionnaires have been identified an effective way of increasing response rates [12]. A type of personalisation is social incentive, which involves persuading people to act in a certain way, and that this behaviour will be noticed [13]. There is no clear evidence at yet that a social incentive cover letter is effective for trial retention [13].

Objective of this SWAT

To evaluate the effectiveness of including a cover letter with Social Incentive text with the 4, 12, 18- and 24-month questionnaires on questionnaire response rates of participants of the SOFFT study.

Background: the host trial

The SWAT will be hosted in the 'Simple Olecranon Fracture Fixation Trial (SOFFT). SOFFT aims to undertake a multi-centre parallel group RCT to determine whether tension suture repair is not inferior to tension band wiring for surgical fixation of Mayo Grade IIA fractures of the olecranon in consenting patients over the age of 16 years. The primary outcome is the

Disabilities of the Arm Shoulder and Hand (DASH) score at 4 months follow-up. The additional objectives are to undertake an analysis of the rate of re-operation and other secondary outcomes and a cost-effectiveness analysis of the two interventions from the NHS perspective.

SWAT Methods

Interventions and comparators

Participants allocated to the Social Incentive cover letter group will receive this cover letter and those randomised to the control group will receive the standard cover letter.

Eligibility criteria for the SWAT

All participants in SOFFT will be eligible to be included in the social incentive cover letter SWAT.

Method for allocating to intervention or comparator

We will use block randomisation stratified by the host trial's treatment arm to avoid imbalance between the SWAT intervention arms. The allocation ratio will be 1:1. A researcher (e.g. trial statistician) not involved with posting the questionnaires will undertake generation of the allocation sequence independently.

Outcome measures:

Primary Outcome: The primary outcome will be the proportion of participants in each group who complete and return the 18 month questionnaire to York Trials Unit.

Secondary outcomes:

1. Time taken to return 18 month questionnaire form
2. The completeness of the 18 month questionnaire
3. Cost effectiveness of the sending the social incentive cover letter.
4. Time taken to return the 4, and 12 month questionnaire forms and completeness of those questionnaires

Sample size calculations

As is usual with a SWAT the sample size will be constrained by the start date of the embedded trial and the host trial sample size. We anticipate that approximately 200 participants will be randomised into the SWAT (100 to each of the trial arms).

Analysis plans

Analyses will be undertaken by a statistician blind to the SWAT allocation on an intention-to-treat basis. Statistical analyses will be conducted in STATA version 15 or later (StataCorp, College Station, TX, USA). Participant baseline data will be summarised descriptively by embedded trial allocation.

The primary outcome of completion and return of questionnaires will be analysed via a logistic regression model adjusting for age, host trial treatment allocation, whether they received a pen or not, and whether they received a social incentive cover letter or not. The odds ratio, corresponding two-sided 95% confidence interval and p-value for the intervention type received will be presented. Time to questionnaire completion will be analysed using Cox Proportional Hazards regression, adjusting for the same covariates as in the primary analysis model. Hazard ratios and their associated 95% confidence interval will be provided. The proportional hazards assumption will be evaluated using Schoenfeld residuals [14].

Completeness of response by a linear regression model. All models will adjust for main trial treatment allocation. For the primary and secondary outcomes the possibility of an interaction between the pen and social incentive cover letter will be explored. For each outcome, the corresponding regression model used to explore the main effects will be repeated, with the addition of an interaction term between whether a pen was sent and the type of cover letter [15]. The interaction effect size estimate and its corresponding 95% confidence interval and p-value will be presented. Cost effectiveness will be calculate for each group using the total cost of the pen/letter/postage/stationary and staff time.

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