# SOFFT

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

STATISTICAL ANALYSIS PLAN

v1

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# Contents

# 1. Document scope and relevant SOPs and guidance documents

This analysis plan deals only with the statistical analysis of efficacy, the cost-effectiveness analysis will be detailed in a separate plan. Nor does this plan discuss the design or analysis of any SWATs (Studies within a Trial) embedded within this trial, these will be detailed separately.

This analysis plan was written prior to the end of follow-up.

This SAP was prepared according to YTU SOPs and guidance documents. Data and documents relevant to the statistician will be kept in a Statistical Master File following the directory structure detailed in the YTU SOP entitled "DS01 Directory structure and version control".

# 2. Definition of terms/acronyms

| | |
|---|---|
| AE | Adverse event |
| AIC | Akaike information criterion |
| CACE | Complier average causal effect |
| CI | Confidence interval |
| CONSORT | Consolidated standards of reporting trials |
| CRF | Case report form |
| DASH | Disabilities of the Arm, Shoulder and Hand |
| EQ-5D-5L | EuroQol-5 dimension-5 levels |
| ITT | Intention-to-treat |
| PROM | Patient reported outcome measures |
| REC | Research ethics committee |
| ROM | Range of movement |
| SAE | Serious adverse event |
| VAS | Visual analog scale |
| YTU | York Trials Unit |

# 3. Design

SOFFT is a large pragmatic, two-arm, parallel group, individually randomised, multi-centre, non-inferiority, controlled trial. The two arms are: standard tension band wiring (control); tension suture repair (intervention). There will be a 9-month internal pilot to assess assumptions about recruitment and fidelity of implementation of the tension suture technique.

This document has been written based on information contained in the study protocol, in which full details of the background and design of the trial are presented [1].

# 4. Trial Objectives

## 4.1 Primary objective

The primary aim of this study is 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 (≥16 years old).

### 4.2 Secondary objectives

Secondary aims are to:

- Undertake a 9-month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility.
- Assess the rate of re-operation and other secondary outcomes, including patient satisfaction, pain, radiological union, range of elbow movement, and the occurrence of complications.
- 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 (economic evaluation not detailed in this analysis plan, this will be written separately).

## 5. Follow-up

Following baseline, randomisation and treatment, all participants will be followed up for 18 months including a follow up visit at 4 months post-treatment, then questionnaires to be completed by the participant at 12 months and 18 months post-randomisation. Those patients that reach 24 months within the planned follow-up period will be asked to complete an additional questionnaire at 24 months.

In the event of local restrictions arising from COVID-19, the 4-month visit may be conducted remotely via telephone or video call.

## 6. Outcomes

### 6.1 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 [2].

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 [3].

Baseline assessment will be completed prior to randomisation and will ask participants about their functioning in the week before their injury and their functioning since their injury (but prior to their surgery).

### 6.2 Secondary outcomes

Secondary outcomes will be collected at 4, 12 and 18 months post-randomisation for all participants, 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. These time points will enable identification of early complications and later re-operations and gather data to inform resource use and work impact. The following secondary outcomes will be assessed:

- **DASH** score (at 12, 18, and 24 months) [3]

- **Pain using a visual analog scale (VAS)**: A continuous scale, the scale is anchored by "no pain" (score of 0) and "worst imaginable pain" (score of 100), using a 100-mm scale, measuring average pain over the past week [4].
- **Net Promotor Score (Patient Satisfaction)**: This 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' [5].
- **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 [6]. This will be assessed as part of the health economic analysis.
- **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.
- **Complications**: Information on all complications will be collected. Expected complications that will be recorded will include (but not be limited to) deep wound infection, superficial infection, rehospitalisation, nerve and skin problems. Intra-operative complications and post-operative complications (at 4, 12, 18 and 24 months) will be collected and reported.
- **Elbow range of movement (ROM)**: 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 (this assessment will not be performed where local COVID-19 restrictions require the 4 month visit to be conducted remotely).
- **ROM (participant reported)**: Participants will be asked to obtain photographs of full elbow flexion and extension at 4 months following trial specific instructions. Images will be transferred to YTU and sponsor in order for measurement of ROM to be undertaken by a central reviewer using the procedure described by Meislin et al. [7]. Two independent assessors will perform each measurement three times, an average will be calculated across all measurements (3x measurements per 2x assessors = 6 measurements in total).
- **Re-operations related to the injury or to remove the fixation material**: 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**: Costs associated with each type of surgery and related complications, hospital stays, primary care consultations, work impact of both interventions will be collected (economic evaluation will be given in a separate analysis plan).

**Scoring of instruments**

*DASH*

Participants will be asked at baseline (pre and post injury) and at 4, 12, 18 and 24-months (for those reaching 24-months within the follow-up period) post-randomisation to complete the DASH questionnaire. The DASH questionnaire comprises of 30 questions measuring symptoms and function. All items are scored on a 5-point scale from 1 (no difficulty/symptoms) to 5 (extreme difficulty/symptoms). The arithmetic mean of at least 27 of the 30 items is transformed by (mean -1)*25 into the scale from 0 = no symptoms/full function to 100 = maximal symptoms/no function for the DASH total score [3]. At least 27 out of the 30 items must be completed for a score to be calculated, if less than 27 items are completed then a score will not be calculated. If more than one box per item is selected and the boxes are adjacent, then the worst case will be selected, otherwise the item will be treated as missing.

## 6.3 Other collected variables

In addition to the primary and secondary outcomes the following information will also be collected during the trial:

- date of birth
- sex
- ethnicity
- co-morbidities (cardiovascular disease, respiratory disease, diabetes mellitus, other endocrine diseases, renal disease, neurological, musculoskeletal, cancer, other illnesses)
- COVID-19 status on admission to surgery
- fracture details (which elbow is injured, is it the dominant arm, how the injury occurred)
- fracture history (previous fractures or previous surgery to injured elbow)
- concomitant injuries
- living arrangements
- smoking status and smoking history
- alcohol consumption
- current medications
- qualifications
- working status
- treatment preference (for consenting and non-consenting patients)

The change of status CRF will be used to record any changes in participant status within the study including the patient withdrawing from treatment; the patient no longer attending hospital visits but agreeing to complete postal questionnaires; the patient no longer completing trial postal questionnaires but agreeing to allow research staff to collect data from medical records; the patient no longer wishing to complete any follow-up questionnaires; the patient withdrawing from all aspects of the trial; patient death (in the event of death a SAE form will also be completed).

# 7. Data

## 7.1 Case Report Forms

Participants are posted a paper case report form (CRF) questionnaire at 12, 18 and 24 months (for those that reach 24-month time point) post-randomisation. Completed questionnaires will be returned to YTU to be scanned and processed by YTU data management. The 4 month visit will be conducted in clinic, but may be conducted remotely in the event of local restrictions arising from COVID-19. Participants will be asked to indicate the method of collection by ticking the relevant box (in person, by telephone, other) on the front of the CRF.

The data collected by sites using paper CRFs, will be mailed to YTU to be entered/scanned into a secure web-based interface. When necessary, a site can securely return the CRF electronically. Data collected via telephone or video call will be collected onto paper CRFs or entered directly into a spreadsheet.

A copy of the CRFs with the variable names from the database (known as ‘specs’) will be kept by the Trial Statistician in the Statistical Master File.

## 7.2 Electronic/non-paper data

Anonymised intra-operative photographs taken by the clinical team will be securely transferred to YTU by email or other agreed secure NHS electronic imaging transfer method.

Anonymised photographs taken by participants to assess ROM will be transferred to YTU by email or printed copies posted. Measurements from the photographs will performed by independent physiotherapists based on the Meislin et al., (2015) paper. Measurements will be entered directly into an excel spreadsheet and provided for analysis. The following information will be provided: Patient ID,

Date sent to physiotherapists, Date of physiotherapist review/measurement, Initials of physiotherapist, Image quality level, Measurement 1 - Left arm flexion (degrees), Measurement 2- Left arm extension (degrees), Measurement 3 - Right arm flexion (degrees), Measurement 4 - Right arm extension (degrees).

### 7.3 External datasets

No external datasets are required for this study.

### 7.4 Management database

All participant-reported data is identified solely by the unique participant trial ID. No other identifying details will be printed or input onto these documents. These CRFs are returned by post or electronically to YTU where they are scanned, using Teleform data capture software, into a bespoke data management system. This system is separate from the trial management system and contains no identifying details. All data are error checked and validated to ensure accuracy according to procedures detailed in the trial Data Management Plan. The paper CRFs are held securely in a controlled access area in locked cabinets but separate from the consent forms.

Both the trial management system and the data management systems are held on secure University of York servers with access limited to specified members of YTU staff as detailed in the delegation log.

## 8. 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 [2, 8-12]. 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 [3, 10]. 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 upper 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.

## 9. Randomisation and blinding

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/) 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. Participants will be randomly allocated in a 1:1 ratio to either tension suture repair or tension band wiring, using computer generated permuted blocks of random sizes, stratified by centre.

The Statistician will not be blinded to group allocation, nor will other members of the study team who are actively involved in the administration of the study. Participants will not be informed of which treatment they have received and the surgical wound is the same. However, 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. The investigator will record on the 4-month follow-up CRF whether they are aware of any inadvertent un-blinding of the participant (without asking the participant).

# 10. Analysis of internal pilot phase

There will be a 9-month internal pilot phase to assess assumptions about recruitment and the fidelity of implementing the tension suture repair technique.

The recruitment rate (defined as the proportion of eligible patients recruited) and 95% confidence interval (CI) will be estimated from the data collected up to the end of the pilot phase.

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.

Any deviations from technique recorded on the Surgery Fidelity Checklist CRF will be reported, with reasons where provided.

# 11. Final analysis

## 11.1 Analysis software

All analyses will be conducted in Stata v17 (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA), or later (to be confirmed in final report).

## 11.2 Analysis principles and populations

Analyses will follow the principles of intention-to-treat (ITT) with participant's outcomes analysed according to their original, randomised group, where data are available, irrespective of deviations based on non-compliance. One-sided 97.5% confidence limits (equivalent to the upper bound of the two-sided 95% confidence interval) will be reported for the primary outcome and secondary analysis of DASH scores. There will be no pre-defined non-inferiority margins for the remaining secondary outcomes, these will be compared for evidence of superiority and two-sided tests at the 5% significance level will be used.

## 11.3 Screening, eligibility, recruitment and follow-up data

Recruitment graphs presenting the overall recruitment by month, and the actual vs target recruitment will be produced.

The flow of participants through the trial will be presented in a CONSORT diagram (see Appendices).

Follow-up response rates to the participant questionnaires (including time to response) will be summarised overall and by treatment group.

The number, type and timing of withdrawals will be presented overall and by treatment group, with reasons where provided.

The type of consent provided (remote or in clinic) and the method of follow-up at 4-months (in-person, telephone interview, other) will be reported as frequencies and percentages.

## 11.4 Baseline data

Participant baseline data will be summarised descriptively by trial arm and presented in tabular form (as randomised and as analysed). No formal statistical comparisons will be undertaken. Continuous measures will be reported as means and standard deviations (and/or median, interquartile range, and minimum and maximum as appropriate) and categorical data (e.g., data on further procedures and complications) will be reported as frequencies and percentages. Example tables are provided in the appendix (Section 15.2.1).

## 11.5 Primary analysis

DASH scores will be analysed using a mixed-effects regression model, with DASH scores at 4, 12 and 18-months follow-up as the dependent variable, adjusting for baseline DASH scores (pre-injury), age at randomisation (continuous), prescribed NSAIDs (binary; prescribed NSAIDs or not prescribed NSAID), previous elbow fractures (binary; previous elbow fracture or no previous elbow fracture), diabetes status (binary; diabetic or non-diabetic), smoking status (binary; current regular smoker or not a current regular smoker), drinks alcohol (binary; drinks alcohol or does not drink alcohol), randomised treatment group, time, and treatment group-by-time interaction as fixed effects and including treating centre and participant as random effects.

The DASH measure will be taken twice at baseline; pre and post-injury. We have outlined that the pre-injury measure will be used in the primary analysis model as pre-injury function is more relevant. The post-injury scores will be examined for balance and if there is an imbalance across arms this will also be added to our primary analysis model.

The correlation of observations within participants over time will be modelled using participant as a random effect. The Akaike information criterion (AIC) will be used to compare models specifying different correlation structures (smaller values preferred), the most appropriate pattern will be used for the final model. All model assumptions will be checked, and if they are in doubt transformations of the outcome data will be considered. The estimated treatment group differences at 4 months will be reported as the primary endpoint with its associated one-sided 97.5% confidence interval. Example tables are provided in the appendix (Section 15.2.2).

Non-inferiority will be accepted if the upper bound of the one-sided 97.5% confidence interval (equivalent to the upper two-sided 95% confidence limit) for the treatment difference at 4 months lies below the non-inferiority margin of 10 points. Further details on this decision can be found in appendix 15.1.

Primary analysis will be checked by a second statistician on completion, this will be documented using *F16: Primary Analysis Sign Off* Form.

## 11.6 Sensitivity analyses

*Intervention adherence*

A Complier Average Causal Effect (CACE) analysis to assess the impact of compliance on treatment estimates will be undertaken for the primary outcome (DASH score at 4-months). Compliance will be based on whether the participant received allocated treatment and also using surgeon self-report forms and image analysis of intra-operative images for fidelity. A two-stage IV regression approach will be used with mixed-effects regression to reflect the primary analysis. This model will be fit using the `ivregress` stata command. The primary analysis model will be repeated but the variable for randomised treatment group will be replaced with the variable for compliance. The option `vce(cluster )` will be used to account for repeated measures.

*Missing data*

We anticipate that missing data for the statistical analysis will be relatively small. The primary outcome will be collected at the 4-months clinic visit which is a routine visit. In the event participants cannot attend in person, procedures are in place to collect the data remotely.

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 amount of missing data will be reported for each randomised arm, and we will also compare the baseline characteristics of participants who are included in the primary analysis to ensure that any attrition has not produced any imbalance in the groups in important covariates. To account for any possible bias, a logistic regression will be run to predict non-response (no questionnaires received post-randomisation) including variables collected prior to randomisation. The primary analysis will then be repeated including as covariates all variables found to be significantly predictive of non-response to determine if this affects the parameter estimates.

The primary analysis and the above model including variables associated with outcome and missingness will assume missing outcome data are missing at random (MAR). However, it is possible that participants who failed to complete follow-up questionnaires differed from those who completed follow-up questionnaires (e.g. had poorer recovery and therefore would have scored lower on the DASH if they had completed the follow-up). This would mean the data were missing not at random (MNAR), and would represent a departure from the MAR assumption.

The sensitivity of the primary analysis results to departures from the MAR assumption may be explored using a pattern-mixture model, implemented using the `rctmiss` Stata command (13, 14) This command currently supports the use of fixed-effect models only, and therefore a linear regression model comparing the primary outcome at 4-months post-randomisation will be used, adjusting for treatment group, age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, and drinks alcohol.

The pattern mixture model works by including a sensitivity parameter quantifying the departure from the MAR assumption. For example, if we expected that those who failed to complete the follow-up at 4-months post-randomisation on average would have scored two points lower on the DASH than those who did attend the follow-up, the sensitivity parameter would be equal to 2. The pattern-mixture model can then be used to obtain an estimate of the treatment effect given this level of departure from the MAR assumption. The `rctmiss` command estimates the treatment effect for varying values of the sensitivity parameter ranging from zero up to any positive value, which allows for the assessment of the impact of varying degrees of departure from the MAR assumption on the treatment effect estimate.

The `rctmiss` command will be used to produce a graph of the adjusted mean difference in DASH score between treatment groups for varying values of the sensitivity parameter. This will be done assuming the value of the sensitivity parameter is equal in both groups (missing data are equally informative in both groups), and also assuming the sensitivity parameter is equal to zero in the control group and varying in the intervention group, and vice versa (missing data are only informative in one group and not the other).

While the results of this sensitivity analysis will not be directly comparable to the primary analysis model, it will be able to give an indication of how sensitive the estimate of the treatment effect is to departures from the MAR assumption in the primary outcome data.

In addition to the above analysis, patterns of missingness amongst participants will be summarised descriptively.

## 11.7 Subgroup analyses

A subgroup analysis will be undertaken to explore the hypothesis that the benefit of tension suture repair (intervention) over tension band wiring (control) will be larger in older patients (aged ≥ 50 years) than younger patients (aged < 50 years).

The same model as used for the primary analysis will be applied but an additional treatment group × age subgroup interaction term will be included. Descriptive summaries of the DASH score will be reported for each combination of treatment group and subgroup, parameter estimates and corresponding p-value for the interaction will also be reported. Results will be interpreted with caution given the study had not been powered to detect interactions.

## 11.8 Analysis of secondary outcomes

*DASH*

From the primary analysis model, an estimate of treatment group differences at 12 and 18 months will be reported with the associated upper one-sided 97.5% CI's (equivalent to the upper two-sided 95% confidence limit). A secondary model will also be fitted, which will include the 24-months' time point in the primary model for those participants who have reached that time point, treatment group differences at 24 months will be reported with the associated upper one-sided 97.5% CI.

*Pain (VAS), and Net Promotor Score (Patient Satisfaction)*

VAS score and Net Promotor score will be analysed using a mixed-effects regression model, with scores at 4, 12, and 18-months follow-up as the dependent variable, adjusting for baseline score (except for the Net Promotor score which is not collected at baseline), age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol, treatment group, time, and treatment group-by-time interaction as fixed effects, and including treating centre and participant as random effects, as in the primary analysis.

As in the primary analysis, different correlation structures will be compared and the most appropriate pattern will be used for the final model. The adjusted mean difference and its associated 95% CI and p-value will be extracted for each individual time point and overall. All model assumptions will be checked, and if they are in doubt transformations of the outcome data will be considered.

An additional model will be fitted, which will include the 24-months' time point in the above model for those participants who have reached that time point, treatment group differences at 24 months will be reported with the associated 95% CI and p-value. Example tables are provided in the appendix (Section 15.2.3.1).

*Radiological union*

Assessment of union will be performed for the 4-months' time point only. Two independent radiologists will assess whether there is any evidence of bridging trabeculae across the fracture site from the antero-posterior and lateral x-rays. Reviewers will discuss any discrepancies and come to a final decision. The proportion of participants with evidence of bridging trabeculae (identified on the antero-posterior or lateral x-ray) will be compared between treatment groups. Mixed-effects logistic regression will be performed adjusting for treatment group, age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol, and centre (random effect). The odds ratio and associated 95% CI and p-value will be reported.

The reviewers will be asked to indicate whether the fracture appears united in their opinion, there are three response options: 'appears united', 'suspected non-union', 'definite non-union'. Reviewers will discuss any discrepancies and come to a final decision. Responses will be ranked on a 3-point scale and analysed using ordinal logistic regression. Analysis will be adjusted for treatment group, age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol, and centre (random effect). The odds ratios and associated 95% CI and p-value will be reported. Example tables are provided in the appendix (Section 15.2.3.2).

*Complications*

Intra-operative complications will be collected using the primary surgery CRF. Data will be reported as frequencies and proportions. The proportion of participants who experienced at least one intra-operative complication will be analysed by mixed-effects logistic regression, adjusting for treatment group, age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol, and centre (random effect). Odds ratios and their associated 95% CI and p-value will be provided. The frequencies and proportions of each type of inter-operative complication (e.g., fracture, nerve injury, vascular injury) will also be reported.

Post-operative surgical and general medical complications will be collected at 4, 12, 18 and 24-months (24-months only applies to participants who reach this time point). Data will be reported as frequencies and proportions. Provided there are sufficient data, the following secondary outcomes will be analysed by mixed-effects logistic regression, with 4, 12 and 18-months follow-up points as the dependent variable, adjusting for age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol, treatment group, time, and treatment group-by-time interaction as fixed effects and centre (random effect), participant will also be included as a random effect to account for repeated measures:

- Proportion of participants who had at least one surgical complication related to the affected arm post-surgery
- Proportion of participants who had at least one general medical complication post-surgery

Odds ratios and their associated 95% CI and p-value will be reported for each individual follow-up point and overall.

The above model will also be fitted including the 24-month follow-up point (in addition to the 4, 12 and 18-months' time points). The Odds ratios and their associated 95% CI and p-value will be reported for the 24-month follow-up point.

For each type of surgical and medical complications (e.g., ulna nerve lesion, vascular injury, infection at surgical site, skin problems) the frequencies and proportions will be reported for each treatment group at each follow-up time point (4, 12, 18, 24-months). The frequency and proportion of complications that resulted in a secondary procedure will also be reported by treatment group. Any treatment crossovers will be identified in the table (e.g., by superscripts and footnotes), if there are a large number of treatment crossovers then separate tables may be produced by treatment received (i.e. in addition to the table by randomised treatment group).

Example tables are provided in the appendix (Section 15.2.3.3).

*Elbow range of movement (ROM)*

ROM will be assessed by the outcome assessor and the patient separately at the 4-month follow-up point. Patient reported ROM refers to photographs taken by the patient, which will then be assessed by independent physiotherapists who will measure ROM from the photographs. Descriptive summary statistics (including N, Mean, Median, Standard Deviation, 1$^{st}$ and 3$^{rd}$ quartiles, Minimum, and Maximum) will be reported for each measure (flexion, extension, pronation, and supination) and each method (In-clinic assessment and Patient reported, where applicable) by each treatment group. For the following secondary outcomes, mixed-effects regression analysis will be performed for each measurement separately adjusted for treatment group, age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol as fixed effects, and centre (random effect):

- ROM measured in-clinic: flexion, extension, pronation, and supination.
- Patient reported ROM measurements: flexion, extension (pronation and supination measurements will not be collected from patient reported measurements).

The adjusted mean difference will be reported for each measurement along with corresponding 95% confidence intervals and p-values. Example tables are provided in the appendix (Section 15.2.3.4).

*Re-operations related to the injury or to remove the fixation material*

The frequency and proportion of participants requiring additional surgery or procedures will be reported by treatment group. Provided there are sufficient data, the following outcomes will be analysed by mixed-effects logistic regression adjusted for treatment group, age at randomisation, prescribed NSAIDs, previous elbow fractures, diabetes status, smoking status, drinks alcohol, as fixed effects, and centre (random effect):

- Proportion of participants requiring at least one additional surgery/procedure
- Proportion of participants requiring more than one additional surgery/procedure

Odds ratios and their associated 95% CI and p-value will be provided.
For participants requiring more than one additional surgery or procedure the frequencies for the number of procedures performed will be reported for each treatment group.

The type of procedure (e.g., revision of fixation, removal of fixation, bone graft, drainage of abscess, wound debridement) and the reasons (e.g., failure of fixation, deep infection, non-union, delayed union, malunion, complications) will be reported as frequencies and proportions.

Example tables are provided in the appendix (Section 15.2.3.5).

## 11.9 Adverse events

The adverse event (AE) reporting period for this trial begins as soon as the participant consents to be in the study and ends 12 months following their treatment.

For this trial, 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 section 6.2 of the protocol [1]. These should not be reported as an AE since they are well known complications of surgery for which the specialist clinical care teams will be experienced in managing. These complications will however be recorded via the CRFs (Primary surgery form and Investigator follow-up forms). All related and unexpected AEs will be recorded on the study AE form by the research staff and sent to YTU.

Any serious adverse events (SAEs) will be notified to the Principal Investigator and to YTU within 24 hours of the research staff or clinical team becoming aware of the event. SAEs that are deemed to be unexpected and related to the trial will be notified to the Research Ethics Committee (REC) and sponsor. Details of any SAEs reported to the YTU will be recorded using a SAE form.
For this trial, a Serious Adverse Event (SAE) is defined as any untoward occurrence that:

(a) Results in death
(b) Is life threatening
(c) Requires unplanned hospitalisation or prolongation of existing hospitalisation
(d) Results in persistent or significant disability or incapacity
(e) Is another important medical condition

Adverse event data will be summarised descriptively by event type (serious, non-serious) for each treatment group. This will include total number of events, number of participants reporting at least one event, number of events per participant, event outcome and event details (where provided). Any treatment crossovers will be identified in the table (e.g., by superscripts and footnotes), if there are a large number of treatment crossovers then separate additional tables may be produced by treatment received rather than randomised treatment group.

## 11.10 Planned formal interim analyses

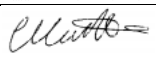
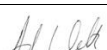
There are no planned interim analyses.

## 12. SAP amendment log

| Amendment/addition to SAP and reason for change | New version number, name and date |
|---|---|
| Some minor changes were made as previous version was written by a statistician who is no longer on the study. Changes made:<br>• Removed one of the sensitivity analyses as it was very similar to the one already specified (section 11.6)<br>• Further detail was added about how the primary analysis will be interpreted (appendix 15.1)<br>• Specified which baseline DASH will be used in the primary analysis model<br>• Some minor changes to reflect staff changes (page 0) | Version 1 (not previously signed off) 21/02/2024 |
| | |
| | |
| | |

## 13. Signatures of approval

Sign-off of the final approved version of the Statistical Analysis Plan.

| Name | Trial Role | Signature | Date |
|---|---|---|---|
| Luke Strachan | Trainee Statistician |  | 27/02/2024 |
| Laura Mandefield | Statistician |  | 21/02/2024 |
| Catherine Hewitt | Senior Statistician |  | 27/02/2024 |
| Professor Adam C Watts | Chief Investigator |  | 17/03/2024 |
| Liz Cook | Study Manager |  | 29/02/2024 |

## 14. References

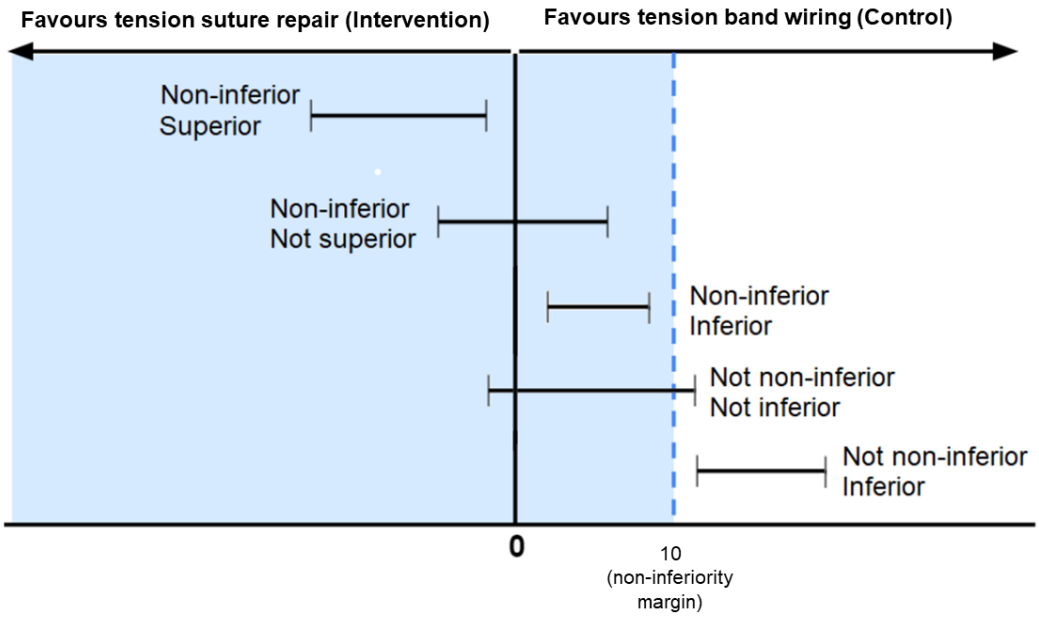

1. Suture fixation versus tension band wiring for simple olecranon fracture fixation: a multi-centre randomised controlled trial (Simple Olecranon Fracture Fixation Trial -SOFFT) Protocol [Online]. Available from: https://fundingawards.nihr.ac.uk/award/NIHR127739
2. Duckworth AD, Clement ND, White TO, Court-Brown CM, McQueen MM. Plate Versus Tension-Band Wire Fixation for Olecranon Fractures: A Prospective Randomized Trial. J Bone Joint Surg Am. 2017;99(15):1261-73.
3. Angst F, Schwyzer HK, Aeschlimann A, Simmen BR, Goldhahn J. Measures of adult shoulder function: Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and its short version (QuickDASH), Shoulder Pain and Disability Index (SPADI), American Shoulder and Elbow Surgeons (ASES) Society standardized shoulder assessment form, Constant (Murley) Score (CS), Simple Shoulder Test (SST), Oxford Shoulder Score (OSS), Shoulder Disability Questionnaire (SDQ), and Western Ontario Shoulder Instability Index (WOSI). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S174-88.

4. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S240-52.
5. Hamilton DF, Lane JV, Gaston P, Patton JT, Macdonald DJ, Simpson AH, Howie CR. Assessing treatment outcomes using a single question: the net promoter score. Bone Joint J. 2014 May;96-B(5):622-8. doi: 10.1302/0301-620X.96B5.32434. PMID: 24788496.
6. van Reenen MaJ, B. EQ-5D-5L User Guide: Basic information on how to use the EQ-5D-5L instrument. The Netherlands: EuroQol Research Foundation 2015(Version 2.1).
7. Meislin MA, Wagner ER, Shin AY. A Comparison of Elbow Range of Motion Measurements: Smartphone-Based Digital Photography Versus Goniometric Measurements. The Journal of Hand Surgery. 2016;41(4):510-5.e1.
8. Costa ML, Achten J, Plant C, Parsons NR, Rangan A, Tubeuf S, et al. UK DRAFFT: a randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a dorsally displaced fracture of the distal radius. Health Technol Assess. 2015;19(17):1-124, v-vi.
9. Angst F, John M, Goldhahn J, Herren DB, Pap G, Aeschlimann A, et al. Comprehensive assessment of clinical outcome and quality of life after resection interposition arthroplasty of the thumb saddle joint. Arthritis Rheum. 2005;53(2):205-13.
10. Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). J Orthop Sports Phys Ther. 2014;44(1):30-9.
11. MacDermid JC, Wessel J, Humphrey R, Ross D, Roth JH. Validity of self-report measures of pain and disability for persons who have undergone arthroplasty for osteoarthritis of the carpometacarpal joint of the hand. Osteoarthritis Cartilage. 2007;15(5):524-30.
12. Chiari-Grisar C, Koller U, Stamm TA, Wanivenhaus A, Trieb K. Performance of the disabilities of the arm, shoulder and hand outcome questionnaire and the Moberg picking up test in patients with finger joint arthroplasty. Arch Phys Med Rehabil. 2006;87(2):203-6.
13. White I. RCTMISS: Stata module to analyse a randomised controlled trial (RCT) allowing for informatively missing outcome data. 2018.
14. White IR, Kalaitzaki E, Thompson SG. Allowing for missing outcome data and incomplete uptake of randomised interventions, with application to an Internet-based alcohol trial. Statistics in medicine. 2011;30(27):3192-207.

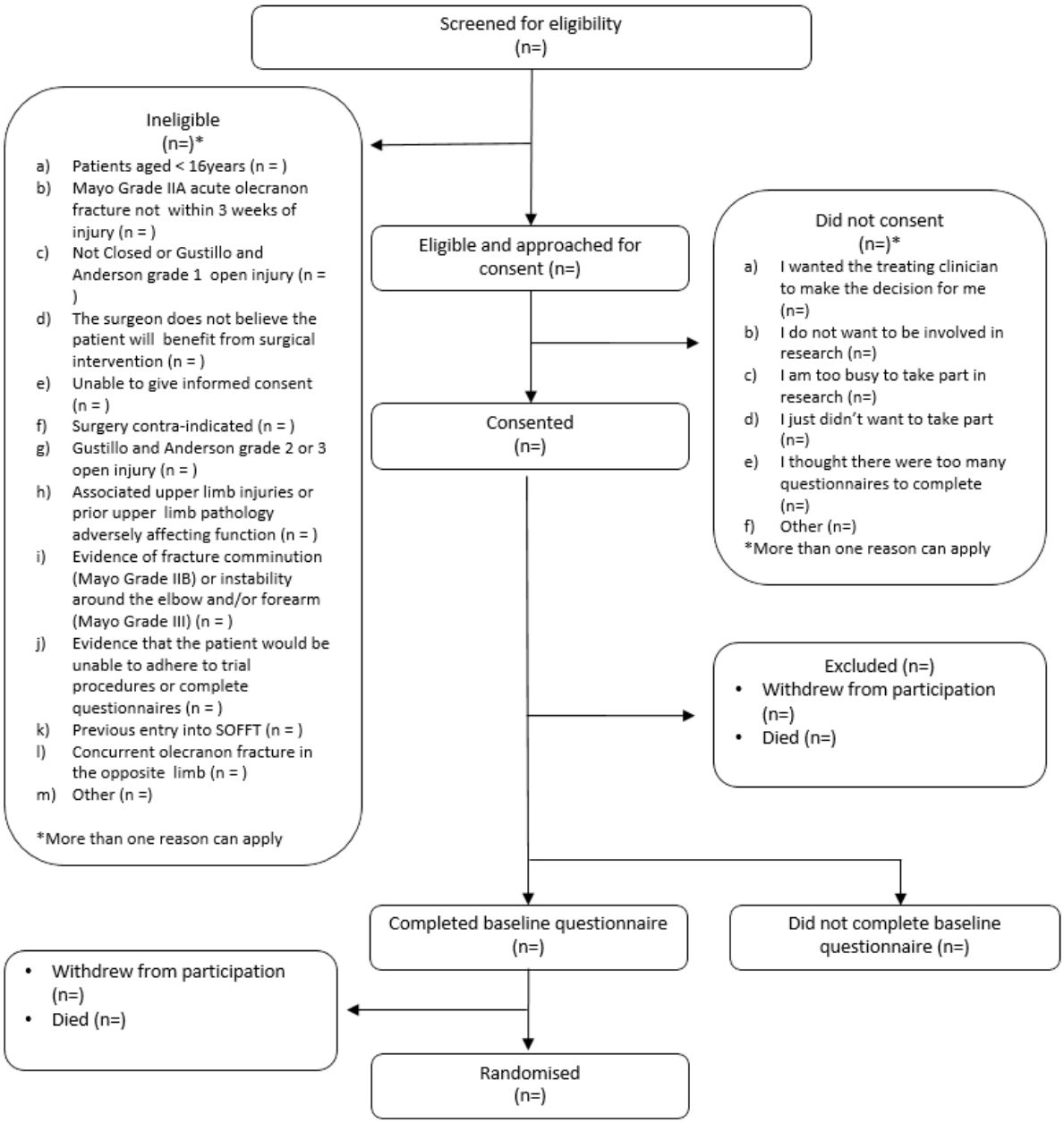
# 15. Appendices

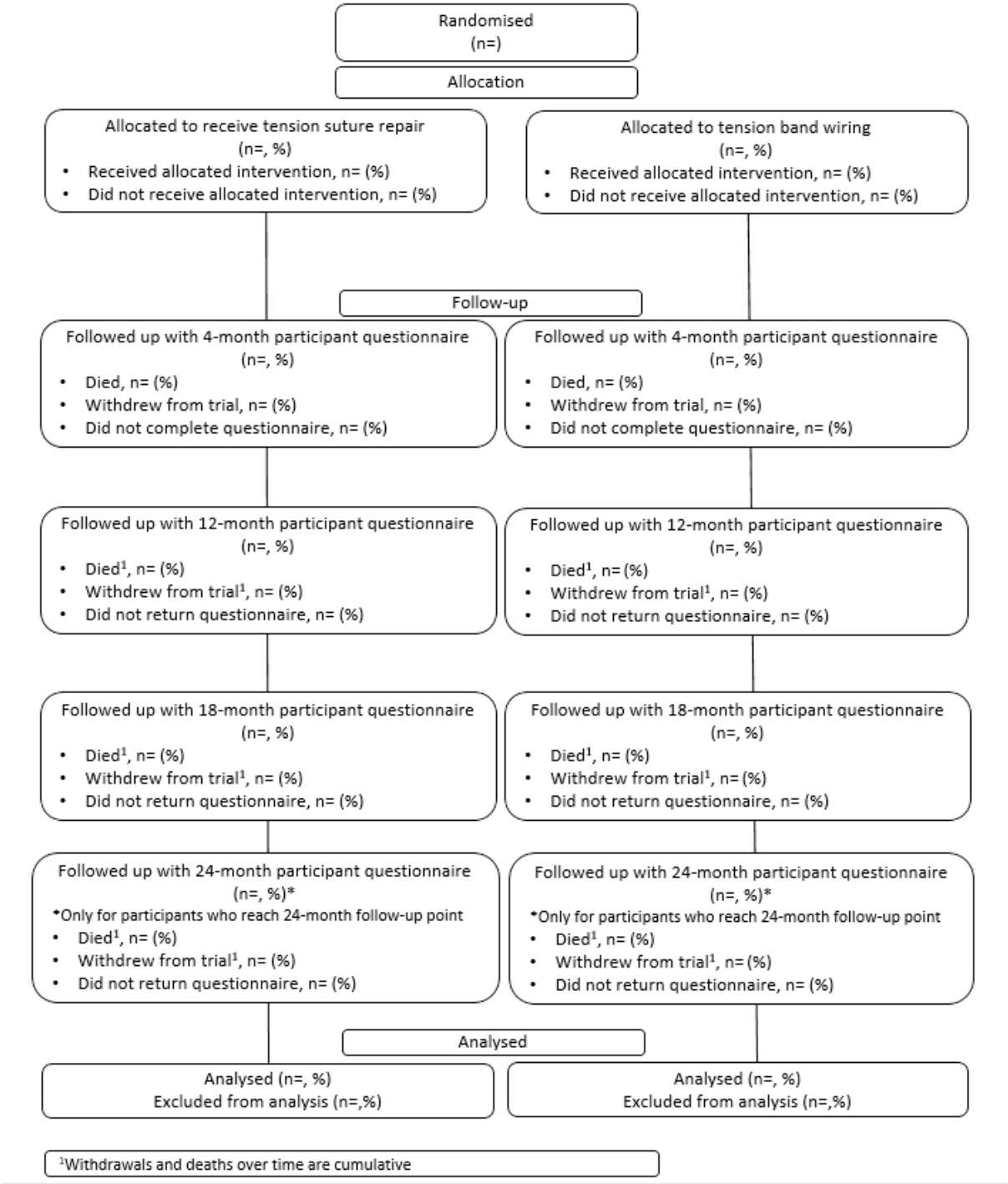
## 15.1 Accepting non-inferiority

Section x outlines how we will determine whether tension suture repair is non-inferior to tension band wiring. The primary endpoint is the DASH score at 4 months. For treatment to be effective we are looking for a reduction in DASH scores (lower DASH scores are more favourable). When modelling the treatment effect, the treatment allocations will be coded as 1= intervention (tension suture repair) and 0= control (tension band wiring). Therefore a positive effective will mean the treatment difference will be negative. The non-inferiority margin has been specified as 10 and non-inferiority will be accepted if the upper bound of the of the one-sided 97.5% confidence interval for the treatment difference at 4 months lies below the non-inferiority margin of 10 points. Figure 1 shows how we will interpret different possible results.



## 15.2 CONSORT Diagram




Randomised
(n=)
Allocation
Allocated to receive tension suture repair
(n=, %)
• Received allocated intervention, n= (%)
• Did not receive allocated intervention, n= (%)
Allocated to tension band wiring
(n=, %)
• Received allocated intervention, n= (%)
• Did not receive allocated intervention, n= (%)
Follow-up
Followed up with 4-month participant questionnaire
(n=, %)
• Died, n= (%)
• Withdrew from trial, n= (%)
• Did not complete questionnaire, n= (%)
Followed up with 4-month participant questionnaire
(n=, %)
• Died, n= (%)
• Withdrew from trial, n= (%)
• Did not complete questionnaire, n= (%)
Followed up with 12-month participant questionnaire
(n=, %)
• Died[1], n= (%)
• Withdrew from trial[1], n= (%)
• Did not return questionnaire, n= (%)
Followed up with 12-month participant questionnaire
(n=, %)
• Died[1], n= (%)
• Withdrew from trial[1], n= (%)
• Did not return questionnaire, n= (%)
Followed up with 18-month participant questionnaire
(n=, %)
• Died[1], n= (%)
• Withdrew from trial[1], n= (%)
• Did not return questionnaire, n= (%)
Followed up with 18-month participant questionnaire
(n=, %)
• Died[1], n= (%)
• Withdrew from trial[1], n= (%)
• Did not return questionnaire, n= (%)
Followed up with 24-month participant questionnaire
(n=, %)*
*Only for participants who reach 24-month follow-up point
• Died[1], n= (%)
• Withdrew from trial[1], n= (%)
• Did not return questionnaire, n= (%)
Followed up with 24-month participant questionnaire
(n=, %)*
*Only for participants who reach 24-month follow-up point
• Died[1], n= (%)
• Withdrew from trial[1], n= (%)
• Did not return questionnaire, n= (%)
Analysed
Analysed (n=, %)
Excluded from analysis (n=,%)
Analysed (n=, %)
Excluded from analysis (n=,%)
[1]Withdrawals and deaths over time are cumulative

## 15.2 Template Tables

### 15.2.1 Demographic and baseline data

Table 1 and 2 will be generated for the ITT population.

**Table 1:** Demographic and baseline characteristics presented by treatment allocation for the 'as randomised' and 'as analysed' participants for the ITT population.

| | As randomised (n=) | | As analysed (n=) | |
|---|---|---|---|---|
| | **Tension suture repair (n=)** | **Tension band wiring (n=)** | **Tension suture repair (n=)** | **Tension band wiring (n=)** |
| **Sex, n (%)**<br>Male<br>Female<br>Rather not say<br>Missing | | | | |
| **Age at randomisation (years)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | | |
| **Ethnicity, n (%)**<br>White<br>Black<br>Asian<br>Chinese<br>Other<br>Missing | | | | |
| **Highest level of education, n (%)**<br>No formal qualifications<br>Some qualifications/no degree<br>Degree or higher | | | | |
| **Working status, n (%)**<br>Employed part-time<br>Employed full-time<br>Self-employed<br>Student/studying<br>Retired<br>Looking after family/home<br>Not employed but seeking work<br>Currently unable to work<br>Other<br>Not known | | | | |
| **Living arrangements, n (%)**<br>Live alone<br>Live alone but with support<br>Live with wife/husband/partner<br>Live with friends<br>Live with relatives<br>Other<br>Missing | | | | |
| **Regular smoker, n (%)**<br>Yes<br>No | | | | |

| | | | | |
|---|---|---|---|---|
| **Drinks alcohol, n (%)**<br>Yes<br>No | | | | |
| **Diabetes, n (%)**<br>Yes<br>No | | | | |
| **Osteoporosis, n (%)**<br>Yes<br>No | | | | |
| **Currently taking steroids, n (%)**<br>Yes<br>No | | | | |
| **Health Status (EQ-5D-5L index)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | | |

**Table 2:** Baseline fracture details presented by treatment allocation for the 'as randomised' and 'as analysed' participants for the ITT population.

| | **As randomised (n=)** | | **As analysed (n=)** | |
|---|---|---|---|---|
| | **Tension suture repair (n=)** | **Tension band wiring (n=)** | **Tension suture repair (n=)** | **Tension band wiring (n=)** |
| **DASH score baseline pre-injury (0-100)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | | |
| **DASH score baseline post-injury/pre-surgery (0-100)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | | |
| **Pain (VAS) score (0-100)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | | |
| **Time since injury (days)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | | |
| **Injured elbow, n (%)**<br>Left<br>Right | | | | |
| **Injured dominant arm, n (%)**<br>Yes<br>No | | | | |
| **Previous problems with injured elbow, n (%)**<br>Previous injury<br>Arthritis | | | | |

| | | | | |
|---|---|---|---|---|
| Other | | | | |
| **Previous fractures to elbow, n (%)**<br>Yes<br>No | | | | |
| **Previous orthopaedic surgery to elbow, n (%)**<br>Yes<br>No | | | | |
| **Injury mechanism, n (%)**<br>Low energy fall<br>High energy fall<br>Road traffic accident<br>Contact sports injury<br>Other | | | | |
| **Treatment preference, n (%)**<br>Tension band wiring<br>Tension suture repair<br>No preference<br>Missing | | | | |
| | | | | |

### 15.2.2 Primary Analysis

**Table 3:** DASH score at 4-months presented descriptively by treatment group for the ITT population. Adjusted mean differences alongside corresponding 95% confidence intervals are presented.

| | **Mean estimates** | | **Adjusted Mean Difference (one-sided 97.5% CI)[#]** |
|---|---|---|---|
| | **Tension suture repair** | **Tension band wiring** | |
| ***DASH Score*** | | | |
| Number of participants | | | |
| 4 Months | | | |

The sensitivity analysis of the primary analysis model will be reported in a similar fashion as Table 3.

### 15.2.3 Secondary Analysis

#### 15.2.3.1 DASH score, Pain score, Patient satisfaction

**Table 4:** Secondary outcomes presented by treatment group. Adjusted mean differences alongside corresponding 95% confidence intervals are presented.

| | **Mean estimates** | | **Adjusted Mean Difference (95% CI)[#]** |
|---|---|---|---|
| | **Tension suture repair** | **Tension band wiring** | |
| ***DASH score*** | | | |
| Number of participants analysed | | | |
| 12 months | | | |
| 18 months | | | |
| Averaged over 18 months | | | |
| 24 months* | | | |
| ***Pain (VAS) score*** | | | |

| | | | |
|---|---|---|---|
| Number of participants analysed | | | |
| 4 months | | | |
| 12 months | | | |
| 18 months | | | |
| Averaged over 18 months | | | |
| 24 months* | | | |
| ***Patient satisfaction (Net Promotor Score)*** | | | |
| Number of participants analysed | | | |
| 4 months | | | |
| 12 months | | | |
| 18 months | | | |
| Averaged over 18 months | | | |
| 24 months* | | | |

*****Additional time point for those that reach 24 months follow-up, estimated from a separate model. # One-sided upper 97.5% confidence limits will be reported for DASH scores.

#### 15.2.3.2 Radiological union

**Table 5:** Radiological union assessment at 4-months (secondary outcome) presented by treatment group. Odds ratio alongside corresponding 95% confidence intervals and p-values are presented.

| | **Proportion** | | | |
|---|---|---|---|---|
| | **Tension suture repair (n=)** | **Tension band wiring (n=)** | **Odds Ratio (95% CI)** | **p-value** |
| ***Radiological union*** | | | | |
| **Bridging trabeculae**<br>Yes<br>No | | | | |
| **Assessment of union**<br>Appears united<br>Suspected non-union<br>Definite non-union | | | | |

#### 15.2.3.3 Complications (Intra-operative and post-operative)

**Table 6:** Frequency of intra-operative and post-operative complications for each follow-up time point, presented by treatment group.

| | **Tension suture repair** | **Tension band wiring** | **Total** |
|---|---|---|---|
| ***Intra-operative complications*** | | | |
| **Type of complication, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Fracture | | | |
| Nerve injury | | | |
| Vascular injury | | | |
| Loss of fixation | | | |
| Other | | | |
| ***Post-operative surgical complications*** | | | |
| **4 months, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Ulna nerve lesion | | | |
| Radial nerve lesion | | | |

| | | | |
|---|---|---|---|
| Vascular injury | | | |
| Median nerve lesion | | | |
| Radioulnar synostosis | | | |
| …(all complications will be reported) | | | |
| **12 months, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Ulna nerve lesion | | | |
| Radial nerve lesion | | | |
| Vascular injury | | | |
| Median nerve lesion | | | |
| Radioulnar synostosis | | | |
| …(all complications will be reported) | | | |
| **18 months, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Ulna nerve lesion | | | |
| Radial nerve lesion | | | |
| Vascular injury | | | |
| Median nerve lesion | | | |
| Radioulnar synostosis | | | |
| …(all complications will be reported) | | | |
| **24 months*, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Ulna nerve lesion | | | |
| Radial nerve lesion | | | |
| Vascular injury | | | |
| Median nerve lesion | | | |
| Radioulnar synostosis | | | |
| …(all complications will be reported) | | | |
| ***Post-operative general complications*** | | | |
| **4 months, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Deep vein thrombosis | | | |
| Pulmonary embolism | | | |
| Myocardial infarction | | | |
| Stroke | | | |
| Chest infection | | | |
| …(all complications will be reported) | | | |
| **12 months, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Deep vein thrombosis | | | |
| Pulmonary embolism | | | |
| Myocardial infarction | | | |
| Stroke | | | |
| Chest infection | | | |
| …(all complications will be reported) | | | |
| **18 months, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Deep vein thrombosis | | | |
| Pulmonary embolism | | | |
| Myocardial infarction | | | |
| Stroke | | | |
| Chest infection | | | |
| …(all complications will be reported) | | | |
| **24 months*, n (%)** | **n=xxx** | **n=xxx** | **n=xxx** |
| Deep vein thrombosis | | | |
| Pulmonary embolism | | | |
| Myocardial infarction | | | |
| Stroke | | | |
| Chest infection | | | |
| …(all complications will be reported) | | | |

*****Additional time point for those that reach 24 months follow-up.

**Table 7:** Proportion of participants experiencing intra-operative complications, and post-operative complications at each follow-up point (secondary outcomes) presented by treatment group. Odds ratio alongside corresponding 95% confidence intervals and p-values are presented.

| | Proportion | | Odds Ratio (95% CI) | p-value |
|---|---|---|---|---|
| | Tension suture repair | Tension band wiring | | |
| ***Complications*** | | | | |
| **Number of participants reporting ≥ 1 intra-operative complication** | | | | |
| 4 months | | | | |
| **Number of participants reporting ≥ 1 post-operative surgical complication** | | | | |
| 4 months | | | | |
| 12 months | | | | |
| 18 months | | | | |
| Averaged over 18 months | | | | |
| 24 months* | | | | |
| **Number of participants reporting ≥ 1 post-operative general complication** | | | | |
| 4 months | | | | |
| 12 months | | | | |
| 18 months | | | | |
| Averaged over 18 months | | | | |
| 24 months* | | | | |

*****Additional time point for those that reach 24 months follow-up, estimated from a separate model.

#### 15.2.3.4 Elbow range of movement

**Table 8:** Elbow range of movement at 4-months for affected elbow (secondary outcome) measured by the outcome assessor and patient, presented by treatment group.

| | Tension suture repair (n=) | Tension band wiring (n=) | Total (n=) |
|---|---|---|---|
| ***Outcome assessor measurements (In-clinic)*** | | | |
| **Extension (º)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | |
| **Flexion (º)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | |
| **Supination (º)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | |
| **Pronation (º)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | |

| | | | |
|---|---|---|---|
| ***Patient reported measurements*** | | | |
| **Extension (º)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | |
| **Flexion (º)**<br>n (%)<br>Mean (SD)<br>Median (IQR)<br>Min, Max | | | |

**Table 9:** Range of movement (º) at 4-months by treatment group. Adjusted mean differences alongside corresponding 95% confidence intervals and p-values are presented.

| | **Mean estimates** | | **Adjusted Mean Difference (95% CI)** | **p-value** |
|---|---|---|---|---|
| | **Tension suture repair** | **Tension band wiring** | | |
| ***Range of movement*** | | | | |
| Number of participants | | | | |
| Extension (º) | | | | |
| Flexion (º) | | | | |
| Supination (º) | | | | |
| Pronation (º) | | | | |

#### 15.2.3.5 Re-operations

**Table 10:** Frequency of secondary procedures, type of secondary procedures performed and reasons for secondary procedures, presented by treatment group.

| | **Tension suture repair (n=)** | **Tension band wiring (n=)** | **Total (n=)** |
|---|---|---|---|
| **Total secondary procedures performed, n (%)** | | | |
| **Type of Secondary Procedures, n (% of total secondary procedures):** | | | |
| **Revision of fixation** | | | |
| **Reason, n (% of revision of fixations)**<br>Failure of fixation<br>Deep infection<br>Non-union<br>Delayed union<br>Malunion<br>Complication<br>Other | | | |
| **Fixation device removed** | | | |
| **Reason, n (% of fixation device removals)**<br>Failure of fixation<br>Deep infection<br>Non-union<br>Delayed union<br>Malunion<br>Complication<br>Other | | | |
| **Bone graft** | | | |

| | | | |
|---|---|---|---|
| **Reason, n (% of bone grafts)**<br>Failure of fixation<br>Deep infection<br>Non-union<br>Delayed union<br>Malunion<br>Complication<br>Other | | | |
| **Drainage of abscess** | | | |
| **Reason, n (% of drainage of abscess)**<br>Failure of fixation<br>Deep infection<br>Non-union<br>Delayed union<br>Malunion<br>Complication<br>Other | | | |
| **Wound debridement** | | | |
| **Reason, n (% of wound debridement)**<br>Failure of fixation<br>Deep infection<br>Non-union<br>Delayed union<br>Malunion<br>Complication<br>Other | | | |
| **Other** | | | |
| **Reason, n (% of other)**<br>Failure of fixation<br>Deep infection<br>Non-union<br>Delayed union<br>Malunion<br>Complication<br>Other | | | |

**Table 11:** Proportion of participant's requiring additional surgery/procedures (secondary outcome) presented by treatment group. Odds ratio alongside corresponding 95% confidence intervals and p-values are presented.

| | **Proportion** | | | |
|---|---|---|---|---|
| | **Tension suture repair (n=)** | **Tension band wiring (n=)** | **Odds Ratio (95% CI)** | **p-value** |
| ***Secondary procedures*** | | | | |
| Number of participants requiring ≥ 1 additional surgery/procedure | | | | |
| Number of participants requiring > 1 additional surgery/procedure | | | | |