Site Initiation Visit

Funder: NIHR Health Technology Assessment NIHR133784

IRAS: 316277

REC: 23/NW/0004

ISRCTN: 10918157

Sponsor: South Tees Hospitals NHS Foundation Trust

SIV Version: 1.6

Date: 01.07.2024

Funding Acknowledgement:
This project was funded by the NIHR Health Technology Assessment Programme (Reference: NIHR133784). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social

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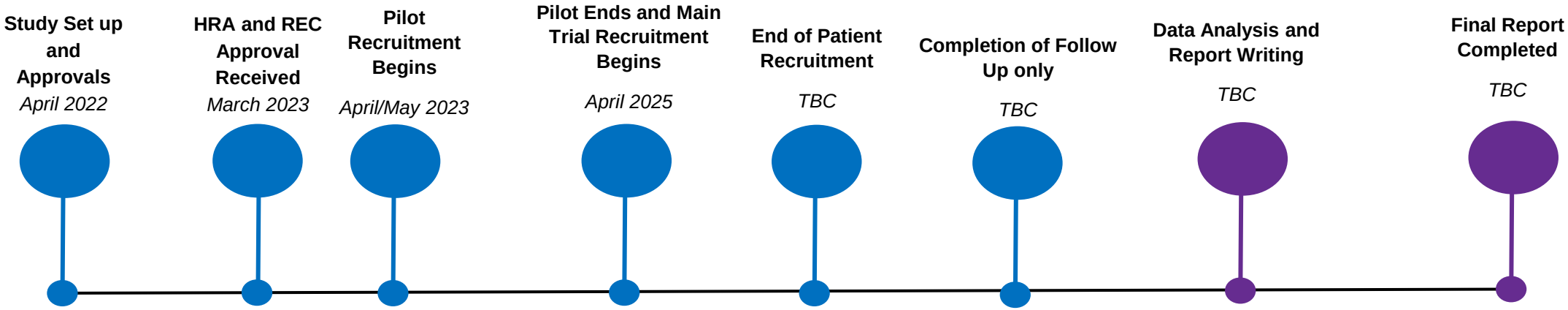
SIV Agenda

- FLARE Trial Timeline
- FLARE Trial Background, Aims and Objectives
- FLARE Trial Recruitment Process and Data Collection
- Adverse Events
- Training Requirements
- Monitoring
- Protocol Deviations
- Study Documents
- Trial Finances
- Site Close Out Visit
- What happens next?

FLARE Trial Timeline



FLARE Sites

Current FLARE Sites include:

- Frimley Health NHS Foundation
- South Tees Hospitals NHS Foundation
- Leeds Teaching Hospitals NHS Foundation
- North Cumbria Integrated Care NHS Foundation
- Manchester University NHS Foundation Trust
- University Hospitals Birmingham NHS Foundation Trust
- Royal Cornwall Hospital NHS Trust
- Guys and St Thomas' NHS Foundation Trust
- Hampshire Hospitals NHS Foundation Trust
- Newcastle Hospitals NHS Foundation Trust
- County Durham and Darlington NHS Foundation Trust
- Buckinghamshire Healthcare NHS Trust
- St George's University Hospitals NHS Foundation Trust
- Cambridge University Hospitals NHS Foundation Trust
- Northumbria Healthcare NHS Foundation Trust
- East and North Hertfordshire NHS Trust
- Hull University Teaching Hospitals NHS Trust
- Oxford University Hospitals NHS Foundation Trust
- University Hospitals of North Midlands NHS Trust
- NHS Forth Valley
- University Hospitals of Derby and Burton NHS Foundation Trust
- NHS Lothian
- Swansea Bay University Health Board
- Chelsea and Westminster Hospital NHS Foundation Trust
- University Hospitals Coventry & Warwickshire NHS Trust
- Queen Victoria Hospital NHS Foundation Trust
- Northampton General Hospital NHS Trust
- Sandwell and West Birmingham NHS Trust
- Sheffield Teaching Hospitals NHS Foundation Trust

Open to recruitment

In set up

Regulatory & Ethics Approvals

Funding Body: National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (NIHR133784)

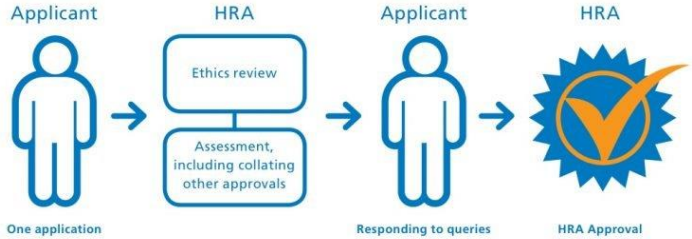
FUNDED BY
NIHR | National Institute for Health and Care Research

Initial Approvals

- **HRA Initial Assessment Letter:** 15.12.2022
- **REC Favourable Opinion:** 07.03.2023
- **HRA approval granted:** 07.03.2023

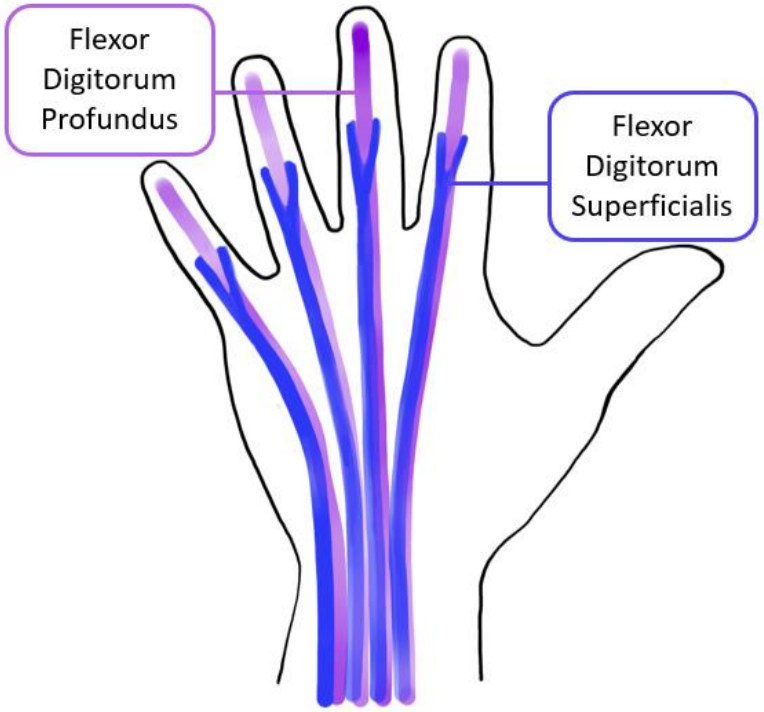
Amendments

- **NSA01:** Patient CRF updates- No approval required 27/03/2023
- **NSA02:** Protocol update- HRA approval received 05/05/2023
- **SA01:** Animated Patient Information Sheet- HRA & REC approval received 09/05/2023
- **NSA03:** Additional Sites- No approval required 20/07/2023
- **NSA04:** Updated mNCA- HRA approval received 18/07/2023
- **NSA05:** Additional Sites- No approval required 08/12/2023
- **NSA06:** Additional Site- No approval required 04/03/2024
- **NSA07:** Additional Sites and Change of Principal Investigators- HRA approval received 03/04/2024
- **NSA08**: Revision to planned recruitment period-No approval required 03/05/2024
- **NSA09**: Change of PI and new site-No approval required 28/05/2024
- **NSA10:** Change of PI and new sites- HRA approval received 16/08/2024



Trial Background and Rationale

- When both FDP and FDS flexor tendons have been severed within zone 2, the repair is technically difficult and there is a higher risk of scar tissue forming between the flexor tendons.
- Service evaluations have demonstrated that there is no consensus among surgeons as to whether FDP and FDS should be repaired, or just FDP alone.
- Both surgical treatments are currently being practiced throughout the NHS.
- A randomised controlled trial is required to inform clinical practice of whether the repair of FDP alone is as beneficial to the patient as the repair of FDP and FDS.



Aims and Objectives

Primary Hypothesis

FDP repair alone is not inferior to FDP and FDS repair for the treatment of recent complete zone 2 flexor tendon injuries in adults based on the patient reported outcome Patient Evaluation Measure (PEM) at 6-months post-randomisation.

Primary Objective

The primary objective is to ascertain the clinical and cost effectiveness of repairing FDP alone versus repair of both FDP and FDS for treatment of complete zone 2 flexor tendon injuries in adults aged 16 years and above.

Secondary Objectives

- Undertake an 8 month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility
- Assess range of motion and grip strength
- Compare the complications of both types of repair
- Assess and compare Patient Related Wrist/Hand Evaluation
- Comparison of costs, quality adjusted life years and cost effectiveness of both interventions (repairing FDP alone or both FDP and FDS)
- Undertake an embedded qualitative study

Study Design

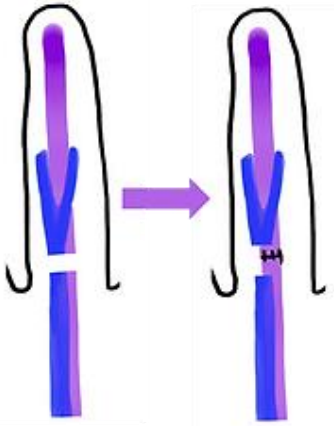
Study Design: Multi-centre, two-arm, blinded, non-inferiority, parallel group, randomised controlled trial with an internal pilot, economic evaluation and nested qualitative study

Two arms: Repair of FDP alone vs repair of both FDP and FDS

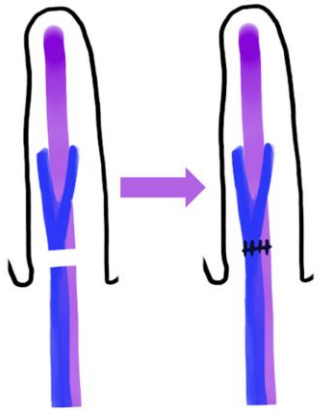
Setting: Participating Hand Trauma Centres within the UK treating flexor tendon injuries and with facilities to support research activity

Sample Size: 310 (155 in each arm)

Number of Sites: up to 40



Repair of Flexor Digitorum Profundus alone



Repair of Flexor Digitorum Profundus and Flexor Digitorum Superficialis

Outcome Measures

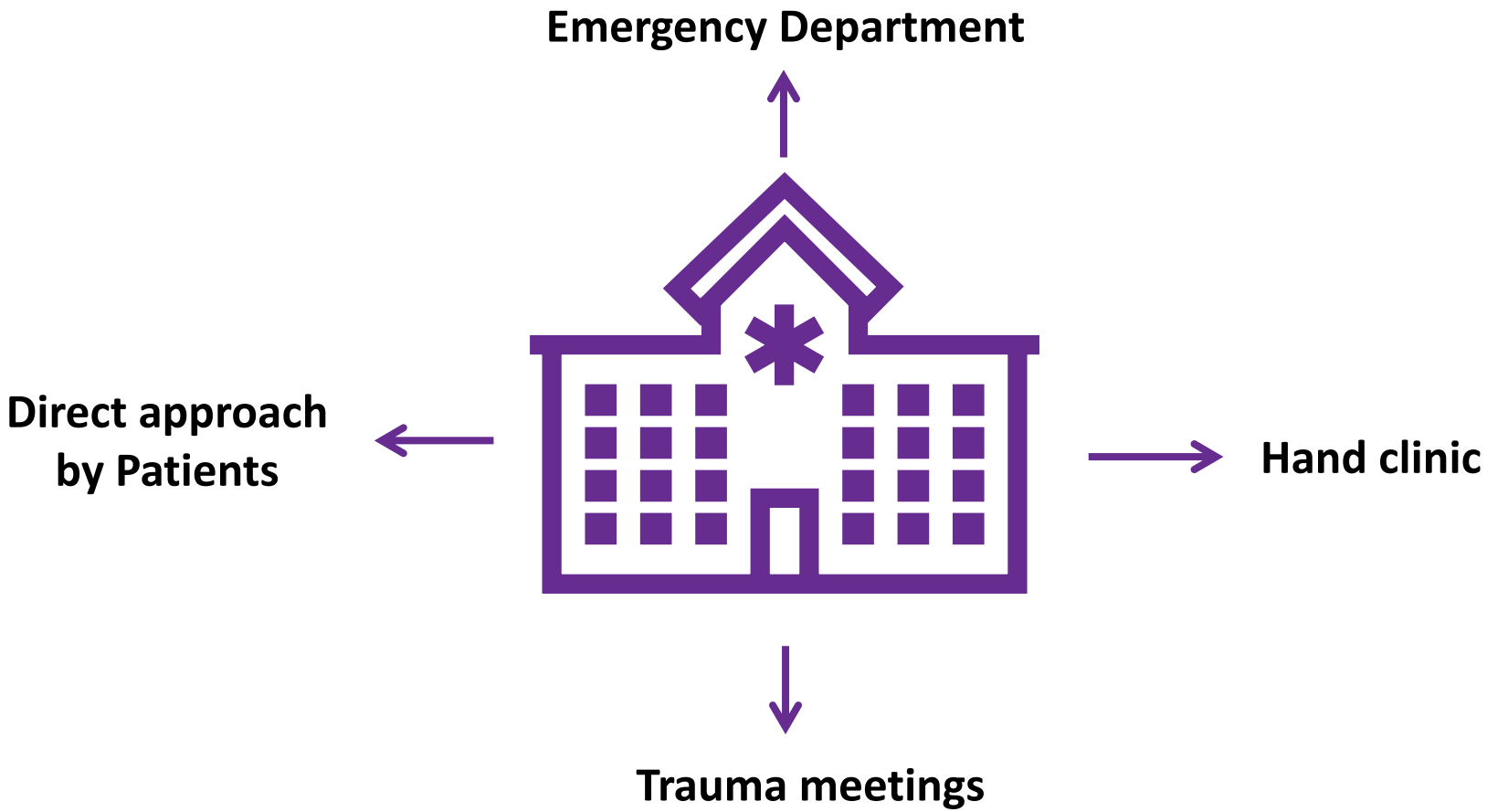
Primary Outcome- collected 6 months post randomisation

- Patient Evaluation Measure (PEM)

Secondary Outcomes- collected at respective timepoints; within 7 days, 6 weeks, 3 months and 6 months post randomisation

- Patient Related Wrist/Hand Evaluation (PRWHE)
- Total Range Of Motion (ROM)
- Grip strength
- Quality of life (EQ-5D-5L)
- Work outcomes
- Treatment and outcome satisfaction
- Healthcare resource use
- Adherence to therapy regimen
- Adherence to splint regimen
- Complications
- Nested qualitative study

Participant Identification



Trial Participant ID Number

Seven digit Participant ID number

See example below:

- Your site will be given a batch of Participant ID numbers.
- Assign and enter a unique Participant ID number on REDCap for each person screened (participants and non-participants).
- If the Participant ID is entered incorrectly, do not amend, please notify YTU.

Screening Eligibility Assessment

Screening population: All patients who are 16 years old and over with lacerations in the palm or finger consistent with a zone II flexor tendon injury

Inclusion Criteria for Screening

- Patients aged ≥ 16 years old

Exclusion Criteria for Screening

- Injuries affecting more than one digit or the thumb
- Injuries outside of Zone 2
- Injuries affecting multiple zones
- Clinically infected wounds
- Closed flexor tendon injury
- Previous tendon, bone or joint injury in the affected digit
- Patient does not have capacity to give informed consent
- Patient unable to complete follow up requirements
- Contraindication to surgery

One digit injured only with both FDS/FDP tendons severed ✓

Multiple digits injured - only one digit with both FDS/FDP tendons severed, any other injured digits have superficial injury ✓

Multiple digits injured – only one digit with both FDS/FDP tendons severed, other injured digits may have a partial tendon injury ✓

Multiple digits injured – multiple digits with both FDS/FDP tendons severed ✗

REDCap Research Electronic Data Capture

Complete Screening and Eligibility Instrument for all screened patients (eligible and ineligible)

Approaching Patients

Patient Information Resources available:

- Summary Patient Information Sheet
- Patient Information Sheet
- Patient Information Sheet- Infographic
- Patient Information Sheet- Audio Recordings
- Animated Patient Information Sheet

These resources are available within the FLARE electronic Investigator Site File and the FLARE Trial website (www.flaretrial.com).

Clinical **equipoise** is important when approaching patients– We do not know yet if the repair of FDP is as beneficial to the patient as the repair of FDP and FDS

Informed Consent

- **Patients must have capacity to consent**
- **Electronic consent form completion**
  - *Completed in person or remotely on REDCap via email*
  - *If paper version is used, upload a copy into the patient's REDCap record*
- **Witness can be used for:**
  - Patients who have injured their writing hand
  - Patients who cannot read or write

  Witness requirement: to be someone other than the person gaining consent as the researcher on the Informed Consent Form
- **Please document eligibility and consent in the patient's medical records, stating their participant ID**

Complete via REDCap (one only):

- *Patient Information Sheet & Participant Consent Form Instrument*
- *Participant Consent (Paper) Instrument*

Baseline Data Collection

Patient completes:

- Patient Baseline Questionnaire Instrument

Site completes:

- Consent Status Instrument- *for eligible patients approached for consent*
- Baseline Investigator Instrument
- Contact Details Instrument

Please check that the pre-randomisation instruments are marked as complete on REDCap prior to surgery, to ensure that the patient can be randomised during surgery

Eligibility Assessment at Surgery

Inclusion Criteria for Randomisation

- Complete division of FDP and FDS in zone 2 of a single finger
- Injury amenable to primary repair

Exclusion Criteria for Randomisation

- Injuries with loss of tendon substance or skin necessitating reconstruction
- Division of both digital arteries resulting in revascularisation of injured digit
- Division of both digital nerves

If the patient has a multiple digit injury, all digits should be examined intraoperatively to ensure the patient meets the eligibility criteria stated in the initial screening assessment.

Surgeon re-assess' the participant's injury

- *If the patient is eligible: continue to randomisation via REDCap*
- *If the patient is not eligible: continue with standard care, and inform patient after the surgery that they are no longer participating in the trial. You do not need to complete the Change of Status instrument.*

REDCap Research Electronic Data Capture *Complete Eligibility and Randomisation Instrument (for all patients, whether eligible or not)*

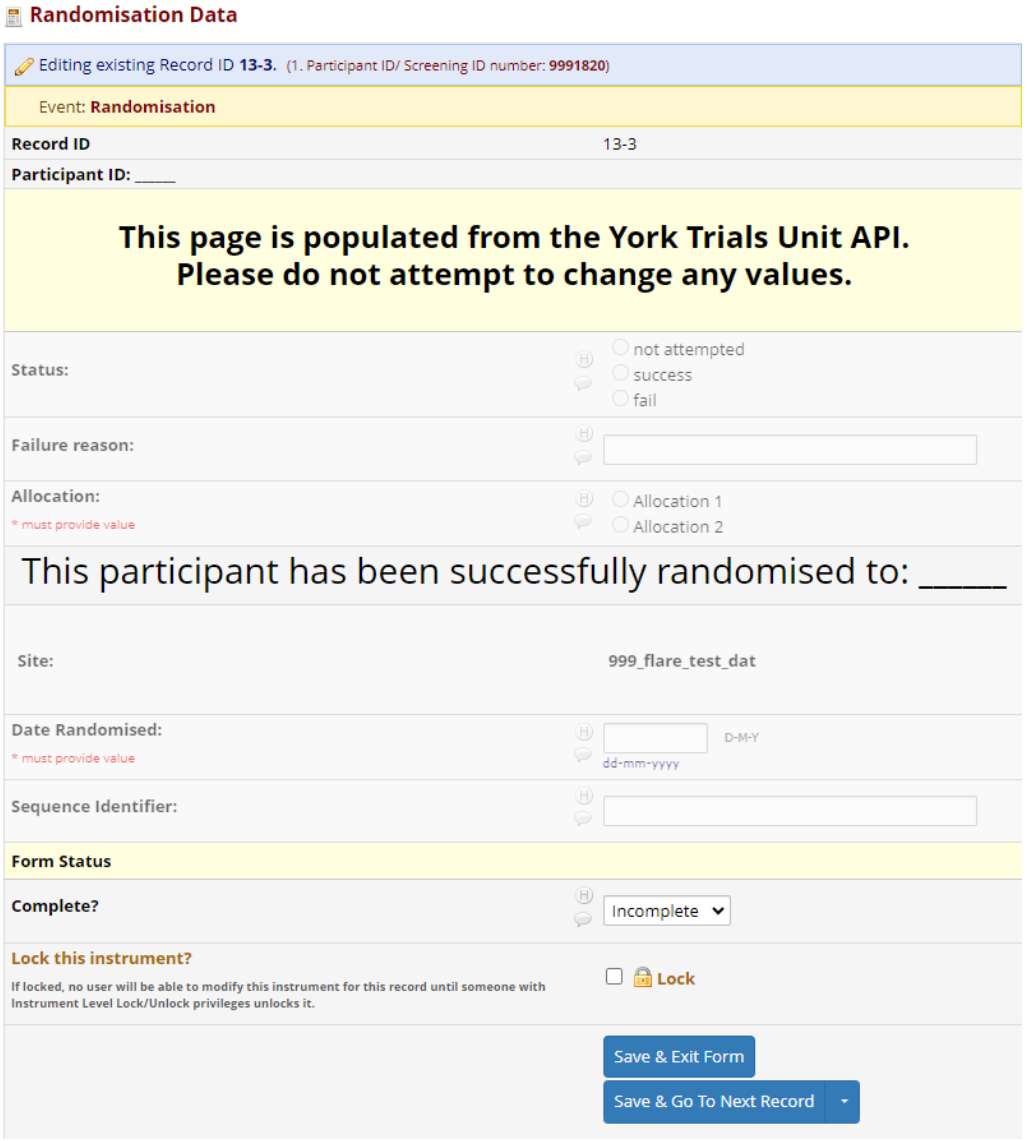
Randomisation Tasks

Once you have completed the intraoperative eligibility assessment, please complete the following steps:

1. **Eligibility and Randomisation instrument-** ensure you select ‘yes’ in response to the question ‘will the patient be randomised?’
2. **Eligibility and Randomisation instrument-** change the Form Status to ‘Complete’, and then click ‘Save and Exit Form’
3. **Prerandomisation Final Check instrument-** change the Form Status to ‘Complete’, and then click ‘Save and Exit Form’
4. **Randomisation Data instrument-** view the randomised treatment allocation

Randomisation

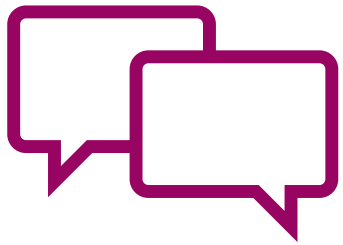
- FDP repair alone OR both FDP and FDS repair.
- Access to randomisation and surgical technical information in REDCap will be limited; blinded site team members cannot access these instruments
- Please do not communicate the treatment allocation to the participant



Post Surgery Activities

All eligible and ineligible patients need to have the following completed:

- Inform patients whether they continue to participant in the FLARE Trial or not
- Write in their medical records that the eligibility for randomisation assessment was completed and whether they were found to be eligible or ineligible



All eligible patients who continue on the trial as participants need to have the following completed:

- Send the FLARE Participant Letter/Email- Eligible to patients who continue on the trial
- Complete Primary Surgery Instrument on REDCap
- Send GP Letter to the participant's GP
- Blinded statement written into the patient's medical notes; treatment allocation and technical information about the repair performed should not be recorded

Blinding documents

- Please do not state whether FDP or FDP/FDS was repaired.

- **When completing the operation note (and referral to hand therapy/discharge letter)**

  Please state "***flexor tendon repair performed as per FLARE Trial***"

- **Any details about the operation (e.g. pulley repair) that are not collected on the Primary Surgery Instrument can be recorded in the medical records.**

Blinding Procedures

Individuals blinded to surgical treatment and technical information:

- Site teams.
- Participants.
- Hand therapists/occupational health therapists/physiotherapists.

Make sure not to document/discuss the surgical treatment or technical information:

- Writing in the patient medical notes - for notes or referrals.
- Speaking with participants or colleagues.
- Referring the patient onto hand therapists/occupational health therapists/physiotherapists.

Blinded medical records:

- Complete as per local standard procedure, e.g. electronic medical alerts or stickers on medical records

Blinded staff cannot view the following REDCap Instruments:

- Randomisation Data
- Primary Surgery

Unblinding Procedures

If unblinding is required…

…Clinicians can contact a delegated surgeon who can then log onto REDCap and view the Randomisation Data instrument.

REDCap
Research Electronic Data Capture

…Clinicians can email the York Trials Team quoting the participant ID written in the patient's surgical note. The Trial Team will then respond within office working hours.

Hand Therapy Regimen

The type of splint used and the hand therapy regimen design is negotiated between the patient and the hand therapist; there are no trial specific requirements.

Short Dorsal- Blocking Splint

Long Dorsal- Blocking Splint

Relative Motion Flexion (RMF) Splint

Follow Up

Site Staff to Complete via REDCap

Within 7 Days Clinic Review (In person)
Secondary data collection completed

Site Staff to Complete via REDCap

6 Week Clinic Review (In person/remotely)
Secondary data collection completed

Site Staff to Complete via REDCap

3 Month Clinic Review (encourage in person visit)
Secondary data collection completed

Site Staff to Complete

End of Trial Activities
Randomisation Data and Primary Surgery instrument is added/uploaded into the patient's medical notes.
Site team reviews participant's medical notes for complications/AEs/SAEs/additional surgery from 3-6 months post randomisation.

York Trials Unit to Complete

6 Week Participant Questionnaire (email/post/phone)

York Trials Unit to Complete

3 Month Participant Questionnaire (email/post/phone)

York Trials Unit to Complete

6 Month Participant Questionnaire (email/post/phone)

York Trials Unit to Complete

End of Trial Activities
Participant is informed of what surgical treatment was completed and receives £10 as a voucher or cash.

REDCap
Research Electronic Data Capture

- *Complete Investigator Form- 1 Week Instrument*
- *Complete Investigator Form- 6 Week Instrument*
- *Complete Investigator Form- 3 Month Instrument*

Data Collection Overview

Assessment	Baseline	Randomisation/Surgery	Within 7 Days Clinic Visit	6 Week Clinic Visit	3 Month Clinic Visit	6 Month Timepoint
Allowed variation in days				+/- 7 days	+/- 14 days	+/- 14 days
Eligibility Screen	Site Team					
Informed Consent	Site Team					
Demographics	Site Team					
Randomisation		Site Team				
Surgical Data		Site Team				
Confirmation of Treatment			Site Team			
Hand Therapy Review			Site Team			
Participant Questionnaires*				YTU	YTU	YTU
Healthcare Resource Use	Site Team	Site Team	Site Team	Site Team	Site Team	Site Team
Total Range of Motion				Site Team	Site Team	
Grip Strength					Site Team	
Complications and AE/SAEs			Site Team	Site Team	Site Team	Site Team

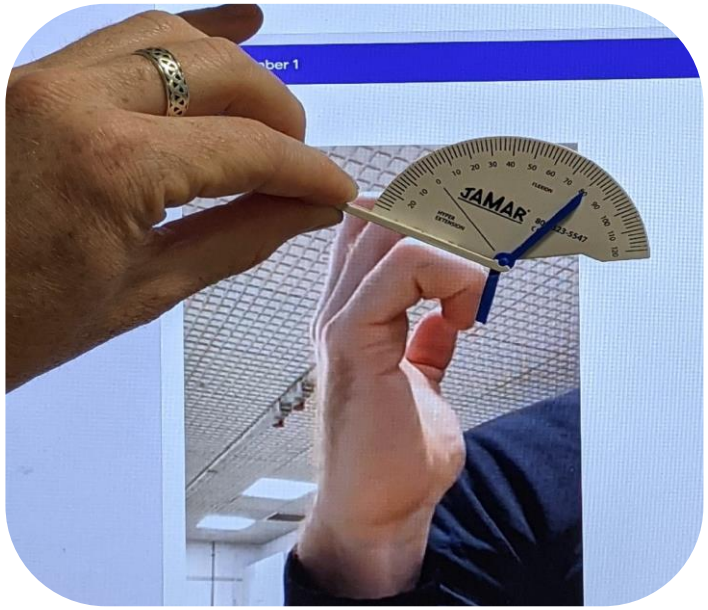
**contains data collection for the following secondary objectives: PEM, PRWHE, EQ-5D-5L, Work Outcomes, Treatment and Outcome Satisfaction, Healthcare Resource Use, Adherence to Therapy Regimen and Splint Adherence*

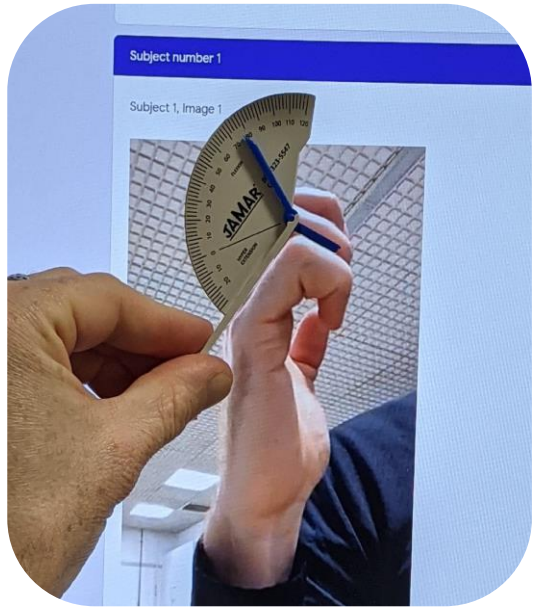
Data Collection

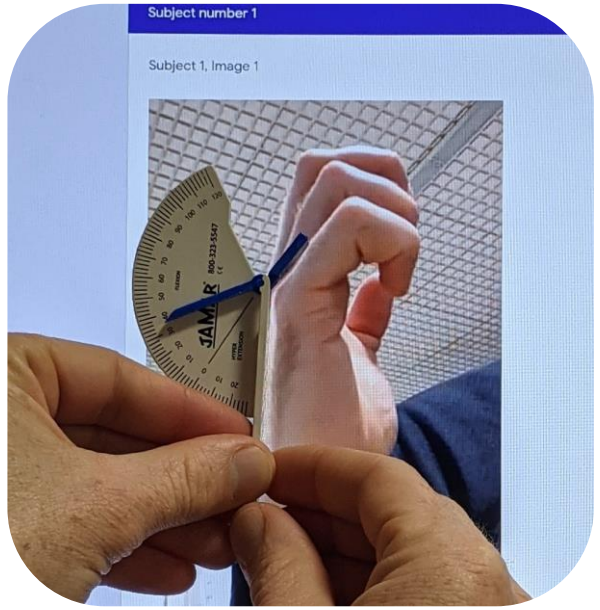
Data Collection Instrument	Screening and Eligibility	Contact Details	PIS and Consent Form	Baseline	Randomisation	Primary Surgery	Investigator Forms	6 Week Follow up	3 Month Follow up	6 Month Follow up	Additional Surgery	(S)AE	Change of Status	Comments	PI Investigator Sign off
Screening And Eligibility	●														
Contact Details		●													
Patient Information Sheet & Participant Consent Form (survey)			●												
Participant Consent (Paper)			●												
Consent Status			●												
Baseline Investigator				●											
Patient Baseline Questionnaire				●											
Eligibility and Randomisation					●										
Prerandomisation Final Check					●										
Randomisation Data					●										
Primary Surgery						●									
Investigator Form - 1 Week							●								
Investigator Form - 6 Weeks							●								
Patient 6 Week Follow Up Questionnaire (survey)								●							
Investigator Form - 3 Months									●						
Patient 3 Month Follow Up Questionnaire (survey)									●						
Patient 6 Month Follow Up Questionnaire (survey)										●					
Additional Surgery											●				
(S)AE												●			
(S)AE Follow-Up												●			
Change of Status													●		
Comments														●	
Principal Investigator Sign off															●

Total Range of Motion

Can be calculated in person clinic visit or via remote consultation. Further details in the Trial Site Manual.







Please use the JAMAR Finger/Toe goniometer shown in the images above.

Adverse Events

Adverse Events

Definition:

'…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 FLARE, we will only collect AE data for events that are related to the original finger injury and unexpected.'

Serious Adverse Events

- 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 participant'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.

Complications

General Surgical Complications	
Deep wound infection	Superficial infection
Bleeding /haematoma	Suture abscess
Surgical site infection	Rehospitalisation
Delayed wound healing/wound dehiscence	Unexplained pain
Tourniquet related nerve injury	

Anaesthetic-related Complications	
Myocardial infarction (MI)	Block related nerve lesion
Cerebrovascular accident (CVA)	Local anaesthetic toxicity
Venous thromboembolism (VTE)	

Complications specific to flexor tendon repair surgery	
Digital nerve injury / neuroma / numbness / altered sensation	Tendon adhesions
Re-rupture of tendon repair	Cold intolerance
Joint stiffness	Bow stringing
Complex regional pain syndrome	

Hand Therapy-related Complications
Skin problems related to splint fitting

REDCap Research Electronic Data Capture

Complete (S)AE Instrument and (S)AE Follow-Up Instrument

Adverse Events

- If you are unsure whether an event should be reported as an Adverse Event (AE) or Serious Adverse Event (SAE), please contact York Trials Unit at ytu-flare-trial@york.ac.uk prior to reporting.

- Please ensure that each AE/SAE is reported separately and not combined on one form.

- To report an AE or SAE, complete the AE/SAE Instrument on REDCap (within five days for an AE and within **<u>24 hours</u>** for a SAE).

- Use the AE and SAE tracking log to allocate the event a reference number and track follow-up activities.

- Complete AE/SAE Follow Up Instrument if required.

- York Trials Unit will advise as to if any further action is required.

- Report all AEs/SAEs to your host institution in line with local arrangements.

Complete (S)AE Instrument and (S)AE Follow-Up Instrument if required

Change of Status

Each participant has the right to withdraw from the study at any time without prejudice. In addition, the investigator may discontinue a participant from the study at any time if the investigator considers it necessary for any reason.

FLARE Participant Change of Status Instrument should be completed on REDCap if

- Participant wishes to no longer complete hospital visits and/or questionnaire follow ups but agrees to allow the research staff to collect data from their medical records
- Participant wishes to make a full withdrawal
- The patient has died

If the patient requests <u>full withdrawal during a study visit</u>, please ask the participant if they would be willing to complete the current study visit questionnaires.

REDCap Research Electronic Data Capture *Complete Change of Status Instrument*

Confidentiality and Data Transfers

All screened patients are allocated a 7-digit Participant ID number

No Identifiable patient information should be entered into Comment instrument.

Identifiable patient information must not be sent to York Trials Unit by email.

Please check with the York Trials Unit team prior to sending if you are unsure

Trial Supplies

- One calibrated **dynamometer** supplied per site.

- We will send this once the contracting process has been started.

- Once received, the site is responsible for maintenance and re-calibration of the dynamometer.

- Participants will be sent pre-paid envelopes with their follow up questionnaires. Sites are provided with pre-paid envelopes should there be an occasion where these are required.

End of Patient Participation Activities

Once the participant has completed the 6 month questionnaire:

Site Team Tasks

- Upload/file a copy of the Randomisation Data and Primary Surgery Instrument into the patient's medical records.
- Review the participant's medical notes and report any complications, AEs, SAEs or additional surgical procedures that occurred 3-6 months after randomisation into their FLARE REDCap record

York Trials Unit Tasks

- Sends the participant a letter to inform them of which surgical treatment they received.
- Sends the participant a £10 reward as a thank you for completing the 6 month patient questionnaire, as a minimum.
- FLARE qualitative researcher will contact 40 participants, if they consented to be contacted, to invite them to participate in a qualitative interview.
- Send trial results when available, if the participant requested this information.

Qualitative Study

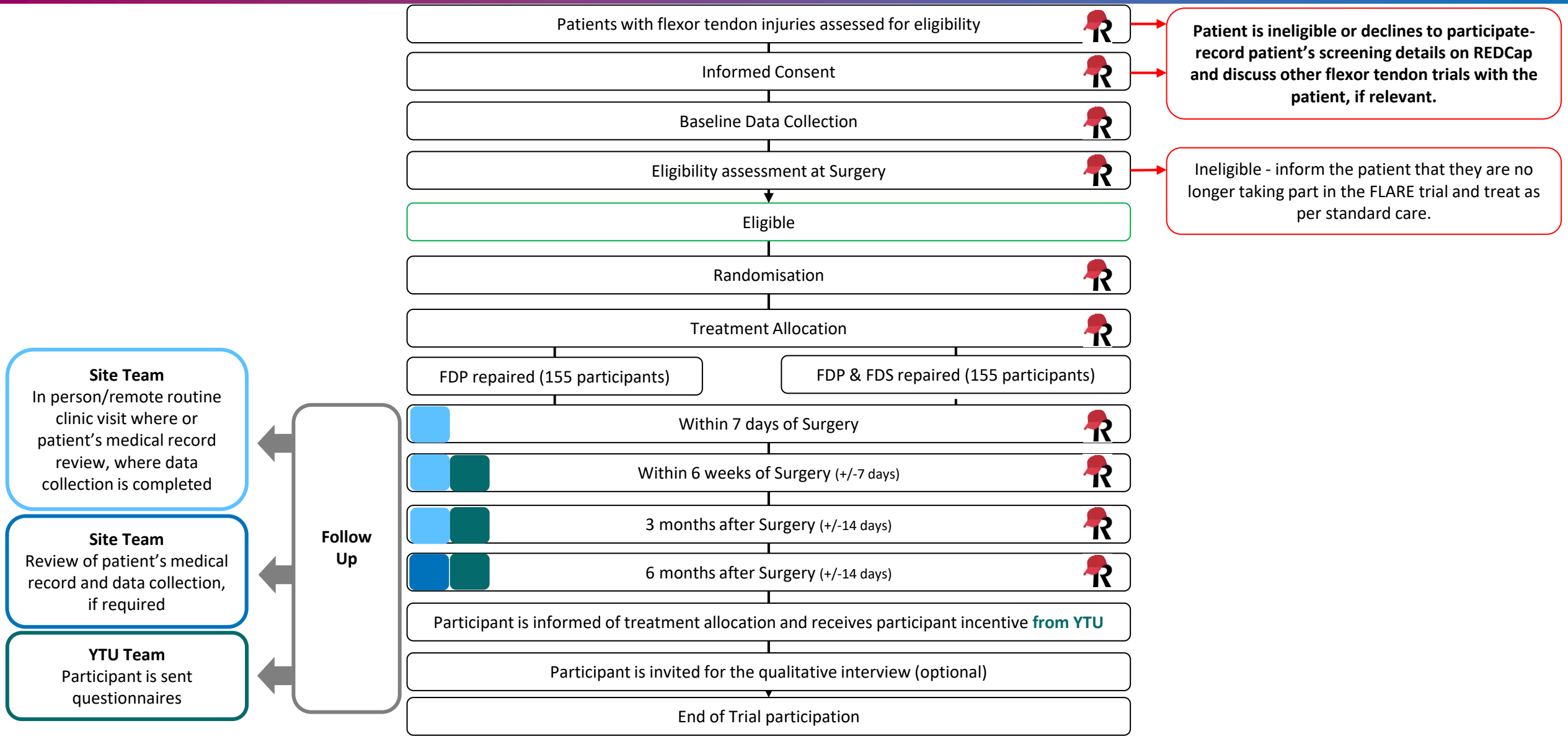
Aim: to ascertain vital information relating to acceptability and experience of the surgical procedure and the rehabilitation regimens.

Study Technique: Interviews via Zoom or MS Teams.

Sample

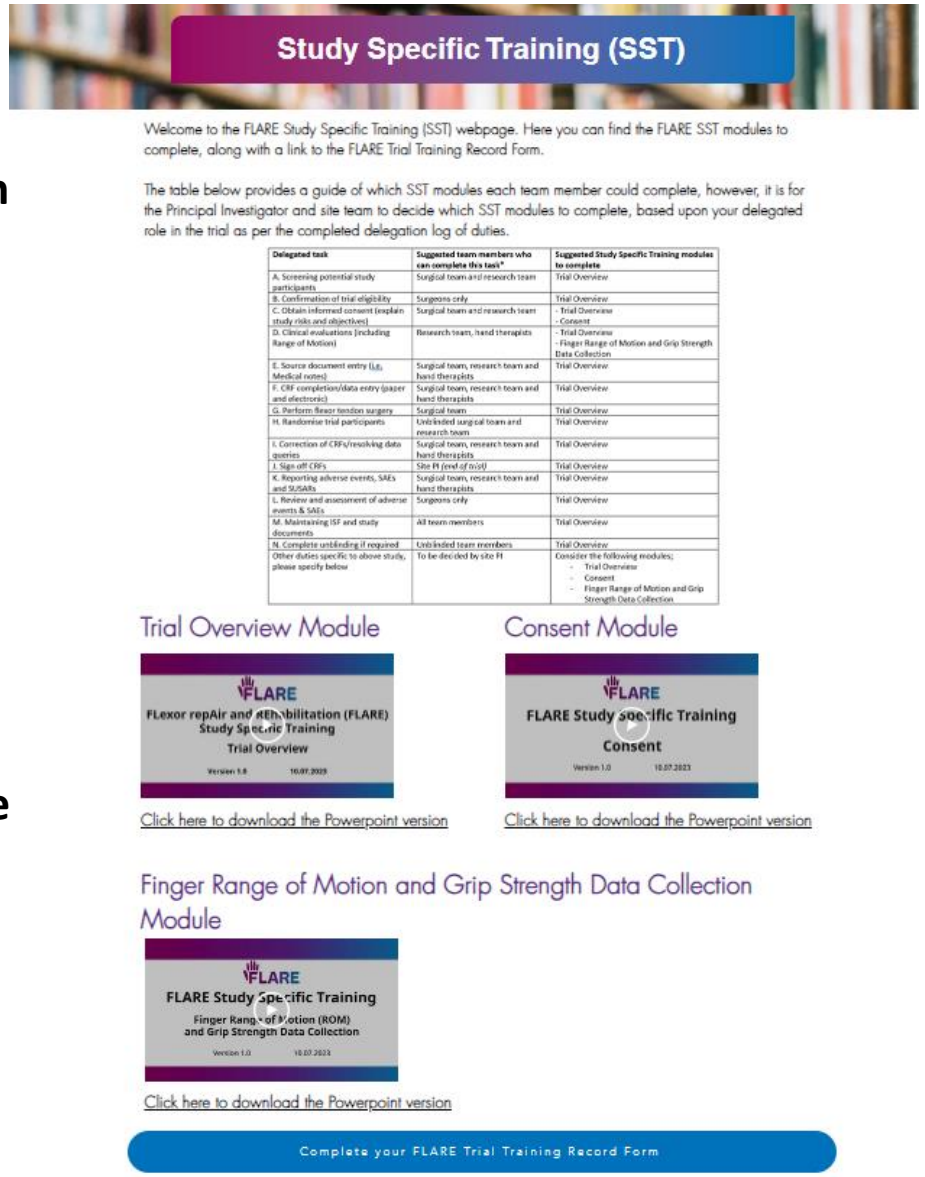
- 40 FLARE Participants.
- 10 Surgeons.
- 10 Hand Therapists.

Any questions about the Patient Process?



Training Requirements

- **CV and GCP requirement for Principal Investigators only.**
- **Everyone needs to complete FLARE Study Specific Training based upon their delegated tasks.**
- **Study Specific Training Modules**
  - Trial Overview - everyone to complete
  - Consent
  - Finger Range of Motion and Grip Strength Data Collection
- **Once you have completed all relevant FLARE training, please complete FLARE Trial Training Record Form**
- **Training modules and Training Record Form are available via www.flaretrial.com**



Additional Training

We would recommend that the following trial documentation is read:

- FLARE Trial protocol
- FLARE Trial Site Manual
- FLARE patient information material and consent form (for those delegated to complete the informed consent process)

This documentation is available within the electronic FLARE Investigator Site File and on the FLARE Trial website (https://www.flaretrial.com/trial-documentation).

GRANULE training

- Hosted by the NIHR as an e-learning course to equip researchers with the knowledge and initial practical skill set to recruit patients into randomised trials whilst maintaining equipoise.
- Further information available via https://starsurg.org/granule/
- Completion of the GRANULE training is a recommendation and not mandated for the FLARE trial

Delegation Log

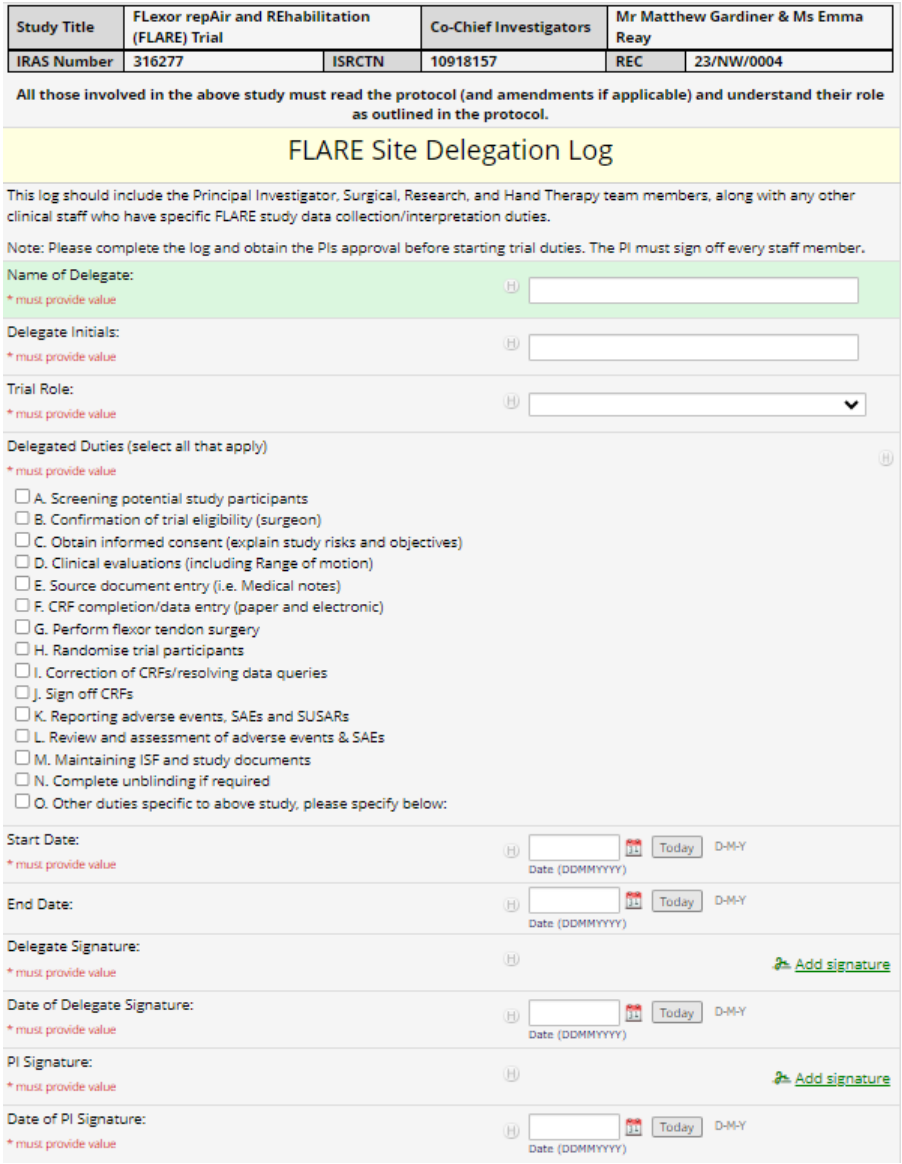
FLARE Delegation Log is completed via REDCap.

To gain access to the FLARE Delegation Log:

- Site to contact YTU team with NHS email addresses of those requiring FLARE Delegation Log access
- YTU team will arrange access to the FLARE Delegation Log

Please ensure you are using your own REDCap account when completing the delegation log.

For further delegation log guidance, please refer to the FLARE Trial Site Manual, or if you have any problems accessing REDCap, please email the YTU team.



Study Title	FLexor repAir and REhabilitation (FLARE) Trial		Co-Chief Investigators	Mr Matthew Gardiner & Ms Emma Reay	
IRAS Number	316277	ISRCTN	10918157	REC	23/NW/0004

All those involved in the above study must read the protocol (and amendments if applicable) and understand their role as outlined in the protocol.

FLARE Site Delegation Log

This log should include the Principal Investigator, Surgical, Research, and Hand Therapy team members, along with any other clinical staff who have specific FLARE study data collection/interpretation duties.

Note: Please complete the log and obtain the PIs approval before starting trial duties. The PI must sign off every staff member.

Name of Delegate:
* must provide value

Delegate Initials:
* must provide value

Trial Role:
* must provide value

Delegated Duties (select all that apply)
* must provide value

- A. Screening potential study participants
- B. Confirmation of trial eligibility (surgeon)
- C. Obtain informed consent (explain study risks and objectives)
- D. Clinical evaluations (including Range of motion)
- E. Source document entry (i.e. Medical notes)
- F. CRF completion/data entry (paper and electronic)
- G. Perform flexor tendon surgery
- H. Randomise trial participants
- I. Correction of CRFs/resolving data queries
- J. Sign off CRFs
- K. Reporting adverse events, SAEs and SUSARs
- L. Review and assessment of adverse events & SAEs
- M. Maintaining ISF and study documents
- N. Complete unblinding if required
- O. Other duties specific to above study, please specify below:

Start Date:
* must provide value
Today D-M-Y
Date (DDMMYYYY)

End Date:
Today D-M-Y
Date (DDMMYYYY)

Delegate Signature:
* must provide value
Add signature

Date of Delegate Signature:
* must provide value
Today D-M-Y
Date (DDMMYYYY)

PI Signature:
* must provide value
Add signature

Date of PI Signature:
* must provide value
Today D-M-Y
Date (DDMMYYYY)

Protocol Deviations

Any activity that does not comply with the FLARE trial protocol must be reported to York Trials Unit as soon as possible.

- Comments instrument should be completed to detail deviations related to data collection or to an individual patient only.

- File notes should document incidents that have a wider affect.

- Documenting the protocol deviation and any corrective or preventative actions taken should be approved and signed by the Principal Investigator.

- A copy of the file note should be retained in the electronic Investigator Site File and a copy provided to YTU.

- YTU will report deviations to the Sponsor when required.

Study Documents

Electronic Investigator Site File (eISF)

- Sent through University of York DropOff Service.

Key document current versions

- **Protocol:** version 1.1 (dated 17.03.2023)
- **PIS:** version 1.1 (dated 16.01.2023)

Documents that can be requested by the Site from the YTU team

- A copy of the site's training log

Documents that can be used by the Site but are not a Trial requirement and will therefore not be monitored are:

- Screening and Enrolment Log

Associate Principal Investigator Scheme (API)

- FLARE is registered with the NIHR API scheme.
- Sites are encouraged to utilise Associate PIs (API) to work with local PI to help to coordinate recruitment of patients, particularly out of hours.
- Six month in-work training opportunity.
- Provides practical experience for healthcare professionals starting their research career for people who would not normally have the opportunity to take part in clinical research in their day-to-day role.
- The chance to experience what it means to work on, and deliver, an NIHR portfolio study under the mentorship of an enthusiastic Local PI.
- http://www.NIHR.ac.uk/AssociatePIScheme

Trial Finances

Area of Cost	Payment (£ Sterling)
Per participant payment for completion of all baseline study activities up to and including Surgery. Dataset includes the following items: Eligibility and consent data Baseline data Treatment confirmation Surgery data	**£87.81**
Per participant payment for completion of all data up to and including 3 month follow-up Adverse event data 7 day post-surgery visit 6 Week data 3 Month data	**£132.51**
Per participant payment for completion of all remaining study activities (including the return of all data and resolution of all Sponsor/representative data queries) up to and including 6 month follow-up. Dataset includes the following items: Adverse event data 6 Month data	**£95.16**
TOTAL:	**£315.48**

Site payments will be processed on a 6-month cycle.

Monitoring

- Performed remotely once a year.
- ‘Remote Monitoring Checklists’ will be sent out for sites to complete and return to York Trials Unit.
- On-site monitoring will not occur unless triggered by issues identified at a site.

Site Close Out Visit

- Performed remotely.
- ‘Closeout Checklists’ will be sent out for sites to complete and return to York Trials Unit.
- The FLARE Investigator Site File and all essential documents will be archived locally and retained for a minimum of 5 years after study completion.
- The eISF should remain accessible until formal, written notification is issued to confirm files can be moved to archive.

What Happens Next?

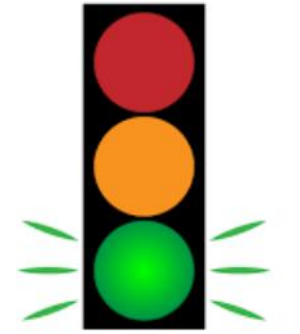
YTU team to do

- Issue email - Confirmation of SIV to include outstanding actions prior to recruitment green light.

Site team to do

- Work with the YTU team to resolve any queries and pending actions at site.
- Complete and sign mNCA.
- Provide confirmation of capacity and capability.

Green Light - Permission to begin recruitment will be given on an individual site basis by YTU.



Thank you for your time.

Any questions?

Alternatively please…

…contact us on the FLARE Trial email address: **ytu-flare-trial@york.ac.uk**

…follow us for the latest FLARE trial news: **@FLARE_ _Trial**

…go to the FLARE Trial Website: **www.flaretrial.com**

…join the all site FLARE WhatsApp group