# Flexor injury rehabilitation splint trial

Submission date 13/07/2022	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered	
		[X] Protocol	
Registration date	<b>Overall study status</b> Completed	Statistical analysis plan	
20/07/2022		[_] Results	
Last Edited 03/05/2024	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	[_] Individual participant data	
		[] Record updated in last year	

## Plain English summary of protocol

### Background and study aims

Flexor tendons attach to the muscles in our forearms and give us the ability to bend our fingers. In the UK, more than 7000 people a year cut their flexor tendons. Without surgery to repair the tendons, the fingers would never bend and our hands would become useless. Following surgery, a 'made-to-measure' splint is needed to prevent the repaired tendon from re-rupturing. However, people who have had this operation have told us that wearing a splint is awkward and often means they can not work. They also told us that sometimes they do not wear their splint at all. There are currently three splints available on the NHS: long, short and mini. We do not know which of the three splints is best. The aim of the FIRST study is to determine which splint gives people the best chance of getting back their normal hand use, what is it like to wear each splint, if people wear these as instructed, and whether one splint is better value for money.

### Who can participate?

Patients aged 16 years and over who have undergone a zone I/II flexor tendon repair

### What does the study involve?

Participants will be randomised into 3 groups and given either the long, short or mini splint following their surgery. They will be monitored for a year. We will ask questions about their hand and wrist use and how long they had off work. We will measure how much they can move their hand and how strong their hand is. We will also ask if they have any pain in their hand or wrist, or had any other troubles because of their injury. We will put heat sensors in each splint which will monitor how much they are wearing their splint and each patient will be surveyed to find out what aspects of wearing the splint are important to them. Alongside this, we will interview 20 patients and ask them what it was like to wear the splint, we will ask if they removed their splint and why this was. We will investigate the number of appointments people have had and if they needed any extra operations or treatments to fix their hands. All of this information will be used to understand which splint is best clinically and provides the best value for money.

### What are the possible benefits and risks of participating?

The study is providing information in this area as participants will be contributing to important research that will inform treatment choices for patients in future. They will be under close follow-up contact which is normal for those taking part in a research study. All flexor tendon repair patients will have a splint to wear during rehabilitation, whether or not they participate in the study. Splints have the potential risk to be uncomfortable and can cause skin irritation and

stiffness. Participants will be provided with site-specific contact details in case they experience any problems with their splint.

Where is the study run from? University of Sheffield Clinical Trials Research Unit (United Kingdom)

When is the study starting and how long is it expected to run for? January 2022 to May 2025

Who is funding the study? National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) (United Kingdom)

Who is the main contact? Hannah Berntsson (United Kingdom) h.berntsson@sheffield.ac.uk

**Study website** https://pulvertafthandcentre.org.uk/first-study/

## **Contact information**

**Type(s)** Scientific

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**Type(s)** Principal Investigator

**Contact name** Mrs Emma Bamford

ORCID ID http://orcid.org/0000-0002-1588-5708

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### Type(s)

Public

**Contact name** Miss Hannah Berntsson

## **Contact details**

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## Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 310986

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers CPMS 52908, IRAS 310986

## Study information

## Scientific Title

Prospective randomised controlled trial comparing three splints for finger flexor tendon repairs (FIRST study).

### Acronym

### FIRST

### **Study objectives**

The trial hypothesis is that any one of the splints may be superior, in terms of the mean postrandomisation scores (based on data collected at 6, 12, 26, and 52 weeks) for self-reported wrist /hand pain and functioning outcomes, to any of the others.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 07/06/2022, South West - Cornwall & Plymouth Research Ethics Committee (Ground Floor Temple Quay House, 2 The Square, Bristol, BS1 6PN; +44(0)207 104 8071; cornwallandplymouth.rec@hra.nhs.uk), ref: 22/SW/0074

### Study design

Parallel-group superiority analyst-blind multi-centre individual participant-randomized controlled trial

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied

Injuries and accidents

### Interventions

The trial will be conducted in approximately 20 hospitals. Patients listed for, or who have undergone surgical repair of zone I/II flexor tendons will be identified from hand clinics/ theatre or hand therapy services and provided with study information. Potentially eligible patients will be given information sheets by delegated site staff and invited to consent at their first clinic visit post-surgery. Recruitment posters and/or business cards directing potential participants to the study website, where the PIS will be available online, will also be available in hand clinics at participating sites.

Participants will be randomised to receive either the long, short, or mini splint and will be followed up at 6, 12, 26 and 52 weeks post-randomisation. All follow-up visits will take place in the clinic, with the exception of the 52-week visit which will be done remotely.

The Patient-Reported Wrist and Hand Evaluation (PRWHE) questionnaire (primary outcome) will be completed at each follow-up visit. The PRWHE is a 15-item patient-reported outcome for assessing wrist and hand pain/disability on a scale of 0 to 100. The primary outcome will be the mean post-randomisation total PRWHE score. Participants will also be asked to complete questionnaires about their hand and wrist function, general health, quality of life and work productivity and activity. Participants will be asked about any adverse events at each follow-up visit. Range of movement and grip strength will be assessed by site staff blinded to treatment allocation, range of movement at baseline, 6, 12 and 26 weeks and grip strength at 12 and 26 weeks.

The project also includes a process evaluation sub-study, which will explore how patient preferences for splint attributes and patient-reported acceptability of splints influence splint adherence. This aspect will involve a survey on participant preferences (stated preferences) at baseline, and on 'revealed' preferences and acceptability of splints at 6 weeks. To understand determinants of nonadherence to the different splints and their associated harm-benefit profiles, 20 partially-nested semi-structured interviews will be conducted, sampling based on splint type and known influential factors such as employment type and dependence on vehicle use. Interviews will be audio-recorded, transcribed and analysed using qualitative techniques. Temperature sensors will be inserted into splints to measure adherence to splint prescription.

### Intervention Type

Device

**Phase** Not Applicable

## Drug/device/biological/vaccine name(s)

Primary outcome measure

Mean post-randomisation total score measured using the Patient Reported Wrist and Hand Evaluation (PRWHE) questionnaire at 6, 12, 26 and 52 weeks post-randomisation

## Secondary outcome measures

1. Patient-reported outcomes:

1.1. Level of care received, function, pain and wellbeing measured using the Patient Evaluation Measure (PEM) at baseline, 6, 12, 26 and 52 weeks

1.2. Work productivity and activity impairment (WPAI) score measured at baseline, 6, 12, 26 and 52 weeks

1.3. Quality of life measured using the EuroQoL EQ-5D-5L questionnaire at baseline, 6, 12, 26 and 52 weeks

1.4. Details of any litigation/compensation for injury measured using a study-specific, single-item patient-reported questionnaire at 52 weeks

1.5. Change in general health measured using the global rating of change questionnaire at 6, 12, 26 and 52 weeks

1.6. Preferences for splint attributes (stated and revealed) and splint acceptability measured using study-specific surveys at baseline and 6 weeks

2. Clinical outcomes:

2.1. Range of movement measured using a goniometer and calculated as a Strickland score at

baseline, 6, 12 and 26 weeks

2.2. Grip Strength measured using the GripAble tool at 12 and 26 weeks

2.3. Adherence to the splinting protocol measured using a temperature sensor inserted into the participants' splint at baseline and removed at splint removal, at 6 weeks

2.4. Complications and adverse events measured via case report forms completed by site staff throughout participant follow-up

## Overall study start date

01/01/2022

## **Completion date**

22/03/2025

## Eligibility

## Key inclusion criteria

- 1. Aged 16 years old and over
- 2. Primary repair of zone I/II finger flexor tendon
- 3. Surgical repairs according to BSSH guidelines

## Participant type(s)

Patient

Age group

Adult

**Lower age limit** 16 Years

Sex

Both

### **Target number of participants** Planned Sample Size: 429; UK Sample Size: 429

## Total final enrolment

430

## Key exclusion criteria

- 1. Patients with associated fractures requiring fixation or additional splintage
- 2. Tendon lacerations involving 3 or more fingers
- 3. Revascularization surgery and/or digital nerve reconstructions requiring a nerve graft
- 4. Presented for treatment more than 3 weeks following the original injury
- 5. Patients unable to consent or comply with the rehabilitation regime, for example, due to cognitive, psychological or physical disabilities
- 6. Co-enrolment in another hand trial

## Date of first enrolment

22/08/2022

Date of final enrolment 22/03/2024

## Locations

**Countries of recruitment** England

Scotland

United Kingdom

Wales

**Study participating centre Royal Cornwall Hospital (treliske)** Treliske Truro United Kingdom TR1 3LJ

**Study participating centre University Hospitals Birmingham NHS Foundation Trust** Queen Elizabeth Hospital Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2GW

**Study participating centre Royal Derby Hospital (nuh)** Uttoxeter Road Derby United Kingdom DE22 3NE

**Study participating centre Swansea Bay University Local Health Board** One Talbot Gateway, Seaway Drive Seaway Parade Industrial Estate Baglan Port Talbot United Kingdom SA12 7BR

#### Study participating centre Chelsea & Westminster Hospital 369 Fulham Road London United Kingdom SW10 9NH

#### **Study participating centre Preston Acute Hospitals NHS Trust** Royal Preston Hospital Sharoe Green Lane North Fulwood Preston United Kingdom PR2 9HT

### **Study participating centre NHS Lanarkshire** 14 Beckford Street Hamilton United Kingdom ML3 0TA

### **Study participating centre John Radcliffe Hospital** Headley Way

Headington Oxford United Kingdom OX3 9DU

### **Study participating centre Royal Free London NHS Foundation Trust** Royal Free Hospital Pond Street London United Kingdom NW3 2QG

Study participating centre James Cook University Hospital Marton Road Middlesbrough United Kingdom TS4 3BW

**Study participating centre Northampton General Hospital NHS Trust** Cliftonville Northampton United Kingdom NN1 5BD

#### Study participating centre Amersham Hospital Whielden Street Amersham United Kingdom HP7 0JD

### **Study participating centre Royal United Hospitals Bath NHS Foundation Trust** Combe Park Bath United Kingdom

BA1 3NG

### Study participating centre

**St Thomas' Hospital (alliance Medical Scanning)** St. Thomas's Hospital Westminster Bridge Road London United Kingdom SE1 7EH

## Study participating centre

### Hull Royal Infirmary

Anlaby Road Hull United Kingdom HU3 2JZ

#### Study participating centre Queen Alexandras Hospital Southwick Hill Road

Cosham Portsmouth United Kingdom PO6 3LY

## Study participating centre

Walsgrave General Hospital Clifford Bridge Road Coventry United Kingdom CV2 2DX

## Study participating centre

Queen Victoria Hospital NHS Foundation Trust Holtye Road East Grinstead United Kingdom **RH19 3DZ** 

### Study participating centre The Shrewsbury and Telford Hospital NHS Trust

Mytton Oak Road Shrewsbury United Kingdom SY3 8XQ

## Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust Colney Lane

Colney

Norwich United Kingdom NR4 7UY

#### Study participating centre Barts Health NHS Trust

The Royal London Hospital 80 Newark Street London United Kingdom E1 2ES

#### **Study participating centre North Bristol NHS Trust** Southmead Hospital Southmead Road

Westbury-on-trym Bristol United Kingdom BS10 5NB

#### **Study participating centre Cambridge University Hospitals NHS Foundation Trust** Addenbrookes Hospital Cambridge United Kingdom CB2 0AU

Study participating centre University Hospitals of Leicester NHS Trust Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

### **Study participating centre The Newcastle upon Tyne Hospitals NHS Foundation Trust** Freeman Hospital Freeman Road High Heaton

Newcastle upon Tyne United Kingdom NE7 7DN

Study participating centre Salisbury NHS Foundation Trust Salisbury District Hospital Odstock Road Salisbury United Kingdom SP2 8BJ

## Sponsor information

**Organisation** University Hospitals of Derby and Burton NHS Foundation Trust

Sponsor details Royal Derby Hospital Uttoxeter Road Derby England United Kingdom DE22 3NE +44 (0)1332 724639 Uhdb.sponsor@nhs.net

**Sponsor type** Hospital/treatment centre

Website https://www.uhdb.nhs.uk/

ROR https://ror.org/04w8sxm43

## Funder(s)

**Funder type** Government

**Funder Name** 

National Institute for Health and Care Research; Grant Codes: NIHR133582

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type** Government organisation

### Funding Body Subtype

National government

**Location** United Kingdom

## **Results and Publications**

### Publication and dissemination plan

- 1. Planned publication in a high-impact peer-reviewed journal
- 2. Conference presentation
- 3. Publication on website
- 4. Submission to regulatory authorities

### Intention to publish date

30/11/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

### IPD sharing plan summary

Available on request

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>HRA research summary</u>			28/06/2023	No	No
Protocol file	version 2.2	29/06/2023	03/11/2023	Νο	No
Protocol article		16/03/2024	18/03/2024	Yes	No