

# A comparison of surgical and non-surgical management of thumb osteoarthritis

<b>Submission date</b> 15/08/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/08/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Several different treatments are available for clinicians to use with patients who have osteoarthritis in the base of their thumb. The SCOTT study aims to find out if there is any difference in outcome for patients with base of thumb osteoarthritis by comparing three different treatments. The first treatment is non-surgical, it involves a specialist-enhanced hand therapist-led package. The second treatment is a trapeziectomy (surgical). The third treatment is a thumb joint replacement (surgical). It is unknown which of these treatments works best in improving patients' thumb base pain. This research study aims to find out which treatment is best.

### Who can participate?

Adults with symptomatic base of the thumb osteoarthritis can take part in this study if their treating clinician thinks that any of the treatments available in this study would be suitable for them.

### What does the study involve?

Taking part in the study means that the participants' treatment will be decided by a scientific process called randomisation. The process is commonly used in research to help us work out which treatment is best. Participants will receive either the ENGAGE package, a trapeziectomy or a thumb joint replacement. Participants will be asked to complete 8 questionnaires over 18 months to find out how they are doing. Some of these can be done at home, online or over the phone, and some of them will be part of a clinic appointment as they will also involve measurements such as thumb range of movement and grip strength. Participants will receive two £15 vouchers as a thank-you for completing follow-ups in the study. Participants might also be invited to interview with a researcher.

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

Treatment for the base of thumb osteoarthritis can only be improved with the help of patients. Taking part in this study means that you could help improve the care of future patients who need treatment for the base of thumb osteoarthritis. There is no increased risk to you by participating in the study. The NHS has treated patients with the treatments that are compared in this study. Participants will face the same surgical and anaesthetic risks (if they receive a

surgical treatment) and receive the same care as patients who have any of these treatments without taking part in the study.

Where is the study run from?

York Trials Unit at the University of York (UK) manages the day-to-day running of the study

When is the study starting and how long is it expected to run for?

January 2024 to December 2027

Who is funding the study?

The National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA)

Who is the main contact?

Emma Reay, emma.reay1@nhs.net

## Contact information

### Type(s)

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### Type(s)

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# Additional identifiers

**Integrated Research Application System (IRAS)**  
336574

**Central Portfolio Management System (CPMS)**  
64089

**National Institute for Health and Care Research (NIHR)**  
154694

## Study information

### Scientific Title

Surgery versus Conservative Osteoarthritis of Thumb Trial (SCOOTT). An RCT to determine clinical and cost effectiveness of treating arthritis of the base of the thumb, with or without surgery, and to determine the clinical and cost effectiveness of trapeziectomy versus base of thumb joint replacement

### Acronym

SCOOTT

### Study objectives

1. There is no difference in the AUSCAN score at 12 months post-randomisation between adults ( $\geq 16$  years old) with BTOA treated with surgery versus non-surgical management.
2. CMCJR is inferior to trapeziectomy for the treatment of BTOA in adult patients ( $\geq 16$  years old) as measured by the AUSCAN score at 12 months post-randomisation.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 29/08/2024, Wales Research Ethics Committee 2 Cardiff (Health and Care Research Wales, 5 Castlebridge, Cardiff, CF11 9AB, United Kingdom; -; wales.rec2@wales.nhs.uk), ref: 24/WA/0237

### Study design

Randomized controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

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

Base of the thumb osteoarthritis

### Interventions

This study is a randomised controlled trial which aims to recruit 656 adults with basal thumb osteoarthritis who have been referred to secondary care. Recruitment will take place over 2 years from approximately 20 NHS trusts across the UK. Participants will be randomised to one of three treatment options: (1) Trapeziectomy surgery, (2) Thumb joint replacement surgery, or (3) ENGAGE therapy package (non-surgical).

#### Recruitment:

The research team will work closely with the clinicians and research staff at each recruiting site to optimise the screening and recruitment procedures for their local circumstances. All members of staff involved in eligibility sign-off and the informed consent process (including surgeons) will have training in Good Clinical Practice (GCP) or study-specific training. The NIHR Associate Principal Investigator (API) scheme will be utilised at participating sites to involve aspiring researchers to co-ordinate study recruitment. The APIs will be trained in study processes and will be supervised by the PI at the site. Potential participants will be provided with information about the study including a patient information sheet (PIS) at the earliest possible opportunity following presentation.

#### Consent:

Consent will be recorded via paper consent forms, which will be uploaded onto the secure web-based data collection interface 'REDCap' once complete, or via participant e-consent directly within the REDCap system. Informed consent will be obtained by an authorised and trained member of the trust research team or clinical staff.

#### Baseline data collection:

Once participant eligibility has been confirmed and consent has been obtained, a baseline visit will be completed to collect all baseline data. The following measures will be collected at baseline:

- Demographic measures collected via patient self-report: ethnicity, education, employment status, housing/accommodation status.
- Questionnaire measures: Australian/ Canadian Osteoarthritis Hand Index (AUSCAN) questionnaire, PEM Score, EuroQol 5 dimensions (5L) score (EQ-5D-5L) and Patient satisfaction
- Physical measures: Total range of motion (radial and palmar abduction), Kapandji opposition score, Grip strength and Key pinch strength.
- Grade/severity of OA and condition history
- Date of birth

#### Randomisation:

Following the baseline assessment, randomisation will be undertaken by a member of the Trust's research team using REDCap. The outcome of the allocation will be communicated to the participant where possible in person but may also be communicated via telephone or email.

Follow-up data collection. Follow-up data collection will involve participants completing questionnaires (which can be done remotely), but for some time points, there will be physical measurements too which will require them to attend a clinic appointment. Follow-up time points will be 6, 12\* and 18 months after the date of randomisation and Day of treatment\*, 6 weeks\*, 3 months, and 6 months\* after the date of treatment. Those marked with an asterisk will be required to attend a clinic visit.

#### Qualitative interviews

There will be a nested qualitative interview study within the trial which will look at the experience and acceptability of the interventions. Approximately 10-15 participants from each of the three treatment arms will be selected and approached for interview. In addition, interviews will be conducted with approximately 15-20 clinicians (hand surgeons/ hand

therapists and occupational therapists). These will include those who were involved in the trial and also those who were outside of the trial delivery. Written or verbal consent will be taken for all interview participants prior to the start of each interview. Where verbal consent is taken, this will be recorded by the research team separately from the interview.

#### **Patient and public involvement and engagement (PPIE)**

The SCOTT PPIE group have contributed to the design of the trial, the intervention components, participant-facing study documents and the ENGAGE intervention resources

#### **Intervention Type**

Procedure/Surgery

#### **Primary outcome(s)**

Pain is measured using the AUSCAN hand pain index at 12 months post-randomisation

#### **Key secondary outcome(s)**

1. Pain is measured using the AUSCAN hand pain index and the PSEQ-2 at baseline, day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months (PSEQ-2) and 18 months post randomisation
2. Hand function is measured using the AUSCAN hand function and stiffness index and the PEM score at baseline, day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation
3. Range of motion is measured using the Kapandji score and Goniometry at baseline, 6 weeks and 6 months post treatment and 12 months post randomisation.
4. Grip and Pinch strength is measured using Jamar dynamometers at baseline, 6 months post treatment and 12 months post randomisation
5. Healthcare and broader resource implications and comparative cost-effectiveness are collected from participant self-reports and hospital-completed forms at baseline, 6 weeks, 3 months and 6 months post treatment and 6 months, 12 months and 18 months post randomisation.
6. Health-related quality of life is measured by EQ-5D-5L at baseline, day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation
7. Patient acceptability is measured by a global question at day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation as well as with qualitative interviews during the follow up period
8. Complications are measured by reporting of complications and adverse events at 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation

#### **Completion date**

31/12/2027

## **Eligibility**

#### **Key inclusion criteria**

1. Aged 16 years old and over
2. Symptomatic basal thumb osteoarthritis
3. The treating clinician thinks the patient would benefit from surgical intervention
4. The patient is suitable for both types of surgery
5. Able to consent to a surgical procedure

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Sex**

All

**Key exclusion criteria**

1. Inflammatory arthritis
2. Current or past infection around the base of the thumb
3. Previous surgery on the affected thumb joint
4. Any comorbidity which precludes them from undergoing surgical intervention

**Date of first enrolment**

17/12/2024

**Date of final enrolment**

30/06/2028

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The James Cook University Hospital**

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**Study participating centre**

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**Study participating centre**

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**Study participating centre**

**Colchester District General Hospital**

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**Study participating centre**

**John Radcliffe Hospital**

Headley Way  
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Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**Royal Albert Edward Infirmary**

Wigan Lane  
Wigan  
United Kingdom  
WN1 2NN

**Study participating centre**

**Royal Liverpool University Hospital**

Prescot Street  
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United Kingdom  
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**Sponsor information**

## Organisation

South Tees Hospitals NHS Foundation Trust

## ROR

<https://ror.org/02js17r36>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study (fully anonymised) will be available upon request after the publication of the study results from Prof. Catherine Hewitt ([catherine.hewitt@york.ac.uk](mailto:catherine.hewitt@york.ac.uk)). Requests for access to data will be reviewed by the co-Chief Investigators, study Sponsor and trial team. Participants will be informed that information collected about them may be shared anonymously with other researchers and will be asked to consent to this.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes