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SCOOTT

Surgery versus Conservative OsteOarthritis of Thumb Trial

Participant Information Sheet

SCOOTT Participant Information Sheet V1.1 | 20.11.2024 | IRAS ID: 336574

This project was funded by the NIHR Health Technology Assessment Programme (Reference: NIHR154694). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

SCOOTT: Thumb Osteoarthritis Trial Participant Information Sheet

Your hospital is working with other NHS hospitals on study for patients with osteoarthritis in the joint at the base of their thumb (base of thumb osteoarthrtis).

The aim of this important study is to work out which treatment works best for people with base of thumb osteoarthritis, who are being considered for surgery.

Can you help?

We need 656 patients to take part in this study. Could you be one of them?

- You are free to decide whether to take part and if you choose to take part, you can stop at any time you wish.
- If you choose not to take part, it will not affect your care in any way.
- Please read this information sheet carefully. It is important that you understand the study and what it means to take part. Please discuss with family or friends if you find that helpful.
- If you have any questions, please contact us. You can find our contact details on page 13 of this booklet.

Summary of the SCOOTT Study

- We are comparing three different treatments that NHS doctors use for patients with base of thumb osteoarthritis
- Two of these treatments are different types of surgery and the other treatment is an enhanced therapy package. Each patient who takes part in the study will receive one of these treatments.
- We currently do not know which of the available treatments works best. The aim of the study is to find this out.
- We will ask you to complete a total of 8 questionnaires over the course of 18 months to find out how you are doing. Some of these can be done at home and some of them will be part of a clinic appointment.
- You will receive the same standard of care whether or not you decide to take part in the study.

Contents

What is the aim of the SCOOTT study?

There are a number of different treatments available for clinicians to use with patients who have base of thumb osteoarthritis. The SCOOTT 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).

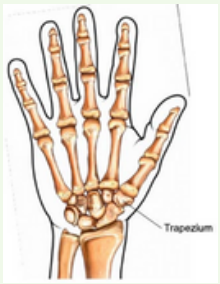
We currently don't know which of these treatments works best in improving patients' thumb base pain. This research study aims to find out which treatment is best.

Treatment 1: ENGAGE Therapy Package

Non-surgical treatment

Specialist hand therapy - to support you to improve hand movement & strength, to reduce pain and to learn to look after your joints

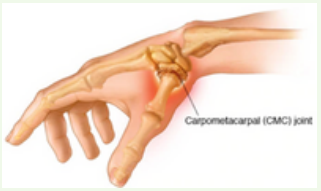
Treatment 2: Trapeziectomy



Removal of one of the bones at the base of the thumb (trapezium).

Currently this is the most commonly used surgical treatment for people with base of thumb osteoarthritis in the NHS.

Treatment 3: Thumb Joint Replacement



Replacement of the thumb base joint.

Increasingly being used in the NHS.

Why have I been invited to take part?

You have been invited to take part in this study because you have base of thumb osteoarthritis, you have pain and/or other symptoms and your treating clinician thinks that any of the treatments available in this study would be suitable for you.

What happens if I take part?

Consent

If you decide you want to take part in the study, we will ask you to sign a consent form. You will be asked to complete a brief questionnaire and provide some further information about yourself and your condition.

Randomisation

Taking part in the study means that your 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. We can use this approach when there are different treatments available in the NHS, but we don't know for certain which one is best. Your treating clinician agrees this is the fairest way to make sure the three groups of patients are similar to allow a reliable comparison.

This process is designed so 164 people will receive option 1 (ENGAGE), 246 people will receive option 2 (trapeziectomy) and 246 people will receive option 3 (joint replacement). You and your treating clinician do not have a choice in which of the three possible treatments you will undergo

Treatment

Once you have been allocated to receive one of the three treatments, you will be added to the waiting list to receive that treatment.

Trapeziectomy

A trapeziectomy is a commonly used surgical procedure in the NHS that is used to improve function and pain relief in patients with base of thumb osteoarthritis. It involves the removal of one of the bones at the base of the thumb called the trapezium.

Thumb Joint Replacement

A thumb joint replacement is another surgical procedure that is being increasingly used in the NHS to improve function and pain relief in patients with base of thumb osteoarthritis. Similar to a hip or knee replacement, this procedure involves the replacement of the joint at the base of the thumb.

ENGAGE Therapy Package

The ENGAGE therapy package is an enhanced therapy package, tailored to your needs, which will involve seeing a hand therapist for a minimum of 2 face to face appointments and 2 telephone appointments. The therapist will assess your needs and prescribe specific exercise, ergonomic task modification, and possibly splints and joint injections. You will also be provided with self-management resources (workbook and optional online videos). These resources will focus on physical therapy and also on pain coping skills. Support will be provided to learn how to self-manage your base of thumb osteoarthritis. There will also be opportunity to attend virtual coffee mornings with other participants in this arm of the trial for peer support.

The timelines associated with the ENGAGE package are shown in the diagram below:

Optional Interview

With your permission, the York Trials Unit team may contact you to ask you if you want to take part in an interview about your experiences and receiving treatment for your base of thumb osteoarthritis and taking part in research. You can opt out of taking part in the interviews, but still take part in the main study. A further information sheet containing detailed information on what is involved in taking part in the interviews will be made available to you. If you are willing to take part in the interviews, you will be asked to sign an additional consent form.

Optional longer-term follow up

With your permission, your contact details will be entered into the UK Hand Registry, a database of information about hand conditions collected across the UK. The registry was set up, is owned and is run by the British Society for Surgery of the Hand (BSSH), the UK's national hand surgery organisation. You will be asked to complete questionnaires after your involvement in SCOOTT has finished. You can opt out of this optional element, but still take part in the main study.

Collecting your Information

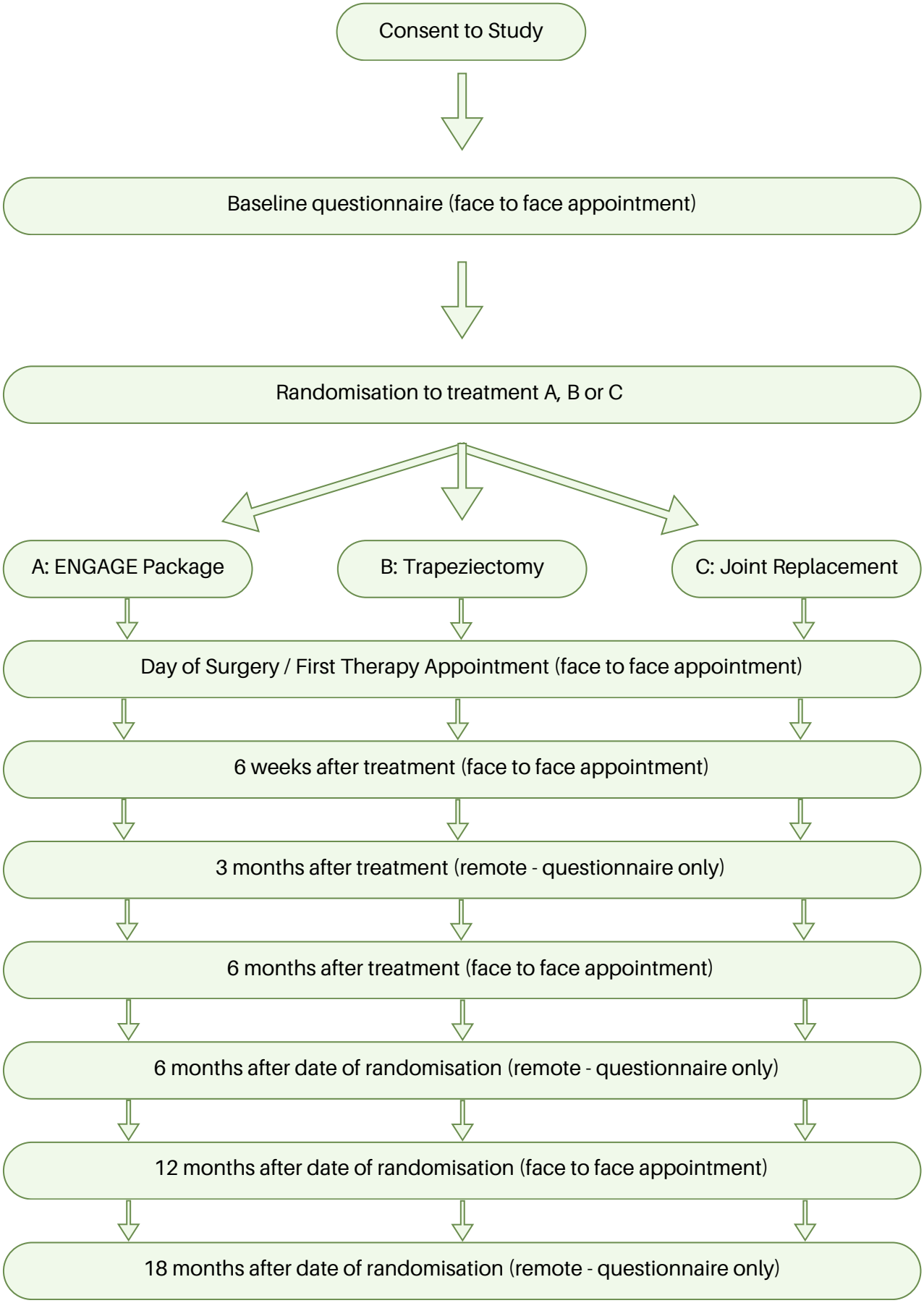
To find out which of the three treatments work best, we will regularly contact all 656 patients in our study to ask how they are doing.

Whichever treatment you receive, you will be contacted to complete questionnaires at 6 months, 12 months, and 18 months after the date you entered into the study **and** 6 weeks, 3 months, and 6 months after the date you receive your treatment. Some of these questionnaires can be done remotely and we will email you a link to complete the questionnaire at home but for some of the follow-up timepoints we will need to see you in clinic to complete some measurements such as thumb range of motion and grip strength alongside the questionnaires. Where possible, research visits will be combined with routine clinic appointments that you would attend if not taking part in the trial.

We will also ask the hospital study team to send us information about your treatment, any complications and rehabilitation using information from your medical records or data collected at research visits. The information may also include information taken from routine X-rays taken as part of usual routine care prior to joining the study and during your involvement in the study.

The timelines for these follow-up timepoints are illustrated in the flow chart on the next page.

Flow Chart


Consent to Study
Baseline questionnaire (face to face appointment)
Randomisation to treatment A, B or C
A: ENGAGE Package
B: Trapeziectomy
C: Joint Replacement
Day of Surgery / First Therapy Appointment (face to face appointment)
6 weeks after treatment (face to face appointment)
3 months after treatment (remote - questionnaire only)
6 months after treatment (face to face appointment)
6 months after date of randomisation (remote - questionnaire only)
12 months after date of randomisation (face to face appointment)
18 months after date of randomisation (remote - questionnaire only)

How will I be contacted?

We will ask you to select your preferred contact method out of the following options:

Email: We will use your email address to send you a link to complete the study questionnaires (for the remote questionnaires only).

Mobile/Landline: We will contact you via telephone when a questionnaire has not been returned.

Post: If you do not wish to receive questionnaire links via email, we will use your contact details to send you questionnaires in the post with a prepaid return envelope.

Whilst the study is ongoing, we may share newsletters or other updates on progress via your preferred method of contact.

During your involvement, you will be asked whether you would like to be informed of the results of the study. If you do tell us that you would like to know, you will be sent a summary of the findings after the study ends and the information obtained has been analysed.

Do I have to take part?

It's your choice

You do not have to take part in this study if you do not want to. Even if you decide to take part now, you can change your mind at any time and tell us that you no longer want to take part. Whatever you decide about taking part in the study, it will not affect the standard of care that you receive.

If you choose not to take part in the study, your treating clinician will discuss with you the options available for your treatment. You may be offered the same surgical options in this study or standard hand therapy available at your hospital. The enhanced ENGAGE package is only available as part of the trial.

What if I do not want to carry on with the study?

You can leave the study at any time. You do not have to give a reason for this. It will not affect your hospital care or rights in any way. All data collected from you, up to the time of your withdrawal from the study will be kept. You can choose to allow the study to continue collecting data from your hospital records only or to fully withdraw and stop all future data collection

What are the possible benefits and disadvantages of taking part?

Treatment for 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 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 we will compare in this study. You will face the same surgical and anaesthetic risks (if you receive a surgical treatment) and receive the same care as patients who have any of these treatments without taking part in the study.

The surgical risks include:

- Wound infection: If this were to occur it is usually treated with antibiotics. There may be wound healing problems.
- In rare cases, there can be damage to nerves and blood vessels.
- Joint replacement only:
  - Implant failure. If it fails, you may need to have another one.
  - Dislocation

Common anaesthetic risks include:

- Feeling or being sick.
- Dizziness or feeling light-headed
- Shivering and feeling cold.

The common side effects of anaesthetic usually do not last very long and wear off on their own.

The length of your surgery and hospital stay will not be increased by taking part in the study.

For the ENGAGE arm, you will not be exposed to any of the risks of having surgery or anaesthetic, but you may experience some hand pain and there is a chance you may still need surgery down the line.

Whichever treatment you receive, you will need to attend a couple of visits over and above usual care and the time taken to fill out the questionnaires will also be over and above what you would expect with usual care.

Radiation Risk:

X-rays of your hand(s) and imaging during surgery or steroid injection are part of your routine care. If you take part in this study, you will not undergo any additional x-rays or fluoroscopy imaging. These procedures use ionising radiation to form images of your body. Ionising radiation can cause cancer which manifests itself after many years or decades. The chances of this happening to you are the same whether you take part in the study or not.

More information about taking part in SCOOTT

What happens if there is a problem?

If you are concerned with any aspect of this study, you should speak to your surgeon or one of the researchers (see contact details at the end of this information sheet).

In the unlikely event that you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it.

If you wish to complain or have any concerns about the way you have been approached or treated, the normal NHS complaints mechanisms are available to you. (e.g. by contacting the Patient Advice and Liaison Services (PALS) at the hospital).

Will my taking part in the study cost me anything, and will I be paid?

Participation in this study should not cost you anything.

Participants receiving the ENGAGE package will be reimbursed travel expenses for attending two therapy appointments.

For all participants, travel expenses for attending two clinic appointments will be reimbursed.

If you choose to complete the questionnaires via post, we will provide you with a prepaid return envelope.

All participants will receive a £15 voucher at the 6 month post treatment visit and a further £15 voucher at the visit 12 months after you join the study, as a thank you for taking part.

Will my taking part be kept confidential?

With your permission, we will tell your GP that you are taking part in the study and contact your GP if we have any concerns about your health during your participation.

1. Contacting you during the study

Your contact details will be stored securely at the University of York and your hospital. Your hospital will contact you about appointments. The University of York will contact you about completing the study questionnaires. Anyone who sees your contact details and your medical records will have a duty of confidentiality.

Your name will not be passed to anyone else outside of the research team. It will only appear on your consent form and contact details form.

To avoid having to use your name when collecting information for the study, we will use a participant study ID number that we will give you. This number will appear on the questionnaires that you will fill in and paperwork that staff will complete at the hospital.

2. End of the study

At the end of the study, we will securely save the information collected from you for a minimum of five years so that the results can be checked if necessary. After that, it will be confidentially destroyed. Study results that do not include your name or personal details may be stored indefinitely so that other researchers can use them in the future. Any identifying information will be kept confidential, and access will be limited to the research team.

3. Keeping your information safe

All of our work to keep your information safe and secure is in line with the rules in the General Data Protection Regulation (GDPR) and the Data Protection Act that we must follow.

If you would like to read more about how we will use your personal data and what your rights are under GDPR, please visit the following websites:
https://southtees.nhs.uk/resources/how-your-personal-information-is-used-by-south-tees-hospitals-nhs-foundation-trust/
https://www.york.ac.uk/records-management/dp/your-info/generalprivacynotice/
https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

More details about information we will collect on you can be found at the end of this information sheet.

Who is organising and paying for the research?

The National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR154694) is paying for this study. It is supervised by South Tees Hospitals NHS Foundation Trust who is the study Sponsor. York Trials Unit at the University of York manages the day to day running of the study and checks the quality of the research. Your treating clinician will not receive payment for their involvement in the study. Your hospital gets paid when a patient agrees to take part and for collecting data. This payment only covers the cost to the hospital for helping with the study.

Who has reviewed this study?

Before any research goes ahead, it is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been approved by the Wales Research Ethics Committee 2 (Reference: 24/WA/0273).

We also spoke with people who have base of thumb osteoarthritis. They commented on our plans for the study and have helped with developing information for patients, including this information sheet. One of them is a member of the SCOOTT study management group.

How to contact us

If you need any further information, please contact us:

Principal Investigator: **[Insert site-specific contact details]**
Research Nurse(s): **[Insert site-specific contact details]**

If you would like independent advice about whether or not to take part, please contact: **<<Patient Advice and Liaison Service (PALS)/ Patient Advice and Support Service (PASS)>>** on: **[Insert site-specific contact details]**.

You can also contact York Trials Unit about the study on: **[add tel no.]** or via ytu-scoott-trial@york.ac.uk. We look forward to hearing from you.

Further details about the information we will collect on you

How will we use information about you?

We will need to use information from you, your medical records, National Joint Registry, central UK NHS bodies and NHS Digital.

This information will include your **<<NHS number/Health and Care number>>**, name and contact details, date of birth, sex, and ethnicity. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a participant code number instead.

We will keep all information about you safe and secure by:

- Storing the information about you from study questionnaires and hospital records on Research Electronic Data Capture (REDCap), which is a very secure 'cloud' hosted server designed to collect and store research data.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a minimum of 5 years after the conclusion of the trial, in accordance with guidelines on Good Research Practice. The study data will then be fully anonymized and securely archived or destroyed.

International Transfers

Your data will not be shared outside the UK.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records, National Joint Registry, central UK NHS bodies and NHS Digital. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how we use your information?

- at www.hra.nhs.uk/information-about-patients/
- at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- Sending an email to the Sponsor's Data Protection Officer Contact: Steven Orley, Email: stees.dpo@nhs.net , Telephone (Main Switchboard): 01642 850850
- South Tees Hospital NHS Trust (sponsor) Patient Privacy Notice is available at: https://southtees.nhs.uk/resources/how-your-personal-information-is-used-by-south-tees-hospitals-nhs-foundation-trust/
- The University of York Data Protection Policy can be accessed here: https://www.york.ac.uk/records-management/dp/

Thank you for reading this information sheet and for thinking about taking part in this study

Please feel free to use this space to make any notes or write down any questions you would like to ask the research team...

SCOOTT is funded by

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NIHR | National Institute for Health and Care Research

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Version 1.1 | Version date: 20th November 2024
IRAS ID: 336574