Participant Information Sheet

SORE Elbow Feasibility Trial
Surgery Or Rehabilitation for persistent tennis elbow

We invite you to take part in a research study

- Before you decide, it is important for you to understand why the research is being done and what it will involve.
- Please read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctor in any way.
- You can ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- We want to find out the best way to treat and improve patient care for people who have had tennis elbow, in one arm for more than 6 months.
- We are comparing two different routine treatment options, physiotherapy and surgery.
- Each patient who takes part will receive either surgery or a programme of physiotherapy rehabilitation.
- We will ask you to complete a questionnaire at the start and then again at 3 months, 6 and 12 months after you join the study to find out how you are doing.
- You can leave the study at any time and this will not affect your treatment.
- Your information will be kept securely and reported in a way that no one can identify you.

How to contact us

If you have any questions about this study, please talk to the doctor or research team that are involved with the study at your hospital.

Additional contact details can be found in section 6. Contacting the team to ask questions does not commit you to taking part.

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1. Why are we doing this study?

Tennis elbow is a common condition that causes pain on the outside of the elbow. This pain can make it difficult to carry out everyday tasks, including your work. While many people find that the condition gets better on its own over time, for others, the symptoms can last much longer and become a persistent problem. When symptoms have persisted for a few months, patients may feel worn down or frustrated, worried about work or income, or anxious about treatment.

There is no current agreement on the best way to treat long-term tennis elbow in the UK. While national guidelines recommend physiotherapy, they also highlight a lack of clear evidence regarding the benefits of surgery.

Our long-term goal is to find out which treatment will best help future patients with tennis elbow that lasts for more than 6 months. We also want to find out which treatment makes the best use of NHS resources. First, we need to undertake this smaller study which aims to help decide if it would be possible to carry out a larger study comparing physiotherapy and surgery. This is called a feasibility study.

Why have I been invited to take part?

You have been invited to take part in this study as you have had tennis elbow for 6 months or longer and meet the criteria for inclusion. Your surgeon agrees that both treatment options are appropriate for your condition.

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2. What will taking part involve?

We hope to enrol 80 patients for the study from a number of hospitals in the UK.

What will happen to me if I take part?

In this study, half of the patients will receive surgery, and the other half will receive the SORE Elbow physiotherapy rehabilitation programme. Involvement in the study will last for 6 months. Patients joining early on will be asked to complete an additional questionnaire after 12 months. This will be explained at the point you join the study.

If you choose to take part in the study you will:

- Be given the opportunity to discuss your involvement and ask any questions you may have.
- Be asked to sign a consent form.
- Have information collected about you to confirm that you are suitable for the study. This information will include your age, general health, weight, height and details about your elbow problem.
- Find out whether you have been allocated to surgery or a specially designed standardised physiotherapy programme.
- Receive treatment, delivered with the same standard of care that you would receive if you were not in the study.
- Be asked to complete a brief questionnaire at 3, 6 and possibly 12 months depending on when you joined the study.
    - The questionnaires are important, as they tell us how your condition may still be affecting your daily life. These questionnaires should not take longer than fifteen minutes to complete. The quickest and easiest way to do this is online. We will email a secure link directly to your inbox. If you prefer to receive a paper copy instead, we can post one to you with a prepaid return envelope. You can also choose to be contacted by telephone to provide the questionnaire information verbally. You are welcome to ask a friend or relative to help you with either version. All your information is kept strictly confidential and used only for the study.

      We may also email or telephone you if we have not received your completed questionnaire, to check that we hold your current address and that you have received the questionnaire. These reminders are there to support you. It might be that you need help with completing the questionnaire or you would like to ask more questions. Asking for help or receiving reminders does not mean that you have let the study team down or failed the study in any way.

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You will not be asked to attend extra visits for this study. Your appointments will be exactly the same as the routine care you would receive if you were not taking part.

On completion of the study, we will send you a summary of the results.

With your agreement, we may also contact you in future regarding this study, or other related studies.

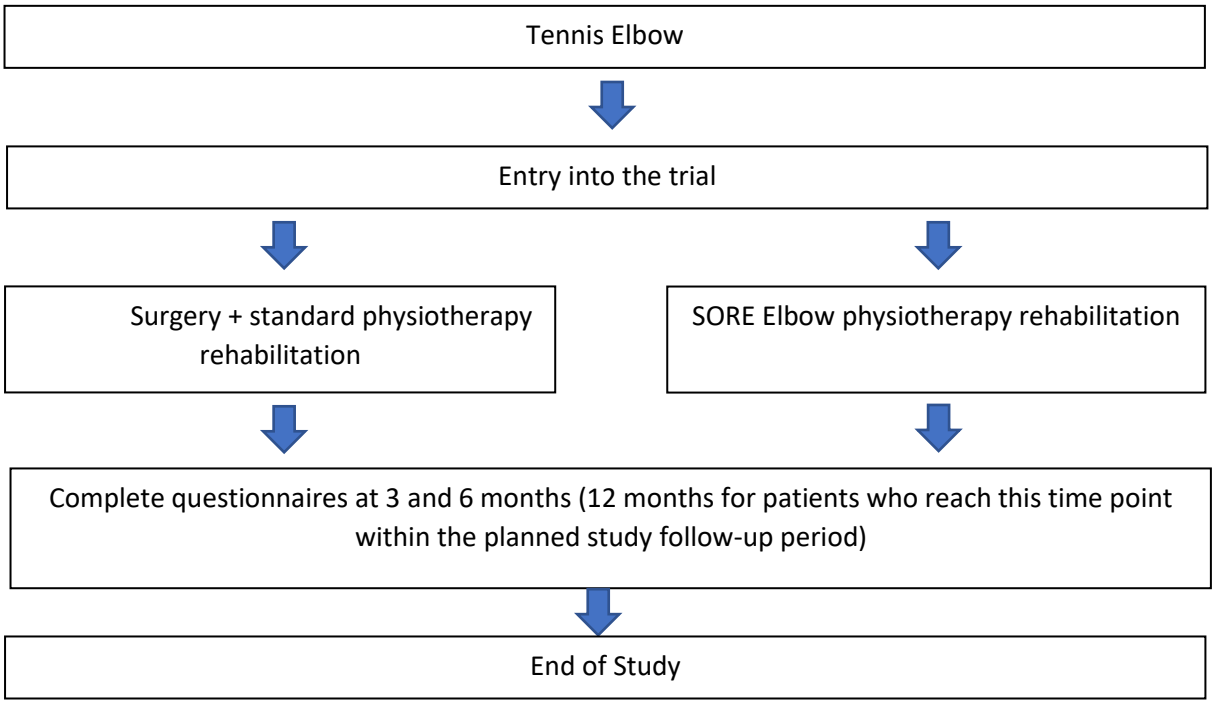
Additional interview study

With your permission, a researcher from the York Trials Unit team may contact you to ask you if you want to take part in a face to face, online or telephone interview. This would ask about your experiences of receiving treatment for your tennis elbow and taking part in research to help us understand the patient's perception of their treatment and recovery. The information will be used to help the design of a full trial based on patient needs and experiences.

The interviews will be recorded with your permission and be kept confidential. You can opt out of being contacted about 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 interested in finding out more. If you are willing to take part in the interviews, you will be asked to sign an additional consent form.

There is no additional payment for taking part in the interview.

Patient involvement in the study



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What treatment will I get?

Taking part in this study means you and your surgeon can't choose the treatment for your tennis elbow. Instead, we will use a process called randomisation that will give you an equal chance of receiving either treatment.

Your surgeon agrees this is the fairest way to reliably compare the two treatments and find out which one works best for patients.

The process is designed so that 40 patients will receive surgery, and 40 patients will receive the SORE Elbow physiotherapy rehabilitation.

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

1. **Surgical treatment**

An operation to remove the damaged part of the tendon in your elbow. The operation is usually performed as a day case and as keyhole surgery. The length of your surgery and hospital stay will not be increased by taking part in the study. After your surgery, you may be asked to attend clinic visits and receive physiotherapy, the same as patients who are not taking part in the study.

You should attend any other routine clinical appointments that may be scheduled as part of your ongoing care.

2. **SORE Elbow physiotherapy rehabilitation programme**

This is not a new programme and has been tested and designed in partnership with patients. It is a specific programme of exercises and an education package to help you control your symptoms and encourage your elbow to heal. The programme will involve seeing a physiotherapist for a series of face to face or online appointments. The number of sessions you attend will be decided by you and your physiotherapist. The programme is supported by written and online resources.

What if I have done physiotherapy before and it didn't work?

The SORE Elbow physiotherapy rehabilitation programme is likely to have certain parts that are different to the treatment you have already had. This may be different exercises, a different amount or frequency of exercises, or additional lifestyle modifications that encourage healing. Your physiotherapist may also offer other treatments on top of the SORE Elbow physiotherapy rehabilitation programme that you may not have tried, if they

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think it will help. If your symptoms are not improving after 3 months of SORE Elbow physiotherapy rehabilitation, you can choose to have surgery.

Do I have to take part?

No. It is for you to decide. Taking part is completely voluntary. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. Even if you agree to take part at first, you are still free to change your mind and withdraw from the study at any time, without giving a reason.

A decision not to take part, or to withdraw from the study at any time, will not affect the standard of care you receive now or in the future.

What are the alternatives to taking part?

If you choose not to take part, your surgeon will discuss with you the options available for your treatment. Whatever you decide about taking part in the study, it will not affect the standard of care that you receive.

3. What are the possible benefits of taking part?

We cannot promise that as an individual you will see any personal benefit from taking part, but you will be contributing to information and knowledge that we hope will help improve the treatment for people with persistent tennis elbow in the future.

If enough people take part, and if it seems promising to do so, a larger scale study may be carried out to find out whether surgery or physiotherapy is a better treatment for tennis elbow lasting 6 months or more.

The possible advantage of having surgery is that you may be able to return to normal function sooner. The duration of any persisting pain may also be reduced.

The possible benefit of receiving the SORE elbow physiotherapy rehabilitation is that your symptoms may improve without any of the risks associated with having a surgical procedure.

The treatment you receive for your tennis elbow is the only part of your care that is decided by taking part in the research. All other aspects of your care and treatment will be delivered according to routine practice at your hospital.

4. What are the possible disadvantages and risks of taking part?

There is no increased risk to you by participating in the study. The NHS has treated previous patients with both treatments being compared in this study.

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The clinicians treating you are experienced in the treatment options used in this study and will take every opportunity to reduce risk. Your progress will be monitored at 3, 6 and 12 months (for those reaching this time point during the study) and if your symptoms are not improving, the treating clinician will decide on any further or additional treatment or procedures that may be necessary.

The possible risks related to surgery include:

Common risks: pain caused by the operation itself which usually settles down after approximately 48-72 hours, bleeding, visible scar, ongoing symptoms and persistent pain.

Less common risks: Infection, bleeding, wound problems, abnormal scarring, nerve injury, stiffness in the arm, elbow instability and problems related to the anaesthetic.

You will face the same surgical and anaesthetic risks (if you receive surgical treatment) and receive the same postoperative care as patients who receive surgery for their tennis elbow without taking part in the study.

Possible risks associated with physiotherapy includes:

Common risks: a temporary increase in pain when doing rehabilitation exercises.

For the SORE Elbow physiotherapy rehabilitation, 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 in the future.

What if something goes wrong?

Your legal rights are not affected by taking part in this study.

This study only includes treatments that are already used in routine practice. The clinicians treating you will take every opportunity to reduce risk. In the unlikely event that something were to go wrong, they will offer the best possible solution to resolve it. If you have a concern about any aspect of this study, you should speak to us – our contact details can be found on the front page and at the end of this document.

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedure is available to you.

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

Participation in this study should not cost you anything.

There are no more visits to hospital than you would attend if you were not taking part in the trial.

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

All participants will receive a £15 voucher following completion of the 6-month questionnaire, as a thank you for taking part.

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

You are free to leave the study at any time. You do not need to give a reason and this will not affect your future care or rights in any way.

Simply tell us that you no longer wish to take part by contacting the research team using the contact details in section 6 of this document, so we know not to contact you in future.

5. How will we use information about you?

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

This information will include your NHS number, name and contact details, email address, date of birth, sex, weight, height 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.

International transfers

Your data will not be shared outside the UK.

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How will we use information about you after the study ends?

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 anonymised and securely archived or destroyed.

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 already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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 your information is used?

You can find out more about how we use your information:

- www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the Sponsor's Data Protection Officer: uhl-tr.infogov@nhs.net
- or telephone: 0300 303 1573 (main switchboard)

Who is organising and funding the research?

This study is funded by the 'National Institute for Health and Care Research' Health Technology Assessment Programme (project number NIHR170489). The Sponsor is University Hospitals of Leicester NHS Trust.

York Trials Unit at the University of York will carry out the day-to-day study management.

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Your treating clinician will not receive any payments for their involvement in the study. The hospitals receive payments for when a patient agrees to take part and for collecting follow-up data. This 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. This is to protect your interests. This study has been reviewed and given favourable opinion by North East - Tyne & Wear South Research Ethics Committee.

In addition, we have consulted with people who have undergone treatment for tennis elbow and who have provided useful feedback on the design of the study and the information provided in this document from a patient's perspective.

I would like to take part in the study…what next?

If you decide to take part, we will discuss the study again with you face-to-face to ensure everything is clear and to answer any questions you may have. We will then go through the study consent form with you.

6. How to contact us

If at any time you need more information, please contact us.

If you would like specific information about this study, please contact the SORE ELBOW trial team at York Trials Unit on: 01904 321522 or by emailing ytu-sore-elbow-trial@york.ac.uk.

Associate Prof Harvinder Singh is a Consultant Orthopaedic Surgeon based at the University Hospitals of Leicester NHS Trust and Dr Marcus Bateman a Consultant Physiotherapist, University Hospitals of Derby and Burton NHS Foundation Trust. They are the investigators in overall charge of the study and can be contacted at: ytu-sore-elbow-trial@york.ac.uk

If you would like independent advice about whether or not to take part, the Patient Advice and Liaison Service (PALS) or Patient Advice and Support Service (PASS). Please contact the SORE Elbow trial team at York trials Unit for details of your local site PALS or PASS contacts: ytu-sore-elbow-trial@york.ac.uk

We look forward to hearing from you.

Thank you for taking the time to read this information sheet and for considering whether to take part.

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