Optimising Physiotherapy for people with Tennis Elbow – a mixed methods pilot & feasibility randomised controlled trial

Patient Information Sheet

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Tennis Elbow is a common problem but we do not know the best way of treating it. Physiotherapy is often recommended. This can involve a variety of treatments, for example: exercise, taping, acupuncture, manual therapy, ultrasound or laser. Different physiotherapists prefer different treatments, dependent on how they were trained, but research suggests that the best treatments are not always used. We have designed an optimised physiotherapy treatment package based upon research evidence and expert opinion that we want to test with patients. This is focussed on three elements:

1. Advice and education so that patients can learn to manage the problem themselves
2. A specific exercise regime to improve function
3. A Tennis Elbow brace to control pain

The purpose of this study is to evaluate if it is feasible to run a large-scale study to establish whether this optimised physiotherapy treatment package is more effective than usual physiotherapy in reducing pain and improving function in people with Tennis Elbow. We will look at how willing people were to be involved, how well they engaged with the treatments and how well the treatment effect could be measured. We will also be inviting some people to discuss their experience of being involved to identify what worked well and what could be improved for a large national trial.

Why have I been invited?

You are being invited to take part because you may have Tennis Elbow.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your medical care or legal rights. If you decide not to take part, we will ask you whether you wish to be interviewed as to your reasons why. Again, this is optional but this information will help us to improve our research design. Likewise, you can agree to take part in the physiotherapy trial but decided not to be interviewed. People that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held in the physiotherapy department.

What will happen to me if I take part?

You will be invited to attend the physiotherapy department to undergo a short examination carried out by a qualified physiotherapist. This is to confirm that you do have Tennis Elbow and see if you are eligible to participate in the study. The examination will last up to 30 minutes and will involve asking questions about the problems you have, as well as an examination of your arm. If you do not meet the criteria you will not be eligible to participate in the study, and your physiotherapy appointments will continue as normal in line with the usual arrangements within the department.

If you are eligible then you will be asked to fill in a questionnaire to help us understand how your elbow pain affects you. This should take 10-15 minutes. You will be asked to complete a similar questionnaire again after 6 weeks, 3 months and 6 months. You will be given the choice of doing this online or on paper. If you choose the paper method, the questionnaires will be posted to you along with a free-return envelope. The online method is provided by Amplitude Clinical. They will send you links to the questionnaires by email or SMS text message and you can complete the questions on a smartphone, tablet or computer. If you choose the online method, we will share your email address and telephone number with Amplitude Clinical. This information will be stored on servers in the UK and will be deleted at the end of the trial. Completing the questionnaires is very important to this research so we will send reminders by email or telephone if you forget.

Because we don't know which is the best way to treat patients, we need to compare the different treatments. This is the reason why we perform a randomised controlled trial, where we put an equal number of patients into each group and then compare treatments. To make sure that each group is similar, patients are put into their groups by chance (randomly). So, once you have completed the questionnaires you will be randomly assigned to receive either the optimised physiotherapy treatment package, or usual physiotherapy. There is equal chance you will be treated with one or the other option. Usual physiotherapy treatment may involve a range of different treatments, whereas the optimised physiotherapy treatment package focusses on advice and education, exercise and using an elbow brace. The optimised physiotherapy treatment package does not include other treatments such as acupuncture or electrotherapy. If randomised to the optimised physiotherapy treatment package, you will be asked to attend physiotherapy appointments approximately once per month for at least three months and will be supported to exercise at home. You will be given a detailed treatment booklet and have access to a private website containing advice and exercise videos.

We will also measure your maximum grip strength and the amount of gripping that you can do pain-free using an electronic device called a Squegg. Participants receiving the OPTimisE treatment package will be given a Squegg device to take home and keep. We will ask you to repeat your grip strength measurements at home when you complete the questionnaires at 6 weeks, 3 months and 6 months. If you are allocated the usual physiotherapy treatment, you will be sent a Squegg device by post after 6 months, in time to measure your grip for the 6-month questionnaire. To use the Squegg device you will need to install the Squegg App on an Apple or Android smartphone/tablet and create an account, or log in using a Facebook or Google account. For data privacy reasons it would be recommended to use an

email address rather than Facebook to create a user account, however this is your own personal choice. No data will be shared between the research team and Squegg.

If you are asked to take part in the optimised physiotherapy treatment programme you will be asked to complete a short exercise diary to let us know how much of the exercise you were able to complete. You will be asked to complete the diary daily, and return it at 3 months in a stamped envelope provided.

Some information will be retrieved from your medical records, such as how many physiotherapy treatments you received and the types of treatments given.

During the study we will invite some of the participants to attend a short interview to discuss their experience of the process. The interviews will be relaxed and informal, may last up to 1 hour and can be arranged face-to-face, either in a quiet room at the physiotherapy department or in your own home, or by telephone, or online using video-conferencing.

These interviews are optional and should you wish, you can choose to not volunteer to take part in them while completing the consent form.

Interviews will be audio-recorded and some quotes used in the written-up report. Any quotes or discussions will be anonymised, so no one will know it was you who made the comments. There will be no other use of the recordings.

Expenses and payments

Travel expenses will be reimbursed for the first visit to the physiotherapy department as this research assessment is not part of normal physiotherapy care. Participants will receive a £20 Amazon/Love2shop voucher after completing all of the study questionnaires at 6 months.

Participants that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held in the physiotherapy department.

What are the possible disadvantages and risks of taking part?

You will have to take time to complete the questionnaires on 3 separate occasions at home and attend the initial research assessment. Apart from that there are no disadvantages or serious risks to taking part in this research. Both groups of patients will still receive physiotherapy treatment for their Tennis Elbow. If invited to take part in the interview, should you feel uncomfortable with any of the discussions, you are free to end the discussion at any point.

What are the possible benefits of taking part?

It is expected that you will gain benefit from the treatment you receive, in terms of pain reduction and improved function. But we cannot promise the study will help you. The information we get from this

study may help inform future research and direct future treatment to other patients with a similar complaint.

What happens when the research study stops?

Your involvement in the study will end when you complete and return your questionnaires at 6 months after starting the study, or after completing the interview if you are invited. Your physiotherapy appointments will end at the discretion of your physiotherapist, in agreement with you. When your involvement in the study ends, if you still require any further treatment for your Tennis Elbow, please consult your GP.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. You may also contact your local Patient Advice Liaison Service (PALS) for any concerns or complains that you might have on {add local PALS details}

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from Keele University and University Hospitals of Derby and Burton NHS Foundation Trust. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Electronic information will be stored on UK servers. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, email, telephone number) will be kept for up to 6 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 5 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

How will we use information about you?

We will need to use information from you for this research project.
This information will include your

- Initials
- NHS number
- Name
- contact details (address, email, telephone number)

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 code number instead.

We will keep all information about you safe and secure.

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.

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.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to uhdb.sponsor@nhs.net
- https://mysquegg.com/privacy-policy/

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

It is anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who is organising and funding the research?

This research is being organised by University Hospitals of Derby and Burton NHS Foundation Trust and is being funded by the National Institute of Health Research (NIHR) and the Chartered Society of Physiotherapy Charitable Trust.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Sheffield Research Ethics Committee (reference number: 21/YH/0121).

Further information and contact details:

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