A trial of **TR**eatments of **E**xercise **A**n**D** **O**rthotics for pla**N**tar heel pain: TREADON research trial

Participant Information Leaflet
Version 2.1, date 08-Jun-2023, IRAS: 314272

We are inviting you to take part in a research trial called TREADON. Before you decide whether or not to take part it is important for you to understand why the research is being undertaken and what it would mean to you if you were to take part.

Please take time to read the following information carefully and discuss it with others (such as friends and family) if you wish.

This Participant Information Leaflet is provided in English. Keele Clinical Trials Unit (CTU) can help with language translation if needed. Their contact information can be found on the last page.

What is the purpose of this trial?

Trial Background

- Pain under the heel (called plantar heel pain or plantar fasciitis) is a common condition.
- Plantar heel pain can reduce an individual's quality of life and wellbeing by restricting their ability to walk and to complete everyday tasks including work.
- Only four out of ten individuals with plantar heel pain are referred by their GP to other NHS health professionals (such as physiotherapists or podiatrists) for treatment as it is uncertain about what is the best treatment for plantar heel pain.

Trial Aim

The goal of this research trial is to find out whether exercises, orthoses (insoles), or exercises and orthoses (insoles) provide more relief for people with pain under the heel than self-management advice, and whether they are good value for money for the NHS.

Why have I been invited?

You are being invited to take part in the TREADON trial because you have either recently been to see your GP about pain under your heel or have completed a survey about foot pain that suggests you may have plantar heel pain. You may have contacted us after hearing about the trial on social media or from other sources.

Do I have to take part?

No. Taking part in TREADON is **completely voluntary**. Whether you take part in this research trial or not, your right to use health services at your GP practice or elsewhere will not be affected. Even if you decide to take part now, you are still free to withdraw from the trial at any time without giving a reason. If you do decide to take part a letter will be sent to your GP telling them that you are taking part in the trial.

What do I have to do, and how long will it take?

You have given us your telephone number and in the next week a researcher will call you and go through any questions you have about the trial, and check that you are eligible and that it is safe for you to take part. If after this conversation you wish to take part, the researcher will ask for your verbal consent to the following:

- To complete the trial consent form and baseline questionnaire and submit online/return it using the freepost return envelope **(no stamp needed)**.
- To receive one of the treatments outlined below that will be allocated to you by chance.
- To reply to a weekly text message, or phone call, over the 12-week trial period which will ask you to tell us about your heel pain. After 12 weeks you will receive these text messages/phone calls monthly, up until your 12-month follow up. For text messages, you will be charged at your standard message rate.
- To carry out the treatments you have been allocated in your own time.
- To attend up to 6 sessions with either a physiotherapist or podiatrist, over the 12-week trial period, if allocated to treatment arms 2-4 below.
- To keep a simple and brief diary about their treatment, if allocated to treatment arms 2-4 below.
- To complete and return the follow-up questionnaires that we will send you, via email or by post, at 12 weeks, 6 months and 12 months.

Participants who agree and are suitable to take part in the TREADON trial will be allocated by chance (called randomisation) to one of the following treatments:

1. ***Self-management advice***
   You will be provided with an advice booklet containing information and advice about plantar heel pain. The booklet provides information on stretching exercises and self-help messages about pain relief, suitable footwear, rest and weight loss that can all help to reduce pain in the heel.
2. ***Self-management advice plus stretching and strengthening exercises***
   You will receive an advice booklet and an assessment of your foot to decide the best exercises for your plantar heel pain. This assessment will be performed at a clinic by either a physiotherapist or podiatrist. You will be taught how to carry out these exercises so that you can continue doing them in your own time. You may be asked to

attend up to a maximum of six sessions with the physiotherapist or podiatrist over a 12-week treatment period.

3. ***Self-management advice plus shoe insoles***
   You will receive an advice booklet and an assessment of your foot. This assessment will be performed at a clinic by either a physiotherapist or podiatrist. The assessment is required to fit a shoe insole to help your plantar heel pain. You will be taught how to use the insole and asked to wear it for at least 4 hours per day. You may be asked to attend up to a maximum of six sessions with the physiotherapist or podiatrist over a 12-week treatment period.
4. ***Self-management advice and a combination of both exercise and shoe insoles***
   You will receive an advice booklet alongside a combination of exercise and shoe insoles (see above 2. & 3.). You may be asked to attend up to a maximum of six sessions with the physiotherapist or podiatrist over a 12-week treatment period.

For the 12 weeks of the trial, we ask you not to use any other types of treatment or devices for your heel pain, other than medication that your GP may provide.

We do not know which treatment works best for patients so it is important to remember that everyone who takes part in the trial, whichever treatment they receive, is providing an equally valuable contribution.

Will anything change during the trial?

We will monitor the participants carefully through the trial. When 80 people have been recruited to each treatment, we will examine the information you and other participants have provided. If one of the treatments seems to be much less effective than the others, then we will stop recruiting any further participants into this treatment. Patients already randomised to this treatment will continue with this treatment until their participation finishes.

What might be the risks of taking part?

The treatments used in this trial are considered to be safe and are commonly used in routine clinical care by physiotherapists and podiatrists. In some individuals, exercises or shoe insoles can cause temporary mild soreness and in some limited cases, shoe insoles may cause blisters.

The questions you are asked on the questionnaires are similar to those that your GP or other healthcare professional might ask you about your pain and related symptoms.

If you would like to speak to somebody about how you are feeling after answering these questions you could contact your GP. Alternatively, If you would like to speak to somebody about the trial, you can call the TREADON trial team during office hours on 01782 732950.

Unfortunately, we cannot reimburse you for travel and car parking costs that you may have to pay for attending clinic appointments. We are also unable to pay for any charges incurred for sending SMS text messages (your standard message rate applies).

What are the possible benefits of taking part?

Self-management advice, exercises and shoe insoles are commonly used treatments for plantar heel pain. Although no direct benefits can be guaranteed for you, your heel pain may improve over the course of the treatment and involvement in the trial will provide important information about plantar heel pain.

Will my taking part in this trial be confidential?

Yes. The information you provide in the questionnaire and during the trial period will be dealt with in the **strictest confidence**. Each person who responds to the questionnaire will be given a trial number so that any personal information **cannot be identified** or be traced back to you (anonymised).

The anonymised paper questionnaires will be stored securely for 10 years. After this time the questionnaires will be destroyed. Anonymised data will be kept indefinitely so that it can be used in future research. Members of staff from regulatory departments may require access to your records to check that the research is being carried out to a high standard.

What will happen to the results of this trial?

Regular updates about the progress of the trial will be posted on the TREADON trial website www.keele.ac.uk/treadon. We intend to publish the results of the trial. At the end of the trial, the key findings from this trial will be written in an easy-to-read summary and will be provided to participants and available to view on the TREADON trial website. You will not be identified in any report or publication that is produced.

Who is organising and funding the trial?

The TREADON trial is being led by Professor Edward Roddy (Keele University) and other researchers at Keele University, the University of Leeds and Glasgow Caledonian University. They are working in partnership with Keele Clinical Trials Unit (CTU), Clinical Research Networks in England, Regional Health Boards in Scotland, and with patients, GPs, physiotherapists, podiatrists and other healthcare professionals in England and Scotland. The trial is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (ref: NIHR131638).

Who has reviewed the trial?

All research carried out within the NHS is assessed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This trial has been reviewed by West of Scotland Research Ethics Committee 5 (Reference: 22/WS/0165).

What will happen to the information collected about me during the trial?

Keele University is the sponsor for this trial which is based in the United Kingdom. Keele University will be using information from you to undertake this research and will act as the data controller for the data collected during this trial.

If you decide to take part in this trial, the information collected about you will be treated in strict confidence and in accordance with the general data protection regulations (Data Protection Act 2018).

This means that we are responsible for looking after your information and using it properly. Keele University will keep the information you provide for 10 years after the research has finished. This is normal in research of this nature.

Your identifiable data will be securely stored by Keele Clinical Trials Unit (CTU). Consent forms will be stored separately to the other data that you provide. Data shared to other researchers will be anonymised.

How will we use information about you?

We will need to use information from you for this research trial.

This information may include your NHS number, name, age, date of birth, sex and contact details. Authorised individuals from Keele University and regulatory organisations will use this information to do the research or to check your records to make sure that the research is being done properly. If you are allocated to receive treatment at a clinic, your details will be shared with the clinic site in order to arrange your appointment.

People who do not need to know who you are will not be able to see your name or contact details. The data you provide will be anonymised which means your data will have a unique trial ID number instead.

We will keep all information about you safe and secure.

Once we have finished the trial, 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 trial.

What are your choices about how your information is used?

- You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have. Similarly, you can stop completing a questionnaire at any time, without giving a reason, but again we would like to keep any answers that you have given to that point as a partially completed questionnaire. If you would like to opt out of us keeping those answers, please contact us on ctu.treadon@keele.ac.uk or 01782 732950.
- 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.

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

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 www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/checkyourinformationisbeinghandledcorrectly/researchparticipants
- by asking one of the research team
- by sending an email to dpo@keele.ac.uk, or
- by ringing us on 01782 734311.

Contact for further information

If you have any questions or would like any further information, please contact the TREADON Research Team at **Keele Clinical Trials Unit** on:

01782 732950

Office hours are Monday - Friday 9am - 5pm

E-mail:

ctu.treadon@keele.ac.uk

If you have any questions or concerns about taking part in research, you can also contact Keele University's Head of Project Assurance: research.governance@keele.ac.uk

Alternatively, you can contact NHS England on Tel: 0300 311 2233, email: england.contactus@nhs.net

If you have any questions or concerns about your healthcare, you can also contact the Patient Advice and Liaison Service (PALS), which offers confidential advice, support and information on health-related matters at https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

This patient information leaflet and survey are provided in English. Keele CTU can help with language translation if needed and can be contacted by telephone 01782 732950, or email ctu.treadon@keele.ac.uk

Thank you for taking the time to read this information leaflet and for considering taking part in this research trial.

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