



Treatments of Exercise AND Orthotics for plantar heel pain: TREADON FOOT PAIN SURVEY

Patient Information Leaflet

Version 2.0, Date: 08-Jun-2023

We are inviting adults, aged 18 years and over, who are experiencing heel pain to receive more information about the TREADON trial.

The goal of the TREADON research trial is to find out which treatments provide more relief for people with pain under the heel, and whether they are good value for money for the NHS.

The following information leaflet outlines the purpose of the foot pain survey and what it will involve. Thank you for taking the time to read the following information.

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

What is the purpose of the reply form & foot pain survey?

We are asking adults aged 18 years and over, who are experiencing heel pain, to let us know if they would like to receive further information about the TREADON trial, or would like to take part. If interested, we invite you to complete a reply form and, if applicable, foot pain survey.

The aim of the foot pain survey is to find out about any foot pain you may have experienced in the last month. This is the first stage of the TREADON trial and it will help us check that you are eligible for the next stage.

Please complete a reply form prior to completing the foot pain survey. If you decide you **do** want to receive more information or take part, you will have the opportunity to complete the foot pain survey.

Why have I been invited?

Adults, aged 18 years and over, who are experiencing heel pain are being invited to express an interest in whether they would like to receive more information about the TREADON trial.

We are advertising this trial through GP practices, NHS physiotherapy and podiatry services as well as advertising through social media, broadcasting and local communities; so you may have found out about the TREADON trial through any of these routes.

Do I have to take part?

No. Filling in the reply form and, if applicable, foot pain survey is **completely voluntary**. Your healthcare will not be affected in any way, whether or not you decide to take part and return the reply form and, if applicable, foot pain survey.

How long will it take and what do I need to do?

It should take approximately 2 minutes to complete the reply form and indicate if you would like to receive further information about the study.

If you **do** give your permission, you may be contacted again but please note, there is no commitment to taking part in the trial. If you **do not** give your permission, we will ask for some basic details to ensure we do not contact you again.

If you decide you **do** want to receive more information or take part, you will be invited to complete the foot pain survey. The foot pain survey should take approximately 5 minutes to complete.

What are the possible benefits of taking part?

Whilst there is no direct benefit of completing the reply form and, if applicable, foot pain survey, we hope that what we learn from the trial will help patients with heel pain in the future.

What are the possible disadvantages and risks to taking part?

There are no risks (in terms of safety or physical harm) involved in completing the reply form and, if applicable, foot pain survey. The questions you are asked on the survey are similar to those that your GP or other healthcare professional might ask you about your pain and related symptoms.

Will my taking part in this trial be kept confidential?

Yes. The information you provide in the survey will be dealt with in the **strictest confidence**. Each person who responds by completing a reply form and, if applicable, foot pain survey will be given a trial number so that any personal information **cannot be identified** or be traced back to you.

Who is organising and funding the research?

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: 131638).

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 REC 5 Research Ethics Committee (Reference: 22/WS/0165).

What will happen to the information collected about me?

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 respond to the reply form and, if applicable, foot pain survey, the information collected about you will be treated in strict confidence and in accordance with the general data protection regulations (Data Protection Act 2018). You can stop completing the survey at any time, without giving a reason, but we would like to keep any answers that you have given to that point as a partially completed survey. If you would like to opt out of us keeping those answers, please contact us on ctu.treadon@keele.ac.uk or 01782 732950.

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). Reply 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 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.

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 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.

- 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

- 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

What if I have any questions or concerns?



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**](mailto: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/>

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

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