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Treatments of exercise and orthotics for plantar heel pain: TREADON

Submission date
16/11/2022

Recruitment status
Recruiting

Registration date
06/12/2022

Overall study status
Ongoing

Last Edited
10/06/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Pain under the heel (called plantar heel pain, PHP) is a common condition affecting 1 in 10 adults during their lifetime. It makes walking and completing everyday tasks, including going to work, difficult. Most patients who consult in general practice are given pain medication and advice, yet the problem often continues. In our successful pilot and feasibility trial, foot orthoses and exercises showed promise for improving pain and function, but a large, high-quality main trial is needed to confirm this.
The aim of the TREADON trial is to show whether exercises and/or foot orthoses (shoe insoles) provide more pain relief for adults with plantar heel pain (PHP) than a self-management advice booklet alone, and whether this is good value for money.

Who can participate?
Up to 696 adults, 18 years and over, with Plantar Heel Pain (PHP) will be recruited to this trial.

What does the study involve?
Participants will be randomly allocated to receive one of the following four treatments: 1) Self-management advice (SMA) booklet only (control arm), 2) SMA booklet plus individualised exercises, 3) SMA booklet plus prefabricated foot orthoses, 4) SMA booklet plus individualised exercises and prefabricated foot orthoses.
Patients will be involved in the trial for a duration of 12 months follow up. During this period, all participants will be sent a weekly text-message/ phone call to collect pain scores for up to 12 weeks and then monthly from 3 to 12 months. All participants will be asked to complete a questionnaire at baseline, 3, 6 and 12 months. Half-way through the trial, only treatments that appear to be reducing pain will continue to be offered and the trial will stop recruiting any further participants into this treatment. Patients already randomised to this treatment will continue with this treatment until their participation finishes.
In addition to the text message/phone calls and questionnaire, the participants who are allocated into arms 2 to 4 will receive the trial interventions which will be delivered by site clinicians. These participants will receive up to a total of 6 sessions over 12 weeks. The first session is anticipating to be approx. 1 hour and subsequent visits will be approx. 30 minutes.

What are the possible benefits and risks of participating?
Self-management advice, exercises and shoe insoles are commonly used treatments for plantar heel pain. Although no direct benefits can be guaranteed, heel pain may improve over the course of the treatment and involvement in the trial will provide important information about plantar heel pain. 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 asked on the questionnaires are similar to those that GPs or other healthcare professionals might ask about pain and related symptoms but you could contact your GP if you would benefit from speaking to somebody about how you are feeling after answering these questions. Unfortunately, travel and car parking costs that may apply when attending clinic appointments cannot be reimbursed. We are also unable to pay for any charges incurred for sending SMS text messages as part of the trial.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
January 2022 to November 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Laura Bowyer, l.bowyer@keele.ac.uk

Study website
https://www.keele.ac.uk/treadon/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
314272

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54528, NIHR131638, IRAS 314272

Study information

Scientific Title
Clinical and cost-effectiveness of individualised exercises and foot orthoses in the treatment of plantar heel pain: a randomised multi-arm multi-stage (MAMS) adaptive trial

Acronym
TREADON

Study objectives
The aim of the TREADON trial is to show whether exercises and/or foot orthoses (shoe insoles) provide more pain relief for adults with plantar heel pain (PHP) than a self-management advice booklet alone, and whether this is good value for money.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/11/2022, West of Scotland Research Ethics Committee 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 3140213; WoSREC5@ggc.scot.nhs.uk), ref: 22/WS/0165

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Hospital

Study type(s)
Treatment

Participant information sheet

https://www.keele.ac.uk/treadon/

Health condition(s) or problem(s) studied
Plantar heel pain

Interventions
Eligible patients who consent to take part in the trial will be allocated to one of four treatment arms:
1. Self-management advice (SMA) booklet (control arm)
2. SMA booklet plus individualised exercises (SMA-exercises)
3. SMA booklet plus pre-fabricated foot orthoses (SMA-orthoses)
4. SMA booklet plus individualised exercises and pre-fabricated foot orthoses (SMA-combined).
A self-management (control) arm has been included as this is the closest intervention to GP usual care described as a watchful waiting approach.
The duration of the intervention regardless of group allocation will be 12 weeks. Participants will be asked not to use other types of treatments, other than medication that their GP has provided, during the intervention period if possible; however, any additional healthcare and self-care use will be recorded in the 12-week follow-up questionnaire, 6-month follow-up questionnaire and 12-month follow-up questionnaire.
Participants will be sent a weekly text-message to collect pain scores for up to 12 weeks and then monthly from 3 months to 12 months (Patients who do not wish to use text-messaging will be offered the option of brief telephone calls at the consent stage) as well as a questionnaire at 12-weeks, 6 and 12 months.

Intervention Type
Behavioural

Primary outcome measure
Change in plantar heel pain intensity score is measured using a 0-10 numeric rating scale (NRS) at baseline and an average score from 6, 7, 8, 9, 10, 11 and 12 weeks.

Secondary outcome measures
1. Short-term pain trajectories measured using a 0-10 NRS at baseline, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 weeks
2. Pain measured using a 0-10 NRS at baseline, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 months
3. First step pain measured using a 0-10 NRS at baseline, 3, 6 and 12 months
4. Physical function measured using Foot Function Index disability (9 items) and activity limitation subscale (5 items), 10 point Likert scale at baseline, 3, 6 and 12 months
5. Patient global rating of change using global impression of change score (6 point scale) at baseline, 3, 6 and 12 months
6. Pain self-efficacy using pain self-efficacy questionnaire (10 items, 6 point scale) at baseline, 3, 6 and 12 months
7. Illness perceptions using brief illness perception questionnaire (8 items, 10 point scale) at baseline, 3, 6 and 12 months
8. Health related quality of life using EuroQuol:EQ5D-5L at baseline, 3, 6 and 12 months
9. Ability to work using work loss and presenteeism questionnaire at baseline, 3, 6 and 12 months
10. Treatment satisfaction using self reported treatment adherence, satisfaction with care and treatment credibility questionnaires at baseline, 3, 6 and 12 months
11. Cost-effectiveness using self-reported healthcare use for plantar heel pain at baseline, 3, 6 and 12 months.

Overall study start date
01/01/2022

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over
2. Self-reported localised pain under the heel which is worst when standing after rest and after prolonged weight-bearing
3. Symptom duration at least 4 weeks with pain > = 2 (0-10 Numerical Rating Scale [NRS])
4. Access to a mobile phone that can send/receive SMS text-messages or a landline telephone
5. Able and willing to participate and provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 696; UK Sample Size: 696

Key exclusion criteria
1. Inflammatory arthritis, systemic lupus erythematosus, gout, fibromyalgia
2. Heel pain of neurologic cause e.g. tarsal tunnel, entrapment neuropathy, radiculopathy
3. Serious pathologies requiring urgent medical attention (e.g. trauma, tumour, infection)
4. Current treatment or treatment in the last 3 months by a physiotherapist or podiatrist for PHP, or currently using a contoured foot orthosis
5. Previous surgery or awaiting surgery on the affected foot
6. Corticosteroid injection into the affected foot in the last 3 months
7. Extracorporeal shockwave therapy to the affected foot in the last 3 months
8. Unlikely to tolerate the interventions (e.g. allergies to common orthotic device materials) or unable to attend for treatment

Date of first enrolment
30/01/2023

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NIHR CRN: West Midlands
James House
Newport Road
Albrighton
Wolverhampton
United Kingdom
WV7 3FA

Study participating centre
NIHR CRN: North West Coast
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
NIHR CRN: Yorkshire and Humber
8 Beech Hill Road
Sheffield
United Kingdom
S10 2SB

Study participating centre
Leeds Community Healthcare NHS Trust
Stockdale House
8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre

NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
NHS Ayrshire and Arran
PO Box 13, Boswell House
10 Arthur Street
Ayr
United Kingdom
KA7 1QJ

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Sponsor information

Organisation
Keele University

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Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Summary results will also be shared with participants, participating GP and NHS sites and be publicly available on the TREADON trial website (web address tbc).

Intention to publish date
30/08/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Data Custodian Dr Martyn Lewis a.m.lewis@keele.ac.uk, type of data = anonymised password protected database file release in suitable format (e.g. Excel, Stata, SPSS), available after main publication of the primary and key trial results (available indefinitely),

shared with password protection, for analyses deemed suitable for purpose (following review by the Keele Data Custodian Academic Proposal (DCAP) committee), by electronic password protected transfer by the data custodian, consent for research study has been obtained from participants (data will be anonymised data release), data will be anonymised, ethics consideration around confidentiality/ anonymisation of the data and suitability of data sharing (as deemed whether fit for purpose).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		01/05/2025	10/06/2025	Yes	No