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The TREADON study: Treatments of exercise and orthotic devices for plantar heel pain

Submission date
08/06/2016

Recruitment status
No longer recruiting

Registration date
05/07/2016

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pain under the heel, known as planter heel pain (PHP) is a relatively common condition with up to 1 in 10 adults affected at some point in their lives. PHP can restrict the ability to walk and to complete everyday tasks including work. Only four of every ten patients are referred by GPs to other NHS health professionals, such as physiotherapists or podiatrists, for treatments of adjustable shoe insoles (called prefabricated foot orthoses) and/or exercise. The reason that patients are not routinely referred for these treatments may be because evidence is lacking as to whether exercise or shoe insoles or a combination of both, are the best possible treatment options. This study will investigate the clinical and cost-effectiveness of individualised exercise or adjustable shoe insoles delivered by physiotherapists and podiatrists compared with self-management advice for patients with PHP. In order to determine this, a large scale trial is needed and so the aim of this study is to conduct an initial study looking at how best to recruit patients, how acceptable the treatments are to patients and how well patients are able to follow the different treatment programs.

Who can participate?
Adults with heel pain which is made worse by putting weight on it.

What does the study involve?
Participants are randomly allocated to one of four groups. Those in the self-management group receive an advice booklet about PHP, which includes information about stretching exercise, pain relief, suitable footwear, and weight loss to help lower pain levels. Those in the exercise and self-management group also receive the advice booklet as well as up to six appointments over 12 weeks with a physiotherapist or podiatrist (person qualified to treat disorders of the foot, ankle or lower leg) to learn individualised exercises to help lower pain. Those in the orthoses and self-management group receive the advice booklet as well as up to six appointments over 12 weeks with a physiotherapist or podiatrist who will prescribe them special insoles to wear in their shoes to help reduce pain. Those in the exercise, orthotics and self-management advice group receive the advice booklet, exercise sessions and insoles. Participants in all groups are sent a weekly text message or phone call so they can rate their current level of pain. At the start of the study and then after 12 weeks, participants complete a number of questionnaires to measure foot pain and function, as well as their quality of life. At the end of the study, the amount of patients who

took part and the acceptability of the treatments to participants is also measured using questionnaires.

What are the possible benefits and risks of participating?
There are no direct benefits and there are no risks over and above those already known as these are interventions commonly used in routine clinical care.

Where is the study run from?
Arthritis Research UK Primary Care Centre, Keele University (UK)

When is the study starting and how long is it expected to run for?
November 2015 to November 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Linda Chesterton (scientific)
l.s.chesterton@keele.ac.uk
2. Dr Nicola Halliday (scientific)
n.halliday@keele.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Linda Chesterton

Contact details
Arthritis Research UK Primary Care Centre
Research Institute for Primary Care & Health Sciences
Keele University
Keele
United Kingdom
ST5 5BG
+44 1782 734888
l.s.chesterton@keele.ac.uk

Type(s)
Scientific

Contact name
Dr Nicola Halliday

Contact details
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele University
Keele

United Kingdom
ST5 5BG
+44 1782 733899
n.halliday@keele.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The TREADON (TReatments of Exercise AnD Orthotic devices for plaNtar heel pain) Pilot and Feasibility Trial

Acronym
TREADON

Study objectives
The aim of this study is to inform the robust design of a future, main, randomised controlled trial of advice, exercise and foot orthoses as interventions for adults with plantar heel pain (PHP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Four-arm multi-centre randomised pragmatic pilot and feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will be randomised to one of four intervention arms. Randomisation will be conducted at Keele CTU using block randomisation (block size of 4) to ensure parity in allocation from each of the three invitation methods and for each treating centre.

Self-Management Advice:
Participants will receive an advice booklet 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.

Exercise and Self-Management Advice:
Participants will receive an advice booklet about plantar heel pain and attend up to six clinical appointments over a 12 week period with a treating clinician (physiotherapist or podiatrist). During an initial appointment participants will be taught how to perform and progress prescribed exercises and will be given an individualised and detailed exercise sheet describing the regimen and showing pictures of the exercises.

Orthoses and Self-Management Advice:
Participants will receive an advice booklet about plantar heel pain and attend up to six clinical appointments over a 12 week period with a treating clinician (physiotherapist or podiatrist). During an initial appointment participants will be prescribed foot orthoses and instructed on their use.

Exercise, Orthotics and Self-Management Advice:
Participants will receive an advice booklet about plantar heel pain and attend up to six clinical appointments over a 12 week period with a treating clinician (physiotherapist or podiatrist). During an initial appointment participants will be prescribed foot orthoses and instructed on their use.

Participants in all groups will be required to reply to a weekly text message or take a phone call regarding their current heel pain measured using the Numerical Rating Scale.
Twelve weeks following randomisation all participants will be mailed a follow-up pack containing a cover letter, a 12-week questionnaire and a pre-paid return envelope. Participants will be asked to complete the questionnaire and return it in the pre-paid envelope.
For non-responders, minimum data collection (MDC) to capture the primary outcome measures (NRS, MFPDI-PS and FFI-PS) will be undertaken by telephone approximately 3 weeks after the initial mailing. During this phone call if a participant declines to provide MDC over the phone they can be offered the choice to receive a postal MDC questionnaire.
All patients randomised to an exercise or foot orthoses intervention will be asked to keep a single page (5 questions) weekly paper diary over the 12 weeks of the intervention. This will capture adherence and general patient engagement with the intervention. Participants will be asked to return the diary to Keele CTU using a pre-paid envelope provided at 12 weeks.

Intervention Type
Mixed

Primary outcome(s)
Identification of primary outcome measure for the main trial, using the following options:
1. Average plantar heel pain over the last 7 days is measured using the Numerical Rating Scale (NRS 0-10) of plantar heel pain collected at baseline in the self report questionnaire, weekly via text messaging for 12 weeks and at the 12 week follow up via self report questionnaire
2. Foot pain is measured using the Manchester Foot Pain and Disability Index (MFPDI) pain subscale at baseline and 12 weeks via self report questionnaire
3. Foot pain is measured using the Foot Function Index Pain Subscale (FFI-PS) at baseline and 12 weeks via self report questionnaire

Key secondary outcome(s))
Process outcomes:
1. Adherence to treatment is measured using adherence with interventions (variable number according to intervention) adapted from previous research at 12 weeks via self report questionnaires and through weekly self report diaries

2. Satisfaction with treatment is measured using a 3 x Likert scale adapted from previous research at 12 weeks via self report questionnaires
3. Credibility of treatment is measured using a 5 x Likert scale adapted from previous research at 12 weeks via self report questionnaires
4. Adverse events are measured at 12 weeks via self report questionnaires and through weekly self report diaries
5. Patient views on treatment adherence, satisfaction and credibility are measured using free text at 12 weeks via self report questionnaires

Clinical outcomes:
1. Presence of pain in the heel is measured with a yes/no question at baseline via self report questionnaires weekly via text messaging for 12 weeks and at 12 week follow-up via self report questionnaires
2. First step pain is measured using a Numerical Rating Scale 0-10 at baseline and 12 weeks via self report questionnaires
3. Plantar heel pain at 12 weeks relative to the pain at baseline is measured using the Global Impression of change score at 12 weeks via self report questionnaires
4. Presence of pain in the heel is measured with a yes/no question at baseline via self report questionnaires, weekly via text messaging for 12 weeks and at 12 week follow-up via self report questionnaires
5. Foot Function is measured using the Foot Function Index disability (9 items), activity limitation subscale (5 items) and a 10 point Likert scale at baseline and 12 weeks via self report questionnaires
6. Foot function and appearance is measured using the Manchester Foot Pain and Disability Index (MFPDI) functional subscale (10 items) and personal appearance (2 items) at baseline and 12 weeks via self report questionnaires
7. Health related quality of life is measured using the EQ5D-5L at baseline and 12 weeks via self report questionnaires

Healthcare cost outcomes:
1. Employment status is measured using Current Employment Status questions at baseline and 12 weeks via self report questionnaires
2. Performance at work is measured using a Numerical Rating Scale 0-10 at baseline and 12 weeks via self report questionnaires
3. Work loss (absenteeism) is measured with a number of days lost question at baseline and 12 weeks via self report questionnaires
4. Plantar heel pain health care utilisation is measured using questions to capture the use of prescribed or over-the-counter medications or interventions e.g. foot orthoses, heel pads, hospital investigations and use of private healthcare at 12-week follow-up

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Adults aged ≥ 18 years
2. Self-reported localised pain under the heel which is aggravated by weight bearing activities, worst when first standing or after a period of rest, especially on getting out of bed in the morning, or following periods of prolonged sitting
3. Symptom duration of episode of at least 4 weeks with a minimum pain score of 2 on a

Numerical Rating Scale (NRS 0-10)
4. Owns or has access to a mobile phone that receives text messages or a landline telephone
5. Able and willing to participate and provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
82

Key exclusion criteria
1. Inflammatory arthritis (e.g. rheumatoid arthritis, ankylosing spondylitis, reactive arthritis, systemic lupus erythematosus, gout, psoriatic arthritis), fibromyalgia
2. Serious pathologies or serious suspected pathologies (e.g. malignancy, trauma, infection)
3. Current treatment for plantar heel pain or treatment in the last 3 months by a physiotherapist or podiatrist
4. Previous surgery or on waiting list for surgery on the affected foot
5. Corticosteroid injection into the affected foot in last 3 months
6. Unwilling or unable to participate with the interventions or unable to attend clinics for treatment
7. Unable (even with telephone support) to complete follow-up questionnaires written in English or unable to receive text messages or phone calls
8. Known skin allergies to common orthotic device materials (e.g. adhesives, latex, sock dyes, certain shoe types)

Date of first enrolment
01/11/2016

Date of final enrolment
15/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele University
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele University
Staffordshire
Keele
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2021	04/03/2022	Yes	No