



Self-management advice, exercise and foot orthoses for plantar heel pain: the TREADON pilot and feasibility study

Participant Clinical Trial Results

Who was responsible for the trial?

Keele University was the sponsor for the trial. It was organised by the universities of Keele and Glasgow Caledonian, working with a number of GP practices. The trial was funded by the National Institute for Health Research.

General information about the clinical trial

Plantar heel pain (pain under the heel, often called plantar fasciitis) is common. Despite impact on quality of life, the best management is unclear. Commonly used treatments include general self-management advice, exercise and shoe insoles (orthoses). However, we do not know which treatment provides the best and quickest pain relief.

The aim of the pilot and feasibility trial was to work out how best to design a future larger scale trial. We wanted to know if we would be able to recruit enough people to take part in a future trial and find out whether people felt the exercise and orthoses treatments were acceptable.

Who was included in the trial?

82 adults over the age of 18 years across the West Midlands and Cheshire who had attended their GP practice for plantar heel pain or responded to a postal questionnaire were recruited into the trial.

Which treatments were studied?

The three treatments that were studied in the trial are explained below:

Self-management advice (SMA)

A booklet about plantar heel pain with advice on how to relieve and manage pain.

Exercise

Personalised exercise for plantar heel pain based on a clinical examination.

Orthoses

Personalised orthoses (insoles) for plantar heel pain based on a clinical examination.

On the 'flip of a coin' participants were randomised to:

SMA or SMA+exercise or SMA+orthoses or SMA+exercise+orthoses.

What were the overall results of the trial?

- Our methods of identifying people with plantar heel pain from their general practice or population survey were successful.
- 67% of people who started the study completed it at 12 weeks.
- All treatments were successfully delivered by physiotherapists and podiatrists.
- Most participants were happy to engage with treatments, with self-management advice *plus* exercise and/or orthoses providing the most satisfaction.
- We were able to work out how big a future study would need to be to fully answer this question for the NHS.

How has this pilot and feasibility trial helped patients and researchers?

The study showed that if we build on this work we will be able to carry out a future larger clinical trial comparing self-management advice, exercises and/or foot orthoses for plantar heel pain.

We will work with physiotherapists and podiatrists from across the UK.

Are there plans for future studies?

We have designed a large-scale trial that has been funded by the National Institute for Health Research. The study will start in 2022 and will run for 5 years.

The goal of this main study are to:

- Invite 696 people from across England and Scotland to take part in a 12 month trial through their GP or social media.
- Provide patients and health professionals with best practice treatment information for plantar heel pain with self-management advice, exercise and orthoses.
- Find out which treatments are most cost-effective for the NHS.

Where can I find more information about the pilot and feasibility trial?

The study has been published in a journal called *Pilot and Feasibility Studies*.

The findings can be found here:

<https://pilotfeasibilitystudies.biomedcentral.com/track/pdf/10.1186/s40814-021-00808-0.pdf>

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