# Are orthotic insoles effective in pain reduction for plantar fasciitis in general practice or sports physician?

Published: 16-07-2015
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To examine the effectiveness of custom made orthotic insoles by a podiatrist, compared to sham orthotic insoles and education alone in patients with plantar fasciitis in terms of pain, function and recovery.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Tendon, ligament and cartilage disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45150

**Source**
ToetsingOnline

**Brief title**
STAP-trial

### Condition

- Tendon, ligament and cartilage disorders

**Synonym**
heel spur, Plantar fasciitis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** foot, insoles, plantar fasciitis, podiatrist

## Outcome measures

### Primary outcome

After 12 weeks:

- pain at rest and during activity (11-point NRS scale)

### Secondary outcome

After 6 en 26 weeks:

- pain at rest and during activity (11-point NRS scale)

- foot function (FFI)

- recovery (measured on a 7-point Likert scale ranging from *completely

recovered* to *worse than ever*)

26 weeks:

- cost-effectiveness of the interventions

# Study description

### Background summary

In both primary and secondary care, many intervention strategies are applied in patients with plantar fasciitis. The most frequently studied and applied treatments include biomechanical treatment (including footwear modification), stretching, shock wave therapy, and cortisone injections. However, there are few data from high-quality randomized controlled trials that support the efficacy of these therapies. A pilot study among 19 general practitioners (GPs) in the region of Rotterdam shows that during a first visit for foot complaints, 32% of the patients are directly referred to a podiatrist for an orthotic insole. Another 29% received direct advice for (prefabricated) insoles by their general practitioner. So orthotic insoles are the most frequent applied interventions for plantar fasciitis in general practice. Unpublished data shows that 4% of all consultations are diagnosed by the sports physician with plantar

fasciitis , which corresponds to approximately nine consultations per month. Previous research has shown that plantar fasciitis is the third most common running injury. However, there is insufficient evidence that insoles can reduce pain and improve function in these patients.

### Study objective

To examine the effectiveness of custom made orthotic insoles by a podiatrist, compared to sham orthotic insoles and education alone in patients with plantar fasciitis in terms of pain, function and recovery.

### Study design

Three-arm Randomised Clinical Trial with a follow-up of 6 months

### Intervention

All patients will receive an information leaflet including stretching and loading exercises that can be performed at home. Patients randomised to either the sham or custom made insole group will visit the podiatrist who will proceed with a standard intake and will execute the same procedure in all patients. All patients allocated to the intervention group will receive a custom made orthotic insole while patients allocated to the sham control group will receive a flat insert (placebo insole). The participants in these two study groups will be blind to their treatment allocation

### Study burden and risks

There are no risks associated with participation. All patients included in our study will receive the usual care according to the clinical guideline.
The only tests that are used are questionnaires, which will take about 15 minutes each at 2,4,6, 12 and 26 weeks. THe baseline questionnaire will take about 25 minutes. Altogether this will take the patient approximately 100 minutes over a period of 1/2 year . The questionnaires that are used are not associated with physical or physiological discomfort. In the intervention group, patients will. Patients randomised to the sham or custom made insole group will all be referred to a podiatrist This will take 60 minutes for two visits.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Patients with plantar fasciitis, characterized as pain at the medial hind foot, presenting themselves to a GP or sports physician and aged between 18 and 65 years and a minimal pain duration of 2 weeks are eligible for participation. The diagnosis of plantar fasciitis can be made with reasonable certainty on the basis of clinical assessment alone. Patients typically report a gradual onset of pain in the inferior heel that is usually worse with their first steps in the morning or after a period of inactivity. And secondly there is a localized area of maximal tenderness over the anteromedial aspect of the inferior heel.

## Exclusion criteria

Recurrent complaints of plantar fasciitis for more than 2 years; complaints caused by trauma; earlier treatment for plantar fasciitis by a podiatrist or treatment with orthotics; suspected (osteo)arthritis in the subtalar or talonavicular joint; suspicion on tarsal tunnel syndrome, stress fractures, infections or tumours, systemic diseases (Bechterew, psoriasis or multiple sclerosis); no understanding of the Dutch language.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-09-2015 |
| Enrollment: | 185 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | orthotic insole |
| Registration: | No |

# Ethics review

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| Approved WMO Date: | 16-07-2015 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 14-03-2016 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

Approved WMO

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|---|---|
| Date: | 12-12-2016 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 16-10-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 15-12-2017 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 21365
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL52185.078.15 |
| OMON | NL-OMON21365 |