Plantar heel pain. A pragmatic randomized single blinded clinical trial comparing the use of customized insoles, night splints and a barefoot technology shoe.

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A pragmatic randomized single blinded clinical trial was designed with the objective to compare the use of customized insoles, night splints and a barefoot technology shoe for the treatment of plantar heel pain syndrome.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Synovial and bursal disorders
Study type	Interventional

Summary

ID

NL-OMON34189

Source
ToetsingOnline

Brief title
Plantair heel pain study.

Condition

- Synovial and bursal disorders

Synonym
heel pain syndrome heelspur

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Aanvraag zal worden gedaan bij Stichting Klinisch Wetenschappelijk Onderzoek Slotervaart Ziekenhuis (SKWOSZ)

Intervention

Keyword: Calcaneodynie, Heel pain syndrome, Masai barefoot technology shoe, Plantar fasciitis

Outcome measures

Primary outcome

Pain Visual Analog Scale

Foot Function Index-5pt (Verbal Rating Scales).

Secondary outcome

Satisfaction VAS

Study description

Background summary

Proximal plantar fasciitis is an inflammatory reaction from chronic irritation of the plantar fascia at its calcaneal origin, possibly resulting from chronic irritation. It is characterized by pain and tenderness under the heel on weightbearing, resulting in limitations of physical activity. The condition affects about 10% of the population at some time during life.

Little is known of the clinical course of the condition, and some patients may recover spontaneously. The most recent Cochrane review (2003) on interventions for treating plantar heel pain concluded that there is limited high-level evidence upon which to base clinical practice and asked for well designed and conducted randomized trials.

Study objective

A pragmatic randomized single blinded clinical trial was designed with the objective to compare the use of customized insoles, night splints and a

barefoot technology shoe for the treatment of plantar heel pain syndrome.

Study design

This study is designed as a pragmatic prospective randomized single blinded clinical trial to evaluate the difference in functional outcome after treatment with customized inlays versus night splints and MBT shoes for the treatment of plantar heel pain. The patients will be randomly allocated into one of the three groups. Randomization will be performed by computer assignment and concealed allocation. Blinding of patients is not possible, but the observer will be blinded at follow-up. Analysis of the data will be performed in a blinded fashion as well.

Intervention

Group 1: Patients will wear orthopaedic insoles during daytime for at least 6 hours a day during 6 weeks minimum.
Group 2: Customized night splints will be used during sleeping hours for a minimum of 6 hours per day and 6 weeks minimum.
Group 3: Participants will wear MBT shoes during daytime for at least 6 hours per day and 6 weeks minimum.

All patients will be asked not to use additional treatments like physical therapy or analgetics.
Minimal duration of treatment will be 6 weeks. After these 6 weeks, patients are allowed to continue their prescribed treatment if complaints persist. If not, patients can stop the treatment.

Study burden and risks

To our knowledge there are no potential risks for the included patients, as all treatments are safe with little or no chance of complications.

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 18 years old or older
Pain and tenderness under the heel on weight bearing with associated limitation of activity.
Pain should be present for a minimum of 6 weeks.
Patients must be willing and able to sign the informed consent

Exclusion criteria

Achilles tendon injury
Acute traumatic rupture of the plantar fascia
Patients with a rigid hindfoot valgus or varus
Patients with ankle or foot arthritis
Patients with chronic ankle instability

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2011
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Masai Barefoot Technology Shoe
Registration:	No

Ethics review

Approved WMO Date:	23-12-2010
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	28-06-2011
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL33362.048.10