Individually optimised rocker profiles to reduce mechanical load in patients with Achilles Tendinopathy and Plantar Fasciitis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22022

Source
NTR

Brief title
IndiRock

Health condition

Achilles Tendinopathy and Plantar Fasciitis

Sponsors and support

Primary sponsor: UMCG, Centrum voor Revalidatie
Source(s) of monetary or material Support: Samenwerkingsverband Noord-Nederland (SNN), Provincie Groningen

Intervention

Outcome measures

Primary outcome

Ankle dorsiflexion angle, moment and power. Peak plantar pressure of the Region of Interest (ROI).

Secondary outcome

Sagittal kinematics and kinetics of the knee (angle and moment) and hip (angle and moment); VAS pain; VAS comfort.

Study description

Background summary

Plantar fasciitis and Achilles tendinopathy are two of the most common types of foot injuries. Several nonsurgical
treatment options, including orthopaedic footwear are used to relieve the symptoms, which are
commonly caused by mechanical overloading. Rocker profiles (outsoles) are the most commonly prescribed
external therapeutic shoe modifications. However, the design criteria for rocker profiles have historically been
based on theoretical considerations with minimal scientific study and validation. In this study, rocker profiles
are calculated and constructed, based on a custom-made algorithm that uses individual gait parameters as
input. This innovative process needs further research to evaluate its efficacy. Therefore, the aim of this study
is to investigate the efficacy of individual optimised outsoles (rocker profiles) to reduce the mechanical
overloading for patients with plantar fasciitis and Achilles tendinopathy.

Study objective

The objective of this study is to evaluate the biomechanical effect of the newly developed rocker soles aiming to reduce the mechanical load in patients suffering with Achilles tendinopathy and plantar fasciitis. A secondary objective is to evaluate use of the product and the effect of use (4 weeks) on pain and comfort.

Study design

Pre-test, after +-2 weeks Post-Test where the primary (and biomechanical secondary) endpoints will be determined. After the post-test a 4 weeks follow-up for the secondary endpoints VAS pain and VAS comfort will be determined

Intervention

Participants will be fitted with individual orthopaedic shoes which are a standard shoes with a 3D-printed outsole by a certified orthotist. Shoe characteristics are calculated by a self-made algorithm based on gait parameters (measured during M1) of the participant. The non CE-marked medical device will be used as intended.

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosed with Achilles tendinopathy and/or Plantar Fasciitis by a health care professional
- 18 years or older

Exclusion criteria

- Using additional orthopaedic devices (excluding insoles) for the lower extremity
- Self-reported other problems affecting gait
- Body weight > 130 kg
- age 60 years or older
- Shoe size > EU 46 (Male) / EU 41 (Female)
- Shoe size < EU 41 (Male) / EU 37 (Female)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-08-2019
Application type:	First submission

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
NTR-new	NL7976
Other	METC Groningen : METc 2019.326

Study results