

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

Gepubliceerd: 20-08-2019 Laatste bijgewerkt: 13-12-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22022

Bron

NTR

Verkorte titel

IndiRock

Aandoening

Achilles Tendinopathy and Plantar Fasciitis

Ondersteuning

Primaire sponsor: UMCG, Centrum voor Revalidatie

Overige ondersteuning: Samenwerkingsverband Noord-Nederland (SNN), Provincie Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	20-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7976
Ander register	METC Groningen : METc 2019.326

Resultaten