Individually optimized rocker profile and self-adapting insole to reduce the plantar peak pressure in Diabetic patients with loss of protective sensation

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Offloading the peak plantar pressure in Diabetic patients with loss of protective sensation by using the self-adjusting insoles and individually optimized rocker profiles. The secondary objective is to evaluate the effect of the self-adjusting...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON52218

Source ToetsingOnline

Brief title

combination: optimized rocker profile and self-adapting insole

Condition

- Diabetic complications
- Peripheral neuropathies

Synonym peak pressure, plantar pressure

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** EIT Health

Intervention

Keyword: diabetes, foot ulcers, individual, prevention

Outcome measures

Primary outcome

- In-shoe plantar pressures, measured with a pressure insole (Pedar-X):

- 1. Peak Pressures (PP)
- 2. Pressure Time Integral (PTI)
- Balance with and without perturbations, measured with clinical tests and the

force plate treadmill (and Vicon system) of the GRAIL lab of the Center for

Rehabilitation of the UMCG, Beatrixoord:

- 1. Time taken to stand up-walk- and sit (TUG)
- 2. Root Mean Square (RMS) of net anterior-posterior (AP) & medio-lateral (ML)

direction during eyes open and closed condition (static balance)

3. Margins of stability during normal gait, AP & ML perturbations (dynamic

balance)

Secondary outcome

kinetics and kinematics of the lower extremity

Study description

Background summary

Up to 25% of all patients with diabetes will develop a diabetic foot ulcer.

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These ulcers can eventually result in (partial) amputation of the affected limb. The UMCG developed two products (an individually optimized rocker profile and a self-adjusting insole) that help prevent ulcerations by reducing peak pressures. Although the first measurements of the products showed reduction of peak pressures in diabetic patients, we can*t generalize the results. The number of included patients was too low (n=4) and also the rocker shoes were slightly different from the rocker shoes in this study (the rocker shoes in this study have 1 optimal setting, that is chosen out of a lot of different settings to offload the peak pressure vs. the adjustable rocker shoes that have limited amount of settings). Therefore, this study is needed to continue the development of both products, and to further improve offloading of the diabetic foot.

Study objective

Offloading the peak plantar pressure in Diabetic patients with loss of protective sensation by using the self-adjusting insoles and individually optimized rocker profiles. The secondary objective is to evaluate the effect of the self-adjusting insoles and individually optimized rocker profiles on balance.

Study design

Pre-Posttest design

Intervention

1) Unadapted reference shoe (Dr.Comfort, Mequon, WI, USA) + standard insole (visit 1)

2) Unadapted reference shoe + self-adjusting insole (visit 2)

3) Rocker shoe + standard insole (visit 2)

4) Rocker shoe + self-adjusting insole (visit 2)

5) Rocker shoe + self-adjusting insole (slightly changed version) (visit 3)

6) Unadapted reference shoe + self-adjusting insole (slightly changed version) (visit 3)

Study burden and risks

No added risks compared to walking with current footwear.

Contacts

Public

Universitair Medisch Centrum Groningen

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

For the Diabetic patients: Adult Diabetes mellitus (type I or II) Loss of protective sensation (10 gr filament & 128Hz tunning fork) Ambulatory without use of walking aids (with the exception of the use of orthopaedic footwear) Shoe size between 36 and 46

For the healthy reference group: Ambulatory without use of walking aids Age between 40-70 year Shoe size between 36-46

Exclusion criteria

For the Diabetic patients:

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Current ulcer(s) and ulcer(s) in the past Use of walking aids (with the exception of the use of orthopaedic footwear) Extreme foot deformations (e.g. Charcot foot) or toe or foot amputations that do not allow participants to fit semi-ready-to-wear shoes Body weight >130kg

For the healthy reference group: Use of walking aids Foot complications (injuries that can influence gait) that do not allow participants to fit ready-to-wear shoes Body weight >130kg Any self-reported injury or disease that affects walking ability

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2021
Enrollment:	35
Туре:	Actual

Medical products/devices used

Generic name:	optimized rocker profile and self-adapting insole
Registration:	No

Ethics review

Approved WMO	
Date:	11-03-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	12-10-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	29-09-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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 CCMO **ID** NL76273.042.20