

Reliability and construct validity of pressure measurement systems in neuropathic diabetic patients

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The primary objective is to investigate the intra- and inter-session reliability and construct validity of the FootWork Pro platform and in-shoe system in neuropathic diabetic patients. The secondary objective is to investigate the feasibility of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON54952

Source

ToetsingOnline

Brief title

Reliability & validity FootWork Pro diabetic patients

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Peripheral neuropathies

Synonym

Diabetes, Diabetes Mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Zorginstelling (RondOm Podotherapeuten)

Intervention

Keyword: Diabetic foot, Pressure measurement, Reliability, Validity

Outcome measures

Primary outcome

Intra-class correlation coefficients of several pressure measurement parameters

Secondary outcome

The degree to which the scores of the FootWork Pro PMS are consistent with a priori formulated theoretical hypotheses (construct validity).

Study description

Background summary

Pressure Measurement Systems (PMS) are frequently used in research to objectify plantar pressure and evaluate conservative treatment in neuropathic diabetic patients. PMS are valuable tools since it is known that increased plantar pressure is a causal factor for foot ulcers in this patient population. The FootWork Pro PMS are frequently used in clinical practice. However unknown is whether they provide reliable and valid information in clinical practice in neuropathic diabetic patients.

Study objective

The primary objective is to investigate the intra- and inter-session reliability and construct validity of the FootWork Pro platform and in-shoe system in neuropathic diabetic patients. The secondary objective is to investigate the feasibility of the protocol to measure pressure measurement parameters with the FootWork Pro platform and in-shoe system in neuropathic diabetic patients.

Study design

Cross-sectional study

Study burden and risks

There are low risks for participants associated with participation in this study. Measurements (walking and standing on PMS) belong to usual podiatry care. Barefoot walking and standing might theoretically slightly increase the risk of ulceration. However, the risk will be negligible due to the short measurement times. In addition, to minimize any risk of ulceration, the study location will be clear of (sharp) objects, there will be sufficient rest between repeated measurements and the researchers will check for redness and other skin features that may indicate overload. The burden of participants falls within acceptable limits and consists of two short measurement moments (+/- 25 minutes) within two weeks. There is no randomization, no behavioral changes are imposed and there is no invasive intervention.

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

Presence of diabetic peripheral neuropathy, indicated by insensitivity to a 10 g Semmes-Weinstein Monofilament for at least two out of three times at the hallux, first metatarsal head or fifth metatarsal head.

Exclusion criteria

Unable to walk or stand (barefoot)
Use a walking aid
Current foot ulcer
Bilaterale amputation proximal to the metatarsals
Non-diabetic neurological deficit

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-07-2021

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 21-10-2020

Application type: First submission

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL74536.018.20