The effects of random vibrations on the vibratory perception threshold of the foot and standing balance in people with diabetic neuropathy

Published: 30-07-2014
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To investigate the effects of vibrating insoles on vibration perception threshold (VPT) and balance of people with diabetic neuropathy.

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

Summary

ID

NL-OMON41029

Source
ToetsingOnline

Brief title
The effect of random vibrations on perception and balance

Condition

- Diabetic complications
- Peripheral neuropathies

Synonym
diabetic neuropathy, loss of sensation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,Phoenix Technologies LLC

Intervention

Keyword: - balance, - neuropathy, - vibrations, - vibratory perception threshold (VPT)

Outcome measures

Primary outcome

- Vibration perception threshold

- Balance (displacement of Centre of Pressure)

Secondary outcome

- mediolateral velocity from balance measurements

- anteriorposterior velocity from balance measurements

Study description

Background summary

People with diabetes mellitus often suffer from polyneuropathy. Reduced somatosensation of the feet due to polyneuropathy is one of the major risk factors for ulceration at the plantar side of the feet and may often cause problems in balance. It has been shown that the application of a mechanical noise signal to the feet (a vibration with a random frequency) can reduce the sensation threshold and improve standing balance. However, techniques used in research so far have several problems that limit applicability in daily practice. New vibrating insoles have been developed that overcome these problems, but it is unknown if these insoles have the same effects.

Study objective

To investigate the effects of vibrating insoles on vibration perception threshold (VPT) and balance of people with diabetic neuropathy.

Study design

A double-blind cross-over design in a controlled laboratory setting where

participants will serve as their own controls.

Intervention

The intervention will be the use of vibrating insoles. These are insoles that are developed to be put on the market. As an immediate effect of the insoles is expected, measurements will be performed during the intervention lasting less than 1 minute per intervention/measurement. The control intervention is the use of the same insoles, but with the vibration turned off.

To enable the measurement of VPT the insoles are adapted. Holes are made in the insole to allow for access to the plantar skin of the foot with the probe of the biothesiometer.
Standard insoles and standard shoes are used for the balance related outcomes.

Study burden and risks

Participants have to visit Ziekenhuisgroep Twente once for testing. Preparation and measurements will take up to one hour. There are no known risks for the participants.

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

- Diabetes mellitus, type I or type II
- Aged 18 years or older
- Diagnosed with neuropathy
- VPT between 25-45V
- Understand Dutch or English

Exclusion criteria

- A history of neuropathic conditions other than diabetes mellitus
- Problems with the somatosensory or motor system that affect balance or plantar sensation, not related to DM (for example: CVA)
- Severe visual problems
- Current ulcer
- (a history of) amputation

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2014
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	30-07-2014
Application type:	First submission
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	ID
CCMO	NL48517.042.14
Other	nog geen nummer bekend