

Effects of vibrating insoles on balance in diabetic neuropathy. Research into the optimal characteristics of the applied noise signal.

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The objective of this study is to compare the effects of noise with different characteristics on balance in patients with diabetic neuropathy

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

Summary

ID

NL-OMON32484

Source

ToetsingOnline

Brief title

Optimal signal characteristics for vibrating insoles

Condition

- Diabetic complications
- Peripheral neuropathies

Synonym

Diabetes, Diabetes Mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W, Annafonds en Stichting Beatrixoord Noord Nederland

Intervention

Keyword: Balance, Noise, Signal characteristics, Stochastic resonance

Outcome measures

Primary outcome

Center of pressure displacements and velocity, which are measures for balance, with and without the application of a noisy vibration to the feet.

Secondary outcome

n.a.

Study description

Background summary

Patients with neuropathy often show a decreased sensibility at the feet and therefore a decreased balance control and an increased risk of falling. Improvement of the tactile feedback from the plantar side of the feet concerning pressure distribution, is a way to improve balance control. A new technique that may improve tactile, and possibly proprioceptive feedback, is the application of mechanical noise (vibration with a randomly varying frequency) to the plantar surface of the feet. By adding noise to a subthreshold sensory input, the sensory threshold may be crossed. In this way a signal that is not detected during normal circumstances can be detected. The mechanism, by which signal detection is improved by noise, is called stochastic resonance. A few studies have shown that the application of noise can improve tactile sensitivity and balance.

Study objective

The objective of this study is to compare the effects of noise with different characteristics on balance in patients with diabetic neuropathy

Study design

First the degree of neuropathy will be tested with monofilaments. Moreover

vibrotactile sensitivity will be tested with a tuning fork.

Following the patient has to stand on a pair of vibrating insoles placed on a forceplate. The threshold for the noisy vibration will be determined. Each measurement consists of standing on the vibrating insoles for one minute during which the insoles will be turned on and off for 30s. Based on the forceplate recordings the center of pressure displacements will be determined. Because balance problem appear mostly with poor vision or when attention is distracted, balance will be tested under two conditions.

1. Eyes closed, no dual task
2. Eyes closed, dual task

Intervention

Appliction of mechanical noise at the plantar side of the feet by vibrating insoles.

Study burden and risks

Participation takes about an hour, the burden for the patients is minimal and there is no specific risk for them.

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

Neuropathy

age 40-60

Exclusion criteria

Ulcerations

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2008

Enrollment: 10

Type: Anticipated

Medical products/devices used

Generic name: vibrating insoles

Registration: No

Ethics review

Approved WMO

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	NL24925.042.08