Use of a vibrotactile feedback belt in people with chronic disabling unilateral vestibular hypofunction: a single-case experiment.

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The primary objective is to study the impact of continuous vibrotactile feedback during waking hours in daily life on balance, (fear of) falling, fatigue, and overall functioning. The secondary objective is to study the impact of a vibrotactile…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON53173

Source
ToetsingOnline

Brief title
Vibrotactile feedback belt in patients with UVH (VIBE)

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
unilateral vestibular hypofunction, unilateral vestibulo pathy

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen

Source(s) of monetary or material Support: Gelre Ziekenhuizen;subsidie Stichting Wetenschapsfonds Gelre Ziekenhuizen

Intervention

Keyword: vestibular hypofunction, vestibular rehabilitation, vibrotactile feedback

Outcome measures

Primary outcome

The primary outcome is the experienced mobility and balance in daily life which will be measured by means of the Mobility and Balance Score (MBS), a score between 0 and 10.

Secondary outcome

Secondary study outcomes are: NRS for general functioning, fear of falling, fatigue, modified Clinical Test of Sensory Interaction, Dynamic Gait Index and Timed Up and Go Test.

Study description

Background summary

For patients with severe bilateral vestibular loss it has been shown that vibrotactile feedback provided by a *balance belt* was effective in improving mobility and balance in daily living and quality of live. It is our hypothesis that this could also be an effective aid for patients with uncompensated unilateral vestibular hypofunction and persistent balance problems.

Study objective

The primary objective is to study the impact of continuous vibrotactile feedback during waking hours in daily life on balance, (fear of) falling, fatigue, and overall functioning. The secondary objective is to study the impact of a vibrotactile feedback belt on static and dynamic balance and gait in controlled laboratory conditions.

Study design

The study is designed as a single-case experiment (SCE) with a reversal design and with randomization of phases.

Intervention

Each participant goes through a baseline phase, a sham phase (i.e., wearing the BalanceBelt without it being switched on), and an intervention phase (i.e., wearing the BalanceBelt while it is switched on).

Study burden and risks

Following the risk classification of the NFU we rate the risk of this study to be negligible. A potential benefit of the study is an improved balance and functioning. If patients consent to enter the study, they follow the study protocol which consist of an 8 weeks trial period. There are total of 9 contact moments, of which four are mandatory at Gelre Hospitals location Apeldoorn. During seven weeks participants are asked to fill in a daily diary (estimated time 5 minutes/day). In addition, at visit 1 and 9, the participants will be asked to fill in a questionnaire and three balance and gait tests will be done (estimated time 90 minutes). No other procedures will be performed for the study (i.e., no invasive procedures, clinical tests, laboratory tests, etc.).

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

- chronic (>3 months) unilateral vestibular hypofunction and balance complaints
- motivated to try the BalanceBelt

Exclusion criteria

- Presence of neurological, psychiatric or orthopaedic disorders, reduced proprioceptive sensitivity or impaired vision which influences the postural stability, PPPD.
- age <18 years
- not able to understand instructions and questionnaires in Dutch
- not willing/able to visit Gelre hospitals location Apeldoorn several times

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2024
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	BalanceBelt
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-09-2023
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	NL84562.075.23