Vestibular rehabilitation by sensory substitution.

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Clinical evaluation of the effectiveness and safety of the BrainPort Balance Device in the rehabilitation of patients with unilateral vestibular disorders with different etiology. The effectiveness of the device will be compared to natural...

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

Summary

ID

NL-OMON30075

Source
ToetsingOnline

Brief title
VRSS-study

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Balance disorders, Vestibular Disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Sensory substitution therapy, Vestibular Disorders

Outcome measures

Primary outcome

Our main outcome will be the Dizziness Handicap Inventory (DHI), our power calculations are based on this psychometric test. Further, physiological and psychological evaluation of the treatment will be performed with various other tests: Electronystagmography (ENG), Vestibular Evoked Myogenic Potentials (VEMPs) and the questionnaire: Activities-specific Balance Confidence (ABC) Scale.

Secondary outcome

Secondary outcome is the safety of the BrainPort Balance Device in clinical use. This will be measured by the frequency, type and severity of adverse events. Telephone contacts will provide such information. In the in home use period patients will be called 1 time a week for the first six weeks and one time a month after that.

Study description

Background summary

Loss of vestibular function leads to severe impairment and reduced quality of life. At this time no causative treatment of vestibular loss is available and an expectative approach is the most common one, which is understandable because an effective spontaneous mechanism of vestibular compensation exists. Rehabilitation therapy through exercises is an alternative for this expectative approach. In recent years sensory substitution of the vestibular apparatus has been developed as yet another alternative. The goal of vestibular therapy through sensory substitution is a greater awareness of postural balance, more

adequate reactions to environmental changes, quicker rehabilitation and improved quality of life.

Study objective

Clinical evaluation of the effectiveness and safety of the BrainPort Balance Device in the rehabilitation of patients with unilateral vestibular disorders with different etiology. The effectiveness of the device will be compared to natural compensation in relation to the expectative approach and accelerated compensation in relation to conventional vestibular rehabilitation therapy.

Study design

Randomised, prospective monocentre trial performed in a tertiary medical centre.

Intervention

Patients will be randomised for participation of one of three patients groups: the device group (1), the rehabilitation therapy by exercises group (2) or a control group (3) in which an expectative approach is adopted. Patients in the device group will be trained to perform specific postural exercises. Patients will continue for 26 weeks of in home use of the device after the clinical training phase of the study. Patients in the exercise group will perform the same specific exercises as the groups with the provided devices for 6 months. After 4 and 12 weeks and after 6 months, patient groups will be compared to each other.

Study burden and risks

The specific patient group continuously requests attention from clinical professionals but hardly ever gets it. Therefore, participants will probably not consider their participation in the study as an unbearable burden. The potential risks arising from use of the BrainPort Balance Device are minor and can be managed, after mandatory training, by setting the stimulus level according to the preferred intensity, adhering to the instructions in the user manual. As mentioned before, at this moment an expectative approach is the regular treatment. When the BrainPort Balance Device and/or the Rehabilitation therapy through exercises show an added effect compared to an expectative approach, this could be beneficial for all patients with vestibular loss.

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

• Adults
• Complaints of persistent vertigo due to peripheral vestibular disorder of different etiology. (unilateral vestibular loss)
• Proven peripheral vestibular disease on calorisation, torsion test or VEMP test.

Exclusion criteria

1) Additional neurological disorders (e.g. CNS malignancy)
2) Patients with severe vision defects
3) Patients with severe orthopaedic disease affecting the musculoskeletal system
4) Intra-oral pathologies
5) Patients with reduced propriocepsis (e.g. DM)
6) Low ability to communicate in Dutch language due to co-morbidity or impaired language competence.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2007
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	BrainPort Balance Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL11375.041.06