Head-Mounted Vibrotactile Prosthesis for Patients With Chronic Postural Instability

NCT03330262

Study Protocol

Document Date: 01/25/2021

OVERVIEW

Background information:

An initial pilot study (Goebel et.al., 2009) revealed that vibrotactile stimulation of the head with orientationally-correct information provided significant improvement in postural stability in vestibular loss patients as seen in decreased falls and increased Time To Fall measurements. It also revealed that there was no effect noted upon perceived verticality during eccentric rotation. Overall, it concluded that the utility of a head-mounted balance prosthesis had broader applications besides use in patients with severe vestibular loss and that such a device might also be useful for rehabilitation in a variety of patients with partial vestibular, visual or even somatosensory loss or cases with abnormal sensory integration (i.e. traumatic brain injury).

Goebel JA, Sinks BC, Parker BE Jr, Richardson NT, Olowin AB, Cholewiak RW. Effectiveness of Head-Mounted Vibrotactile Stimulation in Subjects with Bilateral Vestibular Loss: A Phase 1 Clinical Trial. Otol Neurotol. 2009 Feb; 30 (2):210-6. PMID: 19106768

A recently completed Phase 1 SBIR effort revealed, based on the usability questionnaire results, that the balance cap (BALCAP) was well-received by the participants. Significance was demonstrated for several hypotheses, and overall trends indicated that in general, use of the BALCAP prosthesis resulted in better scores on standard balance assessments (i.e., assistive benefit); and that in general, the proposed BALCAP-based therapy resulted in improved assessment scores (i.e., rehabilitative benefit). Although refinements to the BALCAP device are warranted (e.g., a smaller electronics package, more control of stimulation amplitude, etc.), feasibility for the BALCAP concept has been shown.

Rationale:

Chronic imbalance leads to significant problems. This study is designed to evaluate a device (cap) which can potentially improve the balance of these patients.

Research Objectives:

The goal of this project is to provide individuals who have demonstrated chronic imbalance, independent of etiology, a tactile prosthesis that will help them maintain a correct sense of orientation with respect to the gravity and improve posture control.

The proposed work will evaluate the assistive efficacy of such a balance prosthesis in a population of chronic imbalance patients spanning a wide range of disease etiologies.

It will also investigate the rehabilitative potential of the BALCAP device based on a 6-week structured training regimen that includes both static and dynamic

exercises. If rehabilitative training to achieve residual balance retention is possible, expanding training to include both static and dynamic activities is most likely to make it evident.

Potential Contribution:

This proposal addresses a National Institute on Deafness and Other communication Disorders (NIDCD) research topic that emphasizes the "development of assistive devices for balance disorders".

If the hypothesis concerning the assistive benefit is supported, a head-mounted vibrotactile prosthesis product would enable immediate benefit to be provided to a large number of patients with chronic postural instability.

If rehabilitative training to achieve residual balance retention is possible, it would open new areas of research, such as how to optimize training to maximize residual retention of balance improvements.

METHODS

Timeline:

Each subject will be enrolled for up to twelve weeks. There will be a sufficient number of devices manufactured to enable all subjects to be completed within one year from start of device availability.

Inclusion/Exclusion criteria:

Subjects will include patients between the ages of 21-89 years of age with chronic balance dysfunction spanning a range of etiologies (e.g., peripheral dysfunction, central dysfunction, and multi-factorial disequilibrium, also referred to as disequilibrium of aging).

Inclusion Criteria:
1.Males and Females age 21-89
2.Ambulatory
3.Chronic imbalance for at least 1 year
4.Have reached a functional performance plateau with respect to their balance performance
5.Have a DGI score of <19
6.Fall below age and gender matched normative data for gait speed

Exclusion criteria:
1.Subjects who are unwilling or unable to adhere to all study requirements, including completion of the training period, evaluation tests, and return to clinic

for a follow-up visit.
2.Women who are pregnant (women will self report possible pregnancy).

Recruitment:

Participants are recruited from the population seen by the Department of Otolaryngology-Head and Neck Surgery. This is also where the research is conducted. The consent process and study visits will be conducted in a quiet, private exam room. Records are kept securely under a triple lock system. Data reported is de-identified however coded.

Design:

One study group that consists of chronic postural instability.

Procedures: (if applicable)

The research will be conducted at the Center for Advanced Medicine (CAM) building up to three occasions (week 1, week 6, and week 12). The first visit will last for approximately 2 hours. The second and third visits will last approximately 1 hour each visit.

During weeks 2, 3, 4, and 5 the “BALCAP” subjects will be asked to use the device (cap) daily for a prescribed period of time doing different activities. A physical therapist will provide them with written instructions that will be determined by their individual ability. These activities are typical exercises that are given to people with balance disorders and they might have been asked to do them previously. This time however, they will be asked to do them while wearing the cap that will provide them with cues. The subject will be asked to keep a diary of their daily use of the cap (time, duration, comments). They will be contacted weekly by the study coordinator via telephone to make sure they do not have any problems with the device or any questions. The “CONTROL” subjects will not take the device home for weeks 2,3,4 and 5 but will do the exercises that were prescribed by the physical therapist. After their week 6 evaluation they will transition and use the BALCAP device at home under the same conditions as the BALCAP subjects. The subjects who were assigned the balcap will go home and continue their exercises without the device. This will determine any lasting effects of the BALCAP device. Subjects will be randomly assigned to a group.

If the subject had never completed the dynamic gait index test (DGI) or the gait speed test as part of their medical assessment or their results are not part of their medical record, they will be completed during the first visit. If the results from those two tests show that the subject’s balance problem is not significant enough to receive the cap, the subject will be excused at that time.

During the first visit (week 1) the subject will complete the Computerized Dynamic Posturography (CDP) test, a spontaneous nystagmus test utilizing infra-red goggles while the vibration tactors are active to look for any resulting nystagmus, the DGI test, and the gait speed test. They will perform these tests both with and without the vibration stimulus from the cap. Finally, they will fill out two questionnaires. The Activities-specific Balance confidence (ABC) Scale and the Dizziness Handicap Inventory (DHI) questionnaires will also be completed.

On the second visit (week 6) all testing completed during week 1 will be repeated. In addition, a third survey questionnaire will be completed asking about the design and comfort of the cap device for those in the BALCAP group.

On the third visit (week 12) all testing completed during weeks 1 and 6 will be repeated and the design and comfort survey will be completed by those who just completed the BALCAP portion of the study.

Ten subjects will be randomly selected to be interviewed by a third party determined by the sponsor to ask questions regarding the cap device and get more thorough usability input for future marketability.

Follow-up*:*

N/A