A pilot project to investigate the use of an external vestibular prosthesis potential to improve clinical management of Chronic Subjective Dizziness (CSD)

NCT# 02048670

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IRB Minimal Risk Protocol Template

General Study Information

Principal Investigator: Jeffrey P. Staab, M.D.

Study Title: **A pilot project to investigate the use of an external vestibular prosthesis potential to improve clinical management of Chronic Subjective Dizziness (CSD)**

Protocol version number and date: 01, 22 JUL 2013

Purpose

Hypothesis: #1The use of the BalanceBelt™ will provide differential information about body sway movements during specific clinical balance and gait tasks in patients with CSD that is not currently available through routine measures.

Hypothesis: #2 The use of the BalanceBelt™ will provide for a more rapid rate of reduction in patient symptoms compared to the historical data from the traditional habituation therapy method.

Aims, purpose, or objectives: #1 Motion detectors contained in the BalanceBelt^{TM} will be used to record information about the subtle changes in posture and gait that are thought to occur in patients with CSD with the tractors turned off. The goal of this portion of the study will be to improve diagnostic strategies for CSD.

Aims, purpose, or objectives: #2 In this second portion of the study we will test the benefits of a 1-week intensive rehabilitation program using the BalanceBelt^{TM} with tactors activated in 10 patients with CSD. The goal of this study will be to develop a treatment that is quicker and more effective than current therapies.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc.*):

Chronic subjective dizziness (CSD) is the second most common condition identified in patients referred to Mayo Clinic for persistent dizziness. We manage nearly 500 patients with CSD each year. CSD is a syndrome of persistent non-vertiginous dizziness and unsteadiness that may be worsened by patients' own motion, exposure challenging visual stimuli such as busy shopping areas, or performance of precision visual tasks such as reading. CSD develops in about 25% of patients following medical events that acutely disrupt balance. Once established, CSD may last for many years, even if the problems that triggered it resolves. As a result, CSD causes considerable distress and functional impairment, even to the extent of work disability and disruption of family and social life (Staab, 2012).

Over the last decade, the Mayo Clinic Integrated Neurotology team, and other investigators around the world have developed two treatment strategies for CSD. One uses serotonergic medications such as sertraline (Zoloft) and venlafaxine (Effexor). The other is a variation of vestibular and balance exercises known as vestibular habituation. These therapies reduce symptoms for 60-80% of patients when administered by experts in the field

(Staab, 2012). However, they have important shortcomings. They are time-consuming, taking a minimum of 2-3 months of diligent treatment to achieve best results. They usually achieve a partial reduction in symptoms, which improves patients' functioning, but falls short of a cure. They can make patients worse, rather than better, when used by clinicians who are unfamiliar with them.

A new theory about altered postural control mechanisms in CSD suggests that it could be diagnosed more accurately and treated more quickly by using an external vestibular prosthesis to enhance sensory feedback during vestibular exercises. A suitable prosthesis is the BalanceBelt™, which is currently in final beta testing by BalanceTek, the company that developed it. This device has been shown to have efficacy in reducing sway behavior in patients that have bilateral vestibular hypofunction (Sienko et al, 2010). For those patients with deficient vestibular systems the belt provides information that is missing from the lack of vestibular system cues for detecting sway or leaning behavior, hence drawing attention to the information that is missing. The BalanceBelt™ is a comfortable, self-contained unit worn under the clothes around the waist. It has sensitive motion detectors and small tactors that vibrate against the skin at four locations to provide information about posture and motion. Patients with CSD do not have permanent vestibular deficits, but underutilize vestibular signals because they develop visual or somatosensory dependence. We expect the BalanceBelt™ to reset this error by providing patients with reliable motion stimuli.

We propose two preliminary studies using the BalanceBelt™ in patients with CSD. In the first study, we will use the motion detectors contained in the BalanceBelt™ to record information about the subtle changes in posture and gait that are thought to occur in patients with CSD. This goal of this study will be to improve diagnostic strategies for CSD. We will compare postural movements recorded with BalanceBelt™ with tactors turned off during quiet stance, normal walking (Dynamic Gait Index), functional reach test, and the Sensory Organization Test in 10 patients with CSD and 10 age and gender matched normal individuals. In the second study, we will test the benefits of a 1-week intensive rehabilitation program using the BalanceBelt™ with tactors activated in 10 patients with CSD. The goal of this study will be to develop a treatment that is quicker and more effective than current therapies.

References:

Staab, J.P: Chronic subjective dizziness. Continuum Lifelong Learning Neurol 2012; 18(5):1118–1141.

Sienko, K.H., Vichare, V.V., Balkwill, M.D., Wall, C: Assessment of vibrotactile feedback on postural stability during pseudorandom multidirectional platform motion. IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, 2010; 57(4): 944-952.

Subject Information – charts, records, images, or specimens are considered 'subjects'

Target accrual: *Proposed number of subjects to be included in your study at your site. "Subjects" may include Mayo Clinic charts, records, or specimens,* ***and/or*** *charts, records, or specimens received at Mayo Clinic from external sources for collaborating analysis by the investigator under this IRB application*:

Subject population: 20 patients with diagnosis of Chronic Subjective Dizziness (CSD) and 10 normal volunteers.

Inclusion Criteria: 1. Subjects will be 25-70 years of age inclusive and pregnant women may participate.
2. Patients will have CSD as their primary diagnosis for the cause of their balance and dizziness complaints provided by the Behavioral Medicine Program for Dizziness, a division of the Department of Psychiatry & Psychology.
3. Normal volunteers will have a negative history of otologic & neurologic disorders and no history of dizziness and balance problems.
4. Normal volunteers will have normal findings on a screening office examination for peripheral and central vestibular system involvement (see methods for details of the examination) and screening for normal or symmetrical hearing loss of explainable origin.

Exclusion Criteria: 1. Patients with positive indications from testing of peripheral and/or central vestibular system involvement that is felt to be influencing the symptoms reported beyond the CSD alone.
2. Patients with mobility restriction that would prevent participating in the tests or the intensive therapy trials.
3. Subjects with hearing impairment that interferes with oral communication.

Will a Certificate of Confidentiality be obtained? *If yes, provide an explanation*.
NO

Study Design

Methods: *Describe, in detail, the research activities that will be conducted under this protocol*:

For Hypothesis and aim #1: Ten consecutive patients, ages 25-70 years, diagnosed with CSD after completion of their routine evaluation in the Dizziness and Balance disorders laboratory and their evaluation by the Behavioral Medicine program for dizziness, would then be recruited for participation in the study. If they agree to participate they will individually be placed through the following evaluations while wearing the BalanceBelt™ with the tractors turned off but the recording elements turned on. Each of these tests is a standard evaluation tool used in the Vestibular and Balance Laboratory on a routine basis:

1. Dynamic Gait Index – evaluates gait under normal walking and under conditions of head turns, walking around two objects on the floor, stepping over a shoe box, walking at different speeds, walking with a stop and 180 degree turn, walking up and down 3 standard steps with hand rails. During the evaluation the physical therapist or the audiologist guards the subjects at all times walking with the subject and the subject wears the harness used for the test in #3 that has a hand grab to prevent falls.
2. Functional Reach Test – the subject stands in a stationary position and reaches out with a single arm as far as they can without taking a step. Here again the physical therapist or the audiologist is guarding the patient during the performance of the test, again with the subject in the harness used in #3 with the hand grab to prevent falls.

3. Sensory Organization Test – this is a 6 condition standard evaluation of balance control performed on a dynamic platform that can record sway movement in the A/P dimension while the sensory inputs from proprioception and vision are varied through the platform and visual surround movements. The subject wears a full chest harness that is fastened to a roll bar above the subject to prevent any falls.

For each of the patients an age and gender matched normal (± 5 years) volunteer will go through the same evaluations. The time for testing will take 45 minutes. Normal subjects will be recruited through written advertisements from visitors and / or accompanying persons for patients to Mayo Clinic. Each of the normal subjects will go through an office vestibular examination that will consist of direct monitoring for nystagmus in all positions of gaze with and without visual fixation present. They will also undergo the head thrust test with visual fixation present and headshake test with visual fixation absent. Pursuit and saccade office examination will be performed with a hearing screening by pure tones only. If any abnormalities are revealed with the screening the normal volunteer will be advised as to formal testing that should be performed via their primary care physician also being notified.

For Hypothesis and aim #2: Ten consecutive patients, ages 25-70 years, diagnosed with CSD who live within a 30 minute drive time of the Rochester Mayo campus will be asked to participate in the habituation therapy activities typically used as treatment of CSD but with an intensive treatment program using the exercises at home for the week. The patients will be using the BalanceBelt™ with the tractors activated. The typical therapy evaluations pre-therapy will be taken in addition to Visual Analog Scales related to the intensity of symptoms provoked by visual motion, head movements and walking in visually complex environments. These same measures will be taken at the end of the week of intensive therapy at a return visit to check their exercise activities prior to continuing their progressive home treatment. The one week of intensive therapy will be performed prior to starting any recommended medications or medication changes for the CSD. The therapy will be conducted by one of the Physical Therapists certified in Vestibular and Balance therapy.

Following the intensive therapy the patient will continue with the therapy activities and medication trials as is standard currently for the CSD patients.

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*:
All of the equipment and procedures described above are already in place and used routinely by the Audiologists and Physical therapists that work in the Dizziness and Balance Disorders Center on Gonda-12 in the department of Otolaryngology. The only acquisition is that of the BalanceBelt™ for which the department of Otolaryngology research committee has approved a request for $7800 from the small grants program to cover the cost of the belt ($6000) and the 30% indirect costs ($1800).

Check all that apply. If none apply, leave blank:

The research involves contact or interaction with subjects, for example, surveys, questionnaires, observation, blood draw.

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Blood Collection

If this study involves prospective blood collection by finger, heel, ear stick or venipuncture, complete the following:

From healthy, non pregnant, adult subjects who weigh at least 110 pounds. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.

Volume per blood draw: _____ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

From other adults and children considering age, weight, and health of subject. For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.

Volume per blood draw: _____ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.)_____

Review of Chart, Images, Specimens

Provide the date range for collection of data and/or specimens that will be included in your research dataset. (*Example: 01/01/2000 to 12/31/2012*)

Date range: From _02/01_/2014 to 01/_31/2015

Check all that apply:

This study involves only data and/or specimens that will be collected after submission to the IRB.

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Data Confidentiality, HIPAA Subject Identifiers

Review the list of subject identifiers below and, if applicable, check the box next to each subject identifier being recorded at the time you are collecting/abstracting data/specimens for use in this study.

Subject Identifiers: Individually identifiable information, including demographic data, that identifies the individual or for which there is reasonable basis to believe it can be used to identify the individual. NOTE: Identifiers apply to subjects enrolled in your study and to the subject's relatives, household members, employers, etc.

Internal refers to subject identifiers that will be included in the dataset maintained by the study team.
External refers to subject identifiers that will be shared with persons outside of the immediate study team, for example, sent to an external collaborator or shared with a national registry.

SUBJECT IDENTIFIERS **Check all that apply**	INTERNAL IDENTIFIER	EXTERNAL IDENTIFIER
Name		
Social Security number		
Medical record/patient registration number, lab accession, specimen or radiologic image number	x	
Study number, subject ID, or any other unique identifying number, characteristic or code that can be used to link the identity of the subject to the data	x	
Dates: All elements of dates [month, day, and year] directly related to an individual. Their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.	x	
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers		
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
If None of the above identifiers will be recorded or maintained in the dataset and/or sent outside of the study team, please check "None".		

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Statistical Information

Note: Power analyses and study endpoints are not needed for a pilot or feasibility studies.

No statistical information. *If checked, please explain*:

Statistical Considerations

Power Statement: Power analyses not used as this is a pilot study.

Data Analysis Plan:

For Hypothesis and aim #1: The outcome parameters from the BalanceBelt™ that represent the total amount of sway and sway activity in the A/P and M/L directions will be compare between the CSD patients and the normal age matched volunteers via the Wilcoxon rank-sum test for mean comparisons.

For Hypothesis and aim #2: The visual analog scale scores pre & post the week of intensive therapy will be compared for the 10 subjects using also the Wilcoxon test for mean comparisons.

Endpoints
As this is a pilot study no fixed endpoints will be used.

Primary:

Secondary: