Efficacy of vestibular rehabilitation using computerized dynamic posturography with virtual reality for stable unilateral vestibular weakness

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Lay Summary

People that have difficulty with balance, such as those with damage to their inner ear, have a higher risk of falling, which may lead to anxiety and reduced quality of life. Some individuals that have lost part of their sense of balance can learn to compensate using information from their vision, their sense of where their limbs are in space, and from other balance organs that are still intact. Our study aims to determine if virtual reality used together with information from footplate sensors can be used to train people with balance problems to compensate for their inner ear deficits.

Background

Vestibular dysfunction is common, with a reported prevalence of over 5% in children(1) and adults(2). In individuals with no equilibrium deficits, balance is maintained by integration of information from vision, somatosensory input, and from the vestibular sensors of the inner ear. Deficits in this system lead to imbalance symptoms, which adversely affect quality of life(3) and are associated with unemployment and poorer quality of life.(4) While most individuals with unilateral vestibular weakness are able to recover some of their balance function, either spontaneously or through rehabilitation, others suffer from persistent dizziness symptoms that are refractory to common rehabilitation approaches.(5)

Two technological advancements may provide a new mode of treatment for such people. The first, virtual reality (VR) has shown promise for rehabilitation of vestibular and mobility deficits.(6) The second, computerized dynamic posturography (CDP), analyzes posture, balance, and sway of the subject using a force plates beneath their feet.(7) Together, these technologies allow for detailed assessment and tailored, interactive compensatory rehabilitation with quantitative measurement of the subject's responses over time.

VR and CDP allow for the controlled quantitative measurement of responses to rehabilitation treatment; however, they may not capture the qualitative changes that reflect improvements in the patient's quality of life and functional capacity. Therefore, it is important to demonstrate

that any quantitative improvement measured by CDP translates to the patient-reported outcomes of increased activity, improved confidence, and reduced fear of falling.(8)

Hypotheses

VR-CDP-based rehabilitation will improve balance performance, as measured by Sensory Organization Test (SOT) scores, for individuals with unilateral vestibular loss.

VR-CDP-based rehabilitation interventions will improve patient-reported vestibular function.

Patients with unilateral vestibular weakness will consent to enrolment, will complete the initial, the post-intervention, and two follow-up assessments, and will successfully complete the prescribed course of 12 rehabilitation sessions.

Justification

Vestibular loss can be a major contributor to morbidity and loss of quality of life, increasing the risk of falls and leading to a reduction or avoidance of activity.(8) Many patients with unilateral vestibular loss report persistent symptoms of dizziness and imbalance despite rehabilitative attempts. Currently, the most common treatment available to such patients are static physiotherapeutic exercises which have not been consistently clinically validated by objective outcomes. The current treatment modalities are limited with respect to targeted therapies for each of the five discreet vestibular end organs, as well and functional outcomes. VR with CDP may offer a more effective and targeted means of promoting global balance compensation to improve the symptoms of dizziness caused by a specific inner ear deficiency in these individuals. However, the efficacy of this type of technology has not been established in the literature and the details of the intervention and the number of sessions required to confer improvement are unknown.

Objectives

Primary objective: To evaluate the efficacy of vestibular rehabilitation therapy using computerized dynamic posturography (CDP) with interactive visual feedback for the amelioration of long-standing imbalance in patients with peripheral unilateral vestibular weakness.

Secondary objectives:
1) To determine the variances (or standard deviations), means, and correlations in order to design a larger study with sufficient statistical power to compare the IVR-CDP intervention with standard care.
2) To estimate numbers of eligible patients and rates of consent for enrolment.
3) To estimate rates of adherence to the study protocol; specifically, (a) the percentage of patients that complete the full course of treatment, (b) complete the initial and follow up measures and (c) the number of missed or rescheduled visits, and (d) the rate of withdrawal from the study.

4) To determine performance scores for the individual exercises within the rehabilitation program, to ensure the difficulty is well-matched to patients' abilities.
5) To evaluate the durability, at 6 weeks and 3 months post-intervention, of any changes in:
    a) Patient-reported vestibular symptoms (as measured by questionnaires);
    b) Objective measures of imbalance (SOT and LOS tests).

Research Design

Study type: Longitudinal cohort; single group assignment; interventional
Intervention: 2x per week for 6 weeks of rehabilitation therapy

Study population

Adults (18-80 years of age) with stable unilateral vestibular weakness.

Recruitment

Subjects previously seen in the Principal Investigators clinic for unilateral vestibular weakness will be contacted and invited to enrol. We hope to enroll 25 subjects as a convenience sample for this single centre study.

Inclusion criteria

- Adult Age 18-80
- Unilateral vestibular weakness confirmed one or more of:
    - Videonystagmography
    - VEMP
- Or unilateral vestibular weakness idiopathic, not yet diagnosed (NYD)
- Persistent imbalance following diagnosis of resolved benign paroxysmal positional vertigo (BPPV)
- Symptomatic
- Long-standing/persistent symptoms greater than one year

Exclusion criteria

- Orthopedic deficit (eg. lower body joint dysfunction or lower joint replacement)
- Neurological deficit or proprioception deficit
- Diabetes
- Poor vision or blindness
- Fluctuating vestibular symptoms, or condition known to fluctuate eg. Menière's disease, perilymphatic fistula (PLF) or superior canal dehiscence (SDCS)
- Active benign paroxysmal positional vertigo (BPPV)
- Undergoing treatment which may affect balance or ability to stand
- Cognitive impairment that prevents understanding and responding to instructions required to complete the study
- Inability to provide informed consent

Study Procedures

Study data will be collected during visit 1 and 14, with two additional follow up visits at 6 weeks (visit 15) and 3 months (visit 16) post-intervention:

1) Validated questionnaires
    a) Dizziness Handicap Inventory (DHI)(9)
    b) Falls Efficacy Scale-International (FES-I)(10)
    c) Activities-specific Balance Confidence (ABC) scale(11)
2) Quantitative posturography assessment
    a) Sensory organization test (SOT)
    b) Limits of Stability (LOS) test

During all visits, a CDP instrument supplemented with interactive visuals will be employed to measure the subjects postural stability. Participants will stand on the instrument's platform and will view the prescribed interactive visuals. They will be prompted to either maintain stable equilibrium or to modulate their COG in response to the interactive visuals, as required for the SOT and LOS tests, respectively.

Details of the SOT Test (Visits 1, 14, 15 and 16)

The SOT has been widely used for research of postural stability for over 30 years.(12) This purpose of this test is to assess the competency of the subject's three modes of sensing equilibrium: vision, proprioception, and vestibular/inner ear sensors.

The SOT consists of 6 conditions, during which the subject will try to maintain their equilibrium. Each trial takes 20 seconds to perform, and each is performed in triplicate for a total of 18 trials. These 6 conditions test the three inputs to the subjects sense of equilibrium: vision, somatosensory, and vestibular. By having the subject close their eyes, by allowing the footplate to change in pitch, or by altering the visual stimulus, each of these inputs can be tested alone and in combination with the others.

The 6 conditions are: (1) eyes open, stable support; (2) eyes closed, stable support; (3) sway-referenced vision, stable support; (4) eyes open, sway-referenced support; (5) eyes closed, sway-referenced support; and (6) eyes open, sway-referenced vision, and sway-referenced support.

Each condition is given a score out of 100 and a composite score is calculated by the software

Details of the LOS test (Visits 1, 14, 15 and 16)

The purpose of this test is to determine the distance that the patient is able to voluntarily displace their center of pressure in different directions without losing balance.

Subjects will stand on the CDP platform with the arms at their sides. The test involves moving a pictogram, which represents their COG, to targets indicated on the visual display. There are eight targets distributed around the subject and the subject's performance in modulating their COG to meet the targets will be measured by software.

Study Intervention

Details of the rehabilitation exercises (Visits 2 to 13)

The rehabilitation exercises will employ the CDP instrument and visual feedback. Subjects will perform a series of exercises in which they will have to modulate their centre of gravity (COG), by shifting their weight side-to-side or front-to-back. By shifting their weight, subjects will direct a pictogram representing their COG to targets presented on the interactive display. All patients will receive the same series of exercises, except to account for the side, right or left, of the vestibular deficit (ie. the exercises for someone with a deficit on their right side will be a mirror image relative to someone with a deficit on their left side).

Over the course of the 12 sessions, the exercises presented to the subjects will become progressively more difficult in order to promote global balance improvement by brain, proprioceptive, visual, and vestibular compensation.

Study Schedule

Visit 1 (75 minutes) – Initial assessment

- Obtain written informed consent
- Verbal health check, any illness/injury that might affect performance?
- Questionnaires that measure disability caused by imbalance and risk of falling
    - Dizziness Handicap Inventory (DHI)
    - Falls Efficacy Scale-International (FES-I)
    - Activity-specific Balance Confidence Scale (ABC scale)
- CDP assessment
    - Sensory organization test (SOT)
    - Limits of Stability (LOS) test

Visit 2-13 (45 minutes) – Rehabilitation exercise

- Verbal health check, any illness/injury that might affect performance?
- Rehabilitation exercises

Visit 14-16 (75 minutes) – Post-intervention assessment and follow up

- Verbal health check, any illness/injury that might affect performance?
- Questionnaires that measure disability caused by imbalance and risk of falling
    - Dizziness Handicap Inventory (DHI)
    - Falls Efficacy Scale-International (FES-I)
    - Activity-specific Balance Confidence Scale (ABC scale)
- CDP assessment
    - Sensory organization test (SOT)
    - Limits of Stability (LOS) test

Safety

When the participants are using the CDP instrument, both for assessment and rehabilitation, they will be secured by a harness at all times to prevent falls. Participants will be informed that they may stop the testing or training or withdraw from the study at any time.

Time to participate
This study will involve 16 biweekly visits to the clinic. Sessions 1, 14, 15 and 16 are expected to take 75 minutes. The 12 rehabilitation sessions are expected to take 45 minutes. In total, the time to participate for the entire study is estimated to be 13 hours. The rehabilitation sessions will take place over a period of approximately 7 weeks with addition follow up visits at 6 weeks and 3 months after the post-intervention assessment.

Missed sessions
Missed sessions will be rescheduled so that subjects may complete the full course of 12 sessions. Subjects that have not completed the full 12 sessions by 10 weeks after their first visit will be scheduled for the post-intervention assessment. Subjects that have not completed the post-intervention assessments within 12 weeks will be excluded from further data collection and analysis.

Follow up sessions will be schedule for 6 weeks (+/- 1 week) and 3 months (+/- 2 weeks) after the post-intervention assessment (visit 14).

Study data and measurements

Demographic and medical history
Demographic and medical history data will be extracted from the patient charts.
Data will be recorded in a Microsoft Excel database designed for this purpose. The PI will monitor the study and perform quality controls of the entered data and ensure the subject's privacy and rights are protected.

Demographic
- Age
- Gender

Vestibular screening or medical history
- Vestibular diagnosis
- Result of tests
    - cVEMP
    - oVEMP
    - vHIT
    - Caloric response

Outcome measurements
Each of the following will be measured during visits **1, 14, 15 and 16**
1. Sensory organization test (SOT) composite score;
2. Mean value of CDP SOT conditions 1 through 6: calculated by software;

3. CDP SOT vestibular contribution value: (mean value of condition 5/mean value of condition 1) × 100;
4. Mean value of directional control of limits of stability in CDP: calculated by software;
5. Mean endpoint excursion value and maximum excursion point of limits of stability in CDP: calculated by software;
6. Dizziness handicap inventory (DHI) score
7. FES-I score
8. Activity-specific Balance Confidence Scale

Statistical analysis

We will enrol a convenience sample of patients previously seen in the Principal Investigator's clinic in order to collect preliminary efficacy data and assess the feasibility of a larger trial.

For continuous variables, we will report the mean, median, standard deviation, and interquartile range. For categorical variables, we will report the percentage of subjects in each category.

Paired analysis by Wilcoxon signed-rank test will be used to compare initial scores to those post-intervention.

1. Brodsky JR, Lipson S, Bhattacharyya N. Prevalence of Pediatric Dizziness and Imbalance in the United States. Otolaryngology Head Neck Surg. 2019;162(2):241–7.

2. Neuhauser HK. Epidemiology of vertigo. Curr Opin Neurol. 2007;20(1):40–6.

3. Perez N, Garmendia I, García-Granero M, Martin E, García-Tapia R. Factor Analysis and Correlation Between Dizziness Handicap Inventory and Dizziness Characteristics and Impact on Quality of Life Scales. Acta Oto-laryngol. 2009;121(545):145–54.

4. Chamelian L, Feinstein A. Outcome after mild to moderate traumatic brain injury: The role of dizziness. Arch Phys Med Rehab. 2004;85(10):1662–6.

5. Arshad Q, Roberts RE, Ahmad H, Lobo R, Patel M, Ham T, et al. Patients with chronic dizziness following traumatic head injury typically have multiple diagnoses involving combined peripheral and central vestibular dysfunction. Clin Neurol Neurosur. 2017;155:17–9.

6. Hillier SL, McDonnell M. Vestibular rehabilitation for unilateral peripheral vestibular dysfunction. Cochrane Db Syst Rev. 2011;(2):CD005397.

7. Cleworth TW, Allum JHJ, Luu MJ, Lea J, Westerberg BW, Carpenter MG. The Effect of Unilateral Vestibular Loss on Standing Balance During Postural Threat. Otol Neurotol. 2020;41(7):e945–51.

8. Murphy SL, Williams CS, Gill TM. Characteristics Associated with Fear of Falling and Activity Restriction in Community-Living Older Persons. J Am Geriatr Soc. 2002;50(3):516–20.

9. Jacobson GP, Newman CW. The Development of the Dizziness Handicap Inventory. Archives Otolaryngology Head Neck Surg. 1990;116(4):424–7.

10. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing. 2005;34(6):614–9.

11. Powell LE, Myers AM. The Activities-specific Balance Confidence (ABC) Scale. Journals Gerontology Ser Biological Sci Medical Sci. 1995;50A(1):M28–34.

12. Peterka RJ, Black FO. Age-related changes in human posture control: sensory organization tests. J Vestib Res Equilib Orientat. 2015;1(1):73–85.