Vestibular Rehabilitation utilizing Virtual Environments to Train Sensory Integration for Postural Control in a Functional Context

NCT04268745

STUDY PROTOCOL

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Methods

This study including all covid modifications was approved by the BRANY institutional review board (IRB, # 19-02-223), the IRB at Icahn School of Medicine at Mount Sinai and New York University Committee on activities involving research subjects.

Participants

All patients signed consent prior to enrolling in the study. We recruited patients referred to an outpatient vestibular rehabilitation clinic with chief complaints of dizziness and/or imbalance. The participants first underwent an initial vestibular physical therapy evaluation of approximately 60 minutes. The evaluation included: detailed history, oculomotor screening which included saccades, smooth pursuit and convergence, assessment of spontaneous and gaze evoked nystagmus with and without infrared goggles, Dix-Hallpike and roll test to rule out benign paroxysmal positional vertigo (BPPV), and bedside head impulse test to screen for vestibulo-ocular (VOR) impairment. The assessment also included gait speed and gait stability with head turns in both horizontal planes and vertical planes, as well as the modified clinical test of sensory integration to assess static balance. Peripheral vestibular hypofunction was diagnosed by either positive findings on bithermal caloric testing during videonystagmography and/or positive bedside head impulse test, head shaking nystagmus and gaze evoked nystagmus and/or clinical history characterized by sudden onset of vertigo lasting hours, aural symptoms unilaterally and ruling out other central causes. Central vestibular conditions were diagnosed based upon history of head injury leading to symptoms, history of resected acoustic neuroma or migraine history with episodic vertigo. We excluded patients if they had bilateral or unstable vestibular loss or another neurological condition, active BPPV, acute orthopedic injuries, peripheral neuropathy and visual impairment not corrected with glasses.

Procedure

When a clinician identified a patient as eligible, they reviewed the informed consent and explained the study procedures. Following consent, patients underwent a baseline assessment including functional measures (Functional Gait Assessment [FGA], Timed-Up and Go [TUG], The Four-Square Step Test [FSST]), and self-reported questionnaires (Visual Vertigo Analog Scale [VVAS][27–29], Activities Specific Balance Confidence Scale [ABC], The Dizziness Handicap Inventory [DHI]. The assessment also included a postural control test using HMD. Standing hips-width apart on the floor, participants experienced two levels of visual surround and white noise while their head sway was recorded via the HTC Vive Pro headset. The total duration of the session was approximately 45 minutes. After the baseline assessment, the patients were randomized to 8 sessions of either traditional vestibular rehabilitation or C.S.I training followed by an immediate post assessment.

System

Our platform runs at 120 frames per second with either HTC Vive or Oculus Rift, on a Windows 10 laptop with 8GB RAM, Intel i7-7820HK CPU, Nvidia GTX 1080 Max-Q GPU, and Bose SoundTrue around-ear headphones II. The software was developed in C# with Unity3D 2018.2.0f1(64-bit) (Unity Technologies, San Francisco, California). The system utilizes SteamVR. Oculus Rift and HTC Vive both operate at 90 Hz refresh rate, 110 degrees field of view, and a high-definition video of 1080x1200 resolution for each eye. The graphics of the subway station, airport terminal building, and subway trains are modeled in Maya and imported to Unity3D. The rest of the 3D objects are modeled in Unity3D. The subway station model and airport model replicate a real subway station in New York City and a real airport terminal in the US. The contents in the system are fully controllable by the user interface (see Figure 3). Three-dimensional sounds were implemented using Wwise middleware and Google Resonance audio plugin. Using the head-tracking data, audio is modulated according to the position of the listener's head. The technology allows for creation of a rich soundscape in all directions around the listener. Audio assets used in the system are divided into two main groups: sound objects and ambiances. Sound objects are attached to the visual objects in the scene and their position is changing accordingly. Sounds include: footsteps, trains, announcements, cars, balls, airplanes, etc. Ambiances are created from original recordings from different locations in New York. These include different background sounds, i.e. sounds of the crowd chatter, distant trains, wind, birds, traffic, and general room tone of each of the spaces. All of the sounds used in the system are assigned to three different intensity levels which relate to the increasing complexity of the soundscape.

Randomization and Group Allocation: We used a blocked randomization method. Instead of randomizing each patient individually, this scheme randomizes several patients at a time in such a way as to ensure that equal numbers are allocated to each group across each segment of time during the length of the study. For example, if the block size is four, we randomize four patients at a time ensuring that two patients are allocated to the C.S.I group and two patients to the traditional group. As it happens, there are six different possible ways we could randomize four patients equally to two treatments. The randomization was done following the baseline assessment and only the study statistician had access to the randomization sequence.

Interventions

Following the baseline assessments, we randomized patients to a C.S.I. group or a traditional vestibular rehabilitation control group. We planned each program to be 8 weeks (1 30-minute weekly session + home program). We conducted a post-assessment, identical to the baseline assessment, within one week from the completion of the 8th intervention session.

The main difference between participants was the timing of progression which was individualized based on patient symptoms (dizziness and / or instability). Each exercise (in clinic or home) was prescribed at the highest level of challenge that was considered safe (i.e., no loss of balance or no significant increase in dizziness). We assigned all patients a home exercise program (the C.S.I group had similar exercises without eyes closed tasks, effectively 2 minutes less exercise per day) which they were asked to complete twice daily, for 5 to 10 minutes. Their home program consisted of gait, gaze stability, and static balance activities.

For patients in the C.S.I. group the progression of environments started with the most salient to the patient and this varied from patient to patient and eventually most patients completed several different environments (e.g., street, subway, airport). The duration varied with starting point at 1 minute with increase in time up to 5 minutes based upon patients' symptoms. Beyond duration, the exact progression the patient underwent varied by therapist. Some therapists chose to change the complexity of the scene (i.e., increased amount people, increased speed of people adding sounds, or changing directions of walking), while others chose to add tasks in the scene (i.e., walking for a maximum. of 4-5 steps, changing base of support or adding head turns).

The following are the exercise variation for the traditional group: **Gait**: walking with head turns, progress with range, speed and planes of head movement; change of walking base of support: wide, normal, tandem; **Gaze:** focus on a target while moving head side to side / up down. Progress with speed, duration, busier background, standing to walking; **Balance:** standing balance tasks, progress with BOS (wide to narrow to tandem), support surface, eyes closed, duration, head turns. See Table 1 for further details.

Table 1. A detailed description of the study's intervention programs

	Experimental Group	**Control Group**
Study Initiation	Eligible participants will be provided with patient education and a basic home exercise program (gait, balance, no exercises with eyes closed) while they are considering participation in the study.	
Program Dose	8 weeks, 1 visit per week, 30 minutes long	
In-Clinic Activities	Progressive immersive training with the C.S.I. app	Progressive gait, gaze stability and balance exercises
Program Guidelines	**Scenes**: start from most salient to the patient, eventually do all **Duration**: start at 60 seconds, increase over time up to 3 minutes per scene **Complexity**: start minimal, gradually increase up to most complex **Tasks**: standing with diverse base of support (BOS), head turns (progress with speed, planes); stepping, turning	**Gait**: walking with head turns, progress with range, speed and planes of head movement; change of walking BOS: wide, normal, tandem **Gaze:** focus on a target while moving head side to side / up down. Progress with speed, duration, busier background, standing to walking. **Balance:** standing balance tasks, progress with BOS (wide to narrow to tandem), support surface, eyes closed, duration, head turns.
Progression / Regression Rule	The highest level of challenge that can be done for 60 seconds with no loss of balance (LOB); No more than moderate symptoms in clinic based on the Simulator Sickness Questionnaire[53]; If symptoms persisted over 2 hours post-session, we will scale back the next time. If symptoms improved immediately, we will repeat the task with the same intensity and duration.	
Home Dose	8 weeks, 6 times per week, twice per day, 10 minutes long	
In-Home Activities	Gait and balance exercises, No exercises with eyes closed	Gait, gaze stability and balance exercises, including exercises with eyes closed
Home Prescription	Highest level of challenge that is safe (no LOB, no increased symptoms) for 60 seconds per task	