THE EFFECT OF VIBROTACTILE FEEDBACK DURING BALANCE AND VESTIBULAR REHABILITATION ON FUNCTIONAL BALANCE OUTCOMES

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Purpose: Postural stability improvements have been observed using vibrotactile feedback (VTF), but the long-term functional benefits of training with VTF is unknown. The purpose of this study was to investigate the effects of VTF on functional outcomes in people with chronic balance disorders immediately following balance training and at 6-months post-training. We also aimed to determine the amount of agreement between participant and physical therapist ratings of participant balance performance.

Participants: Twenty participants with chronic balance disorders between the ages of 21 to 80 years old (70% female, mean age 67 ± 10 years) were enrolled in the study. Three participants were diagnosed with bilateral vestibular hypofunction, nine with unilateral vestibular hypofunction, five with peripheral neuropathy, and three were older adults with balance disorders.

Methods: Eighteen participants completed a 6-week balance training program. Participants were randomized into either the control group (balance training alone) or the experimental group (balance training plus VTF). Group differences in functional balance outcome measures were analyzed using a repeated measures analysis of variance. Postural sway and balance performance ratings from the participant and the physical therapist were collected during training sessions. A quadratic weighted kappa analysis was conducted to investigate the agreement between the participant and physical therapist balance ratings. Regression was used to examine the association between postural sway and balance rating.

Results: The entire sample demonstrated significant improvements in the majority of the functional clinical outcomes following the balance training program, but there were not significant differences between the experimental and control groups. The repeated measures analysis did not indicate that the experimental group had faster improvements compared to the control group, and they did not maintain the improvements longer. Participant and physical therapist ratings had good agreement with quadratic weighted kappa correlation analysis.

Conclusion: The use of VTF during balance training did not improve functional outcomes compared to balance training alone in our small sample. Retention of improvements in functional outcomes following training were not maintained differently between the control and experimental groups at the six-month post-training assessment. Balance rating scales may be useful in determining balance exercise progression.

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PREFACE

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1.0 INTRODUCTION

Balance deficits are related to impaired physical function [1, 2], increased fall risk [3-5], decreased quality of life [6, 7], and increased healthcare costs [8]. Often individuals with chronic balance impairments limit their activity and participation which can result in further balance deterioration and disability, acquisition of additional co-morbidities, and worsening of psychological health [9, 10]. Balance impairments pose a major health problem on the personal and societal level.

Balance and vestibular rehabilitation is a logical solution to address this health problem, as it has been shown to be efficacious in improving balance function and reducing fall risk [11, 12]. However, full recovery is often not achieved for people with chronic balance impairments that result from sensory loss such as uncompensated vestibular hypofunction or somatosensory loss such as peripheral neuropathy [13, 14]. One promising intervention that has received research attention is the use of augmented sensory feedback in the form of vibrotactile feedback (VTF) to improve balance for people with sensory loss. Vibrotactile feedback has been shown to improve postural stability while the wearer is actively receiving the vibratory stimulus (real-time balance) [15], but the long-term carryover effect on functional outcomes following training with VTF is unknown.

Not surprisingly, people with chronic balance disorders have decreased quality of life [6, 7] and there have been studies demonstrating improvements in quality of life following rehabilitation [16]. However, the determination of whether the use of sensory augmentation, optimizes quality of life changes following rehabilitation has not been investigated.

To prescribe a balance training program at a level that is both safe and appropriately challenging, a mechanism by which exercises can be progressed is necessary. A framework for balance training progression has been proposed [17], and this combined with a measure of balance challenge intensity may be an effective mechanism for safely and adequately progressing balance exercises.

The purpose of this study was to measure clinical outcomes following participation in balance and vestibular rehabilitation with and without the use of vibrotactile feedback and to assess quality of life for people with chronic balance disorders following their participation in the balance training. Additionally, we aimed to determine if there was agreement between a balance rating scale measuring the participant's perception of their balance performance and a balance rating scale measuring the clinician's observation of balance performance based on the amount of assistance required.

1.1 SPECIFIC AIMS AND HYPOTHESES

1.1.1 Specific Aim 1

To examine the effect of VTF during balance and vestibular rehabilitation in individuals with chronic balance impairments immediately following a balance training protocol and six-months post-training.

1.1.1.1 Hypothesis 1.1

Individuals who received VTF during rehabilitation will show greater improvements in functional outcome measurements compared to the individuals who received traditional balance and vestibular rehabilitation.

1.1.1.2 Hypothesis 1.2

None of the participants will demonstrate a difference in post- compared to pre-training session postural sway during the normalization exercises (two trials of standing on a firm surface in the semi-tandem Romberg position with eyes closed for 30 seconds at the beginning and end of each of the 18 training sessions).

1.1.1.3 Hypothesis 1.3

The participants in the experimental group who received VTF will demonstrate faster improvement in clinical outcome measures than those that completed the balance training protocol in the control group.

1.1.1.4 Hypothesis 1.4

The participants in the experimental group will have greater retention of the functional outcome improvements at the six-month follow-up compared with the control group.

1.1.2 Specific Aim 2

To examine the change of quality of life in individuals with chronic balance impairments before and after participation in the balance and vestibular rehabilitation program.

1.1.2.1 Hypothesis 2.1

All participants, in both the control and experimental groups, will report a positive change in quality of life, as measured by the SF-12 Health Survey following the balance and vestibular rehabilitation program.

1.1.2.2 Hypothesis 2.2

Participants in the experimental group will show a greater improvement in quality of life compared to the control group immediately following participation in the training protocol.

1.1.3 Specific Aim 3

To examine the amount of agreement between self-perceived balance performance ratings by participants with chronic balance impairments and observed balance performance ratings by the supervising physical therapist.

1.1.3.1 Hypothesis 3.1

The ratings collected from the participant's perception of their balance performance will agree with the physical therapist's rating of their performance during the same exercise.

1.1.3.2 Hypothesis 3.2

Increased trunk sway during balance exercises will correspond with increased ratings from both the: 1) participants perceived balance performance ratings using a 1-5 rating scale; and 2) physical therapist's observed balance performance ratings using a 1-5 Likert scale, which relates to the independence level of the participant during the balance exercise.

1.2 BACKGROUND

There are many clinical populations that experience imbalance. The population of interest for this study included older adults, people with peripheral neuropathy, and people with uncompensated unilateral or bilateral vestibular hypofunction. It is not uncommon for older adults to experience sensory loss in one or more of the three systems that contribute to balance (somatosensory, vestibular, and visual). In peripheral neuropathy, there is disruption of the somatosensory system, and in vestibular disorders there is decreased or absent input from the vestibular organ to the brain. This background chapter will review the pathophysiology of sensory loss that occurs in the three study populations of this project, review the principles of sensory reweighting which provides rationale for balance rehabilitation, and discuss the treatment options available for balance dysfunction. The method by which outcomes are measured during and following rehabilitation will also be discussed.

1.2.1 Pathophysiology of Imbalance

1.2.1.1 Older Adults

The etiology of imbalance in older adults can be multifactorial with a large number of possibilities for contributing factors and/or disorders. Medical conditions including affective disorders and psychiatric conditions, cardiovascular diseases, infectious and metabolic diseases, musculoskeletal disorders, neurologic disorders, and sensory abnormalities (hearing impairment, peripheral neuropathy, and visual impairment) can all result in imbalance [18]. Pain, dyspnea, dizziness, decreased strength, decreased range of motion, poor posture, decreased sensory function, fatigue, and cognitive changes are some examples of how medical conditions manifest into impairments that result in imbalance [18]. Medications can also contribute to balance dysfunction [19]. In 2014, 46.3 million people which constituted 14.5% of the United States population was 65 years or older [20].

1.2.1.2 Peripheral Neuropathy

Peripheral neuropathy can be caused by alcoholism, autoimmune diseases, bone marrow disorders, diabetes, infections (viral and bacterial), inherited disorders (such as Charcot-Marie-Tooth disease), medications, toxicity from exposure to heavy metals or chemicals, trauma, tumors, vitamin deficiencies (B vitamins, vitamin E, and niacin) exposures to poisons, and other diseases (kidney disease, liver disease, connective tissue disorders, and hypothyroidism) [21, 22]. The cause of peripheral neuropathy can also be idiopathic [21]. Regardless of the etiology, the peripheral nerves are damaged and depending on which nerves are involved (sensory, motor, or autonomic), the symptoms can include numbness, tingling, pain, hypersensitivity to touch, decreased coordination, weakness, heat intolerance, bowel/bladder/digestive dysregulation, and/or blood pressure abnormality [23]. Depending on the cause, there may be partial or complete damage to the axon of the peripheral nerve and/or the myelin that surrounds it. It is most common for people to have involvement of many nerves, or polyneuropathy, but it is possible to have mononeuropathy where only one nerve is affected [24]. Peripheral nerves communicate with the central nervous system to produce motor output, with the sensory nerves providing important information to the brain, and the motor nerves receiving information from the brain to produce the appropriate movement. If the damage occurs in the lower extremity, gait and balance dysfunction can result. It was determined from a 1999-2000 health survey that 14.8% of people age 40 years or older in the United States have peripheral neuropathy [25].

1.2.1.3 Vestibular Hypofunction

Peripheral vestibular hypofunction is the result of problems incurred to the vestibular end organs and/or the vestibular nerve. The peripheral vestibular system can sense angular head acceleration via the semicircular canals and linear acceleration and gravity via the otolith organs which provide important information to the central nervous system for balance [26]. People with unilateral vestibular hypofunction and mild to moderate bilateral vestibular hypofunction can compensate for the loss of sensory input either by utilizing the intact labyrinth (such as in unilateral vestibular hypofunction), or by processing the residual inputs from the labyrinths and other sensory inputs [27]. Some common causes of unilateral vestibular hypofunction include vestibular neuronitis, Meniere's disease, vestibular schwannoma, vascular lesion to the vestibular nerve, or traumatic brain injury [26]. Bilateral vestibular hypofunction can be caused by otoxicity, meningitis, head trauma, tumors, vascular ischemia to the vestibular system, and neuronitis bilaterally [26]. It has been reported that vestibular disorders occur in more than 35% of people over the age of 40 in the United States [28].

1.2.2 Sensory Reweighting

When all three sensory systems are intact, appropriate postural sway responses are achieved by a feedback mechanism that weights the vestibular, visual, and somatosensory inputs that maintain stability [29]. Current models in postural control support the theory that stability is dependent upon the combined physiological interactions between the sensory systems to counteract the destabilizing torques that occur in stance [30]. Nashner and Berthoz were able to demonstrate that contributions of sensory systems are dependent upon perturbations applied during stance environmental conditions [31]. The mechanism behind the functional balance improvements following rehabilitation is thought to come from the central nervous systems ability to reweight intact sensory inputs to achieve postural control.

Several clinical tests have been designed to assess sensory reweighting. The Balance Evaluation Systems Test (BESTest) is an example of a multisensory conceptual model of postural control that is used in rehabilitation. This assessment tool was developed to identify the specific system that contributes to postural instability [32]. Information about biomechanical constraints, stability limits/verticality, anticipatory/postural adjustments, postural responses, sensory orientation, and stability in gait are obtained by completing various performance tasks. The premise of this model is that postural control results from interaction amongst many different systems. While this tool contains elements of sensory input it also includes elements of motor output as it assesses physical performance of reaching and reactions to perturbations.

Another example of a test of sensory integration is the Sensory Organization Test on Computerized Dynamic Posturography using the Natus® NeuroCom Equitest. This test collects postural sway data from six conditions in which the participant is instructed to stand as stable as possible with: 1) eyes open, fixed support surface, fixed visual surround; 2) eyes closed, fixed support surface; 3) eyes open, fixed support surface, sway referenced visual surround; 4) eyes open, sway referenced support surface, fixed visual surround; 5) eyes closed, sway referenced support surface; and 6) eyes open, sway referenced support surface, sway referenced visual surround.

1.2.3 Balance Rehabilitation

Balance is dependent upon the input of the visual, vestibular, and somatosensory systems [33], therefore any exercise that alters or removes the input of any of those sensory systems could be classified as a balance exercise. Balance exercises are part of a vestibular rehabilitation program, which is specifically indicated for individuals who have balance impairments of vestibular origin [34]. In addition to challenging our sensory inputs, rehabilitation for an individual with vestibular hypofunction utilizes the strategies of adaptation, habituation, or substitution/augmentation [35, 36].

Adaptation is the process of recalibrating the vestibulo-ocular gain to maintain gaze stabilization during head movement [37]. This is accomplished with exercises that have a person visually focus on a specific target while completing repetitive head movements. In the treatment method of habituation, symptom provoking head movements and body positions are repeated to desensitize the person to the exposures [38]. Optokinetic stimulation is another form of habituation to minimize symptoms over time following exposure to visual stimuli [39]. Substitution strategies can include fall risk education to use visual and proprioceptive cues and assistive devices to improve balance.

To date, the interventions included in balance rehabilitation programs for individuals with peripheral neuropathy has included: balance training [40], monochromatic infrared energy therapy [41], vibrating insoles [42], strengthening exercises for the lower extremity [43], and the use of an assistive device [13]. A systematic review of these interventions (consisting of outcome measure analysis, statistical significance, and clinical relevance) concluded that there was insufficient evidence to recommend or discourage any of the interventions except for lower extremity strengthening which was given a fair recommendation for clinical use for peripheral neuropathy [13]. This was based on an exercise regimen that focused on ankle strengthening and yielded improvements in tandem stance, functional reach, single-leg stance but no significant change in Activities-specific Balance Confidence scale scores [44]. Another systematic review conducted in 2014, concluded that balance training appears to have the best effect on motor and sensory symptoms in diabetic peripheral neuropathy in comparison to strength and endurance training [45].

While vibrating insoles appear to improve postural stability [46], the clinical utility is questionable as the functional benefit is unknown and such devices are not yet commercially available. Other studies have indicated that balance activities, gait training, and resistance exercises might be advantageous for people with peripheral neuropathy [47]. Benefits have also been demonstrated with Tai Chi intervention programs [48, 49]. Another recent study showed that 13 patients with diabetic peripheral neuropathy had improved sensory organization test scores and decreased neuropathy symptoms following 10 sessions of intraneural facilitation (passive muscle stretch, joint mobilization, skin traction, visceral structure distention, and blood vessel distortion) [50].

Balance training for older adults has been investigated through varies methods including gait activities, balance exercises, coordination tasks, functional tasks, strengthening exercises/resistance training, Tai Chi, yoga, walking programs, cycling, and vibration plates [51, 52]. The use of Wii-based exercises has been shown to be equally as effective as other balance exercise programs for older adults [53] and both group and home based exercises have been shown to be effective in providing balance training for older adults [54].

In summary, many different methods of intervening upon balance impairments have been studied and used in the clinical setting. A standardized balance training protocol that incorporates evidence based interventions that have been shown to be effective may improve functional outcomes for people with balance disorders from absent or disrupted sensory inputs.

1.2.3.1 Effectiveness

A systematic review completed in 2007 concluded that there is moderate to strong evidence suggesting that vestibular rehabilitation is effective for adults with chronic dizziness [55, 56]. Research shows significant improvements in postural control [57-62], functional balance [63, 64], vestibulo-ocular reflex (VOR) gain [37, 58, 65], subjective dizziness symptoms [57, 60, 61, 63], motion sensitivity [59], and quality of life [66]. The literature also indicates that vestibular rehabilitation is appropriate for people who have both peripheral [60, 64] or central vestibular etiology [64, 67] and/or unilateral [36, 56, 62] or bilateral hypofunction [14, 36, 62].

Balance and vestibular rehabilitation techniques are designed to improve balance and decrease dizziness, thereby decreasing risk of falls and improving quality of life. Recently published clinical practice guidelines by the American Physical Therapy Association Neurology Section recommends vestibular rehabilitation for people who have functional impairments related to a diagnosis of unilateral or bilateral vestibular hypofunction [36].

Studies have also demonstrated the effectiveness of improving balance with rehabilitation efforts for older adults [68] and for people with peripheral neuropathy [44]. Even though balance and vestibular rehabilitation is recommended for persons with balance disorders and the effectiveness of balance and vestibular rehabilitation is supported by scientific evidence in the literature, there currently is not a standardized balance training protocol with exercise progressions that is used in clinical practice.

1.2.3.2 Exercise progression

A theoretical framework for progressing balance exercises was developed to help guide exercise progression [17]. The framework incorporates various exercise categories that are typically utilized in a vestibular rehabilitation balance program. They include static standing, compliant surface standing, weight shifting, modified center of gravity, gait, and gaze stabilization or vestibulo-ocular reflex (VOR) training. Within each category there are variants with modifications that distinguish each exercise (Figure 1) and affect the level of exercise difficulty.

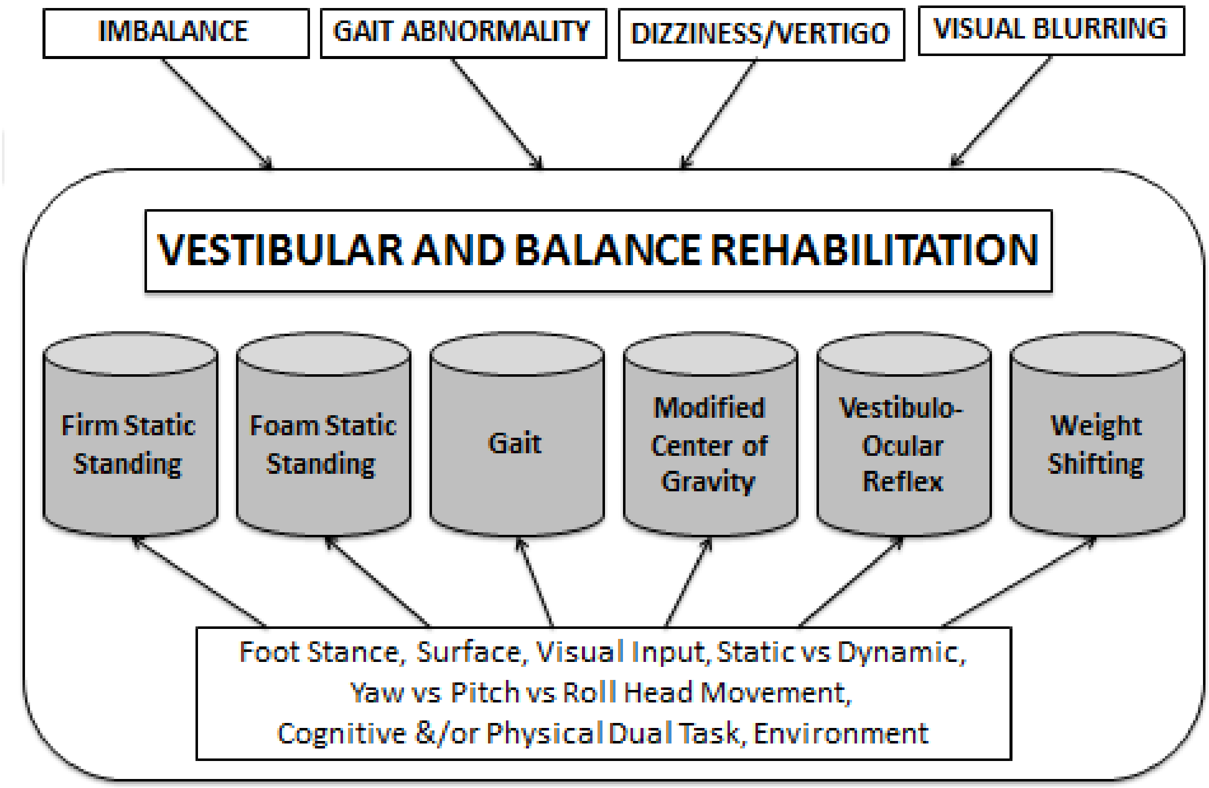

Figure 1. Theoretical balance exercise framework

The progression framework ranks each exercise in order of difficulty within each category (Appendix A). The rankings were established through extensive discussion and through experimentation involving the performance of a large subset of the exercises.

Foot stance. As the base of support (stance) becomes narrower, the maintenance of balance becomes more difficult [69-71]. The following stances progress from easier to more difficult: feet apart, feet together, semi-tandem Romberg, tandem Romberg, and single leg stance. Muelbauer et al. studied healthy young adults while maintaining postural stability in four stances: feet apart, semi-tandem stance, tandem stance, and single leg stance. Participants stood on a firm computerized balance platform with eyes open and as the base of support was reduced, the center of pressure displacements significantly increased [72]. In this framework, each of the exercise categories applies the principle of increasing the challenge of an exercise by narrowing the base of support except for the weight-shifting exercise category, where feet apart stance was maintained throughout the progression.

Surface. Several studies have shown that balance is more challenged when standing on compliant surfaces compared to firm surfaces [73, 74]. Additionally, an increase in the surface slope adversely affects postural stability during standing [75]. Redfern, et al. compared the effect of downhill and uphill walking on postural stability and found that people tend to slip more often while walking downhill due to the increased load of friction force at heel strike [76]. Persons with bilateral vestibular loss demonstrated very large and fast postural sway compared to individuals without vestibular deficits when standing on an inclined surface with eyes closed, which reflects difficulty interpreting surface orientation based on somatosensory inputs alone [77].

The above data, along with the input from our clinical experts, led us to hypothesize that the degree of difficulty and the amount of postural sway increases in the following order for surface progression: firm, firm with incline, firm with decline, and foam. This sequence was used for the modified center of gravity exercise category and the firm to foam progression was used in the VOR and weight shifting categories.

Visual input. Vision affects postural control across all populations. In a study of elite athletes, increased postural sway was observed with eyes closed compared to eyes open [74]. For a person with vestibular loss, the effect of removing visual input results in decreased postural control, especially when standing on an unstable surface [77]. Because of the negative correlation between visual input and balance performance [71], we deemed activities completed with eyes closed to be more challenging than activities with eyes open in the proposed framework. This consideration can be applied to all categories except for the VOR category, as the exercises in this category necessitate that the eyes remain open.

Weight shifting and modification of center of gravity. Within the framework highlighted in Appendix A, we consider the effects of dynamic weight-shifting and upper extremity movements that lead to changes in center of gravity. During weight shifting assessments using the Neurocom Smart Balance Master ® system, subjects were asked to sway in different directions to reach a target that was displayed on a screen. The participants showed better directional control in the medial-lateral direction than in the anterior-posterior direction [78]. Winter and Maki have suggested that poor medial-lateral control is related to increased risk of falling [79, 80]. Additionally, it has been shown that ankle range of motion is an important factor related to balance and functional ability [81, 82]. Medial-lateral directional control may be easier than movement in the anterior-posterior direction. Although postural stability has not been analyzed during weight shifting at different speeds and distances, we propose that balance will be more challenged moving at slower speeds compared to fast speeds.

In the BESTest, Horak et al. included lifting a weight to shoulder level as a test of postural control [32]. Lifting the weight was included in our framework as part of the progression for the modified center of gravity exercises. We hypothesized that completing this task with heavier weights would elicit greater postural sway compared to completing the task with a lighter weight or no weight. Based on our clinical experience, we hypothesize that lifting the weight at slow speeds will cause more sway compared to faster speeds.

Head movements. Cohen et al. has shown that balance is challenged more with head movements compared to static head positions for people with vestibular hypofunction [73]. Head movements often provoke visual blurring, dizziness, imbalance and path veering in patients with peripheral vestibular hypofunction, resulting in limited head movements while walking [66]. In subjects with vestibulopathy, visual acuity degrades as a consequence of head movement, presumably because the vestibular-ocular reflex cannot stabilize gaze [83]. Mamoto et al. found that patients with unilateral and bilateral vestibular involvement adopted head stabilization as a trunk strategy in order to minimize head movements [84].

Whitney et al. reported that patients with vestibular disorders had a higher percentage of lower (worse) scores on the Dynamic Gait Index with head movements in the yaw plane compared to the pitch plane during gait [85]. We therefore proposed that head movements in the yaw direction are more challenging than balance activities incorporating head movements in the pitch direction. No head movement was subsequently deemed the easiest condition of the three variations. In our framework, head movement considerations were used for progressing static standing, compliant surface, gait, and the VOR exercise categories.

Dual tasks. Improved performance would be expected with focused attention toward the task when compared to an activity that is completed with a cognitive or manual dual task challenge. Silsupadol et al. include examples of both cognitive and manual dual task challenges in their case report which investigated dual task training in older adults with balance impairments [86]. Examples of cognitive tasks include, but are not limited to, naming words within an identified category, counting backwards, arithmetic, memorization, and spelling tasks for cognitive tasks. Reaching, throwing/catching a ball, kicking a ball, and carrying an object are some examples of manual tasks [86].

Redfern et al. found that patients with well compensated vestibulopathies require increased attention compared with healthy controls when performing a balance task concurrently with a cognitive task. The effect of the cognitive task had a greater negative impact on performance as the difficulty of the postural task increased [87]. When choosing balance and gait related tasks, the clinician needs to consider whether the elements of the task demand voluntary movement (sweeping the floor), an autonomic postural response (missing a curb step), or an anticipatory postural adjustment (lifting a laundry basket). Patients need to be challenged with a combination of all three conditions for optimal recovery [88].

Environment. Many different environmental variables can alter performance and impact the degree of challenge for an exercise. Some of the considerations include whether the exercise is completed in settings that are: quiet or loud; empty or crowded; high versus low visual contrast; and predictable versus unpredictable standing. Additionally, the following factors can affect performance: the type of compliant surface (foam density, carpet type, outdoor grass or rocky surfaces, slope and variability of uneven surfaces, slippery surfaces); shoe type, the lighting (fluorescent, iridescent, sunlight, dim light); the presence or absence of physical assistance (from the support of a physical therapist, family member, assistive device, wall or other stable object/surface for support); and the tone/inflection of the tester in providing instructions or commands.

Gait. The goal of gait training is to assist the patient in mastering walking on level surfaces and then challenge the patient with progressive variations in the task or environment, while working toward the same quality of independent controlled locomotion [89]. Patients with vestibular involvement typically ambulate with a wide base gait, decreased gait speed, and limited head movement [84, 90, 91]. All of the considerations discussed so far can be applied to gait exercises to alter the balance challenge. Additionally, we included the speed at which someone walks in our framework, where the progression moves from self-selected speed progressing to fast and then slow speeds in order of increasing difficulty. We also used clinical experience in suggesting that backwards walking will be more difficult than forwards walking. Although not included in our framework we recognize that additional gait variations can be included to challenge a patient such as: changing gait speeds, quick stops/starts, stepping over objects of different sizes, sidestepping, braiding, marching, completing 180 and 360 degree turns, walking on toes, or walking on heels.

Gaze stabilization. The VOR, when functioning normally, acts to maintain stable vision during head motion and consists of two components: the angular and linear VOR. The angular VOR is controlled by the semi-circular canals and is primarily responsible for gaze stabilization. The critical stimulus for recalibration of the dynamic VOR response following unilateral vestibular loss is the presence of motion of images on the retina during head movements. Adaptation of the VOR gain is a dynamic process that requires visual experience for its acquisition [92].

Gaze stabilization exercises are an example of adaptation exercises used to improve the gain of the VOR [65]. This exercise progression begins with the VOR X 1 viewing paradigm which involves using a stationary target at a distance of 1 meter, against a plain background while performing either pitch or yaw head movements. The patient is instructed to keep his/her eyes fixed on a target and move their head side to side as fast as they can as long as the target remains stationary and in clear focus. Patients are instructed to slow the speed of their head if the target is moving or blurring consistently. Exercise modifications involve changing the stance position, the stance surface, the distance of the target and progressing from a plain to complex background.

The next suggested phase of VOR exercises is VOR X 2 viewing where the target and head both move, but in opposite directions. In this case, the target and head velocity are equal, but opposite in direction, thereby requiring an angular VOR eye velocity twice as large as head velocity, stimulating a large change in the angular VOR [65]. There is evidence that the VOR gain can increase with gaze stability exercises in individuals with vestibular hypofunction [65]. Herdman et al. found that significant improvements in dynamic visual acuity occurred in adults with unilateral vestibular hypofunction who completed vestibulo-ocular reflex exercises [65].

Substitution exercises are used to treat patients with bilateral peripheral vestibular hypofunction. In this treatment approach, patients are taught to primarily rely on visual and somatosensory cues to maintain postural stability in place of absent vestibular inputs. When there is bilateral peripheral vestibular weakness, but not complete loss, both adaptation and substitution exercises are utilized to maximize function. In a study review involving saccade and VOR motor learning, it was concluded that both the saccade and vestibular ocular motor systems are adaptable and can work together to optimize gaze stability in persons with bilateral vestibular loss [93].

In addition to manipulating sensory inputs to achieve sensory reweighting during balance training as described in the balance exercise framework above, clinicians and scientists have explored the use of technology to substitute or augment postural stability in real time and during balance training. If sensory augmentation modalities are found to be beneficial and acceptable to the users (both the person with the balance disorder and the healthcare provider recommending its use), the use of such devices may address the individual and societal problems associated with disordered balance.

1.2.4 Sensory Augmentation Modalities

Improved postural stability during quiet stance and in perturbed stance has been demonstrated with vibrotactile feedback, electrotactile feedback, and audio-biofeedback in healthy controls and in individuals with balance deficits [15, 94, 95]. All three of these technological devices strive to help control postural sway by replacing the disrupted, or absent, sensory input with supplemental information about body position to the intact sensory systems. The aim of sensory augmentation is to evoke a purposeful response to the supplemental feedback so that postural stability can be regained or maintained.

The main components of the sensory feedback devices include a sensor, a processor, and an interface to acquire, convert, and convey the sensory information to control posture [96]. After the sensory stimuli are received, the impulses travel to the brain and may terminate in the areas of sensory loss [97]. Some researchers have investigated the effects of multiple modes of feedback which combine different types of feedback inputs [98, 99]. Vibrotactile and electrotactile feedback devices both elicit a tactile sensation (mechanical or electrically driven), while a sound is used to elicit a response in audio-biofeedback postural control augmentation. Input has been presented in various anatomical locations on the body including the head, tongue, torso, fingers, and feet [97]. Because each type of feedback uses a different mechanism for providing their sensory inputs, the design and implementation of the systems are unique with different benefits and clinical considerations for the application of each.

1.2.4.1 Audio-biofeedback

Audio-biofeedback prototypes use a sensor for the determination of body position and the information processed is relayed back to the patient via sounds. This closed-loop control mechanism uses audible sounds from the interface to provide information to the individual. The sounds can be encoded to provide direction and/or magnitude of postural sway and this information has resulted in a reduction of postural sway in persons with vestibular hypofunction [94, 96, 100]. One disadvantage of audio-biofeedback is the interference of verbal communication which naturally occurs between the healthcare provider and the client.

1.2.4.2 Electrotactile feedback

Early work with the use of electrotactile stimulation of the tongue has been shown to be effective for optimizing standing posture in individuals with unilateral and bilateral vestibular hypofunction [101-103]. The device (BrainPort Balance Device, Wicab Inc.) used in these investigations delivers an electrical current via electrodes placed on the surface of the tongue to activate cutaneous afferents. The location of the four electrodes used in BrainPort correspond to head position (anterior, posterior, right, left) and the participants are instructed to maintain the stimulus in the center of the array while they complete balance tasks. Normal postural control requires naturally occurring head on body movements and because electrotactile feedback to the tongue relies on head position for feedback, the coupling of head and trunk motion is observed which may interfere with normal posture. Additionally, wearers may find electrical impulses to the tongue uncomfortable because of the stimulus and the location. The location of the stimulus also impedes verbal communication.

1.2.4.3 Vibrotactile feedback

Vibrotactile feedback (VTF) is a type of sensory augmentation which works by replacing the disrupted or absent sensory inputs (vestibular or somatosensory) with supplemental information to the intact sensory inputs by using vibratory sense. The effects of VTF on postural control has been studied in people with unilateral vestibular loss [104], bilateral vestibular loss [105], peripheral neuropathy [106], Parkinson's Disease [107-109], and in older adults [110]. Most of the studies have focused on the ability of VTF to contribute to postural stability in real-time stance activities and the impact of utilizing this type of sensory augmentation device during an intense balance training protocol that follows a controlled research design has not rigorously been explored. The optimal training dosage and the duration of training effects following rehabilitation using vibrotactile feedback are unknown.

The most common location for the application of vibrotactile feedback is on the trunk. Previous research has shown that the use of real-time vibrotactile feedback applied to the trunk of healthy individuals, older adults, and individuals with vestibular deficits results in decreased postural sway in both quiet and perturbed stance [105, 111-113]. Some studies have shown improved stability when vibrotactile feedback was applied to the feet of older adults, individuals post-stroke, and persons with diabetes [46, 80, 114]. Vibrotactile feedback has also been applied to the forehead [115] but this location couples head and trunk movement. The location of the trunk does not interfere with completion of head on trunk movements that are an important component of a vestibular training program. While the trunk location has decreased spatial resolution compared to the tongue, head, or finger [116] which results in slower reaction time when compared with application of the vibrotactile feedback to the more distal body sites, it has been found to have adequate and effective spatial resolution and reaction time to yield positive postural stability results in balance studies [117, 118]. The application of VTF on the trunk is also advantageous because it does not compete with other sensory tasks such as hearing, seeing, or speaking.

It has been demonstrated that VTF applied to the trunk is actively processed by individuals with vestibular hypofunction and that 4 tactors with 90 degree spatial resolution is effective in reducing postural sway [119]. The effect of attractive and repulsive cuing in response to vibration has shown that repulsive cues result in improved balance performance during Sensory Organization Test (SOT) condition 5 and also resulted in decreased RMS sway in the anterior/posterior direction [120]. Repulsive cuing refers to the voluntary trunk and body movement in the direction opposite or away from where the stimulus is applied, while attractive cuing refers to the movement towards the stimulus until the desired posture is achieved.

The effect of VTF on anterior-posterior body tilt in six subjects with vestibular hypofunction were tested and trained on the NeuroCom Equitest [105]. Postural sway was measured using force plate recordings to capture the COP and an inertial measurement instrumentation (IMU) was used to detect body tilt. When the subjects completed condition 5 & 6 on the SOT with VTF, there was less sway than when they completed SOT without VTF. With VTF, the most impaired participant maintained upright posture throughout testing, but without VTF the participant fell [105]. The substitution of VTF in individuals with vestibular deficit had the ability to decrease postural sway for situations where visual and somatosensory inputs were challenged.

Another study used VTF and IMU systems to compare individuals with moderate (n = 9) and severe (n = 8) balance impairments as classified by computerized dynamic posturography (CDP) scores during SOT conditions 5 & 6 and the Motor Control Test (MCT) [15]. Individuals with vestibular deficits used the Natus® NeuroCom Equitest for testing and training. The authors used the score of 45 on combined SOT conditions 5 & 6 to categorize moderate (>45) and severe (<45) balance impairment. In the group with severe deficits, both falls and body tilt, but not COP, were less with the use of VTF during both SOT conditions, compared to no VTF. The group with moderate deficits had less body tilt with VTF but fall rates did not change. When VTF was applied during the medium and large support surface displacements, participants were able to return to the "safety zone" quicker than when VTF was not applied [15].

In a study of people with unilateral vestibular hypofunction (n=10), VTF was applied during narrow base of support ambulation [104]. During completion of 45 trials of 3-meter tandem walking, participants showed a decrease in trunk COM variability, trunk-tilt, and step width when VTF was utilized. However, immediately following the training these improvements were not transferred to performance of the same task without VTF [104].

A double-blinded trial of people with balance disorders was performed to study the effect of vestibular rehabilitation training with VTF using the Vertiguard training device [121]. Participants completed 5 trials of 6 different balance tasks 5 days per week for 2 weeks. The control group performed a similar exercise protocol with a sham device. Trunk sway, composite SOT score, Dizziness Handicap Inventory, and the vestibular symptom score were collected at three timepoints (pre-, immediately post-, and 3-months post-training). A reduction in trunk and ankle sway and the subjective symptom scores was noted in the individuals who received VTF.

Pitch (30%) and roll (31%) trunk sway decreased from before to immediately after training. [121].

The effects of activating vibration from various body locations was studied in six participants with vestibular deficits who all failed SOT conditions 5 & 6 on computerized dynamic posturography. It was determined that there was not a superior location for tactor activation in improving postural stability as measured via RMS sway. The people were perturbed in eight directions during standing while they received VTF at different locations on the torso and when inaccurate VTF was applied, the participant's postural control worsened. The erroneous feedback trials yielded increases in recovery time, RMS pitch sway, RMS phi (roll/pitch vector), RMS COP, and RMS ML sway. Participants also spent less time in the dead zone, or the area where no vibratory stimulus was applied, during the erroneous trials [119].

In another study of people with vestibular disorders, four different ambulatory tasks were performed with use of VTF. The tasks included walking: at self-preferred speed; at slow speed; on a narrow path; and over a foam surface [122]. The subjects walked without VTF, continuous feedback, and feedback that was only applied for 200ms following the initiation of heel strike. The use of continuous VTF yielded decreased RMS tilt for ML trunk sway especially during the narrow walking and foam walking tasks.

Lin et al, investigated the effects of age and VTF on postural sway. Results indicated that age impacts ability to used VTF, with older adults displaying increased reactions times for response to the vibration and necessity for increased training time compared to younger adults [123].

The use of real-time VTF applied to the trunk of healthy individuals, older adults, and individuals with vestibular deficits results in decreased postural sway in both quiet and perturbed stance as well as some challenging ambulatory tasks [104]. The efficacy of VTF to decrease postural sway is dependent upon factors such as age and dual task conditions. To date, there are not published studies that investigate the impact of utilizing this type of sensory augmentation device on long-term functional improvement after repeated balance training sessions. Studying people after many sessions of augmented feedback will help ascertain whether VTF is an intervention that has maintained training effects.

1.2.4.4 Detection of vibration

The afferent receptors of the somatosensory system that contribute to postural control during standing balance are the cutaneous mechanoreceptors and the deep tissue proprioceptors (muscle spindles, Golgi tendon organs, and joint receptors). The mechanoreceptors (free nerve endings, Meissner’s corpuscles, Merkel’s disks, Ruffini’s end-organs, and Pacinian corpuscles) are located in the skin and joint capsules and are sensitive to specific types of physical stimulation.

The determination of which of these mechanoreceptors detects the stimulation is dependent upon the frequency at which the stimuli is applied and each has a specific function in somatic sensation. The free nerve endings function to recognize pain, temperature, and crude touch; Meissner’s corpuscles function in sensing touch and dynamic pressure; Merkel’s disks enable the sensation of touch and static pressure; Ruffini’s corpuscles function to recognize stretching of the skin; and Pacinian corpuscles sense deep pressure and dynamic vibration. Similarly, the deep tissue proprioceptors have specific sensitivity to recognize the somatic inputs with the muscle spindles functioning to sense muscle length; the Golgi tendon organs sensing muscle tension; and the joint receptors providing information about joint position [124, 125]. The vibrations applied during vibrotactile feedback are within 200-300 Hz, which is in the 40-250 Hz sensitivity range of the Pacinian corpuscle.

Information from cutaneous, muscle, and joint receptors modifies the output of circuits at the corresponding spinal cord level that control motor output [126]. Information from the trunk and limbs ascends in parallel systems to the sensory cortex and cerebellum via the dorsal column-medial lemniscal system and the anterolateral system Following the detection of the stimulus in the mechanoreceptor, there is a change in membrane potential and alteration of the ion permeability to allow signal transmission from the dorsal root of the spinal nerve into the spinal cord [127]. The sensory signal used for postural stability in standing balance are carried through the dorsal column-medial lemniscal system (DCML). The DCML pathway ascends through the dorsal column of the spinal cord and decussates in the medulla. At this point the medial lemniscus carries the signal through the brainstem to the thalamus. At the level of the thalamus, the signal travels through the ventral posterolateral nucleus and projects to the cerebral cortex where the information is interpreted for motor output response [128]

Within the primary somatosensory cortex, kinesthetic and touch information from the contralateral side of the body is organized somatotopically into Brodmann's area 1, 2, 3a, and 3b [129]. Cross modality processing from the contributing inputs occurs to integrate information about movement for specific body areas which initiates spatial processing for the coordination of movements in space [130]. Coordinated movement requires information about the position of the body relative to the environment and the other body segments. The motor cortex areas communicate with the sensory processing areas in the parietal lobe and with the basal ganglia and cerebellar areas to identify, plan, and execute desired motor output [131].

1.2.5 Balance outcome measurement

1.2.5.1 Postural stability measurement

Postural sway is an important concept to consider when investigating and treating individuals with vestibular and balance disorders. Reducing falls and improving balance are goals of balance and vestibular rehabilitation and these goals are accomplished by controlling postural sway. Postural sway can be measured with the use of force plates to analyze center of pressure displacement during static standing. It can also be measured by analyzing the displacement of center of mass, detected by movement of the body, sway position, and sway velocity, using inertial measurement instrumentation (IMU) or accelerometry [132]. Postural stability measurements can guide clinicians in treatment techniques to help their patients improve their balance during vestibular rehabilitation and help determine the most advantageous parameters for technology advances that may provide biofeedback to improve postural stability.

1.2.5.2 Functional outcome measures

The composite score of the Sensory Organization Test is a component of the computerized dynamic posturography using the Natus® NeuroCom Equitest. The composite score from the Sensory Organization Test includes postural sway data from six conditions in which the participant is instructed to stand as stable as possible with: 1) eyes open, fixed support surface, fixed visual surround; 2) eyes closed, fixed support surface; 3) eyes open, fixed support surface, sway referenced visual surround; 4) eyes open, sway referenced support surface, fixed visual surround; 5) eyes closed, sway referenced support surface; and 6) eyes open, sway referenced support surface, sway referenced visual surround. Wrisley et al. have shown that this test yields good test-retest reliability in healthy young adults (ICC = 0.67) [133].

The 10-meter walk test is a test that can be used to assess gait speed in persons with vestibular disorders. For this test, the participant is instructed to walk at their preferred speed in a straight path. The tester uses a stopwatch to time a 10-meter distance to attain the average gait speed. Acceleration and deceleration are accounted for by the inclusion of approximately 2/3 of a meter prior to the start and following the completion the timed distance that are not timed. In healthy adults, this test has been shown to have excellent test-retest reliability (r = 0.75 - 0.90) (Watson, 2002).

The Dynamic Gait Index (DGI) and Functional Gait Assessment (FGA) both assess balance during different walking tasks. For both tests, each task is scored by the assessor using the same scale: 0 – equals severe impairment; 1 – equals moderate impairment; 2 – equals mild impairment; and 3 – equals normal ambulation. The DGI has 8 tasks for a total of 24 points and the FGA has 10 tasks for a total of 30 points. For individuals with vestibular disorders, the test-retest reliability for DGI total score has been shown to be excellent (ICC = 0.86) [134] and for community dwelling adults with Parkinson's Disease excellent test-retest reliability (ICC = 0.91) [135] has been shown. The FGA has been shown to have acceptable intrarater reliability (ICC = 0.83) and interrater reliability (ICC = 0.84) for persons with vestibular disorders [136].

The Five Times Sit to Stand Test (FTSTS) is completed by instructing the participant to move from a seated position to a standing position and back to the seated position without using their upper extremities as quickly as possible for a total of five repetitions while the tester uses a stopwatch to record their time. Within a sample of community dwelling older adults this test was shown to have adequate test-retest reliability (ICC = 0.890) [137].

The Mini Balance Evaluation Systems Test (mini-BESTest) is an outcome measure that measures anticipatory postural control, reactive postural control, sensory orientation, and dynamic gait by having the participant complete 14 functional tasks that are scored on a 0-2 scale [138]. In people with balance disorders, the minimal detectable change has been calculated to be 3.5 and the minimally clinically important difference is an improvement of 4 points [139]. This test has been found to have excellent test-retest reliability and excellent interrater/intrarater reliability for people with balance disorders [139]

The Functional Reach test is a test of postural stability where the participant maintains static standing while reaching as far as they are able in the forward direction with their arm outstretched to 90 degrees of shoulder flexion [140]. This test has been shown to have excellent test-retest reliability for community dwelling older adults [140, 141]

The Activities-specific Balance Confidence Scale (ABC) is a 16-item self-report instrument which involves the participant scoring their perceived confidence level (0-100) during activities of daily living, where 0 is no confidence and 100 equates to completely confident. The scores for all items are added together and divided by the total number of items. This test has been shown to have excellent test-retest reliability (r = 0.92, p < 0.001) in the elderly population (Powell and Myers, 1995). Another self-report instrument, the Dizziness Handicap Inventory (DHI), includes 25 activities that the participant scores as either: 0 (no dizziness): 2 (sometimes causes dizziness); or 4 (always provokes dizziness). The scores for each of the 25 items are totaled to yield a score out of a possible 100 points. In persons with vestibular dysfunction the total score of this test has excellent test-retest reliability (r = 0.97, p < 0.0001) [142]. The DHI and ABC have good concurrent validity [143].

1.2.5.3 Quality of life

Many different self-reports have been used to investigate health-related quality of life, impact of symptoms, disability, activities of daily living assessment, and activity/participation levels for people with vestibular disorders [144, 145]. The Dizziness Handicap Inventory, which is a measure that assesses self-perceived handicap related to dizziness, has been used to quantify quality of life within the population of people with vestibular disorders [16, 146]. Other measures that are reported to measure quality of life include the Vestibular Disorders of Daily Living Scale; the Activities-specific Balance Confidence scale; the Vertigo Handicap Questionnaire; the Vertigo, Dizziness, Imbalance Questionnaire; UCLA Dizziness Questionnaire; Dizzy Factor Inventory; Vertigo Symptom Scale; European Evaluation of Vertigo; and the Meniere’s Disease Patients-Oriented Severity Index [147].

Specific health-related quality of life measures for people with diabetic peripheral neuropathy include: health-related quality of life measure for peripheral neuropathy (PN-QOL-97) [148]; the Norfolk Quality of Life Questionnaire-Diabetic Neuropathy (Norfolk QOL-DN) [149]; and the neuropathy- and foot ulcer- specific quality of life instrument (NeuroQoL) [150]. The Nottingham Health Profile has been used for people with diabetic peripheral neuropathy [7]. The SF-36 has been used to measure quality of life for people with chronic peripheral neuropathy [151], people with vestibular disorders [152], and older adults [153, 154].

Quality of life can be measured using the 12-Item Short Form Health Survey (SF-12) [155]. The SF-12 does not target a specific age or diagnostic category. It is a shorter version of the 36-Item Short Form Health Survey (SF-36) used in the Medical Outcomes Study [156]. The SF-12 includes 12 questions that range from 0 to 100 (0 = lowest level of health, 100 = highest level of health). When scored and weighted the survey create two scales that provide information about the individual’s mental and physical functioning as well as the overall health-related-quality of life. Both the mental and physical component summary scores of the SF-12 have been shown to be reliable and valid [157]. The SF-12 has been used as a quality of life measure for people with peripheral neuropathy [158], people with vestibular dysfunction [159], and older adults [160].

1.2.5.4 Subjective perception of performance

Balance impairments often result in decreased confidence and it has been shown that there is an association between confidence and actual performance [161, 162]. The problem is that for some people the perceived balance ability or balance confidence does not accurately correspond to their actual performance [163, 164]. An individual's belief in their ability to succeed in specific situations or with certain tasks is known as self-efficacy [165]. Self-efficacy has been linked to how people approach goals, tasks, and challenges or the amount of physical activity they complete [166-168]. Self-efficacy and confidence have been shown to have a positive association with functioning [169, 170].

There is not a standard tool used to measure self-efficacy or perception of performance in the literature. One study compared physical activity (amount of walking in one week) with psychological (composite perception score of health and balance, scored as “good perception”, “discordant perception”, and “poor perception”) and physiological factors (gait speed, fall history, and tandem stance balance performance) [171]. Others have used the Tinetti Falls Efficacy Scale compared to functional measures [162, 172]. In a study of individuals with Parkinson’s Disease, self-efficacy was inferred as the ability of the participant to accurately estimate whether or not they would be able to reach a target prior to a functional reach trial [173]. The Activities-specific Balance Confidence scale has also been used to measure self-efficacy during tasks that require balance [174] and the modified Gait Efficacy Scale was developed to measure confidence during walking common daily ambulatory challenges in older adults [175].

2.0 THE EFFECTS OF VIBROTACTILE FEEDBACK DURING BALANCE AND VESTIBULAR REHABILITATION TO ADDRESS CHRONIC BALANCE IMPAIRMENTS

2.1 INTRODUCTION

The ability to maintain balance is essential in order to perform basic activities of daily living, engage in the community, and participate in meaningful activities that provide satisfaction, value, and worth [176]. Balance impairments can result in fear of falling, decreased activity and participation, acquisition of additional co-morbidities related to inactivity, and the psychological sequela of social isolation and fear. It is not surprising that impaired balance is associated with decreased quality of life [177, 178].

Balance is dependent on sensory inputs from the somatosensory, vestibular, and visual systems and their communication with the central nervous system. Absent or lost inputs from the three sensory systems can be observed following pathophysiological changes that result from specific neurological diagnoses, medications, or during the aging process. The standard of care for treating balance impairments is physical therapy, which has been shown to be effective for improving functional outcomes [179-181]. However, full recovery is not always achieved and chronic balance dysfunction can result when there is absent or disrupted sensory inputs from any of the three sensory systems that contribute to balance [13, 14].

In recent population studies, 14.8% of people age 40 years or older in the United States have peripheral neuropathy [25], over 35% of people over the age of 40 have vestibular disorders [28], and approximately 14.5% (46.3 million people) are 65 years or older [20]. The impact of balance impairments impacts our society with healthcare costs associated with falls, supportive services, and additional costs associated with the acquisition of other medical diagnoses resulting from the sequela of impaired balance [8]. Even though improvements in functional performance measures and subjective self-reports have been observed following participation in balance and vestibular rehabilitation [11, 12], there are many people that do not fully recovery and have deficits that continue to limit their mobility, activity, and participation [13, 14].

To address the residual deficits that are noted in people with chronic balance dysfunction, the exploration of sensory augmentation has been explored in older adults, people with peripheral neuropathy, and people with vestibular disorders [104, 106, 110, 182]. These studies have demonstrated improved postural stability while actively receiving augmented feedback in the form of audio biofeedback [183], electrotactile feedback (provided to the tongue) [101, 103], vibrotactile feedback (applied to the head, trunk, and feet) [105, 114, 115], visual feedback [184, 185], and a combination of the sensory augmentation modalities [99, 186, 187]. In addition to the investigations of how sensory augmentation can improve real-time balance performance, a few studies have investigated the effects of completing balance training with the feedback devices [102, 103, 109, 187-190]. The vibrotactile training protocols have not been standardized and methods have not been controlled.

The goal of this project was to understand the clinical efficacy of improving functional outcomes by using the sensory augmentation technique of VTF in people with chronic balance deficits. The hypotheses were that individuals with chronic balance disorders who receive traditional balance vestibular rehabilitation with VTF would have improved functional outcomes compared to those who receive balance and vestibular rehabilitation alone and functional improvements will happen faster for the experimental group. Additionally, we hypothesized that the long-term improvements would be better maintained in the group who receives VTF during balance and vestibular rehabilitation.

2.2 METHODS

2.2.1 Trial Design

This was an experimental randomized control trial that incorporates a longitudinal design.

2.2.2 Participants

The study included 20 individuals with vestibular hypofunction or peripheral neuropathy who were between 21 to 80 years of age, and older adults with impaired balance who were aged 60 years and above. Potential participants were identified by a UPMC neurologist, UPMC Centers for Rehab Services physical therapists and study recruitment flyers placed in UPMC Eye and Ear Institute and UPMC Centers for Rehab Services facilities. The study was also advertised on the University of Pittsburgh Research Participant Registry.

2.2.2.1 Inclusion Criteria

Adults aged 21 – 80 years old with the diagnosis of unilateral peripheral vestibular hypofunction, bilateral peripheral vestibular hypofunction, or peripheral neuropathy were included in the study. Additionally, older adults, age 60 and above, who reported balance impairment were recruited for participation. A Montreal Cognitive Assessment (MOCA) score of ≥ 26, bilateral ankle dorsiflexion active range of motion ≥ 10 degrees, and bilateral ankle plantarflexion active range of motion ≥ 20 degrees were required for eligibility.

2.2.2.2 Exclusion Criteria

Exclusionary criteria included confounding neurologic or neuromuscular disorders, pregnancy, inability to stand for three minutes without rest, recent lower extremity fracture/severe pain within the last six months, previous lower extremity joint replacement, incapacitating back or lower extremity pain, and a person whose body was too large for the equipment (waist circumference >50 inches; 290 pounds).

2.2.3 Interventions

The experimental group received VTF during balance and vestibular rehabilitation (11 participants randomized, 10 study completers) and the control group received balance and vestibular rehabilitation without VTF (9 participants randomized, 8 study completers). For the experimental group, the VTF was applied in four of the six repetitions in a randomized fashion for each of the exercise categories except for gait activities. Feedback was not provided in all of the trials because the motor learning literature suggests that a frequency of 100% feedback may result in dependence upon the augmented feedback for skill performance and in contrast, knowledge of results provided at a reduced frequency promotes learning of skills [191].

2.2.4 Outcomes

Outcomes were assessed at baseline, following the 9th training session, 1-week post-training, 1-month post-training, and 6-month post-training. Outcome measurements included: gait velocity, the Dynamic Gait Index (DGI), the Functional Gait Assessment (FGA), the Sensory Organization Test (SOT) using the Natus® computerized dynamic posturography, the Functional Reach, the Mini-BESTest, the Five times sit to stand (FTSTS), the Timed up and go (TUG), the Activities-specific Balance Confidence (ABC), and the Dizziness Handicap Inventory (DHI). Mean RMS trunk sway during the pre-training and post-training normalization exercise trials was collected to investigate the impact of fatigue during each training session.

2.2.5 Sample Size

Because no prior estimates were available from the literature, G*power software was used to generate a range of sample sizes to detect a small, medium, and large effect size for this analysis of 2 groups with five time-points, using a significance of 0.05 and power equal to 0.8. The 0.5 default correlation among the repeated measures was used. Table 1 depicts the results of this power analysis. Due to the longitudinal design of the study we planned to recruit a total of 20 participants to account for possible dropouts. As the physician and physical therapists were aware of the eligibility criteria, we expected most individuals screened would be eligible. A medium effect size was used.

Table 1. The range of effect sizes when using two groups (control and experimental) with five time-point measurements (pre-, midway-, post-, 1-month post-, and 6-month post-training)

Effect Size f	Total sample size
.1	122
.25	22
.4	10

2.2.6 Randomization

Random group assignment was determined through use of a computerized randomization calculator.

2.2.7 Blinding

All participants were expected to complete 18 training sessions with a physical therapist and five additional assessment sessions where outcome measurements were obtained from a blinded assessor who was also a physical therapist.

2.2.8 Instrumentation

Our collaborators in the Mechanical and Biomedical Engineering Department at the University of Michigan developed the vibrotactile feedback unit that was used for this project (Figure 2) which followed the same design conceptualization as the Wall prototype [192]. An inertial measurement unit and vibrating tactors on the trunk were used to provide immediate feedback of body tilt to participants in the experimental group during training. A memorandum of agreement was signed between the two Universities related to the use of the software and hardware.

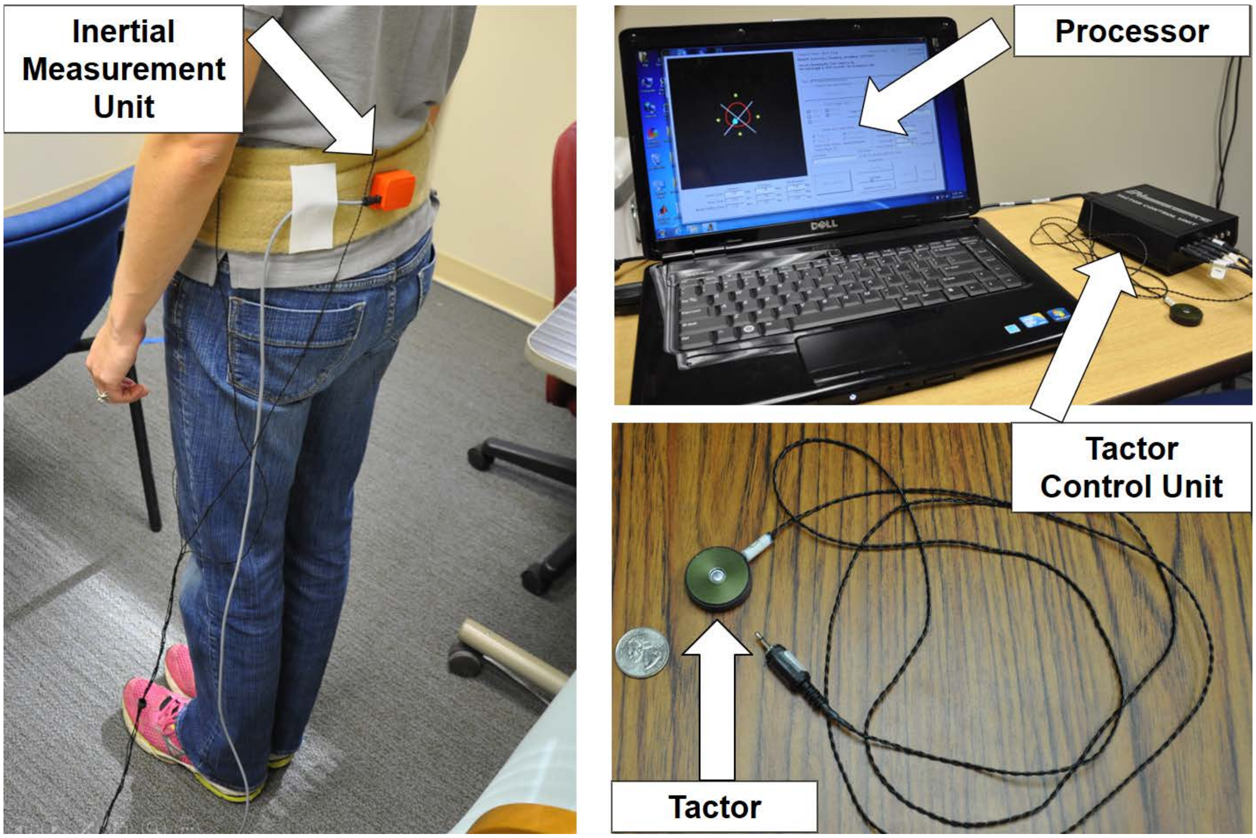

Figure 2. Vibrotactile device

2.2.8.1 Inertial measurement unit (IMU)

Body tilt was detected by a sensor (Xsens Technologies B.V., Enschede, The Netherlands; MTx-28A53G25) which was secured to the posterior aspect of a belt encircling the L4-5 trunk region of the participant. The IMU sensor was comprised of a linear accelerometer, a gyroscope, and a magnetometer.

2.2.8.2 Tactors

The vibration was applied through the four tactors (Engineering Acoustics, Inc, FL, USA). Using the trunk based belt, an anterior, posterior, and two lateral tractors were firmly positioned next to the participant’s body. The tactors vibrated when the participant exceeded a pre-determined threshold and the participant was trained to make corrective trunk tilt responses based on the feedback they received. The thresholds were determined through pilot testing involving repeated trials of every exercise by study team members at the University of Pittsburgh and the University of Michigan. The thresholds for each of the exercise categories are listed in Table 2. The trunk tilt data collected during the pilot testing along with the advice provided by the team members who performed the exercises at different activation thresholds served as determinants for the thresholds used in this study. The vibration was within a 200-300 Hz range which is within the 40-250 Hz range of the Pacinian corpuscle sensitivity.

Table 2. Vibrotactile feedback activation thresholds for the exercise categories within the balance training protocol

		Tactor Activation Thresholds		
Exercise Category	**Foot Position/*Surface***	**Anterior**	**Posterior**	**Right/Left**
Standing on *Firm* Surface	FA; FT; STR	2.00°	1.00°	1.50°
	Tandem; SLS	2.00°	2.00°	2.00°
Standing on *Foam* Surface	FA; FT	2.00°	1.00°	1.50°
	STR	2.50°	1.50°	2.00°
	Tandem	2.50°	2.00°	2.00°
Weight-shifting	FA *Firm; Foam*	1.00°	1.00°	1.00°
Modified Center of Gravity	FA; FT; STR *Firm; Foam; Ramp*	2.00°	4.00°	1.50°
Gaze Stabilization	FA; FT; STR; Tandem *Firm; Foam*	3.00°	1.00°	2.00°

FA = feet apart; FT = feet together; STR = semi-tandem romberg; SLS = single leg stance
Ramp in modified center of gravity exercise category on 10 degree incline or 10 degree decline

2.2.8.3 Tactor Control Unit and Computer Processor

The computer processor was coded using a custom-made software program in Microsoft Visual Studio 2012, and the tactor control unit was acquired from Engineering Acoustics (Engineering Acoustics, Inc, FL, USA). The software program uses the data from the inertial measurement unit to determine sway position and velocity. The angular position plus 0.5 sec times the angular velocity was used as the control signal to determine the activation of the tactor. If the control signal exceeded the pre-determined elliptical-shaped threshold, one of the four tactors were activated in the direction corresponding to the trunk sway beyond the threshold (anteriorly, posteriorly, laterally). The thresholds for tactor activation varied amongst the different exercise categories as some categories incorporated a dynamic movement (i.e. modified center of gravity). The tactor stopped vibrating when the control signal returned to within the elliptical threshold.

2.2.9 Procedures

All balance assessment sessions were conducted at the University of Pittsburgh Medical Center (UPMC) Oakland Balance Laboratory with most of the training sessions taking place within the Balance Laboratory. For participants who were eligible and willing to participate but unable to travel to the clinic for training sessions, home training was offered. Only one participant who was randomized into the control group within the bilateral vestibular hypofunction diagnostic category completed the home training. For home training, the clinician provided the standard supervised and individualized balance training study protocol.

2.2.9.1 Screening

If inclusion/exclusion criteria were met, participants were consented to the study and a physical screen was completed to determine eligibility. The cc was completed for all participants. For the subgroup of participants with peripheral neuropathy, Semmes Weinstein monofilament testing was performed.

2.2.9.2 Training sessions

The balance training protocol was consistent for the experimental and control groups. Within every training session, participants completed six repetitions lasting 30 seconds each, for all of the six different exercise categories. The six exercise categories included the following types of activities: 1) firm surface static standing, 2) foam surface static standing, 3) gait, 4) standing while the center of gravity is perturbed, 5) vestibulo-ocular reflex exercises, and 6) weight shifting tasks. Additionally, 3 trials of saccadic eye exercises were completed in the same stance that the VOR exercises were performed because saccades are considered to be an important strategy in facilitating adaptation [93]. When a complex background was introduced as a variable in a gaze stability exercise, an 8.5 by 11.0 inches checkerboard scene was used. This horizontal landscape consisted of 9 rows and 7 columns of alternating black and white rectangles measuring 1 3/8 inch in length by 7/8 inch in height. The duration of the training session was approximately 45-60 minutes. Participants with peripheral neuropathy did not complete the gaze stabilization exercises.

A published conceptual framework in which to progress balance exercises during a training program was used in our study [17]. This framework includes a ranked ordering of exercises from least to most difficult as different variables are manipulated to alter the challenge of the exercise within each exercise category. Examples of how the exercise is altered to increase challenge includes: narrowing the foot stance position from feet apart to feet together, or completing the exercise with eyes closed compared to eyes open. The six exercise categories (standing on firm surface, standing on foam surface, weight shifting, modified center of gravity, gaze stabilization, and gait) have slightly different types and total number of exercise variations within the category.

For standing of firm surface and standing on foam surface, there were a total of 30 different possible exercises (see Appendix A). The weight shifting exercise category had a total of 32 different exercise variations (see Appendix A). There were 144 possible exercise variations within the modified center of gravity exercise category (see Appendix A). Within the gait training exercise category there were only 17 different exercises (see Appendix A) that could be chosen and the gaze stabilization exercise category had 48 exercise variations (see Appendix A). The exercise labeled as “number 1” was anticipated to be the easiest within the category and the highest number was anticipated to be the most difficult. The ordering of the specific exercises in the framework for each category was determined by available literature, interviews and focus group discussions with physical therapists and postural control experts, and pilot studies of repeated trials of each exercise where sway data was collected.

Participants were progressed within each exercise category based on their performance in the session prior, which was intended to provide an individualized intensity dosage. For the first balance training session, the physical therapist made a “best guess” as to where to start the participant within each category. The physical therapist who determined the starting point was a board certified neurologic clinical specialist with 12 years of clinical experience. The exercises for all future training sessions were determined by following progression rules that were established by the research team. These rules incorporated a 1-5 rating by the participant on their perceived level of balance challenge during the exercise category in the preceding session, and a 1-5 rating by the physical therapist on the observed balance performance of the participant based on their independence level. The participants rating scale was adapted from a scale developed at the Cleveland Clinic [193] and the physical therapist rating scale was adapted from the Functional Independence Measure (FIM) [194] (Figure 3).

Participant Rating			PT Rating from Observation
I feel completely steady	1	1	Independent with no sway
I feel a little unsteady or off-balance	2	2	Supervision with minimal sway
I feel somewhat unsteady or like I may lose my balance	3	3	Close Supervision with moderate sway
I feel very unsteady or like I definitely will lose my balance	4	4	Requires P.T. assist (or step out) after 15 sec.
I lost my balance	5	5	Unable/Falls with immediate assist/step out < 15 sec.

Figure 3. Balance rating scale for the participant and the physical therapist

If the participant and the physical therapist rated an exercise at a "1" or a "2", the participant would be progressed 2 levels within that exercise category the next session. If the participant and the physical therapist rated the exercise as "3", the exercise would be repeated for that category during the next session. Participants would be moved back 1 level to an easier exercise within the category if the participant and physical therapist rated the exercise at a "4" or a "5". If the participant and physical therapist ratings differed, the physical therapist rating was used to determine the progression.

Each participant completed two 30 second trials of a "normalization" exercise (semi-tandem Romberg stance with eyes closed) to start and end the session. The purpose of the normalization exercise was to examine postural stability changes over time by tracking the RMS sway for a single exercise over the course of the 18 training sessions. Additionally, the completion of the same exercise at the beginning and at the end of the training session allowed for determination of whether fatigue impacted performance towards the end of the session.

Vibrotactile feedback was not applied during the normalization exercise trials. The two groups followed the same training protocol, except that the experimental group received one 15-minute training session to learn how to use the vibration inputs during the balance exercises. Participants in the experimental group received VTF during 4 out of the 6 trials for each of the exercise categories to promote motor learning, except for the gait category where no feedback was provided. Feedback was not provided during the gait trials because it is not yet known how to apply the feedback meaningfully other than in tandem gait [104].

2.2.9.3 Assessment sessions

The dependent variables (ABC, DHI, gait velocity, DGI, FGA, SOT, Mini-BESTest, FTSTS, TUG, and Functional Reach) were collected at baseline, after the 9^{th} visit, within 1-week post-training completion, 1-month post-training completion, and 6-months post-training completion. These sessions were separate visits from the training sessions and lasted approximately 90 minutes. The performance-based functional outcome measurements were collected by a physical therapist blinded to group assignment. Rest breaks were allocated between outcome measures with a duration dependent on each participants preference. The order of each outcome measure completed was randomized each visit.

2.2.1 Statistical analysis

Statistical analysis was completed using IBM SPSS Statistics 22. Group differences were investigated, and a mixed ANOVA was used to analyze the data. A significance level of $p = .05$ was used for the repeated measures analysis variance (ANOVA). The assumptions of normality and compound symmetry were tested. To test normality, the Shapiro-Wilk p values for the dependent variables measured on continuous scales were examined and p-values greater than .05 were considered to have a normal distribution. Histograms, boxplots, and q-q plots were examined for outliers. Means, standard deviations, percentiles, and ranges were also examined. The independent variable was group and the dependent variables were the outcome measures. Last-Observation-Carried-Forward (LOCF) method [195] was utilized as we had 2 participants drop out of the study prior to the mid-way assessment session. Additionally, paired-samples t-tests were conducted to compare the mean RMS trunk sway in the normalization exercise trials in pre-training and post-training for each participant so that the effect of fatigue could be explored.

To determine whether the participants who received vibrotactile feedback during training made faster improvements compared to the group who did not receive feedback during balance training, the interaction effects were explored using a mixed model analysis of variance. Compound symmetry was assessed using a significance of $p < .001$ for Box's M and $p < .05$ for Mauchley's test of sphérecity [196]. The dependent variables were the functional outcome measures, while the between subject variable was group allocation (control or experimental) and the within subject variable was assessment time-point (baseline, midway, and immediate post-training).

2.3 RESULTS

Figure 4 illustrates the recruitment flow for our study. Of the 63 potential participants that were phone screened, 36 were ineligible for reasons such as history of a total joint replacement (n=8), lack of interest (n=7), not meeting diagnostic criteria (n=7), unwillingness to commit to the training schedule (n=5), already enrolled in physical therapy (n=4), older than 80 years of age (n=3), and the presence of central nervous system pathology (n=2). There were 7 people excluded secondary to MOCA scores <26/30 during the clinical screen. A total of 20 participants initiated the training program of the study and two of those participants dropped out of the study. One participant had an unrelated orthopedic injury and the other had personal circumstances that prevented her from consistently attending the training sessions. Intention to treat was utilized during our analysis and reflected throughout the results.

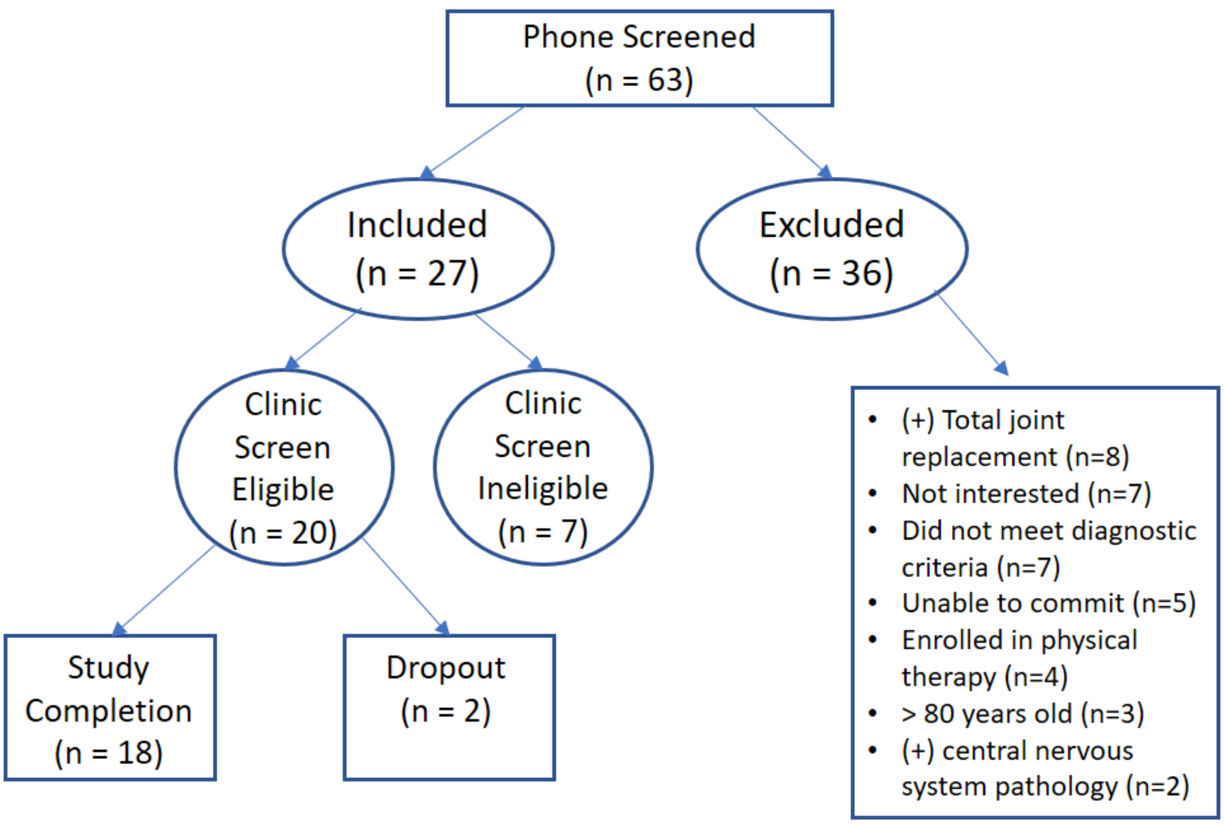

Figure 4. Study flow chart

The participants were categorized into four diagnostic categories and the demographic characteristics of each category are displayed in Table 3. The sample was predominantly female with a mean age of 66.7 ± 9.7 years. The experimental and control groups were similar at baseline in their balance and function as demonstrated by their performance measures obtained prior to initiating the training program (Table 4).

Table 3. Demographic characteristics of study sample

	Unilateral Vestibular Hypofunction (n=9)	Bilateral Vestibular Hypofunction (n=3)	Peripheral Neuropathy (n=5)	Older Adult with Balance disorder (n=3)	Total (n=20)
Female % (n)	78% (n=7)	100% (n=3)	60% (n=3)	33% (n=1)	70% (n=14)
Age (mean ± SD)	66 years ± 8.8	74.6 years ± 3.2	62.5 years ± 13.1	68.2 years ± 9.2	66.8 years ± 9.7
Co-morbidities					
Arthritis	6 out of 9	1 out of 3	2 out of 5	1 out of 3	50% (n=10)
Anxiety	1 out of 9	1 out of 3	1 out 3		15% (n=3)
Aortic Valve disorder		1 out of 3			5% (n=1)
Cancer – Breast	1 out of 9		1 out of 5		10% (n=2)
Cancer – Skin		1 out of 3	1 out of 5		10% (n=2)
Cataract		1 out of 3	1 out of 5		10% (n=2)
COPD			1 out of 5		5% (n=1)
Depression	5 out of 9	1 out of 3	2 out of 5	3 out of 3	55% (n=11)
Diabetes	2 out of 9			1 out of 3	15% (n=3)
Fibromyalgia			1 out of 5		5% (n=1)
Glaucoma		1 out of 3			5% (n=1)
Hypercalcemia			1 out of 5		5% (n=1)
Hypocholesteremia	1 out of 9				10% (n=2)
Hyperlipidemia	1 out of 9	1 out of 3	2 out of 5	1 out of 3	25% (n=5)
Hypertension	4 out of 9	2 out of 3	3 out of 5	2 out of 3	55% (n=11)
Macular degeneration	1 out of 9				5% (n=1)
Migraine	1 out of 9		1 out of 5		15% (n=3)
Osteoporosis	1 out of 9	1 out of 3		1 out of 3	15% (n=3)
Rheumatoid Arthritis		1 out of 3			5% (n=1)
Spinal stenosis			2 out of 5		10% (n=2)
Spine surgery			2 out of 5		10% (n=2)
Thyroid disorder	3 out of 9		2 out of 5	1 out of 3	30% (n=6)
Montreal Cognitive Assessment Score (mean ± SD)	27.78 ± 1.64	26.67 ± 1.47	28.6 ± 0.89	26.33 ± 0.58	27.6 ± 1.47

Table 4. Descriptive statistics of experimental and control group pre-training performance measures

	Control Group (n=9)	Experimental Group (n=11)	Total (n=20)
Activities-specific Balance Confidence	70 ± 19	73 ± 14	72 ± 16
Dizziness Handicap Inventory	38 ± 24 (n=5)	36 ± 24 (n=7)	37 ± 23 (n=12)
Gait Velocity (m/sec)	0.98 ± 0.22	0.97 ± 0.20	0.98 ± 0.21
Dynamic Gait Index ┼	18 ± 4	18 ± 3	18 ± 3
Functional Gait Assessment	19 ± 5	19 ± 5	19 ± 5
Sensory Organization Test	52 ± 16	56 ± 18	54 ± 16
Mini-BESTest	21 ± 5	19 ± 4	20 ± 4
Five time sit to stand (sec)**	14.7 ± 4.4 (n=8)	13.5 ± 2.4 (n=10)	14.0 ± 3.3 (n=18)
Timed up and Go (sec)	11.94 ± 2.05	11.45 ± 2.88	11.67 ± 2.49
Functional reach (inches)	11 ± 3	13 ± 2	12 ± 3

** Five time sit to stand has total n=18 because two participants were unable to complete the test as it was too difficult (one participant was in the control group and one participant was in the experimental group)

┼ Dizziness Handicap Inventory only reported for participants with vestibular diagnoses

When we analyzed the data for all the study participants using independent samples t-tests, there were statistically significant improvements from immediately post- to pre-training for gait velocity, DGI, FGA, SOT, Mini-BESTest, and Functional Reach test outcomes (Table 5) and there were statistically significant improvements from six-month post- compared to pre-training for the SOT, Mini-BESTest and the FTSTS (Table 6). The mean scores for each of the different outcome measures are illustrated by diagnostic group at baseline, post-training, and 6-months post-training in Figures 5-14.

Table 5. Mean paired t-test scores for each outcome measures from immediately post- to pre-training for all participants (n=20) with application of intention to treat

	Difference Mean	Std. Dev	St. Error Mean	t	df	Sig. (2-tailed)
Activities-specific Balance Confidence	-0.75	10.06	2.25	-.334	19	.742
Dizziness Handicap Inventory (n=12) ┼	-4.00	19.09	5.51	-.726	11	.483
Gait Velocity (m/sec)	0.08	.09	0.02	4.18	19	.001
Dynamic Gait Index	1.55	2.59	0.58	2.68	19	.015
Functional Gait Assessment	2.10	2.73	0.61	3.44	19	.003
Sensory Organization Test	7.50	9.15	2.05	3.67	19	.002
Mini-BESTest	2.00	3.34	0.75	2.68	19	.015
Five times sit to stand (sec)	-0.59	2.11	0.51	-1.16	16	.264
Timed up and Go (sec)	-0.95	2.43	0.54	-1.74	19	.097
Functional reach (inches)	1.28	1.48	0.33	3.88	19	.001

┼ Dizziness Handicap Inventory only reported for participants with vestibular diagnoses

Table 6. Mean paired t-test scores for each outcome measures from 6-month post- to baseline for all participants (n=20) with application of intention to treat

	Difference Mean	Std. Dev	St. Error Mean	t	df	Sig. (2-tailed)
Activities-specific Balance Confidence	0.75	11.68	2.61	0.29	19	.777
Dizziness Handicap Inventory (n=12) ┼	-0.67	17.25	4.98	-0.134	11	.896
Gait Velocity (m/sec)	0.05	0.12	0.03	1.93	19	.069
Dynamic Gait Index	0.85	2.87	0.64	1.32	19	.201
Functional Gait Assessment	1.05	2.84	0.63	1.66	19	.114
Sensory Organization Test	8.65	8.79	1.97	4.40	19	<.001
Mini-BESTest	1.55	3.00	0.67	2.31	19	.032
Five times sit to stand (sec)	-2.02	3.17	0.75	-2.70	17	.015
Timed up and Go (sec)	-0.47	2.17	0.48	-0.97	19	.346
Functional reach (inches)	0.55	1.97	0.44	1.26	19	.223

┼ Dizziness Handicap Inventory only reported for participants with vestibular diagnoses

When we investigated whether the participants in the study achieved minimally clinically important differences (MCID) or minimal detectable changes (MDC) in the functional outcomes that showed statistically significant changes from pre- to post-training (Table 7), we found that every participant had at least one MCID that was achieved during training compared to pre-training scores. Nine of the participants attained an MCID or MCD in three or more of the functional outcomes investigated (FGA and functional reach tests were not included as MCID/MDC are not established for the populations in this study).

Table 7. Minimally clinically important differences for all participants in baseline to post-training outcome measures

	Gait Velocity training change (from baseline score)	DGI training change (from baseline score)	SOT training change (from baseline score)	Mini-BESTest training change (from baseline score)
UVH Control 1	+ 0.07 (from 1.17)	+ 1 (from 23)	+ 3 (from 75)	+ 2 (from 25)
UVH Control 2	+ 0.36 (from 0.58)	(-) 2 (from 17)	+ 8 (from 71)	0 (from 25)
UVH Control 3	+ 0.03 (from 0.86)	+ 2 (from 19)	+ 8 (from 45)	+ 2 (from 22)
UVH Control 4	+ 0.17 (from 0.98)	+ 4 (from 17)	+ 26 (from 48)	+ 5 (from 21)
UVH Exp 1	+ 0.31 (from 1.17)	+ 3 (from 21)	+ 4 (from 74)	+ 1 (from 25)
UVH Exp 2	+ 0.27 (from 1.04)	+ 3 (from 18)	+ 8 (from 63)	+ 9 (from 18)
UVH Exp 3	+ 0.12 (from 1.23)	+ 1 (from 21)	+ 7 (from 66)	+ 3 (from 23)
UVH Exp 4	+ 0.01 (from 1.06)	+ 1 (from 21)	+ 18 (from 63)	+ 4 (from 21)
BVH Control 1	+ 0.09 (from 0.86)	(-) 1 (from 14)	+ 9 (from 33)	+ 2 (from 11)
BVH Exp 1	+ 0.06 (from 0.91)	+ 1 (from 19)	+ 5 (from 35)	+ 5 (from 16)
BVH Exp 2	+ 0.15 (from 0.81)	+ 2 (from 17)	+ 13 (from 30)	+ 1 (from 18)
OA Control 1	(-) 0.02 (from 1.07)	+ 7 (from 14)	+ 29 (from 32)	+ 3 (from 18)
OA Control 2	+ 0.15 (from 1.11)	+ 1 (from 22)	+ 11 (from 65)	(-) 1 (from 23)
OA Exp 1	+ 0.01 (from 0.99)	+ 3 (from 17)	+ 8 (from 63)	+ 4 (from 19)
PN Control 1	+ 0.21 (from 0.84)	+ 3 (from 15)	+ 12 (from 43)	+ 2 (from 18)
PN Exp 1	+ 0.11 (from 0.70)	+ 3 (from 15)	+ 13 (from 36)	+ 4 (from 13)
PN Exp 2	+ 0.30 (from 1.15)	+ 2 (from 22)	+ 4 (from 72)	+ 2 (from 24)
PN Exp 3	+ 0.10 (from 0.60)	+ 2 (from 12)	+ 14 (from 38)	+ 6 (from 12)
MCID's (highlighted)	>0.1m/sec	2 pts (DGI < 21) 1 pt (DGI ≥ 21)	8 pts (MDC)	4 pts

DGI = Dynamic Gait Index; SOT = Sensory Organization Test; UVH = Unilateral Vestibular Hypofunction; BVH = Bilateral Vestibular Hypofunction; OA = Older Adult; PN = Peripheral Neuropathy; Exp = Experimental group; MCID = minimally clinically important difference; MDC = minimal detectable change
**MCID/MCD denoted with yellow highlighting

Figures 5 – 14 show the mean scores for each of the outcome measures by diagnostic category at three timepoints. Visual inspection of the two subjective outcome measures (ABC in Figure 5 and DHI in Figure 6), show that two of the larger changes occurred within the bilateral vestibular hypofunction diagnostic group with decreased balance confidence and increased dizziness handicap reported between the post-training and 6-month follow-up timepoints. At 6-months post-training, the mean score for the dizziness handicap inventory increased from 39/100 following training to 53/100 at the 6-month post-training follow-up (Figure 6) for the bilateral vestibular hypofunction diagnostic group. All three of the participants with bilateral vestibular hypofunction had similar increases noted (38/100 to 48/100, 40/100 to 68/100, and 38/100 to 42/100), indicating that their subjective dizziness was worse.

Gait velocity (Figure 7), DGI (Figure 8), and FGA (Figure 9) all show an overall trend for performance to improve from pre- to post-training amongst all diagnostic groups. Gait velocity in the older adults and DGI for bilateral vestibular hypofunction groups both showed continued improvements following training until the 6-month follow-up, but otherwise the scores showed a decrease back towards baseline. It appears that the mean functional improvements in the sensory organization test for each diagnostic group were maintained at the 6-month follow-up better than the other functional outcomes with little decrease from post-training to 6-month follow-up (Figure 10).

With the sensory organization test (Figure 10) and the Mini-BESTest (Figure 11) the people with bilateral vestibular hypofunction had mean scores that were worse than the other diagnostic groups. The mean scores for the Timed Up and Go test did not improve for either of the vestibular diagnostic groups from pre- to post-training (Figure 12). The Five Time Sit to Stand (Figure 13) did not include the diagnostic category of bilateral vestibular hypofunction because two of the three participants in this group were unable to complete the test because it was too difficult for them to do without upper extremity assistance. For the other three diagnostic groups, the mean scores appeared to continue to improve from post-training to the 6-month follow-up timepoint.

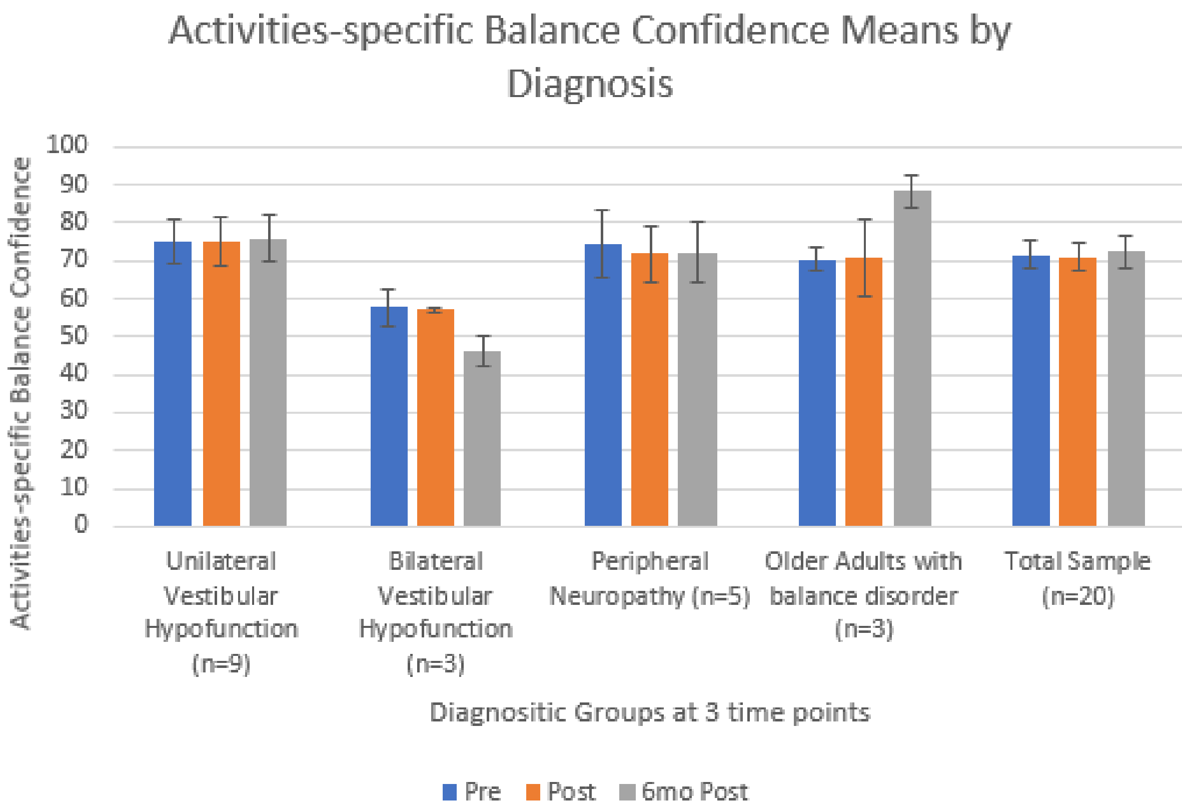

Figure 5. Activities-specific balance confidence mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

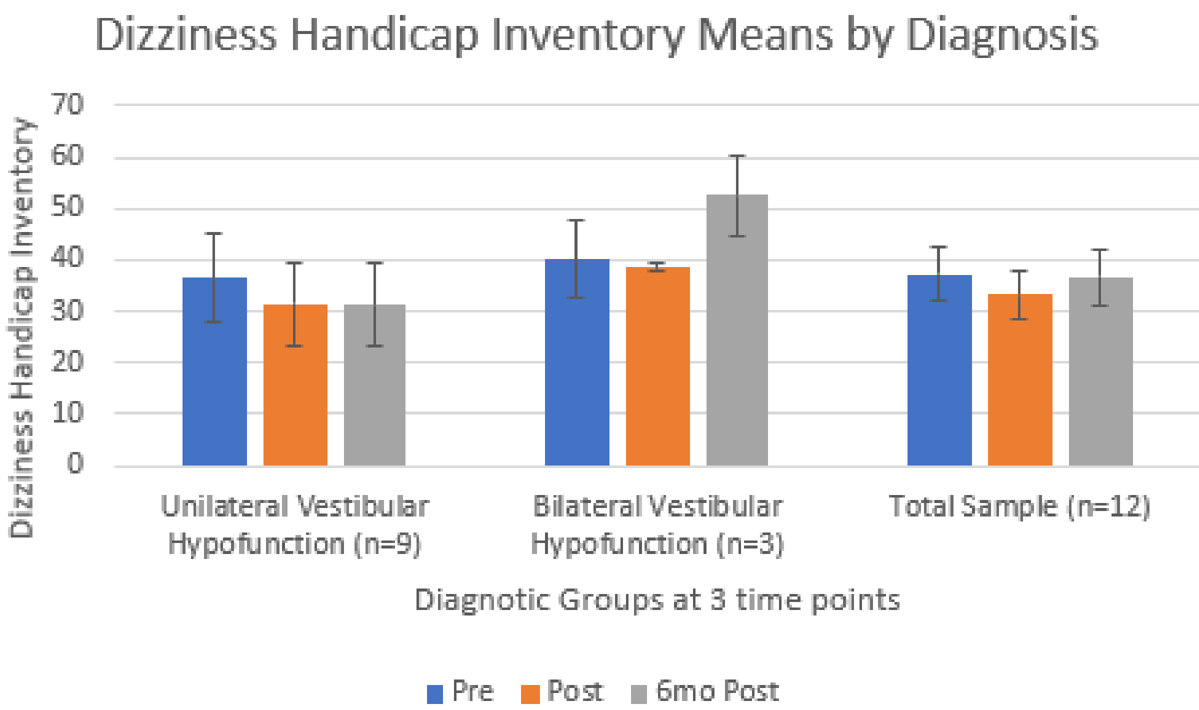

Figure 6. Dizziness handicap inventory mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

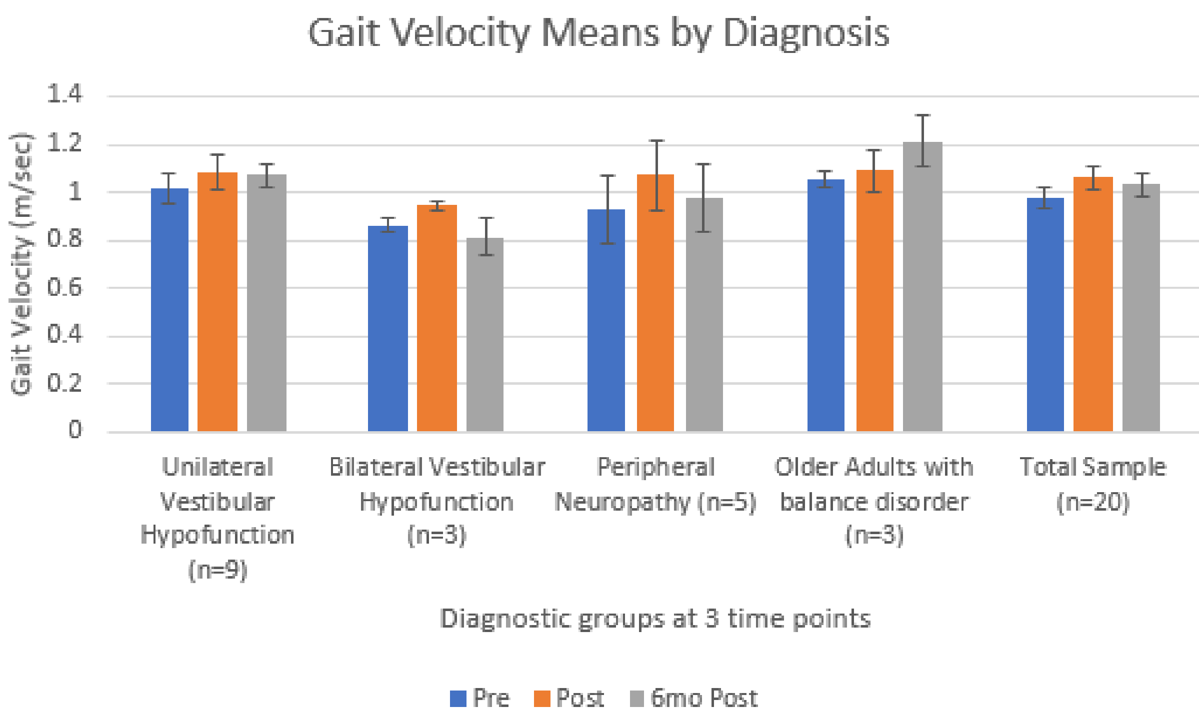

Figure 7. Gait velocity mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

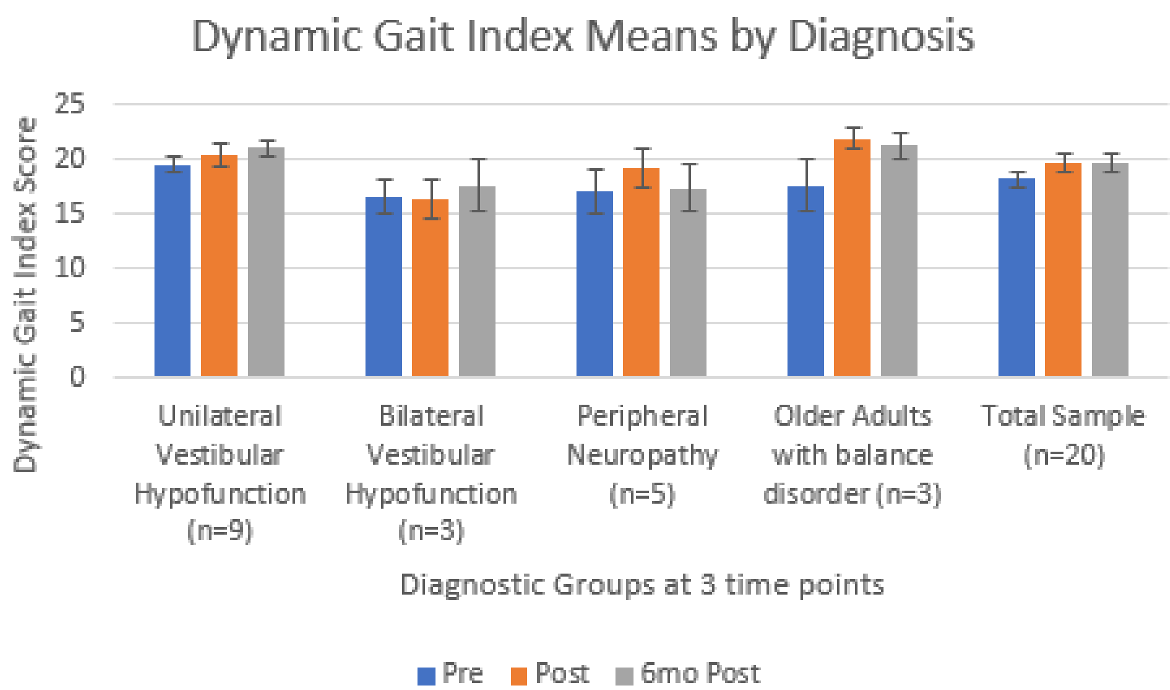

Figure 8. Dynamic gait index mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

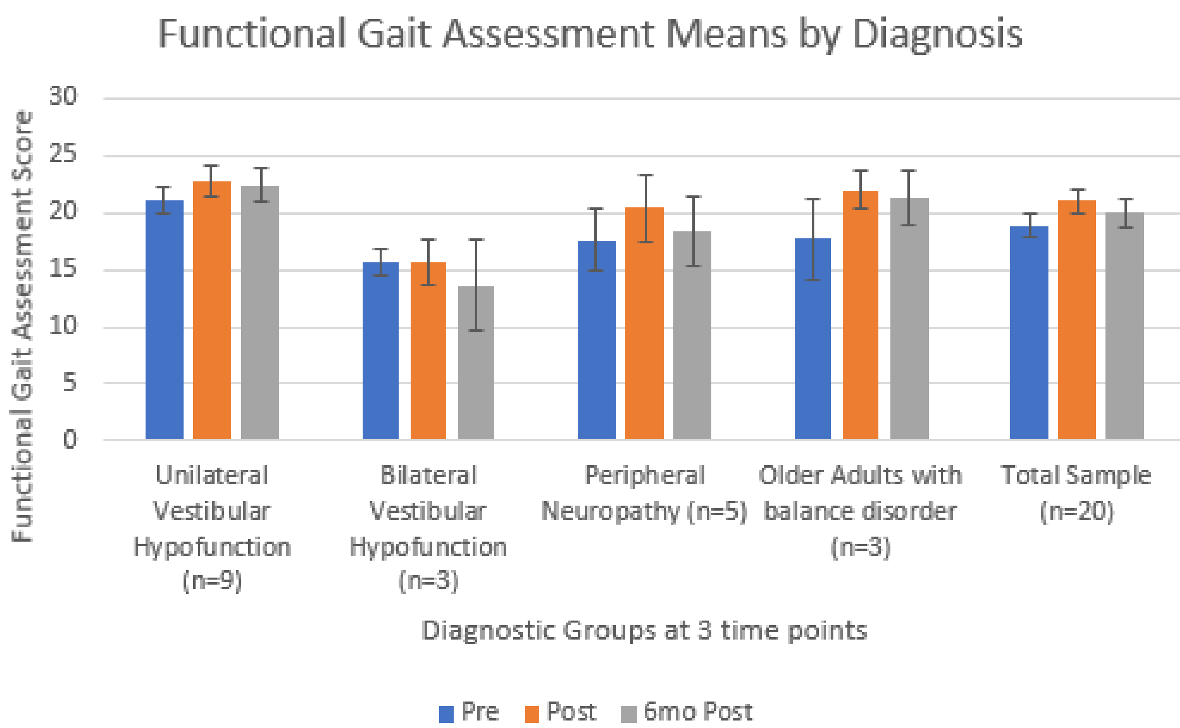

Figure 9. Functional gait assessment mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

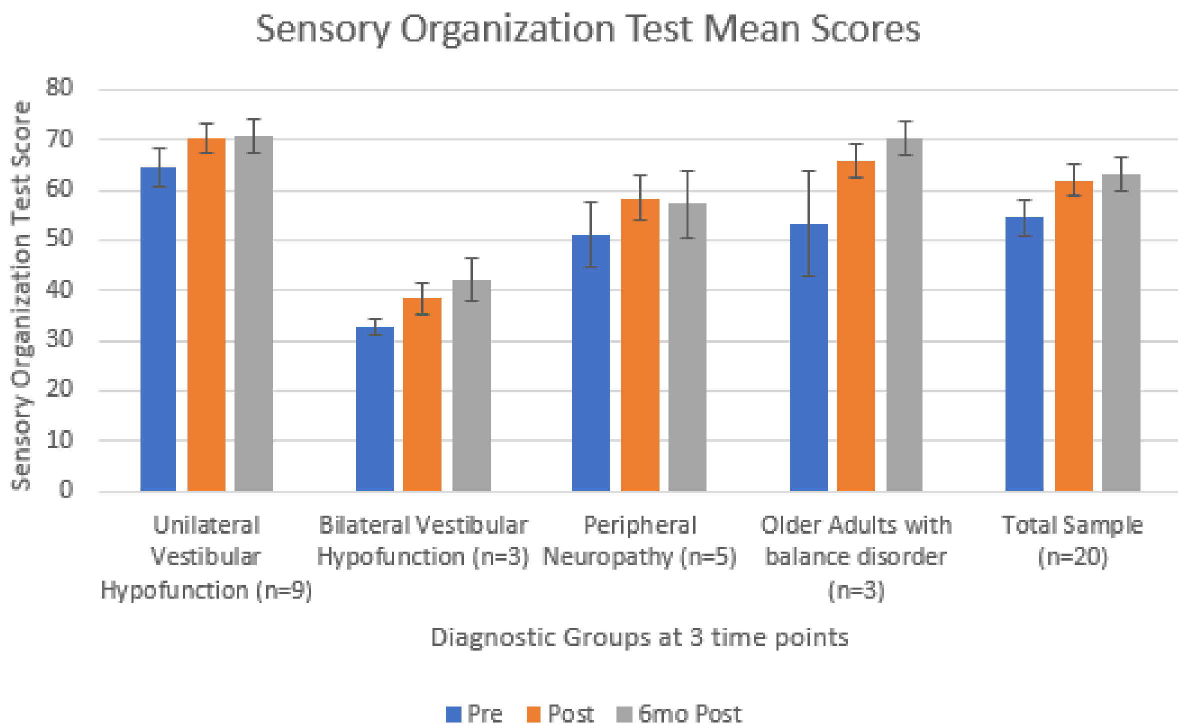

Figure 10. Sensory organization test mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

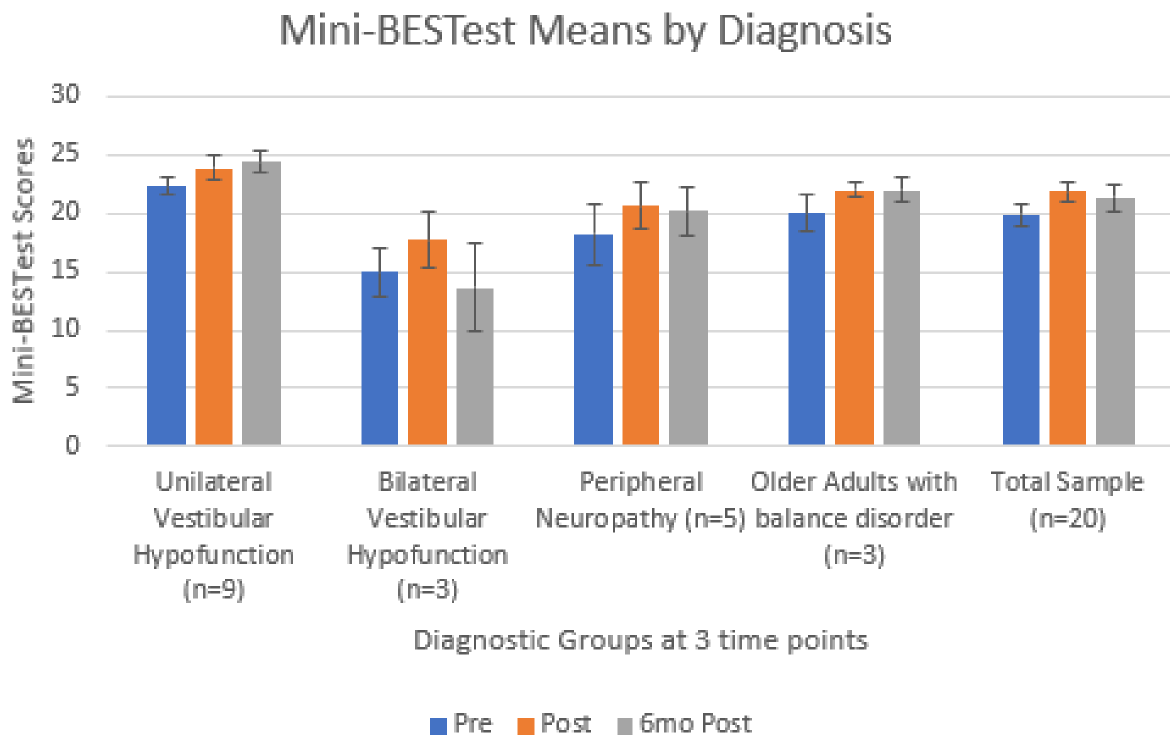

Figure 11. Mini-BESTest mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

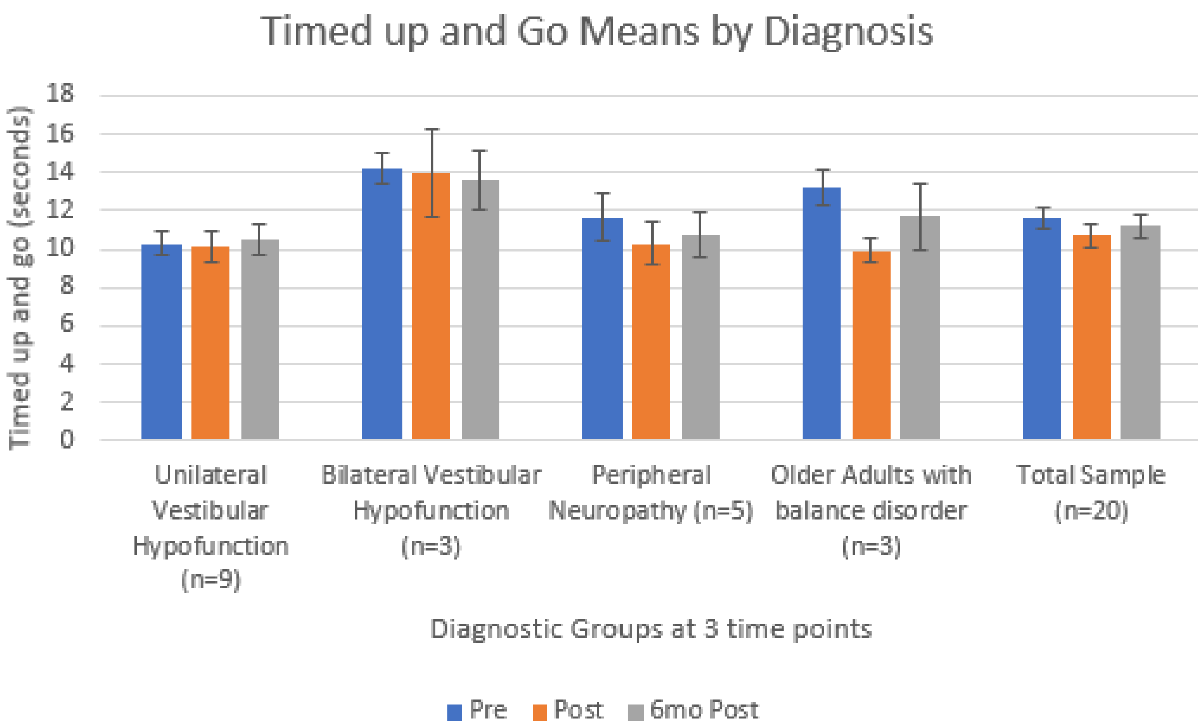

Figure 12. Timed Up and Go test mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

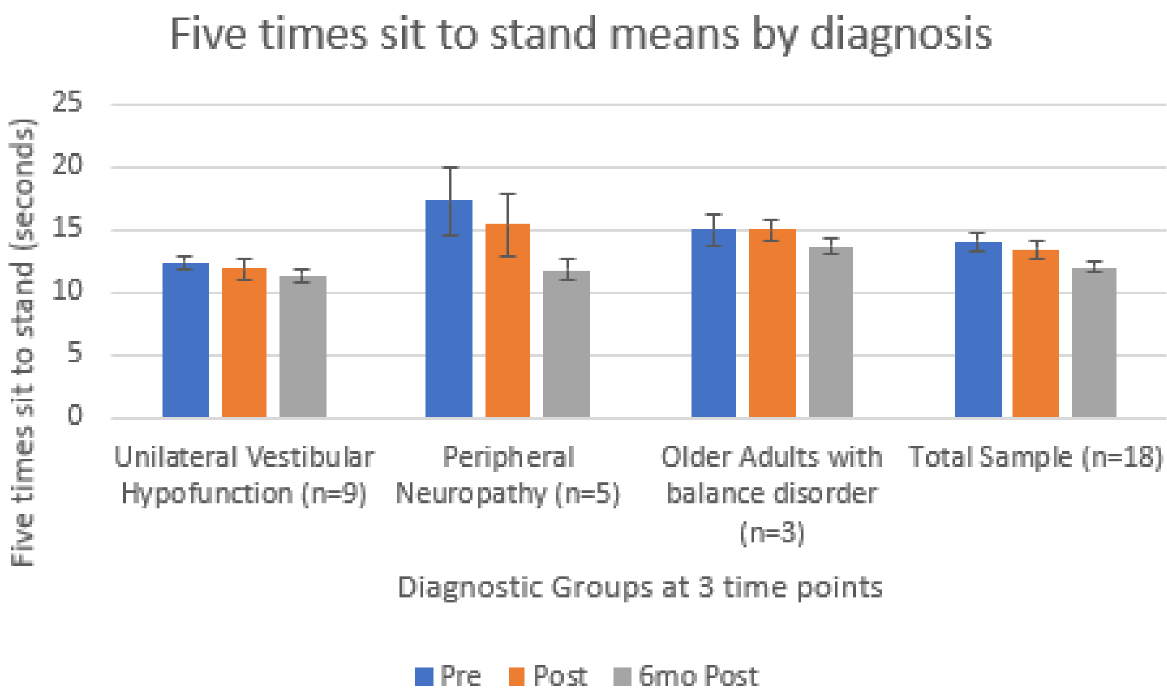

Figure 13. Five times sit to stand test mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

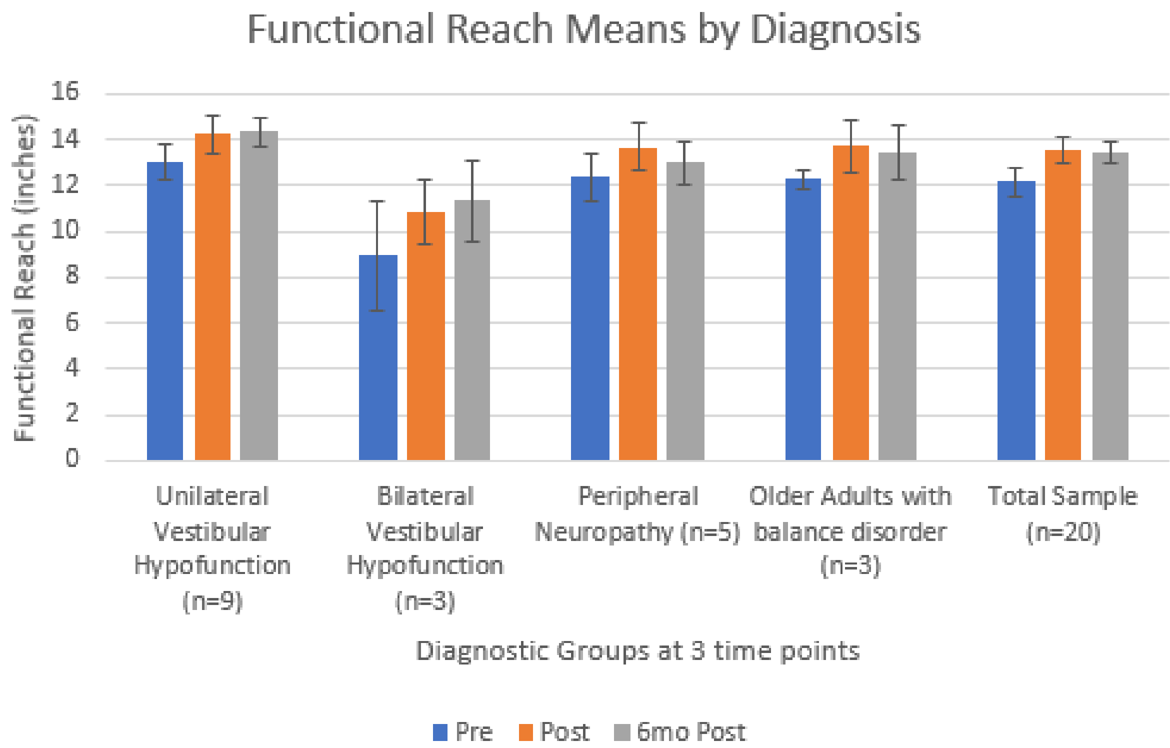

Figure 14. Functional reach test mean scores by diagnosis at pre-training, post-training, and 6-months post-training (error bars denote standard error)

In addition to the clinical outcome measures, we also collected root mean square of trunk tilt during two "normalization" exercise trials to begin and end every training session for all the participants except for the first three who initiated the study. As described earlier, the normalization exercise was completed on a firm surface in the semi-tandem Romberg stance with eyes closed. Each of the four trials (two in the beginning and two at the end of the training session) were 30 seconds in duration. The purpose of this was to monitor the possible impact of fatigue within a training session. If the participant experienced fatigue, we would expect that their RMS sway would increase in the post-training normalization exercise trials compared to the pre-training normalization exercise trials. The results of the paired-samples t-test that were conducted to compare the mean RMS trunk sway in the normalization exercise trials in pre-training and post-training are presented in Table 8. For each participant the average of the two pre- and post-training normalization exercises were calculated and the mean RMS trunk sway for the normalization exercises over the 18 balance training sessions were used for the paired-samples t-test. Fatigue did not appear to influence our results as the six participants (out of 15) who had significant differences in pre- to post-training mean RMS trunk sway calculated from pair-samples t-test analysis had improved postural stability during the post-training normalization exercise. This indicated that postural stability was better at the end of the session for 40% of the sample.

Table 8. Paired-samples t-test scores of RMS trunk sway during pre- and post-training normalization exercise trials for each participant

Participant ID	Pre-training Norm Ex RMS Mean, SD	Post-training Norm Ex RMS Mean, SD	Norm Ex RMS Mean difference, SD	t	df	Significance
UVH Control 2	4.12 ± 2.09	4.11 ± 2.08	0.01 ± 1.53	0.04	17	.967
UVH Control 3	1.39 ± 1.02	1.32 ± 0.47	0.07 ± 0.99	0.31	17	.760
UVH Control 4	1.23 ± 0.20	1.52 ± 0.56	- 0.29 ± 0.60	-2.04	17	.057
UVH Exp 1	2.20 ± 0.54	1.88 ± 0.40	0.32 ± 0.56	2.45	17	.025
UVH Exp 2	1.64 ± 0.66	1.32 ± 0.55	0.33 ± 0.97	1.43	17	.172
UVH Exp 3	3.60 ± 0.93	2.30 ± 1.08	1.30 ± 1.27	4.34	17	<.001
UVH Exp 4	3.67 ± 1.42	2.75 ± 1.08	0.92 ± 1.49	2.60	17	.019
BVH Control 1	2.46 ± 1.10	5.42 ± 9.21	-2.96 ± 9.20	-1.36	17	.191
OA Control 1	2.58 ± 1.65	2.34 ± 1.10	0.24 ± 2.14	0.48	17	.640
OA Control 2	1.10 ± 0.68	1.07 ± 0.72	0.33 ± 0.94	0.15	17	.880
OA Exp 1	2.19 ± 0.66	1.50 ± 0.45	0.69 ± 0.62	4.69	17	<.001
PN Control 1	3.77 ± 1.49	7.01 ± 12.05	-3.24 ± 11.46	-1.20	17	.247
PN Exp 1	3.33 ± 0.99	3.22 ± 0.69	0.11 ± 1.25	0.37	17	.719
PN Exp 2	1.18 ± 0.41	0.84 ± 0.40	0.34 ± 0.59	2.47	17	.025
PN Exp 3	3.05 ± 1.35	1.64 ± 0.79	1.41 ± 1.49	3.91	16	.001
Total	2.50 ± 1.49	2.55 ± 4.26	-0.05 ± 4.07	-0.21	268	0.835

**Norm ex = Normalization Exercise; UVH = Unilateral Vestibular Hypofunction; BVH = Bilateral Vestibular Hypofunction; OA = Older Adult; PN = Peripheral Neuropathy; Exp = Experimental group

Our first hypothesis for this study was that individuals who received VTF during rehabilitation would show greater improvements in functional outcome measurements compared to the individuals who received traditional balance and vestibular rehabilitation. We did not find any statistically significant differences between groups for any of the performance measures. The Mini-BESTest was the closest measure to reaching statistical significance but there was not a significant effect of group on Mini-BESTest score at the $p<.05$ level [$F(1, 18) = 3.46$, $p = 0.079$] using one way analysis of variance statistical testing (see Table 9).

Table 9. One-way analysis of variance results for group effect on functional outcome measures from post-training compared to baseline (n=20)

Functional Outcome Measure	F	Sig.
Activities-specific Balance Confidence	4.94	.039
Dizziness Handicap Inventory (n=12) †	0.35	.565
Gait Velocity	0.86	.366
Dynamic Gait Index	0.03	.861
Functional Gait Assessment	0.22	.646
Sensory Organization Test	0.13	.723
Five Time Sit to Stand Test	0.96	.344
Mini-BESTest	3.46	.079
Timed Up and Go	0.14	.715
Functional Reach	0.62	.440

† Dizziness Handicap Inventory only reported for participants with vestibular diagnoses

Secondly, we hypothesized that the participants in the experimental group who received VTF would improve faster than those that completed the balance training protocol in the control group. In a repeated measure analysis, comparison of within group mean differences at the different timepoints (baseline, midway through training, and immediately following training) were analyzed (Table 10). None of the performance outcomes yielded statistically significant interaction effects between the group allocation and the time which indicated that the experimental group did not improve faster than the control group. Main effects of time were observed in gait velocity, DGI, FGA, SOT, Mini-BESTest, and Functional Reach Test.

Table 10. Interaction effect between time (baseline, midway, immediately post-training) and group (control and experimental) on functional outcome measures; within group effect of time on functional outcome measures; and between group effect of group allocation on functional outcome measures

		Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Gait Velocity	Interaction Effect	0.01	2	0.003	0.53	.591	.029
	Within Groups	0.12	2	0.60	9.40	.001	.343
	Between Groups	.000	1	.000	0.002	.969	.000
DGI	Interaction Effect	1.98	2	0.99	0.40	.674	.022
	Within Groups	24.11	2	12.06	4.86	.014	.213
	Between Groups	2.34	1	2.34	0.07	.789	.004
FGA	Interaction Effect	3.34	2	1.67	0.59	.560	.032
	Within Groups	44.01	2	22.00	7.76	.002	.301
	Between Groups	0.59	1	0.59	0.01	.928	.000
SOT	Interaction Effect	112.03	2	56.01	1.82	.177	.092
	Within Groups	799.36	2	399.68	12.96	<.001	.419
	Between Groups	95.20	1	95.20	0.14	.710	.008
MB	Interaction Effect	17.09	2	8.54	2.46	.100	.120
	Within Groups	40.09	2	20.04	5.76	.007	.242
	Between Groups	1.82	1	1.82	0.04	.846	.002
FTSTS	Interaction Effect	2.13	2	1.07	0.42	.662	.027
	Within Groups	6.84	2	3.42	1.34	.276	.082
	Between Groups	1.26	1	1.26	0.17	.683	.011
TUG	Interaction Effect	2.43	2	1.22	0.57	.569	.031
	Within Groups	11.42	2	5.71	2.69	.082	.130
	Between Groups	4.33	1	4.33	0.30	.589	.016
FR	Interaction Effect	1.33	2	0.67	0.78	.464	.042
	Within Groups	22.47	2	11.23	13.26	<.001	.424
	Between Groups	44.78	1	44.78	2.73	.116	.132

DGI = Dynamic Gait Index; FGA = Functional Gait Assessment; SOT = Sensory Organization Test; MB = Mini-BESTest; FTSTS = Five Time Sit to Stand; TUG = Timed Up and Go; FR = Functional Reach

The final hypothesis of this study was that the individuals in the experimental group would maintain their functional changes longer than the control group following participation in the balance and vestibular rehabilitation program. Using a one-way analysis of variance, we found that the only outcome measure with statistical significance was gait velocity immediately following training to 6-months post-training [$F(1, 18) = 5.97$, $p = 0.025$], however it was the control group that had better maintenance of improved gait speed at 6-months post-training (Table 11).

Table 11. One-way analysis of variance statistical analysis results for group effect on functional outcome measures from 6-month post-training compared to immediate post-training (n=20)

Functional Outcome Measure	F	Sig.
Activities-specific Balance Confidence	0.61	.447
Dizziness Handicap Inventory (n=12) †	0.03	.861
Gait Velocity	5.97	.025
Dynamic Gait Index	0.37	.549
Functional Gait Assessment	0.26	.618
Sensory Organization Test	3.73	.069
Five Time Sit to Stand Test	.367	.553
Mini-BESTest	0.03	.875
Timed Up and Go	1.66	.214
Functional Reach	4.83	.051

† Dizziness Handicap Inventory only reported for participants with vestibular diagnoses

2.4 DISCUSSION

There was no difference in functional outcomes between the vibrotactile training group versus the exercise group following balance training in our sample. While the sample as a whole demonstrated improvement following the training program, the experimental group did not improve faster than the control group. Additionally, the gains that were achieved in functional outcomes were not maintained differently between the two groups. While this may indicate that the use of VTF during a training program does not result in superior outcomes, there were alternative explanations and study limitations to consider.

The following issues related to training effectiveness were considered: balance intensity dosage within the training program; lack of functional tasks within the training program; the effect of fatigue; and influence of each participant's activity and participation outside of the training program. In addition to the unanswered questions about how to best administer the vibrotactile feedback and the specific training dosing to optimize motor learning, it is important to discuss the possibility of group differences at baseline, and the multitude of factors that affect postural stability.

Training effectiveness. Given the convincing evidence supporting the effectiveness of balance and vestibular rehabilitation already published in the literature [55-63], it was not surprising that our study sample as a whole showed improvements following completion of the training program regardless of being in the control or experimental group. All of the participants achieved a minimally clinically important difference or minimal detectable change on at least one of the performance outcome measures. At baseline, 12/18 participants were considered at risk of falling based on their dynamic gait index scores (≤19/24) [197] and 58% of those people that had scores indicative of fall risk moved to a range of scores that suggested less risk of falling at the end of the intervention. This is interesting because all of the participants in our sample had chronic impairments and had previously undergone physical therapy. Similar to what others have shown, our results indicated that continued improvements can be made in people with chronic balance impairments with participation in a balance exercise program [58-60, 198]. However, we question whether or not our training program was prescribed at an adequate dose to achieve optimal training benefits.

Physical therapists are appreciating the importance of prescribing an exercise program that is of an appropriate intensity to achieve functional improvements that are important and it appears as though many older adults and people with chronic neurological disorders that have undergone physical therapy have not been trained at an adequate dose to achieve change [199-202]. The American Board of Internal Medicine Foundation initiated a campaign called "Choosing Wisely" in 2012 to put healthcare recommendation into practice [203] and in conjunction with this campaign, the American Physical Therapy Association released a list of five recommendations to provide evidence-based physical therapy [204]. Physical therapists are urged not to prescribe under-dosed strength training programs for older adults. The recommendation to match the frequency, intensity, and duration of exercise to the individual's ability and goals was stated.

Most of the research on exercise intensity has surrounded cardiovascular and resistance training exercise. Future research needs to investigate ways to measure balance intensity. Additional efforts in establishing guidelines for balance programs that include dose recommendations using the FITT principle (frequency, intensity, time, type) is beneficial for healthcare providers and consumers [205]. During the conception of this project, the intention was to create both an intense program that was individualized for each participant but that also followed a reproducible paradigm consistent with randomized control trial expectations. To do this, we followed progression rules which may have led to an under dosing of exercise intensity. While there is not a recommended intensity dosage for balance programs, other investigators have speculated that balance training in their study lacked effectiveness due to insufficient intensity [206].

Many of the other research trials that have investigated sensory augmentation during balance training programs have not been controlled, but may have been more intense than our balance training protocol. While the duration of our training sessions were 45-60 minutes per session, actual balance exercise for both groups was approximately 18 minutes (6 exercise categories of 6 repetitions were completed, each repetition was approximately 30 seconds). In a study that investigated the effects of electrotactile feedback, participants completed training for 60-90 minutes twice a day for three to four and half consecutive days [103]. Our 18 training sessions were spread out over a 6 week timeframe while some of the other studies completed their training in less sessions but over consecutive days [102, 121, 188]. The studies that have investigated balance training with sensory augmentation have greater variability in the total number of sessions completed in the training methods, ranging from 2 to 40 sessions with variable session duration [118, 207]. The variability within balance training prescription noted in past studies (frequency, intensity, type, time) most likely reflects the variability of balance and vestibular rehabilitation programs being prescribed in clinical practice.

The type of balance exercises included in our program were chosen so that meaningful sensory augmentation feedback could be applied to the participants in the experimental group which primarily consisted of static and dynamic standing tasks where the intent was to keep the center of mass stable. In neuro-rehabilitation, an emphasis is placed upon training that is task-specific to real-world activities [208, 209]. While the majority of research supporting task-specificity has been explored within stroke rehabilitation, it is most likely relevant across the spectrum of neuro-rehabilitation including balance and vestibular rehabilitation.

Studies have shown that repetition alone does not result in neuroplasticity that is associated with motor learning [210, 211]. It is suspected that in the clinical setting, physical therapists will talk to a patient with a balance disorder about their goals and then incorporate that functional task into the training program. This is something that was not included in our training program and may have affected the clinical outcomes and quality of life measures. It has been recommended that rehabilitation incorporates task-specific training that includes activities that are typically performed in everyday life that are intrinsically and extrinsically meaningful [209]. Our study participants may have been more engaged if the tasks were more relevant to their functional goals and perhaps further improvements in function and quality of life would have resulted.

We attempted to control for fatigue within the five balance assessment sessions by randomizing the order that all outcome measures were completed. During the balance training sessions, participants were able to take rest breaks as needed so we did not expect fatigue to impact performance during any of the exercise categories, regardless of whether they were completed in the beginning or end of the training session. To objectively measure if fatigue was impacting balance performance within the training sessions, we had every participant in our research study complete two trials of the same “normalization” exercise (semi-tandem stance with eyes closed for 30 seconds) to begin and end each session so that the sway during the normalization exercise trials at the end the session could be compared to the sway during the normalization exercise trials that were performed in the beginning of the session. It is not uncommon for older adults to experience increased postural sway related to fatigue during balance exercises [212, 213]. The analysis of the sway data for the normalization exercise did not indicate that fatigue significantly impacted our participants. Based on the results comparing the mean RMS trunk sway during the pre- and post-training normalization exercises, 40% of the sample demonstrated improved postural stability at the end of the session. While this improvement is promising relative to motor learning and performance effects from training, the inference that motor learning occurred cannot be made as motor learning represents a relatively permanent change with improvements that generalize to other tasks [214]. However, all six of the participants that had mean improvements in postural stability during the post- compared to pre-normalization exercise demonstrated minimally clinically important differences in DGI scores when comparing post- to pre-training scores (Tables 7-8) but most of the participants in the study (80%) demonstrated a minimally clinically important difference in the DGI. Interestingly, all six of the participants that displayed decreased sway in the post- compared to pre-normalization exercise were in the experimental group. Two participants in the experimental group did not display decreased mean sway in the post- to pre-normalization exercise analysis (Table 8).

Something that was not formally measured was each participant's activity and participation levels outside of their training. We purposefully did not assign a home exercise program during the study trial as we did not want compliance with the home exercise program to confound our results. However, some participants that were encouraged by their progress reported that they continued to practice some of the exercises that they completed during training sessions and some increased their walking and gym activities. The degree to which each participant engaged in physical activity outside of the balance training program and following the balance training program could have positively, or negatively, impacted our results.

Overall, in consideration of the effectiveness of VTF, our results were similar to other findings from investigations that have studied the short-term effects of completing balance training with sensory augmentation. In a study of seven people with bilateral vestibular loss who underwent 12 vestibular rehabilitation training sessions using electrotactile feedback applied to the tongue, participants showed improvements in pre- to post-training sensory organization test composite scores with mean improvements of 38.3 ± 8.7 to 59.9 ± 11.3 [102]. In our study, the three participants with bilateral vestibular loss showed mean SOT composite scores changes from 32.7 ± 2.5 to 38.3 ± 5.7, less than the changes reported by Barros et al. Another study reported improved SOT composite scores following 10 balance training session using electrotactile feedback in patients with bilateral vestibular loss (n=19) with reported mean improvement of 24 points for the group receiving the sensory feedback to the tongue [188]. To date, there have been a limited number of investigations exploring if sensory augmentation utilized during balance training programs improves functional outcomes. The balance training programs have not been standardized in these studies [102, 103, 118, 188]. Additionally, the retention of the functional gains had not been studied previously. The participants in our study had already undergone balance rehabilitation and this may explain why the gains from our training program were not as large as some of the other studies that investigated the effects of sensory augmentation during balance training.

VTF application. We believe that VTF is an attractive sensory augmentation modality for balance and vestibular training because it does not interfere with the wearer’s ability to see, hear, or speak. We also feel that the application to the trunk for feedback is advantageous because of the proximity to the center of mass and results have demonstrated that reaction time and spatial resolution at the trunk is effective for corrective trunk tilt response to feedback applied [113]. The literature also supports our decision to train participants to move away from the vibratory stimulus to achieve desired postural stability, known as repulsive cuing [120]

Currently the optimal threshold for activation of the feedback stimulus is unknown. Whether or not the threshold should change depending on the difficulty of the exercise, or as the balance training program progresses also needs to be determined. In our study, the pre-determined thresholds for activation were stable for every participant throughout the entire training program based on foot position, support surface, and exercise category. Some investigators suggest that there should be subject-specific bandwidths activation thresholds due to the variability in subject response to tactile feedback [186] [215].

Additionally, the optimal frequency of feedback is unknown. We provided feedback 66% of the time for each exercise category (4/6 trials) consistently throughout the training program, but maybe feedback should be provided every trial, or maybe it should be lessened as performance improves, which would follow motor learning principles [191]. Future work to determine the optimal frequency for providing sensory augmentation should be explored. Further investigation also should focus on determining how to use VTF during functional activities. The sensory augmentation in our study was only applied during standing balance activities as it is not yet known how to apply meaningful feedback during normal walking tasks.

Efforts have been initiated to investigate the cognitive load of using sensory augmentation during dual tasks to determine if people can process the feedback for postural stability. This is especially important for older adults who have been shown to have decreased balance during dual task conditions [216, 217]. A study that investigated the effect of multimodal feedback during dual task walking found that older adults had decreased sway walking during a manual dual task but their gait velocity was significantly slower [218]. However, the decrease in sway observed may not have been a result of the feedback applied but instead may have been a result of walking slower. Two other studies of older adults who received vibrotactile feedback during dual task conditions demonstrated that there was increased attentional load but improved postural stability was achieved [123, 219].

Baseline differences. It does not appear that the participants in the experimental and control groups were different at baseline (see Table 4). In comparison to other studies that have investigated effects of balance training it appears that the participants in our sample had functional performance scores that were similar to what other researchers have reported for subjects with the same vestibular diagnoses at baseline [220]. We were able to compare some of our participants baseline performance measures to reported baseline outcomes of the DHI, ABC, TUG, DGI, and SOT from a study examining the effectiveness of vestibular rehabilitation in people with unilateral vestibular hypofunction (n=42) and bilateral vestibular hypofunction (n=19)[220]. Karapolat et al. reported that their sample of people with unilateral vestibular hypofunction had the following mean scores at baseline: DHI was 52/100 ± 25 (compared to 36/100 ± 26 in our sample with n=9), the ABC was 55% ± 20 (compared to 75% ± 18 in our sample), the TUG was 10.1 seconds ± 3.0 (compared to 10.3 seconds ± 2.0 in our sample), and the DGI was 18.6 ± 5 (compared to 19.5 ± 2 in our sample). In comparing the changes noted after rehabilitation, we were able to compare the mean change in post- to pre-training scores. In the Karapolat study, the participants with unilateral vestibular hypofunction (n=42) demonstrated a 17-point improvement in DHI, 19 percent improvement in ABC, walked 2.13 seconds faster on the TUG, and improved 3 points on the DGI [220]. In our study, the participants with unilateral vestibular hypofunction (n=9) demonstrated a 4-point improvement on the DHI (Figure 6), no change in ABC (Figure 5), walked 0.2 seconds faster on the TUG (Figure 12), and improved 1 point on the DGI (Figure 8). The mean improvements reported in the Karapolat study are much greater than the results achieved in our study. A multitude of factors could explain the differences observed in outcomes between the study findings including the possibility of baseline differences in co-morbidities between the two samples, differences in sample sizes investigated (ours was smaller) and the use of a more or less effective balance training intervention employed in the two studies.

The mean baseline scores obtained for the group with bilateral vestibular hypofunction in this study (n=3) were similar to the baseline scores reported in Karapolat et al. study for their group of people with bilateral vestibular hypofunction who had a DHI mean of 46/100 ± 24 (compared to 40/100 ±13 in our sample), the ABC was 49% ± 31 (compared to 58% ± 8 in our sample), the TUG was 10.9 seconds ± 4.3 (compared to 14.2 seconds ± 1.4 in our sample), and the DGI was 16.8 ± 6 (compared to 16.7 ± 2.5 in our sample) [220]. In the Karapolat study, the participants with bilateral vestibular hypofunction (n=19) demonstrated a 12-point improvement in DHI, 20 percent improvement in ABC, walked 2.08 seconds faster on the TUG, and improved 4 points on the DGI following rehabilitation [220]. In our study, the participants with bilateral vestibular hypofunction (n=3) demonstrated a 1-point improvement on the DHI (Figure 6), no change in ABC (Figure 5), walked 0.2 seconds faster on the TUG (Figure 12), and improved 1 point on the DGI (Figure 8). As was the case with the participants with unilateral vestibular hypofunction, the mean improvements reported for the participants with bilateral vestibular hypofunction in the Karapolat study are much greater than the results achieved in our study. The same possible explanations described above may have contributed to the differences in mean functional outcome improvements observed between the two studies. Interestingly, the participants in the Karapolat study had similar mean improvements regardless of whether they had unilateral or bilateral vestibular hypofunction. This was also the case for the participants in our study who showed similar amount of improvements in mean DHI, ABC, TUG, and DGI scores regardless of whether they had a diagnosis of unilateral or bilateral vestibular hypofunction.

Factors that impact postural stability. There are many factors that may have impacted the outcomes for our participants. Some possible factors that affect postural stability in older adults include: brain structure changes or cognitive function reduction, lower extremity muscle weakness, somatosensory system deficits, vestibular changes, and visual acuity [177, 221-225]. Anxiety, dual tasks, fatigue, and increased challenge of the standing task (eyes closed, narrow base of support, support surface) have also been shown to impact postural stability. While we did screen for cognition and vision prior to initiating the balance training program, many of the other contributors to postural stability were not formally assessed.

A major limitation of our study is the small sample size and the heterogeneity of diagnoses. Recruitment for the study was challenged by the commitment required by the participant to fulfill 23 sessions (18 training and 5 testing). This may have biased our sample into investigating people who may be more invested in improving their health and function. In addition to the time commitment, the other two factors that posed a problem to our recruitment was excluding people who had a history of a total joint replacement and excluding people whose MOCA score was <26/30. Eight people interested in the study were excluded during the phone screen because of a history of a joint replacement and 7 people were excluded because they had a MOCA <26 during the clinical screening.

In summary, significant improvements in functional outcomes were observed following the balance training program, but there was not a difference between the control group and experimental group in the amount of improvement, the rate of improvement, or the retention of the improvements made immediately following training to six-month post-training assessment. Important contributions in future studies of VTF during balance and vestibular rehabilitation could include the determination of the optimal balance training intensity, how best to incorporate meaningful functional tasks, and the optimal threshold for vibration activation, including whether or not customized thresholds are most effective.

3.0 QUALITY OF LIFE FOLLOWING PARTICIPATION IN BALANCE AND VESTIBULAR REHABILITATION

3.1 INTRODUCTION

A decrease in quality of life is a common manifestation in people with chronic balance disorders. Activity and participation reductions often occur with balance dysfunction and can result in social isolation and decreased enjoyment in life [226, 227]. Additionally, decreased independence, decreased confidence, increased fear, and other psychosocial sequela of imbalance may also impact quality of life negatively [176, 178].

The American Physical Therapy Association has provided the physical therapy profession with a vision statement which reads: “Transforming society by optimizing movement to improve the human experience” [228]. Human experience through movement is essential for people to “participate in and contribute to society” and achieve “optimal living and quality of life” [228]. This vision of helping our patients achieve optimal quality of life is what should motivate all rehabilitation efforts, and therefore this is an outcome that should be measured.

In the previous study described and reported in Chapter 2 of this dissertation, we investigated the impact of training with sensory augmentation on functional balance outcome measures, but performance measures do not always correlate with perceived improvement [229, 230]. Perception of improvement is important because it has been shown to be more closely associated with activity and participation than performance measures [231]. Not surprisingly, quality of life appears to be dependent upon a person's level of activity and participation [232]. Some researchers have investigated the impact of exercise and balance training [16, 233, 234] but it does not appear that there have been any studies investigating changes in quality of life following the use of sensory augmentation during balance training.

The purpose of this investigation was to determine if quality of life improves following participation in a balance and vestibular rehabilitation program with and without sensory augmentation. Changes in quality of life following balance training were compared to baseline for all participants and also between the group who received VTF during training and the group who received traditional balance and vestibular rehabilitation without VTF. We hypothesized that both groups would show improved quality of life following participation in the balance training program and that the experimental group would have greater improvements in quality of life than the control group.

3.2 METHODS

3.2.1 Trial Design

This was an experimental randomized control trial that incorporated a longitudinal design.

3.2.2 Participants

The sample comprised of seven people with unilateral vestibular hypofunction, two people with bilateral vestibular hypofunction, four people with peripheral neuropathy, and three older adults with balance dysfunction (age 60 and above). Each of the participants completed a balance training protocol with or without vibrotactile feedback depending on their group allocation.

3.2.3 Intervention

Participants completed 18 balance training sessions lasting approximately 60 minutes/session over a 6-week time frame. Both the control group and the experimental group completed 6 x 30 second repetitions of six different balance exercises including standing on firm surface, standing of foam surface, weight shifting, modified center of gravity exercises, gaze stabilization exercises, and gait training, except for the participants within the peripheral neuropathy diagnostic category who did not complete gaze stabilization and therefore only completed 5 exercise categories per session. Participants were randomized into either the control group or the experimental group. The experimental group completed the balance training protocol with VTF applied to the trunk. The control group completed the balance training protocol without the VTF. All participants consented to participate in the randomized control trial investigating VTF during balance training were included in this study, except for the first two subjects enrolled as this investigation was initiated after they initiated the balance training.

3.2.4 Procedure

Prior to initiating the 18-session balance training protocol, participants completed the SF-12v2 quality of life questionnaire. This was repeated immediately following the completion of the balance training.

3.2.5 Statistical Analysis

Statistical analysis was completed using IBM SPSS Statistics 22. A paired samples t-test was conducted for both the physical composite score (PCS) and mental composite score (MCS) of the SF-12v2 to determine if there was a difference in quality of life scores across the sample immediately following training compared to pre-training. Additionally, group differences were investigated using a one-way analysis of variance. A significance level of $p = .05$ was used for the analysis. The assumptions of normality and compound symmetry were tested. To test normality, the Shapiro-Wilk p values for the dependent variables measured on continuous scales were examined and p-values greater than .05 were considered to have a normal distribution [196]. Histograms, boxplots, and q-q plots were examined for outliers. Means, standard deviations, percentiles, and ranges were also examined. The independent variable was group and the dependent variables were the PCS and MCS on the SF-12v2.

3.2.6 Instrumentation

The SF-12v2 quality of life questionnaire [155] provides information about mental and physical functioning as well as the overall health-related quality of life. The self-report consists of 12 questions that range from 0 to 100 (0 = lowest level of health, 100 = highest level of health). These 12 questions were taken from the SF-36 Health Survey [156] which has been criticized for being too cumbersome due to its length. Items are scored into two summary scores, the physical composite score and the mental health composite score. This instrument is not used for a specific diagnostic or age category. In our study, participants completed the questionnaire in paper and pencil format and the scores were calculated using QualityMetric scoring software which required a purchased license agreement for study analysis (license agreement number: QM031340).

3.3 RESULTS

The raw data for the SF-12v2 Physical Composite Score (PCS) and Mental Composite Score (MCS) are presented in Table 12 for each of the participants. A positive change score is indicative of an improvement of quality of life following participation in the balance training program while a negative change score is indicative of a worsening of quality of life. As illustrated in Table 12, 50% of the participants (8/16) had improved PCS scores following the balance training program and of those eight people, three were in the control group and five were in the experimental group. Fifty six percent (9/16) of the participants had improved MCS scores following training and of those people, three were in the control group and six were in the experimental group. There were five participants that demonstrated quality of life improvements in both the PCS and MCS (two people with unilateral vestibular hypofunction, one person with bilateral vestibular hypofunction, and two people with peripheral neuropathy).

Four participants that had worse quality of life following the 6-week balance training program per the PCS and MCS (two people with unilateral vestibular hypofunction, one person with bilateral vestibular hypofunction, and one older adult). Interestingly, all four of the participants with peripheral neuropathy had improved PCS scores following the balance training program. To date the minimal detectable change and minimally clinically important differences have not yet been established for the SF-12v2 measure.

Table 12. Raw data from SF-12v2 Quality of Life Questionnaire for pre-training, post-training, and change (post-pre); plus the Physical Composite Score (PCS) and Mental Composite Score (MCS) of the SF-12

ID	Pre-PCS	Post-PCS	PCS change	Pre-MCS	Post-MCS	MCS Change
UVH Control 1	36.02	36.31	**0.29**	41.64	43.95	**2.31**
UVH Control 2	49.94	52.52	**2.58**	56.59	53.4	**-3.19**
UVH Control 3	49.62	46.28	**-3.34**	54.57	45.14	**-9.43**
UVH Exp 1	51.71	51.21	**-0.5**	44.35	53.81	**9.46**
UVH Exp 2	43.08	46.02	**2.94**	50.05	54.66	**4.61**
UVH Exp 3	55.35	47.19	**-8.16**	55.58	59.73	**4.15**
UVH Exp 4	46.31	45.29	**-1.02**	54.57	46.28	**-8.29**
BVH Control 1	42.42	40.62	**-1.8**	56.82	53.05	**-3.77**
BVH Exp 1	30.36	42.06	**11.7**	44.13	52.75	**8.62**
OA Control 1	28.41	34.46	**6.05**	57.99	63.15	**5.16**
OA Control 2	53.78	57.12	**3.34**	59.61	57.38	**-2.23**
OA Exp 1	49.66	51.95	**2.29**	55.21	49.72	**-5.49**
PN Control 1	35.39	38.23	**2.84**	49.08	52.82	**3.74**
PN Exp 1	49.5	45.69	**-3.81**	49.62	57.58	**7.96**
PN Exp 2	40.59	40.38	**-0.21**	42.32	37.62	**-4.7**
PN Exp 3	54.53	52.52	**-2.01**	49.15	53.4	**4.25**

ID = subject identification; PCS = physical composite score; MCS = mental composite score; UVH = unilateral vestibular hypofunction; BVH = bilateral vestibular hypofunction; OA = older adult; PN = peripheral neuropathy; Exp = experimental group
**Positive changes indicative of improved quality of life are denoted with yellow highlighting

To determine whether or not there was a difference in quality of life for all of the participants (control and experimental groups) immediately following participation in the balance training program compared to baseline, a paired samples t-test was conducted for both the physical composite score and mental composite score of the SF-12v2. The results of this analysis indicated that the difference in scores for PCS pre-training ($M=44.79$, $SD=8.57$) and PCS post-training ($M=45.49$, $SD=6.49$); $t(15) = -0.62$, $p = 0.55$ was not statistically significant. Similarly, there was not a statistically significant difference in scores for MCS pre-training ($M=51.33$, $SD=5.86$) and MCS post-training ($M=52.15$, $SD=6.41$); $t(15) = -0.54$, $p = 0.60$.

We also hypothesized that there would be a difference in quality of life change pre- to post-training between the experimental and control group, however analysis of the data using a one-way ANOVA ($F(1,14) = 0.31$, $p = 0.59$) for PCS and ($F(1,14) = 0.88$, $p = .36$) for MCS showed no statistical significance in pre- to post-training quality of life composite scores.

3.4 DISCUSSION

Our hypothesis that a change in quality of life would be observed following participation in the balance training program was not confirmed. Some possible explanations for this include the small sample size included in our study, the choice of instrumentation to measure quality of life, and the chronic nature of the diagnoses in our sample.

We chose to measure quality of life using the SF-12v2 instrument because we wanted to use a measure that could be generalized amongst our heterogeneous sample that included multiple diagnoses and age-groups. In retrospect it may have been more effective to use a tool that was more specific to the diagnostic categories in our sample. Studies within the Parkinson's population has shown that the SF-12v2 may not be effective in showing change over time [235, 236]. Given the similar chronic nature of Parkinson's and the diagnoses in our study, we may have had a similar problem. Another study reported that the SF-36 might not be the best measure for investigating the individual level of change for older adults with chronic conditions [237].

Additionally, the internal validity of the SF-12 composite scores was not supported in a study of older adults, people with Parkinson's Disease, and people post-stroke [238]. Another limitation of using the SF-12v2 was that it is unknown what constitutes meaningful change.

Some studies investigating quality of life in the vestibular population have used the Dizziness Handicap Inventory as the measurement tool. While it is debatable as to whether the DHI can be interpreted as a measure of quality of life, we analyzed the scores of the DHI with the MCS and PCS scores of the SF-12v2 and did not find associations between the DHI and the SF-12v2 composite scores. As noted in Table 5 of the results section 2.4, there was not a statistically significant change in pre- to post-DHI scores across our sample.

A 2007 literature review aimed at determining if there was a questionnaire that assessed the impact vertigo or dizziness on quality life concluded that there was no such measure that was valid or reliable [147]. Aside from the DHI, the other questionnaires that claimed to measure quality of life for people with vertigo or dizziness within the literature review included: the Vestibular Disorders of Daily Living Scale; the Activities-specific Balance Confidence scale; the Vertigo Handicap Questionnaire; the Vertigo, Dizziness, Imbalance Questionnaire; UCLA Dizziness Questionnaire; Dizzy Factor Inventory; Vertigo Symptom Scale; European Evaluation of Vertigo; Meniere's Disease Patients-Oriented Severity Index [147].

While all of the participants in our study showed some functional improvement following training, 39% (7/18) of the study participants were still at fall risk based on having a gait velocity <1.0 m/second and 28% (5/18) of the participants were at fall risk based on a DGI score of ≤19/24. The residual physical or functional impairments may impact their emotional and mental well-being which may have impacted their quality of life scores [232].

It has been shown that perceived change (as would be drawn from self-reported quality of life instruments) may not correspond with clinical performance measures [229, 230]. In fact, similar to our findings others have reported a decline in self-rating from baseline following an intervention even when the clinical performance measures showed significant and meaningful improvements. Specifically, this was studied in a population similar to ours with older adults where the subjects completed exercise training to improve physical function and decrease fall risk with positive functional gains but decreased balance confidence following the exercise intervention [239, 240]. We speculate that there may have been an increased awareness of functional deficits following rehabilitation efforts. In consideration of the self-efficacy theory by Bandura, perception of improvement is more closely associated with activity and participation rather than in performance-based improvement [231]. This reinforces the notion that as physical therapists we must put attention towards improving the activity and participation for our patients and determine the best way to measure this domain. Pyykko and colleagues investigated quality of life in persons with Meniere's Disease and concluded that activity limitations and participation restrictions were highly prevalent in this population but were not being measured as factors impacting quality of life [241].

There are many reasons that decreased quality of life may be present in people with chronic balance disorders. One possible explanation includes the positive association between balance dysfunction and decreased activity and participation which can result in social isolation and decreased enjoyment in life [226, 227]. Decreased independence and increased reliance on caregivers and medical equipment can create a sense of embarrassment and decreased self-worth [176]. Decreased confidence, increased fear, and other psychosocial sequela of imbalance may also impact quality of life negatively [178].

One psychological factor that healthcare providers must consider is whether or not our patients with chronic diagnoses have accepted, and/or to what extent they have accepted, the sequelae of the diagnosis and disability associated with it. A 2016 study of people with chronic heart failure found that those who did not accept their diagnosis and illness had a significantly lower quality of life than those who scored higher on the acceptance of illness scale [242]. Clinicians often try to encourage their patients by highlighting the benefits of rehabilitation and this false hope may lead to a reduction in quality of life. It has been suggested instead that strategies be implemented that aim to teach patients to cope with disease, which may in turn improve quality of life [243].

The presence of other comorbid conditions may also contribute to their overall view of their quality of life. The presence of anxiety and/or depression which is a known factor that impacts quality of life has been reported to be underdiagnosed in persons seen by psychiatrists [244]. In our sample, 55% (11/18) of the participants had diagnosed depression and 15% (3/18) were diagnosed with anxiety (Table 3). The participants who were diagnosed with depression and anxiety were equally distributed amongst the diagnostic categories. Five of participants with depression were diagnosed with unilateral vestibular hypofunction, one person with bilateral vestibular hypofunction, two with peripheral neuropathy, and three were older adults with balance disorders. Six people with depression were assigned to the control group while the other five participants were randomized into the experimental group. The distribution of a co-morbid anxiety diagnosis was also equally distributed with one person in each diagnostic classification for our study. Two people with anxiety were randomized in the control group and two were randomized into the experimental group.

A recent study found an association between worse recovery following vestibular neuritis and the presence of anxiety/depression [245]. This supports findings from prior work associating worse outcomes and increased symptom duration to anxiety, depression, and catastrophic thinking [246-248] in people with vestibular disorders. It is well established that there is a high prevalence of anxiety and depression in people with dizziness [249-251]. A study investigated the effects of vestibular rehabilitation on anxiety and depression and reported that level of anxiety (as measured by the State-Trait Anxiety Inventory) and depression (as measured by the Centre of Epidemiological Studies Depression Scale) were significantly decreased following vestibular rehabilitation [252].

While vestibular rehabilitation aims to improve the brains ability to adapt to provoking body, eye, and head movements, the incorporation of psychological interventions may be needed to address the emotional aspects to positively change quality of life. The incorporation of mindfulness, cognitive behavioral techniques, and vestibular rehabilitation into five group training sessions has been reported to improve function, patient coping, and satisfaction in people with vestibular disorders [253]. Another study of people with chronic dizziness reported improved function and decreased disability following three sessions of cognitive behavioral therapy, but the subjects with higher levels of anxiety prior to treatment were those with higher disability post-treatment [254].

Another factor that may have impacted our results was whether or not the participants in our study had visual dependency, or an increased weighting of visual inputs. The impact that visual dependency may have on symptom recovery and functional outcomes following a vestibular insult has received increased attention in the past few years [255]. One recent study hypothesized that if too much reliance is placed on visual sensory inputs following vestibulopathy and the central nervous system does not adequately down-regulate the influence of vision, worse recovery will result [245]. It has also been demonstrated that clinical outcomes are not influenced by the recovery of the vestibular system as measured by caloric testing, head impulse testing, or vestibular evoked myogenic potentials [245, 256, 257]. If factors such as anxiety, depression, and visual dependency are improved, it could be hypothesized that an improvement in quality of life would not be expected to improve either.

The hypothesis that the experimental group would have an improved quality of life change compared to the control group following balance training was not supported by our data. There were no differences in quality of life following training for the two groups. In summary, self-reports are subject to bias and may lack responsiveness to change [258-260]. Performance measures lack generalizability to actual real-world function [259, 261]. While both self-report and performance outcome tools have their weaknesses in measuring quality of life, there may be value to using a tool that incorporates a combination of both aspects. Additionally, an improved instrument to measure quality of life for people with chronic balance disorders that is valid, reliable, and can detect change over time appears to be warranted for investigating the effect of interventions on quality of life changes.

4.0 AGREEMENT BETWEEN PARTICIPANT PERCEPTION OF BALANCE AND CLINICIAN OBSERVATION OF PERFORMANCE

4.1 INTRODUCTION

Prescribing an exercise program that is of an appropriate intensity to achieve functional improvements is important for all people engaging in an exercise program. The American College of Sports and Medicine has clearly defined how to measure intensity using heart rate reserve for aerobic activity and one repetition maximum measurement is used to measure intensity for resistance exercise [262]. Additionally, scales that rate perceived exertion have successfully been used to record intensity based on the subjective report from the person completing the activity. Intensity measures can then be used to guide the prescription of exercises that will achieve desired outcomes. Unlike aerobic and resistance intensity exercise guidelines, balance exercise guidelines are not well defined [262, 263]. While there is not a recommended intensity dosage for balance programs, investigators have speculated that balance training has lacked effectiveness due to insufficient intensity [206].

The American Physical Therapy Association supports the mission of the American Board of Internal Medicine Foundation’s campaign called “Choosing Wisely” which puts healthcare recommendation into practice [203]. One of the five proposed recommendations to provide evidence-based physical therapy [204] includes not prescribing under-dosed strength training programs for older adults. The importance of matching the frequency, intensity, and duration of exercise to the individual's ability and goals was stated. We suspect that like strength training, an effort to ensure adequate dosage for balance training programs is needed. Research indicates that many older adults and people with chronic neurological disorders that have undergone physical therapy may not have been trained at an adequate dose to achieve optimal change [199-202]. Without a way to record the intensity of balance activities, progression of exercises is difficult.

Some investigators have attempted to use center of pressure displacement to measure balance intensity while progressively challenging subjects with more difficult standing balance conditions that alter the visual and somatosensory inputs [72]. While this might be helpful in ordering exercises based on level of difficulty, the clinical usability is limited as many physical therapists do not have the resources to record center of pressure within their clinical practice.

Qualitative efforts have also been used to attempt to measure balance intensity by observing non-verbal responses of people performing progressively more difficult balance exercises and analyzing the subjective feedback provided via verbal responses as people perform balance tasks of varying challenge [264]. The non-verbal responses were analyzed by a physical therapist investigator during the balance testing. The responses that were observed as the challenge increased included postural reactions (ankle, hip, and stepping strategies), bracing (stiffening of muscles groups), postural sway, and breathing changes (increased depth and/or rate). The verbal responses analyzed included spontaneous comments made by the participants regarding their opinion of the balance task and their capability to perform the task.

Recently two rating scales of perceived difficulty for balance exercises were investigated and found to have moderate to strong correlation with kinematic postural stability measures [265]. Many of the balance outcome measures that are used clinically incorporate observation skills by the clinician to score, or rate the balance performer [32, 136, 266]. In summary, attempts which aim to measure balance intensity have focused on quantitative postural sway information, subjective self-report perceived difficulty ratings, and observation.

The purpose of this investigation was to determine if the study participants perceive the challenge of a balance exercise to be the same as the observed balance performance rated by a physical therapist. If a scale that rates perceived challenge of a balance exercise by the participant correlates to how much assistance a physical therapist provides during the balance exercise, the use of a perceived balance challenge scale could be clinically applied to progress exercises within a training program.

To determine whether the participant's perception of their balance performance matches the observed balance performance from the clinician, a rating scale created for the participant to rate perception of balance performance and a rating scale for the physical therapist to rate how much assistance they provided the participant during the exercise. The participant and clinician scores were compared to understand the degree of agreement. We hypothesized that participant rating of their perceived balance during the exercise would correlate with the clinicians' observation of balance performance. The second hypothesis was that an increased RMS sway during balance exercises would relate to: 1) an increase on the numerical rating scale from the participant's perceived balance challenge; and to an increased numerical rating score by the physical therapist's observation of balance performance.

4.2 METHODS

4.2.1 Trial Design

This was an experimental study design.

4.2.2 Participants

The participants comprised of seven people with unilateral vestibular hypofunction, two people with bilateral vestibular hypofunction, four people with peripheral neuropathy, and three older adults with balance dysfunction (age 60 and above). Each of the participants completed a balance training protocol and was randomized to complete the training either with or without vibrotactile feedback as described in chapter 2 of this dissertation manuscript.

4.2.3 Intervention

A balance training program consisting of 18 training sessions lasting 45-60 minutes each was completed by all study participants over the course of 6-weeks. During the balance training session, participants completed 6 x 30 second repetitions of six different types of balance exercise including standing on firm surface, standing on foam surface weight shifting, modified center of gravity, gait training, and gaze stabilization. Participants were randomized into either the experimental or control group. The experimental group received trunk-based vibrotactile feedback if they swayed too far in any direction during the balance exercises. The participants in the control group completed the balance training without the augmented feedback. All of the participants who were consented and enrolled in the randomized control trial investigating the effects of VTF during balance training were included in this study investigating the agreement of balance rating scales, except for the first two subjects enrolled.

4.2.4 Procedure

Every participant enrolled in the randomized control trial investigating the effects of vibrotactile feedback during balance training was analyzed in this study except for the first two participants because they initiated training prior to the initiation of this study. The balance training program consisted of five or six balance exercises each session (five exercises/session for those with peripheral neuropathy and six exercises/session for the other three diagnostic groups) over a total of 18 balance training sessions in the program. Each exercise consisted of six trials lasting 30 seconds. Following every exercise, both the participant and the physical therapist recorded a balance rating for the exercise.

All participants in the unilateral vestibular hypofunction, bilateral vestibular hypofunction, and older adult diagnostic categories could have obtained 108 total rating comparisons (18 sessions with six exercises/session). There were three participants that had less than 108 (106 or 107) comparisons due to tester error. There were two participants with more than 108 (111 and 110). For both of these participants, there were two or more exercises that had immediate falls for the first three consecutive trials and another six trials of a less challenging exercise were completed and rated.

For participants with peripheral neuropathy, a total of 90 rating comparisons were expected (18 sessions with five exercises/session). These participants did not complete the vestibulo-ocular reflex exercise category. One participant acquired 91 rating comparisons as they had one exercise that was initiated but resulted in immediate falls for the first three trials and another six trials of a less challenging exercise were completed and rated.

4.2.5 Instrumentation

Following completion of each exercise within an exercise category, the clinician's observed balance performance of the participant (using a 1 to 5 independence level scale) and the participant's perception of balance performance (using a 1 to 5 visual analog scale) was recorded. The physical therapist recorded their rating prior to obtaining the participants rating. The participant was not aware of the numerical rating assigned by the physical therapist, but the physical therapist was aware of the participant rating. The participant rating scale was adapted from a poster presentation from researchers at Cleveland State University [193] and is depicted on the left hand column of Figure 3. Our research team also adapted the physical therapist rating scale from the commonly used Functional Independence Measure [194] which relates to how much assistance is required during a task.

4.2.6 Statistical Analysis

To investigate the inter-rater agreement between the physical therapist and the participant's balance ratings a Cohen's kappa coefficient was calculated for the rating comparisons [196]. The Cohen's kappa is a more vigorous measure of agreement than a basic percent agreement calculation as it accounts for the occurrence of agreement from chance, which was also calculated. Linear and quadratic weighted kappa analysis was performed to account for disagreements between the two raters using Stata® Statistical Software was used to analyze the relationship between ratings of the participant and the physical therapist.

Cohen's kappa coefficient is typically used on nominal scales and weighted agreement coefficients on ordinal scales where the difference between ratings are not considered to have the same importance [267]. The linear-weighted kappa compares the mean distance between the ratings made by the two raters to the mean distance expected by chance. A value of zero indicates that the observed mean distance is expected to be by chance. The quadratic-weighted kappa compares the observed variability of the distance distribution between two raters' classifications about 0 to the variability expected by chance [267]

A Bland Altman correlation using IBM SPSS Statistics 22 was used to examine the effect of postural sway on balance rating so that we could determine whether or not the subjects with greater sway had higher balance ratings [268, 269].

4.3 RESULTS

A total of 1,658 rating comparisons were collected from the 16 participants in our sample. A Cohen's kappa (k) = 0.417 ($p<.001$) with a 59% agreement between the physical therapist and the participant balance ratings (Table 13) was recorded. Percent agreement was calculated by dividing the total number of times that the participant and the physical therapist had exact matching numerical ratings by the total number of rating comparisons. When analyzed individually, the participant with the highest amount of agreement was PN Exp 2 (a person with peripheral neuropathy who was in the experimental group) with k = 0.575 ($p<.001$). When compared to the physical therapist rating, moderate agreement was found in eight of the participants, fair agreement for six participants, and poor agreement was found with two participants. The participant that had the worst amount of agreement with the physical therapist rating was UVH Exp 1 (a person with unilateral vestibular hypofunction who was in the experimental group). Weighted Kappa scores range from 0 to 1 where 0.01 to 0.20 represents poor agreement, 0.21 to 0.40 represents fair agreement, 0.41 to 0.60 represents moderate agreement, 0.61 to 0.80 represents substantial agreement, and 0.81 to 1 represents excellent agreement [270].

Table 13. Percent agreement and Cohen's Kappa for each participant and for entire sample

Subject ID	Percent Agreement	Cohen's Kappa (k)	p
UVH Control 2	55.1%	.394	<.001
UVH Control 3	61.3%	.478	<.001
UVH Control 4	60.4%	.397	<.001
UVH Exp 1	45.4%	.122	.043
UVH Exp 2	56.5%	.321	<.001
UVH Exp 3	65.7%	.410	<.001
UVH Exp 4	68.5%	.542	<.001
BVH Control 1	49.1%	.317	<.001
BVH Exp 2	56.4%	.417	<.001
OA Control 1 rating	68.2%	.521	<.001
OA Control 2 rating	63.9%	.428	<.001
OA Exp 1 rating	57.4%	.285	<.001
PN Control 1 rating	63.3%	.512	<.001
PN Exp 1 rating	49.1%	.85	.091
PN Exp 2 rating	71.1%	.575	<.001
PN Exp 3 rating	47.3%	.310	<.001
Total (n=16)	59.1%	.417	<.001

ID = subject identification; PCS = physical composite score; MCS = mental composite score; UVH = unilateral vestibular hypofunction; BVH = bilateral vestibular hypofunction; OA = older adult; PN = peripheral neuropathy; Exp = experimental group
**UVH Control 1 and BVH Exp 1 were enrolled in the trial prior to initiation of this investigation

Substantial agreement was noted with quadratic weighted kappa analysis, k = 0.742 (p<.001) compared to a moderate agreement with the linear weighted kappa analysis, k = 0.579

(p<.001). With the quadratic weights, the penalty becomes more strict as the difference in rating increases [267]. A quadratic-weighted coefficient compares the variability between pairs of items to the total variability and is equal to the intra class correlation coefficient in a two-way analysis of variance [271, 272]. Tables 14 and 15 illustrate how the weighting differed for the quadratic weighting vs the linear weighted kappa correlation by rating separation. The penalty for being off by each category, or rating, is the same in the linear weighting. In the quadratic weighting, the penalty becomes greater as the separation between ratings increases [267] .

Table 14. Weighting assignments for each of the possible participant and physical therapist rating combinations for the linear weighted kappa correlation analysis

		Participant Rating				
		1	2	3	4	5
Physical therapist rating	1	1.00	0.75	0.50	0.25	0
	2	0.75	1.00	0.75	0.50	0.25
	3	0.50	0.75	1.00	0.75	0.50
	4	0.25	0.50	0.75	1.00	0.75
	5	0	0.25	0.50	0.75	1.00

Table 15. Weighting assignments for each of the possible participant and physical therapist rating combinations for the quadratic weighted kappa correlation analysis

		Participant Rating				
		1	2	3	4	5
Physical therapist rating	1	1.00	0.9375	0.75	0.4375	0
	2	0.9375	1.00	0.9375	0.75	0.4375
	3	0.75	0.9375	1.00	0.9375	0.75
	4	0.4375	0.75	0.9375	1.00	0.9375
	5	0	0.4375	0.75	0.9375	1.00

The cross tabulation raw data for the participant visual analog scale ratings and the physical therapist ratings are presented in Tables 16 - 24 and are grouped by diagnostic categories. In consideration of whether there was a difference between the amount of challenge provided for the control and experimental groups, the balance ratings were compared between the two groups (Tables 25-26). It was noted that for the control group a balance rating of “1” or “2” was recorded by the participant and the physical therapist for 436 exercises which accounted for 59% of the recordings. The experimental group recorded 619 instances where the participant and physical therapist rated the exercise to be a “1” or a “2” on their respective balance rating scales, which represented 67% of the total exercises recorded. While it appears that the challenge was too low for both groups, the experimental group had a higher incidence of low ratings recorded (67% compared to 59% in the control group).

Table 16. Participant and physical therapist balance ratings for the control group with unilateral vestibular hypofunction

		UVH Control 2 rating						UVH Control 3 rating						UVH Control 4 rating					
		1	**2**	**3**	**4**	**5**	**Total**	**1**	**2**	**3**	**4**	**5**	**Total**	**1**	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	11	8	1	0	0	20	19	10	3	0	0	32	10	7	0	0	0	17
	2	3	25	17	3	0	48	4	20	16	0	0	40	6	41	15	2	0	63
	3	0	1	13	9	0	23	0	6	16	0	0	22	0	2	8	5	0	16
	4	0	1	2	7	1	11	0	0	0	1	2	3	0	0	1	3	3	7
	5	0	0	0	2	3	5	0	0	1	1	12	14	0	0	0	1	2	3
	Total	14	35	33	21	4	107	23	36	36	2	14	111	16	49	25	11	5	106

UVH = unilateral vestibular hypofunction

Table 17. Participant and physical therapist balance ratings for the experimental group with unilateral vestibular hypofunction

		UVH Exp 1 rating						UVH Exp 2 rating						UVH Exp 3 rating						UVH Exp 4 rating					
		1	2	3	4	5	Total	1	2	3	4	5	Total	1	2	3	4	5	Total	1	2	3	4	5	Total
Physical therapist rating	1	17	43	1	0	0	61	16	21	1	0	0	38	14	7	0	0	0	21	41	1	0	0	0	42
	2	3	30	8	0	0	41	2	40	11	0	0	53	12	48	2	0	0	62	12	23	3	0	0	38
	3	1	1	2	0	0	4	0	2	2	4	0	8	0	9	6	0	0	15	0	5	4	1	1	11
	4	0	1	0	0	0	1	0	0	1	0	5	6	0	3	1	2	0	6	0	1	1	0	4	6
	5	0	0	1	0	0	1	0	0	0	0	3	3	0	0	2	1	1	4	0	1	1	3	6	11
	Total	21	75	12	0	0	108	18	63	15	4	8	108	26	67	11	3	1	108	53	31	9	4	11	108

UVH = unilateral vestibular hypofunction; Exp = Experimental

Table 18. Participant and physical therapist balance ratings for the control group with bilateral vestibular hypofunction

		BVH Control 1 rating					
		1	2	3	4	5	Total
Physical therapist rating	1	13	10	0	0	0	23
	2	2	30	4	0	0	36
	3	0	7	10	0	0	17
	4	0	7	12	0	0	19
	5	0	1	11	1	0	13
	Total	15	55	37	1	0	108

BVH = bilateral vestibular hypofunction

Table 19. Participant and physical therapist balance ratings for the experimental group with bilateral vestibular hypofunction

		BVH Exp 2 rating					
		1	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	8	10	0	0	0	18
	2	4	31	15	1	0	51
	3	0	0	8	2	0	10
	4	0	1	7	7	1	16
	5	0	0	3	4	8	15
	Total	12	42	33	14	9	110

BVH = bilateral vestibular hypofunction; Exp = Experimental

Table 20. Participant and physical therapist balance ratings for the control group in the older adult category

		OA Control 1 rating						OA Control 2 rating					
		1	**2**	**3**	**4**	**5**	**Total**	**1**	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	31	2	0	0	0	33	47	4	0	0	0	51
	2	13	35	2	0	0	50	20	13	2	0	0	35
	3	0	6	7	1	0	14	1	1	3	0	0	5
	4	0	0	1	0	0	1	0	1	4	1	0	6
	5	0	1	4	4	0	9	0	1	3	2	5	11
	Total	44	44	14	5	0	107	68	20	12	3	5	108

OA = older adults

Table 21. Participant and physical therapist balance ratings for the experimental group in the older adult category

		OA Exp 1 rating					
		1	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	12	7	0	0	0	19
	2	10	45	2	0	0	57
	3	1	11	5	0	0	17
	4	0	7	2	0	0	9
	5	0	1	4	1	0	6
	Total	23	71	13	1	0	108

OA = older adults; Exp = Experimental

Table 22. Participant and physical therapist balance ratings for the control group with peripheral neuropathy

		PN Control 1 rating					
		1	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	17	1	0	0	0	18
	2	11	23	0	0	0	34
	3	0	6	9	1	0	16
	4	0	2	7	3	0	12
	5	0	0	1	4	5	10
	Total	28	32	17	8	5	90

PN = peripheral neuropathy

Table 23. Participant and physical therapist balance ratings for the experimental group with peripheral neuropathy

		PN Exp 1 rating						PN Exp 2 rating						PN Exp 3 rating					
		1	**2**	**3**	**4**	**5**	**Total**	**1**	**2**	**3**	**4**	**5**	**Total**	**1**	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	2	7	0	0	0	9	33	5	0	0	0	38	18	2	0	0	0	20
	2	0	35	1	0	0	36	7	21	4	0	0	32	20	12	1	0	0	33
	3	0	19	0	0	0	19	0	2	6	4	0	12	4	6	5	1	1	17
	4	0	9	5	0	0	14	0	0	1	0	1	2	1	2	5	2	2	12
	5	0	1	9	2	0	12	0	0	0	2	4	6	0	1	1	1	6	9
	Total	2	71	15	2	0	90	40	28	11	6	5	90	43	23	12	4	9	91

PN = peripheral neuropathy; Exp = Experimental

Table 24. Participant and physical therapist balance ratings for the total sample

		All participants					
		1	**2**	**3**	**4**	**5**	**Total**
Physical therapist rating	**1**	309	145	6	0	0	460
	2	129	472	103	6	0	710
	3	7	84	104	28	2	225
	4	1	35	50	26	19	131
	5	0	7	41	29	55	132
	Total	446	743	304	89	76	1658

Table 25. Participant and physical therapist balance ratings for the control group

		All participants					
		1	2	3	4	5	Total
Physical therapist rating	1	148	42	4	0	0	194
	2	59	187	56	5	0	307
	3	1	29	66	16	0	112
	4	0	11	27	15	6	59
	5	0	3	20	15	27	65
	Total	208	272	173	51	33	737

Table 26. Participant and physical therapist balance ratings for the experimental group

		All participants					
		1	2	3	4	5	Total
Physical therapist rating	1	161	103	2	0	0	266
	2	70	285	47	1	0	403
	3	6	55	38	12	2	113
	4	1	24	23	11	13	72
	5	0	4	21	14	28	67
	Total	238	471	131	38	43	921

Table 27 shows the number of exact matches between the physical therapist observed balance ratings and the participants perceived balance challenge ratings using the respective scales. Of the 1,658 balance rating comparisons between the physical therapist and the participant, there were 966 instances (58% of the time) where the exact numerical rating from the visual analog scale used by the participants matched to the numerical rating on the balance scale used by the physical therapist. Of the 692 instances that complete agreement was not achieved between the two rating scales, there were 587 instances where the rating difference was only one number apart (for example, physical therapist rating = "1" and participant rating = "2"), 97 instances where the difference was two numbers apart (for example, physical therapist rating = "5" and participant rating = "3"), and eight instances where the difference was three numbers apart.

Of the 16 participants who were included in the balance rating comparison analysis (the first two participants enrolled in the study initiated the balance training program prior to the initiation of the investigation of the agreement between the balance ratings), nine participants had a greater tendency to rate their balance better (lower numerical rating) than the physical therapist rated the observed balance performance. Six participants had a greater tendency to rate their perceived balance performance worse (higher numerical rating) than the physical therapist balance rating of their observed performance (Table 28). One of the participants (PN Exp 2) had balance ratings that matched 71% of the time. Of the 90 ratings collected for PN Exp 2, there were 26 instances that an exact matched was not achieved and the difference in the numerical ratings between the participant and the physical therapist was only one number apart from each other. Of those 26 instances that were not exact matches for PN Exp 2, the physical therapist rating was worse 12 times and the participant rating was worse 14 times.

Table 27. Physical therapist (PT) and participant ratings that were exact matches, within 1 point of each other, within 2 points of each other, and within 3 points of each other

Participant ID (total # of rating comparisons)	Exact Match of PT and participant ratings	Number of ratings that were within 1 point	Number of ratings that were 2 points apart	Number of ratings that were 3 points apart
UVH Control 1 (n=107)	59 (55%)	43 (40%)	5 (5%)	0
UVH Control 2 (n=111)	68 (61%)	39 (35%)	4 (4%)	0
UVH Control 3 (n=106)	64 (60%)	40 (38%)	2 (2%)	0
UVH Exp 1 (n=108)	49 (45%)	55 (51%)	4 (4%)	0
UVH Exp 2 (n=108)	61 (56%)	46 (43%)	1 (1%)	0
UVH Exp 3 (n=108)	71 (66%)	32 (30%)	5 (5%)	0
UVH Exp 4 (n=108)	74 (69%)	30 (28%)	3 (3%)	1 (1%)
BVH Control 1 (n=108)	53 (49%)	36 (33%)	18 (17%)	1 (1%)
BVH Exp 1 (n=110)	62 (57%)	43 (39%)	5 (5%)	0
OA Control 1 (n=107)	73 (68%)	29 (27%)	4 (4%)	1 (1%)
OA Control 2 (n=108)	69 (64%)	33 (31%)	5 (5%)	1 (1%)
OA Exp 1 (n=108)	62 (57%)	33 (31%)	12 (11%)	1 (1%)
PN Control 1 (n=90)	57 (64%)	30 (33%)	3 (3%)	0
PN Exp 1 (n=90)	37 (41%)	34 (38%)	18 (20%)	1 (1%)
PN Exp 2 (n=90)	64 (71%)	26 (29%)	0	0
PN Exp 3 (n=91)	43 (47%)	38 (42%)	8 (9%)	2 (2%)
Total (n=1658)	966	587	97	8

PT = physical therapist; UVH = Unilateral Vestibular Hypofunction; BVH = Bilateral Vestibular Hypofunction; OA = Older Adult; PN = Peripheral Neuropathy; Exp = Experimental group

Of the 1,658 rating comparisons between the physical therapist and the participant, there were 966 instances where the two balance ratings were exact matches, 383 instances where the physical therapist rated the observed balance performance to be worse (higher numeric rating) than what the participant rated their perception of their balance during the exercise, and 309 instances where the participant percieved their balance to be worse than what the physical therapist observed (see Table 28). There were six participants that tended to rate their balance performance worse than what the physical therapist observed their balance to be and there were nine participants that rated their balance better than what they physical therapist observed their balance to be (physical therapist rating was higher on the 1-5 numeric rating scale). One of the participants had an almost equal occurence of physical therapist vs participant ratings that were worse and this was the same particpant that had the highest percentage of exact rating matchings with the physical therapist (PN Exp 2). Participant PN Exp 2 showed improvements in functional performance measures following participation but entered the study with good balance and high balance confidence.

Table 28. Number of instances that physical therapist (PT) balance rating was worse than participant balance rating

Participant ID	Exact match of participant and PT ratings	PT rating higher (worse) than participant rating	Participant rating higher (worse) than PT rating
UVH Control 2	59 (55%)	9 (8%)	39 (37%)
UVH Control 3	68 (61%)	12 (11%)	31 (28%)
UVH Control 4	64 (60%)	10 (10%)	32 (30%)
UVH Exp 1	49 (45%)	7 (7%)	52 (48%)
UVH Exp 2	61 (56%)	5 (5%)	42 (39%)
UVH Exp 3	71 (66%)	28 (26%)	9 (8%)
UVH Exp 4	74 (69%)	24 (22%)	10 (9%)
BVH Control 1	53 (49%)	41 (38%)	14 (13%)
BVH Exp 2	62 (57%)	19 (17%)	29 (26%)
OA Control 1	73 (68%)	29 (27%)	5 (5%)
OA Control 2	69 (64%)	33 (31%)	6 (5%)
OA Exp 1	62 (57%)	37 (34%)	9 (8%)
PN Control 1	57 (64%)	31 (34%)	2 (2%)
PN Exp 1	37 (41%)	45 (50%)	8 (9%)
PN Exp 2	64 (71%)	12 (13%)	14 (16%)
PN Exp 3	43 (47%)	41 (45%)	7 (8%)
Total	966	383	309

PT = physical therapist; UVH = Unilateral Vestibular Hypofunction; BVH = Bilateral Vestibular Hypofunction; OA = Older Adult; PN = Peripheral Neuropathy; Exp = Experimental group
**The column highlighted in yellow denotes whether the participant fell into the category of having more PT ratings that were higher than participant or vice versa

To determine if the participant rating and the physical therapist rating were reflective of actual balance performance, the RMS sway data collected from the accelerometer was analyzed and the RMS mean and range for each of the five numerical ratings within the balance scales are presented in Table 29-30. This was only completed for the exercise categories of static standing on firm surface and static standing on foam surface. The other categories involve a dynamic movement of either the entire body (weight shifting and gait exercise categories), the upper extremities (modified center of gravity exercise category), or the head (gaze stabilization exercise category).

It was expected that the RMS trunk tilt mean would increase as the difficulty of the balance increased (increased balance rating on the 1-5 physical therapist and participant balance rating scales). The mean RMS trunk tilt increased as expected, except for in the rating category “4” by the physical therapist during the standing of firm surface exercise category where the mean RMS sway was less than the mean for category “3” rating (see Table 29). The sway variables were averaged across the six repetitions within the exercise category for all 18 training sessions. There were 269 comparisons of the RMS sway metrics and the balance ratings by the participant and the physical therapist for the standing on firm surface exercise category and 272 comparisons for the standing on foam surface exercise category (Table 30). The frequency of the number of times the participant and physical therapist used each of the 1-5 numerical balance ratings are listed in Table 31. With 16 participants a maximum total of 288 comparisons of averaged sway to numeric ratings could have been made, but only the exercise categories that had all six sway recordings were used. For the standing on firm surface category, the inertial measurment unit and software had technical difficulty in 7% of the possible 288 exercise category comparisons (19 exercise category ratings and RMS trunk sway were not compared). For the standing on foam surface exercise category, technical difficulty affected 6% of the 288 exercise category comparisons of sway and numerical ratings (16 exercise category comparisons were not analyzed) .

Table 29. Root mean square (RMS) mean trunk tilt and RMS range for the physical therapist and participant 1 to 5 rating categories during standing on firm surface exercise category

	Standing on Firm Surface Exercise Category			
	Physical Therapist		Participant	
Numeric Balance Rating	RMS mean ± SD (degrees)	RMS range (degrees)	RMS mean ± SD (degrees)	RMS range (degrees)
1	1.12 ± 0.37	0.52 to 2.13	1.22 ± 0.41	0.56 to 2.33
2	1.63 ± 0.67	0.51 to 4.30	1.73 ± 0.84	0.51 to 5.03
3	2.48 ± 1.48	0.95 to 10.01	2.01 ± 0.84	0.56 to 4.70
4	2.36 ± 0.86	0.56 to 4.65	2.78 ± 1.85	1.10 to 10.01
5	3.78 ± 2.06	1.28 to 9.69	4.41 ± 2.25	1.43 to 9.69
Total	2.02 ± 1.36	0.51 to 10.01	2.02 ± 1.36	0.51 to 10.01

**For the physical therapist numeric balance rating: 1 = "Independent with no sway"; 2 = "Supervision with minimal sway"; 3 = "Close supervision with moderate sway"; 4 = "Requires P.T. assist or step out after 15 seconds"; and 5 = "Unable with immediate assist or step out"
**For the participant numeric balance rating: 1 = "I feel completely steady"; 2 = "I feel a little unsteady or off-balance"; 3 = "I feel somewhat unsteady or like I may lose my balance"; 4 = "I feel very unsteady or like I definitely will lose my balance"; and 5 = "I lost my balance"

Table 30. Root mean square (RMS) mean trunk tilt and RMS range for the physical therapist and participant 1 to 5 rating categories during standing on foam surface exercise category

	Standing on Foam Surface Exercise Category			
	Physical Therapist		Participant	
Numeric Balance Rating	RMS mean ± SD (degrees)	RMS range (degrees)	RMS mean ± SD (degrees)	RMS range (degrees)
1	1.05 ± 0.30	0.58 to 1.59	1.59 ± 0.52	1.00 to 3.17
2	1.74 ± 0.56	0.85 to 5.07	1.88 ± 0.64	0.58 to 4.29
3	2.35 ± 0.74	1.08 to 4.29	2.45 ± 0.95	0.86 to 5.52
4	3.12 ± 1.11	1.45 to 6.99	3.11 ± 1.13	1.45 to 5.48
5	3.47 ± 1.15	1.55 to 5.52	3.41 ± 1.42	2.17 to 6.99
Total	2.25 ± 0.99	0.58 to 6.99	2.25 ± 0.99	0.58 to 6.99

**For the physical therapist numeric balance rating: 1 = "Independent with no sway"; 2 = "Supervision with minimal sway"; 3 = "Close supervision with moderate sway"; 4 = "Requires P.T. assist or step out after 15 seconds"; and 5 = "Unable with immediate assist or step out"
**For the participant numeric balance rating: 1 = "I feel completely steady"; 2 = "I feel a little unsteady or off-balance"; 3 = "I feel somewhat unsteady or like I may lose my balance"; 4 = "I feel very unsteady or like I definitely will lose my balance"; and 5 = "I lost my balance"

Table 31. Frequency (number of times and percentage that each numerical rating was recorded) of physical therapist and participant ratings using respective balance rating scales during standing on firm surface and standing on foam surface exercise categories

	Frequency of Ratings			
	Standing on Firm Surface		Standing on Foam Surface	
	Physical Therapist	Participant	Physical Therapist	Participant
1	53 (19.5%)	47 (17.5%)	10 (3.7%)	16 (5.9%)
2	112 (41.2%)	112 (41.6%)	114 (41.9%)	131 (48.2%)
3	37 (13.6%)	65 (24.2%)	88 (32.4%)	81 (29.8%)
4	30 (11%)	22 (8.2%)	37 (13.6%)	29 (10.7%)
5	37 (13.6%)	23 (8.6%)	23 (8.5%)	15 (5.5%)
Total	269	269	272	272

To determine if there was a relationship between the RMS sway and the ratings from the physical therapist and the participant, a Bland-Altman correlation method was conducted [268, 269]. The calculated correlation coefficients are listed in Table 32. The RMS sway and physical therapist ratings were more highly correlated than the participant ratings, except for the AP RMS sway during the standing on firm surface exercise category, where the participant and physical therapist each had correlations of 0.51 for sway ratings. The correlation coefficients of 0.51 to 0.65 indicate that both the physical therapist and the participant ratings are consistently matching the amount of sway detected for the exercise category.

Table 32. Bland-Altman regression correlation coefficients for participant and physical therapist ratings compared to RMS (combined roll and pitch sway), AP RMS (pitch sway), ML RMS (roll sway) in degrees

	Bland Altman Regression Correlation Coefficients		
	RMS Sway	AP RMS Sway	ML RMS Sway
Participant Rating Firm surface standing	0.57	0.51	0.59
PT Rating Firm surface standing	0.58	0.51	0.63
Participant Rating Foam surface standing	0.56	0.51	0.47
PT Rating Foam surface standing	0.65	0.60	0.53

RMS = root mean square; AP = anterior/posterior; ML = medial/lateral; PT = physical therapist

4.4 DISCUSSION

The first hypothesis of this study was that the participants and physical therapist ratings would be correlated. This was supported using a quadratic weighted kappa analysis with substantial agreement observed. Despite a classification of substantial agreement, we questioned why the physical therapist and the participant didn't agree more. We considered the following possibilities: 1) a discrepancy between the scale definitions for the two rating scales used in the study; 2) impact of group allocation and/or diagnostic category; 3) presence of comorbidities including depression; 4) study biases (recall bias and/or consistency bias); and 5) impact of personality traits.

Discrepancy between the participant and physical therapist balance rating scales.

There was the possibility that the participants and the research team might not have interpreted the definitions of the anchors linked to the numeric ratings on the participant balance scale to be the same. There may have been a discrepancy in the interpretation of the numeric “5” rating anchor on the participant balance rating scale which was, “I lost my balance”. Participants were reminded that “I lost my balance” was defined as receiving assistance from the physical therapist, stepping out of stance position, or using upper extremity support for assistance. For the physical therapist rating scale, the numeric “5” anchor was, “Unable/Falls with immediate assist/step out < 15 seconds”. Therefore, it would be expected that the agreement for ratings of “5” by both the participant and the physical therapist would be excellent, yet there were 77/132 instances (58% of the time) where the physical therapist rated the exercise as a ‘5” and the participant did not. It is suspected that some participants did not associate receiving assistance from the physical therapist, using upper extremity support, or stepping out of stance position as a “fall”. In conversations between the physical therapist with multiple participants, it was determined that some of the participants, interpreted a “fall” to be an event where a loss of balance could not be recovered and the result was landing on the floor.

Impact of group allocation and/or diagnostic category. We questioned whether the extra knowledge of results (in the form of VTF applied to the trunk with increased sway) would impact the participants perception of their performance. For example, would the participants in the experimental group interpret the feedback they received to indicate worse performance? One participant mentioned to the physical therapist that they didn’t think they were doing well because they were receiving so much feedback during the exercises. Education was provided to each of the participants in the experimental group that the VTF provided was not an indication of performance and that it was meant to provide helpful information. Despite the one anecdotal description above, it does not appear that group allocation impacted our participants perception of performance as only three of the nine people in the experimental group tended to rate their performance worse than what the physical therapist rated them (see Table 28).

However, in exploration of the impact of the diagnostic category, it was revealed that 100% of participants who tended to have perceived balance ratings that were worse than the physical therapist balance ratings (n=6) had vestibular diagnoses (see Table 28). Only three out of nine participants diagnosed with a vestibular disorder tended to have the physical therapist rate their performance worse than they rated themselves. Interestingly, none of the older adults or participants with peripheral neuropathy tended to rate themselves worse than the physical therapist rated them. While it is difficult to make conclusions based on our small sample size, the impact of diagnostic category on perception of balance performance appears to be worthy of future investigation.

Presence of comorbidities including depression. Our results indicated that four of the six participants who tended to perceive their balance to be worse than the physical therapist had a history of depression. Other studies have also found that depression is associated self-perceived function [258, 273]. Having a history of depression was found to be more predictive of worse perception of function than either cognition [273] or actual physical performance measures [258]. Given the small number of people who completed the balance training program within our sample who had a history of anxiety (n=2), it is unrealistic to make inferences but, both participants with anxiety tended to rate themselves worse than the physical therapist.

Study biases. A major limitation of this study was the fact that both the physical therapist and the participant provided one summary rating for each exercise category completed that consisted of six trials. By combining six trials into one rating, it is possible that information based on one specific trial was used to make the rating decision (for example, the rating may have been based on the worst performed trial, the best trial, the first trial, the last trial, etc), rather than a true average/summary score. Therefore, recall bias may have impacted our results from both the participant and physical therapist balance ratings. During this study all 1658 physical therapist ratings were collected from the same research team member (a board certified neurologic clinical specialist with 12 years of clinical experience) and there were 16 different participants from whom balance ratings were collected.

Impact of personality traits influencing rating. Chronic disease is associated with the development of personality traits (decrease in extraversion, emotional stability, conscientiousness, and openness to experience) in adulthood [274] and we question whether different personality types amongst our study sample might explain why participant's rate themselves better or worse than the physical therapist ratings, and if personality may even impact functional outcomes [275]. A 2017 systematic review concluded that personality, especially neuroticism, mastery, optimism, and sense of coherence were associated with psychosocial health-related quality of life more than physical health-related quality of life [276]. Neuroticism has been linked to depression, decreased emotional stability, and decreased self-esteem [277]. Other studies have also linked certain personality traits with self-esteem [278, 279]. We believe that self-esteem could impact perception of performance, quality of life, and activity and participation. A study of people with chronic stroke found that balance self-efficacy (ABC) was more associated with activity and participation than functional performance measures. The authors interpreted this as a need for further evaluation and intervening of psychological factors of balance [280]. The investigation of how personality influences the way a person perceives their balance performance and the impact it has on rehabilitation efforts may provide useful information in future studies.

To determine if the participant rating and the PT rating was reflective of actual balance performance (our second hypothesis), the RMS trunk sway data collected from the accelerometer was analyzed from the exercise categories of standing of firm and foam surfaces. The results indicated that the physical therapist and the participant ratings are consistently matching the amount of sway detected for the exercise category.

One limitation with our data for this hypothesis is that for some of the most difficult exercises the RMS trunk sway may not reflect the actual challenge of the exercise. For example, if the exercise was very difficult, the participant may have received assistance from the physical therapist to prevent maximal RMS trunk sway (i.e. a fall). The participant also might have self-prevented excessive sway by stepping out of the challenging stance. Additionally, the participant had the ability to reach for upper extremity support in the event that their balance was maximally challenged and this use of external support may have reduced a greater amount of sway than would have been observed in maximally challenged exercises if upper extremity support was not available.

To progress a balance training program, it is important to create a program that is appropriately dosed in intensity and challenge. It is also important to ensure that the level of challenge is safe for the patient. To create such a program, a method of rating balance challenge for any given exercise could be useful when combined with a balance exercise progression protocol or framework. In our study, the majority of the balance ratings from both the participant and the physical therapist were at the lower end (perceived as easier) on the balance rating scales. Of the 1658 ratings, 64% of the time both the physical therapist and the participant rated the balance challenge to be a “1” or a “2” (see Table 24). While we do not know the ideal numerical rating to achieve motor learning and functional change, we speculate that the high frequency of “1” and “2” ratings on the balance rating scales may indicate that our participants were not challenged enough. It appears that the challenge was too low for both groups, but the experimental group had a higher incidence of low ratings recorded (67% compared to 59% in the control group).

While using a rating scale for balance is not something that is routinely used during a balance and vestibular rehabilitation program, visual analog scales and rating scales have been shown to be reliable and useful tools to use for monitoring and measuring dizziness, pain and exertion. The subjective units of distress scale [228] is a 0 to 10 subjective scale that records a person’s intensity of discomfort which can be tracked over the course of a treatment or exposure to stimuli and has been used frequently in psychotherapy including cognitive behavioral interventions [281]. Pain scales have been used in clinical practice and research investigations include the Visual Analog Scale for pain [282], the 0-10 Numeric Rating Scale for pain [283], and the Wong-Baker “faces” scale [284]. Scales have also been used to rate vertigo, dizziness, perceived exertion, and dyspnea [285-287]. We had our participants rate their balance performance using an adapted balance rating scale following each exercise category in our training protocol. Concurrently, the physical therapist used an adapted version of the functional independence measure to rate how much assistance was required during each balance exercise.

To date, there is not a standardized scale in which patients rate their balance performance that is used clinically however, recently the same balance rating scale that was used in this study was examined and found to have moderate to strong positive association with sway measures [265]. Our study findings indicate that the participant’s perception of balance performance is correlated to the physical therapist's observation of balance performance. Perhaps even greater correlation may have been observed if the ratings were recorded following individual exercise trials, rather than as a summary of six combined trials. Further exploration is needed to see if specific comorbidities such as anxiety and/or depression impact how a person perceives their balance performance. Additionally, investigation of how personality traits impact the perception of performance during balance activities is warranted.

Consistent with a recent study validating the balance rating scale we used, our results indicate that postural sway is related to how a person rates their balance performance [265]. We believe that the clinical use of a balance rating scale has the potential to guide progression of exercises within a balance training program and gauge the intensity of the exercise program. Additional studies should explore the ideal intensity of balance exercises to promote optimal functional improvements.

5.0 CLINICAL SIGNIFICANCE AND FUTURE RESEARCH DIRECTION

The evidence for using vibrotactile feedback during in-clinic balance training programs was favorable from the outcomes data we collected in this small sample (section 2.4), but not better than customized balance rehabilitation. Our results indicate that people with chronic balance impairments who have already undergone prior episodes of physical therapy care to address balance and functional deficits make clinically meaningful improvements with additional balance training.

More work is needed to determine how VTF and other sensory augmentation modalities can be meaningfully applied during functional tasks like walking. In our study, we did not apply VTF during the gait training trials and the training program only included gait tasks for approximately three minutes per session. We speculate that increased time on functional tasks may be beneficial. To know whether training with sensory augmentation is beneficial, further exploration of using sensory augmentation during walking and other functional tasks is needed.

Additionally, specific VTF application considerations need to be investigated further to understand the optimal threshold for activation of the stimulus. Consideration of whether this threshold should be altered based on the difficulty of the exercise or as the balance training program progresses is important. The thresholds that we used throughout our study (Table 2) were kept consistent for all participants and did not change over the course of the training program. It is important to determine if thresholds for more challenging exercises should be tighter (activation of the feedback occurs sooner, or at a less amount of sway) than the easier examples. For example, in our study the thresholds for activation were greater for the more difficult foot stance positions (tandem and single leg stance compared to feet apart and feet together) so the participant had a greater amount of sway before the vibrotactile feedback was activated. In retrospect, the opposite may be more useful because by the time the participant receives the feedback, it may be too late for them to make the corrective trunk movement that promotes recovery of postural stability. In some of the exercise categories we did not alter the thresholds at all which may not have been ideal for training and needs to be explored further. The frequency in which the feedback is provided should be investigated further and whether the threshold should be subject-specific needs to be determined.

In consideration of the balance training program, a standardized protocol that could be replicated was used in effort to align with the rigor required for a randomized control trial. This protocol was developed based on motor learning principles in effort to provide a mechanism in which to progress people through balance exercises from least to most difficult [17]. This protocol should be further investigated to ensure that the exercises are ordered appropriately by intensity or challenge. The use of the balance rating scales that we used in this study (Figure 3) may be useful in determining the most appropriate ranking of exercises based on challenge and intensity that can be used in future randomized control trials and within the clinic. Acquiring qualitative information regarding the usability of the scales from both the balance performer and the physical therapist would add richness to the information we collected.

Another recommended modification to our study that is also related to intensity is the exploration of determining what the optimal dose of the balance training prescription is. Based on retrospective analysis of the balance ratings provided by both the participants and the physical therapist as well as the consideration of total time exercises were actually completed, we speculate that our participants were under dosed in exercise intensity and frequency. The majority of the numerical balance ratings were either a “1” or a “2”. Further work should explore if making the exercises more difficult would provide better outcomes following training and if so, balance training intensity recommendations to achieve a specific numerical balance rating could be useful for clinical practice dosing guidelines.

If found clinically useful, further work would need to examine the validity and reliability of using the balance rating scales that we have adapted including the inter-rater reliability between raters of different experience levels, which has been done before a study investigating novice and expert raters using a movement screening tool [288]. With specific instructions for scoring, our adapted rating scale would be expected to have similar findings to the movement screening tool. A balance rating scale may also be useful in determining the appropriate level of balance challenge, or intensity, for exercises that are included in a balance training program with the goal of optimally maximizing function quickly in persons recovering from balance disorders. Additional exploration of how personality traits and comorbidities (such as anxiety and depression) impact how people perceive their balance performance and use the balance rating scale is needed.

Additionally, the exploration of whether a training program completed more frequently is worthy of future investigation, especially when considering the prescription of gaze stabilization to improve the function of the vestibulo-ocular reflex. The clinical practice guidelines provided by the American Physical Therapy Association Academy of Neurology [179] reports that current literature suggests that gaze stabilization exercises completed three times a day for a total of 20 minutes results in favorable outcomes. In our study, participants only completed gaze stability exercises for a total of 3 minutes (six 30 second repetitions) three times per week. We purposefully did not include the prescription of a home exercise program because we did not want compliance to confound our results. With the advancement of technology and the potential ability to complete vibrotactile feedback using a home device, the completion of more frequent bouts of daily exercise could be studied.

Another important research direction lies within the need to address quality of life of people with chronic balance disorders. Further exploration into acceptance of diagnosis and strategies to improve their acceptance of their diagnosis may be of great benefit. A 2015 study investigated people with chronic tinnitus and found that increased levels of acceptance of their tinnitus were related to better quality of life and less psychological distress [289]. There currently is not a standardized way in which healthcare professionals approach helping people to accept their altered health condition and physical therapists may have an important role in the identification of people who are not accepting their limitations so that appropriate interventions can be initiated. These interventions may include psychotherapy, cognitive behavioral therapy, self-management promotion, or support groups [290-294]. The use of a quality of life instrument that shows change over time for persons with vestibular and balance disorders will be important for future research efforts.

Consideration of how best to measure activity and participation of people with chronic balance impairments and how to create behavioral changes that will increase meaningful real-world activity and participation appears to be an important aspect that should be investigated in the future. The influence of personality may provide important prognostic information as well as guidance for prescribing the best treatment interventions that will optimize function, activity, participation, and quality of life.

APPENDIX A

CONCEPTUAL FRAMEWORK FOR BALANCE PROGRESSION

Table 33. Firm and Foam Static Standing Progression

	Feet Apart	Romberg	Semi-Tandem Romberg	Tandem Romberg	Single Leg Stance
EO, No head movement	**1**	**2**	**3**	**4**	**5**
EC, No Head Movement	**6**	**7**	**8**	**9**	**10**
EO, Pitch Head Movements	**11**	**13**	**15**	**17**	**19**
EO, Yaw Head Movements	**12**	**14**	**16**	**18**	**20**
EC, Pitch Head Movements	**21**	**23**	**25**	**27**	**29**
EC, Yaw Head Movements	**22**	**24**	**26**	**28**	**30**

Activities are ranked numerically in order of increasing difficulty
EO: Eyes open; EC: Eyes closed

Table 34. Gait Progression

	Walking Speed		
	Self-Selected	Fast	Slow
Forward, Firm, EO, No Head Movement	**1**	**2**	**3**
Forward, Firm, EO, Pitch head Movement	**4**	**6**	**8**
Forward, Firm, EO Yaw Head Movement	**5**	**7**	**9**
Backward, Firm, EO, No Head Movement	**10**		
Forward, On to/Over Foam, EO, No Head Movement	**11**	**12**	**13**
Forward, Firm, EC, No Head Movement	**14**		
Forward Tandem, Firm, EO, No Head Movement	**15**		
Backward, Firm, EC, No Head Movement	**16**		
Backward Tandem, Firm, EO, No Head Movement	**17**		

Activities are ranked numerically in order of increasing difficulty
EO: Eyes open; EC: Eyes closed

Table 35. Modified Center of Gravity Progression

	Type of Weight; Speed of Arm Movements					
	No Weight, Fast	No Weight, Slow	Light Weight, Fast	Light Weight, Slow	Heavy Weight, Fast	Heavy Weight, Slow
EO, Feet Apart, Firm	**1**	**4**	**7**	**10**	**13**	**16**
EO, Romberg, Firm	**2**	**5**	**8**	**11**	**14**	**17**
EO, Semi-Tandem, firm	**3**	**6**	**9**	**12**	**15**	**18**

Activities are ranked numerically in order of increasing difficulty
EO: Eyes open; EC: Eyes closed. Heavy weight = 3 lbs., Light weight = 1 lb.
Repeat Sequence (1-18) with: Eyes Open, Toes Up (19 – 36); Eyes Open, Toes Down (37 – 54); Eyes Open, Foam (55 – 72); Eyes Closed, Firm (73 – 90); Eyes Closed, Toes Up (91 – 108); Eyes Closed, Toes Down (109 – 126); Eyes Closed, Foam (127 – 144)

Table 36. Weight Shifting Progression

	Medial/Lateral Weight Shift	Anterior/Posterior Weight Shift
EO, Firm, Fast Speed, Medium Tilt	**1**	**2**
EO, Firm, Slow Speed, Medium Tilt	**3**	**4**
EO, Firm, Fast Speed, Maximum Tilt	**5**	**6**
EO, Firm, Slow Speed, Maximum Tilt	**7**	**8**

Activities are ranked numerically in order of increasing difficulty

EO: Eyes open; EC: Eyes closed; Medium Tilt = at approximately 50% of their maximum ability to tilt in either the medial/lateral or anterior/posterior direction; Maximum Tilt = at their limit of stability

Repeat sequence(1-8) with Eyes Closed (9-16)
Repeat sequence (1-16) with Foam (17 – 32)

Table 37. Vestibulo-Ocular Reflex Progression

	VOR x1	VOR x2
Firm, Feet Apart, 1 meter, White Background	**1**	**3**
Firm, Feet Apart, 3 meter, White Background	**2**	
Firm, Feet Apart, 1 meter, Complex Background	**4**	**6**
Firm, Feet Apart, 3 meter, Complex Background	**5**	

Activities are ranked numerically in order of increasing difficulty

VOR: Vestibulo-Ocular Reflex

Repeat sequence with: Firm, Romberg (7 – 12); Firm, Semi-tandem Romberg (13 – 18); Firm, Tandem Romberg (19-24); Foam, Feet Apart (25 – 30); Foam, Romberg (31 – 36); Foam, Semi-tandem Romberg (37 – 42); Foam, Tandem (43 – 48)

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