

DISSERTATION

RHYTHMIC AUDITORY STIMULATION TO REDUCE FALLS IN HEALTHY ELDERLY
AND PATIENTS WITH PARKINSON'S DISEASE: A RANDOMIZED CONTROL TRIAL

Submitted by

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ABSTRACT

RHYTHMIC AUDITORY STIMULATION TO REDUCE FALLS IN HEALTHY ELDERLY AND PATIENTS WITH PARKINSON'S DISEASE: A RANDOMIZED CONTROL TRIAL

Background: The risk of falling over the age of 65 is 33% for healthy elderly and 40% for a person with Parkinson's disease over a one year period. A training program to reduce this risk could have significant impacts on health care cost and assist in maintenance of patient safety, independence, and quality of life. **Objective:** The purpose of this study was to investigate whether a home-based Rhythmic Auditory Stimulation (RAS) gait training program would have an effect on gait parameters associated with falls in healthy elderly and PD patients with a history of frequent falls. **Method:** Twenty healthy elderly and twenty PD patients were randomly assigned to a continuous treatment group which underwent 24 weeks with RAS, or a control group which trained intermittently eight weeks with RAS, eight weeks without, for twenty-four weeks. Changes in ankle dorsiflexion, cadence, velocity, stride length, the Berg Balance Scale, fear of falling, the Barthel Index, the timed "up and go" test (TUG) and frequency and severity of falls were evaluated. **Results:** The results for the healthy elderly indicated a statistically significant increase in degrees of dorsiflexion, velocity, cadence, stride length, and the Berg Balance Scale in both groups at each time point, with large effect sizes. Results for the PD treatment groups indicated that there were significant differences in dorsiflexion ($p < .009$), cadence ($p < .009$), velocity ($p < .0001$), stride length ($p < .0003$), severity level 1 falls ($p < .003$), and fear of falling ($p < .0004$), when comparing treatments, with large effect sizes. A correlation matrix combining all 40 participants revealed a significant correlation between fear of falling and

severity level 1 falls at 8 weeks (0.48, $p < .004$); severity level 2 falls at all time periods [baseline (0.42, $p < .01$), 8 weeks (0.42, $p < .01$), 16 weeks (0.42, $p < .01$), and 24 weeks (0.42, $p < .01$)]; and severity level 3 falls at 24 week 0.35, $p < .04$). Other correlations with falls in the healthy elderly group included severity level 2 falls and the Berg Balance scale (0.65, $p < 0.002$), severity level 2 and 3 falls (0.65, $p < .002$), severity level 3 falls and stride length (0.57, $p < .002$) and velocity (0.65, $p < .002$). Significant interactions were seen between the intermittent and continuous treatment groups in dorsiflexion [$F(2,72) = 9.54$, $p < .0002$], stride length [$F(2,72) = 8.17$, $p < .0006$], velocity [$F(2,72) = 7.92$, $p < .0006$], fear of falling [$F(2,72) = 12.97$, $p < .0001$], and the Berg Scale [$F(2,72) = 1.92$, $p < .15$]. **Conclusions:** The findings offer evidence that continuous and intermittent RAS treatment over time can be effective tools to reduce falls in healthy elderly and patients with Parkinson's disease, however continuous RAS treatment results in greater gains in gait parameters associated with safety. Two single variables, the Berg Balance Scale and velocity were seen as a significant fall predictor for healthy elderly. The Barthel Index was a significant indicator for falls with injury for the Parkinson's participants.

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CHAPTER I: INTRODUCTION

Overview

The risk of falling in older adults over the age of 65 is 33% over a one year period, making it the leading cause of both fatal and nonfatal injuries in the elderly population (Tromp,Plijm, Smit, Deeg , Bouter, & Lips, 2001). Twenty to thirty percent of healthy elderly experience falls, which result in moderate to severe injuries ranging from bone fractures to traumatic brain injuries. Additionally, people over the age of 75 are four to five times more likely to be admitted to a long-term care facility for a year or longer after a fall (Scott, 1990). Falling is not only a major health risk to the elderly population, but can also result in loss of independence and substantial medical and economic burden.

Muscle strength and balance are two key factors for safety during ambulation, however decreased muscle strength and balance, which are a natural part of the aging process, also make them the leading risk factors for falls in the elderly. Bean, Leveille, Kiely, Bandinelli, Guralnik, & Ferrucci (2003) identified lower extremity muscle power as a strong predictor of physical performance, functional mobility, and risk of falling among older adults. Older adults who have poor balance or difficulty walking are more likely than others to fall.

Mecagni, Smith, Roberts, & O'Sullivan (2000), specifically found correlations between ankle range of motion (ROM) and balance measures in community-dwelling elderly women with no health problems. Whipple, Wolfson, & Amerman (1987), found that at higher more functional limb velocities, ankle weakness, particularly involving the dorsiflexors, appeared to be an important factor underlying poor balance. Additionally, Horak (1987) identified that a decrease in ankle ROM can result in compensatory movement patterns at the hip and trunk that can compromise balance and decrease postural control. A certain amount of ankle ROM is

needed for safety in functional activities such as walking, which requires a minimum of ten degrees of dorsiflexion (Tiberio, 1987). Unfortunately, range of motion tends to decline as people age, due to changes in the mechanical properties and morphology of joint structures (e.g., decreases in ankle ROM in plantar flexion, dorsiflexion, inversion, and eversion) (Sepic, Murray, Mollinger, Spurr, & Gardner, 1986). Both healthy elderly men and women demonstrate large changes in ankle ROM, however women show greater age-related declines than men do (Vandervoort, Chesworth, Cunningham, Rechnitzer, Paterson, & Koval, 1992).

The risk of falls in a person with Parkinson's disease (PD) increases substantially from healthy elderly, and can vary greatly depending on independent risk factors such as previous fall history, disease duration, cognitive level, and loss of arm swing. A study by Wood, Bilclough, Bowron, & Walker (2002) found that out of 109 subjects with idiopathic PD and a mean Hoen/Yahr rating of 2, 68% experienced falls over a 1 year period. Ashburn, Stack, & Ward (2001), found the risk of falls in PD to be 40%. Gray and Hildebrand (2000) reported 59% of patients with Parkinson's disease falling over a 3 month period in a 1-year prospective study. Both of these studies indicate a very high risk of falling in patients with PD, presenting not only a serious concern over safety, but also over the enormous human and health care cost associated with falling. Falls are among the biggest contributors to loss of independent living, long-term institutionalization, and increased mortality (Johnell, Melton, Atkinson, O'Fallon, & Kurland, 1992). Therefore, a training program to reduce the risk of falls could have a significant impact on health care cost and assist in maintenance of patient safety, independence, and quality of life.

Statement of the Research Problem

Healthy elderly, as well as persons with Parkinson's disease (PD) have an increased risk of falling, often resulting in a loss of independent living, long-term institutionalization, and increased mortality (Johnell et al., 1992). A training program to reduce this risk could have significant impacts on health care cost and assist in maintenance of patient safety, independence, and quality of life. The purpose of this study was to investigate whether an at-home based Rhythmic Auditory Stimulation (RAS) gait training program would decrease the number of falls in healthy elderly and in a person with Parkinson's disease, with a history of frequent falls. The focus was directly on 5 important outcomes: 1) increased patient safety, 2) increased preservation of quality of life, 3) reduction of fall related injuries and mortality, 4) decrease of high fall-related medical costs, and 5) reduction of nursing home admissions.

This study compared a group of healthy elderly and a group of patients with Parkinson's disease who were randomly assigned to either an experimental group, that underwent 24 weeks with RAS training; or a control group, that trained intermittently 8 weeks with RAS and 8 weeks without, for 24 weeks. Changes in ankle dorsiflexion, a kinematic parameter used to assess fall risk in this population; changes in gait parameters including cadence, velocity and stride length; and the number of falls, following an RAS-based ambulation and exercise program were evaluated. Other kinematic and clinical assessments were also used to search for variables that may be associated with falling and potentially predictors for fall risks, including the Berg Balance Scale, the Timed Get up and Go Test, and a fear of falling questionnaire. All parameters assessed have been consistently used in clinical neurological rehabilitation research and therefore were considered to possess appropriate internal and external content validity.

Research Questions

This study investigated whether an at-home based RAS gait training program would decrease the number of falls in healthy elderly and patients with Parkinson's disease who had a history of frequent falls. Additionally, this study evaluated changes in clinical and kinematic parameters commonly used to assess fall risk in these populations. Changes in gait parameters including cadence, stride length, and velocity, following an RAS-based ambulation and exercise program were assessed. Kinematic and clinical assessments were used to search for variables that may be associated with falling and are predictors for fall risks. The problem was broken down into the following research questions:

- 1) Can an at-home based RAS gait training and exercise program have an impact on dorsiflexion, velocity, cadence, and stride length; severity level of falls; and Barthel Index, Berg Balance Scale, fear of falling survey and TUG test scores, when comparing intermittent and continuous treatment at baseline and 8 weeks, baseline and 16 weeks, and baseline and 24 weeks, in healthy elderly and patients with Parkinson's disease who have a history of frequent falls?
- 2) Is there a difference between intermittent and continuous participation in at-home based RAS gait training and exercise program, when comparing degrees of dorsiflexion, number of falls, cadence, velocity, stride length, Berg Balance Scale scores, fear of falling, and Timed "Up and Go" score at 16 weeks, and 24 weeks?
- 3) Is there an association between fear of falling and the level of severity of falls experienced at each of the 4 time points?

- 4) Is there a correlation between dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, or Timed “Up and Go” scores and the level of severity of falls experienced at baseline?
- 5) Is there a difference in change scores in any of the three fall severity levels for each subject between baseline to twenty-four weeks in any of the dependent variables: dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, or Timed “Up and Go”?
- 6) Is there a statistically significant interaction between intermittent and continuous treatment in the HE or PD group or between the HE and PD group over time, for any of the dependent variables?
- 7) Are there variables that can predict the risk of falls in healthy elderly or persons with Parkinson’s disease?

Definition of Terms

Berg Balance Scale

The Berg Balance Scale is a standardized assessment originally developed to evaluate functional balance in the elderly, but today used with a variety of patients with balance deficits (Appendix A). The scale consists of 14 tasks related to different activities of daily living, which are scored on a five-point scale ranging from 0 (inability to perform task) to 4 (ability to perform task independently). The score is based on the time in which a position is maintained, the distance to which the upper limb is capable of reaching out in front of the body and the time needed to complete a task (Berg, Wood-Dauphinee, & Williams, 1989).

Cadence

Cadence refers to the number of steps/minute that a person takes when walking. Cadence is a standard gait parameter measurement with standardized norms across gender and age (Oeberg, 1993). In this study, cadence was measured by performing the ten meter walk using a portable microprocessor and foot switch sensors to record the number of steps.

Cueing of the Movement Period

This concept refers to the fact that when using rhythm in movement cuing, time stability is enhanced by rhythmic synchronization throughout the whole duration and trajectory of the movement and not just at the endpoints of the movement coincidental with the rhythmic beat (Thaut, Miller, & Schauer, 1997).

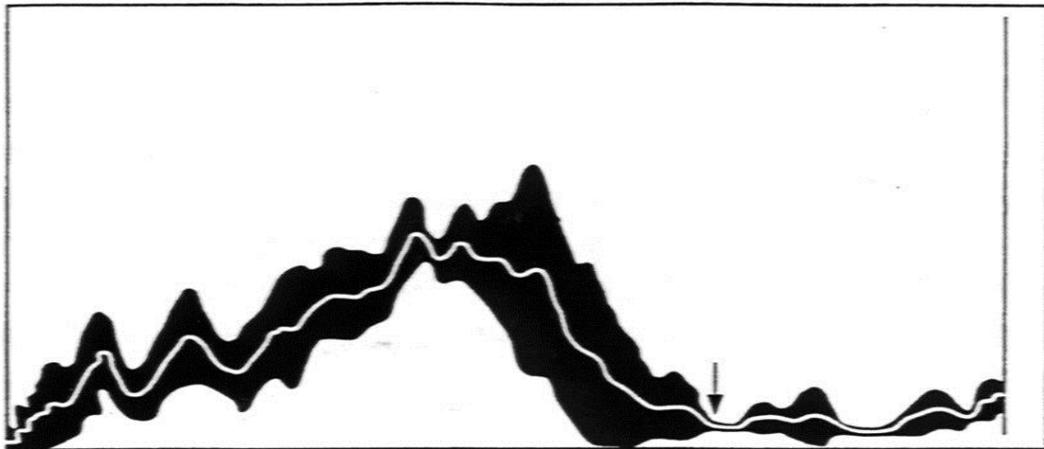
Dorsiflexion

Dorsiflexion refers to flexion at the ankle which takes place during the swing phase of gait in order to clear the toe. Dorsiflexion is measured in degrees of flexion at the ankle joint. Weakness in the tibialis anterior muscle can often result in deviations at the ankle such as decrease dorsiflexion, which has been associated with an increased risk for falls.

Electromyography (EMG)

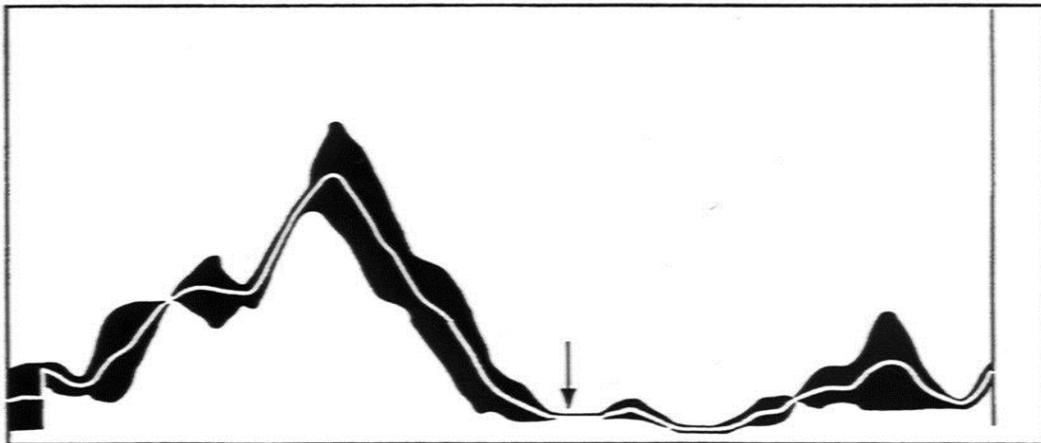
EMG is a test that measures the electrical activity of muscles at rest and during contraction. EMG is frequently used in research to assess variability, onset, duration, and integrated amplitude ratios in muscle activity. A sample of EMG data can be seen in figure 1.1.

Pretest (Gastroc. Paretic Side)



Statistics	Mean	St. Dev.	
Seg-length:	1859.2	63.5	C.V seg.=3.4%
Sum- μ V:	1299.7	304.1	C.V emg.=27.1%
Ave- μ V:	0.70	0.19	

Post test (Gastroc. Paretic Side)



Statistics	Mean	St. Dev.	
Seg-length:	1226.7	18.9	C.V seg.=1.5%
Sum- μ V:	1504.3	170.3	C.V emg.=11.4%
Ave- μ V:	1.23	0.14	

Figure 1.1 Examples of the electromyography patterns on the paretic side of a stroke patient, pre and post-test with 3 weeks of rhythmic auditory stimulation training in between, for one gait cycle (Thaut, McIntosh, Prassas, & Rice (1993).

Gait Cycle

The gait cycle is the sequence that each limb goes through repetitively as we ambulate (figure 1.2). Each lower extremity goes through alternating gait cycles during which the foot is on the ground, called **stance phase**, and the foot is in the air, called the **swing phase** of gait.

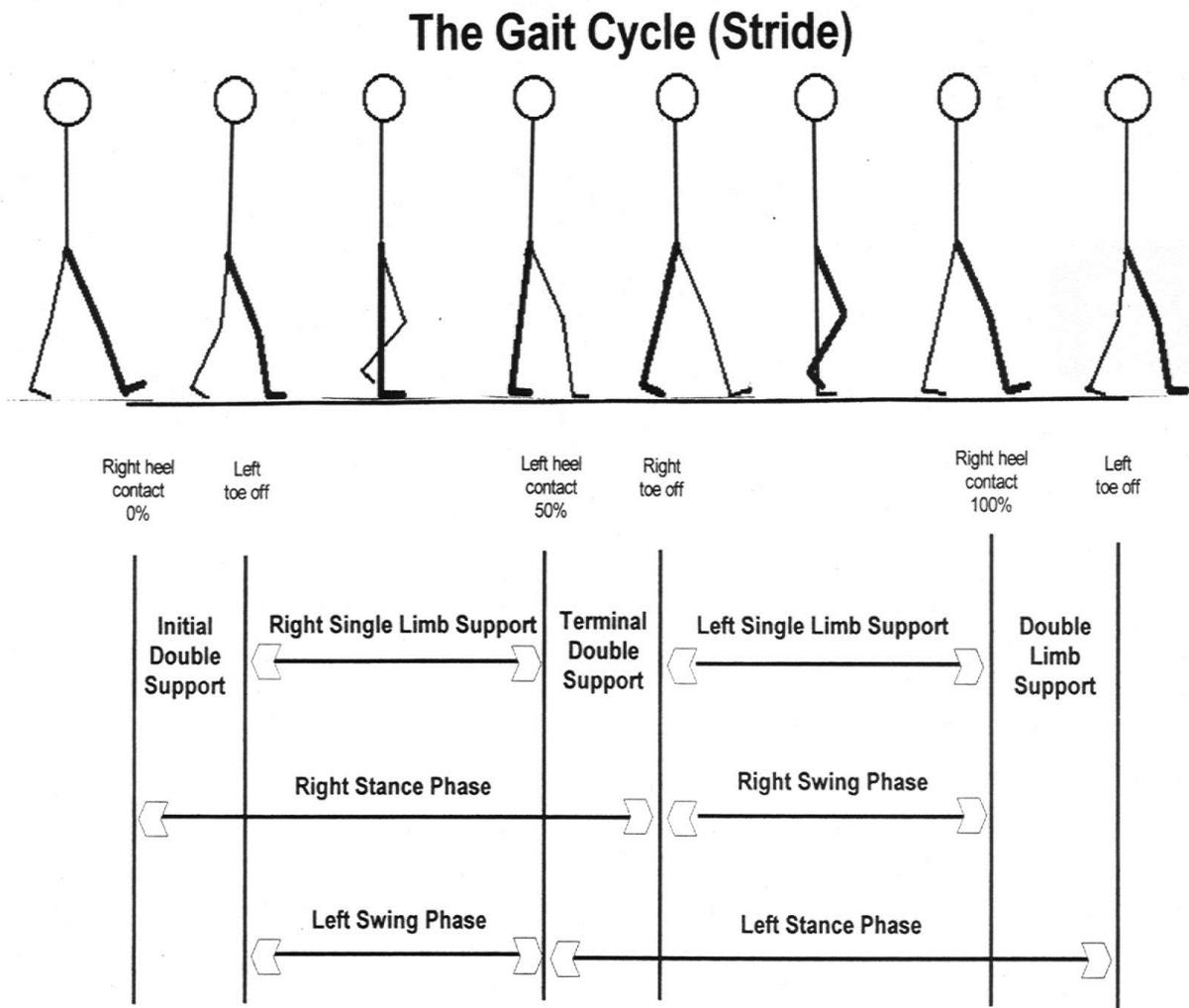


Figure 1.2. Illustration of the gait cycle and the events that take place during normal gait (O’Sullivan & Schmitz, 2007).

Hoehn/Yahr Scale

The Hoehn and Yahr scale is a system commonly used for describing the progression of Parkinson's disease symptoms and the relative level of disability associated with each stage. The stages are not consistent across all patients, and can vary in duration across patients, but are meant to be a general guideline. The original version, published in 1967 in the journal *Neurology* by Melvin Yahr and Margaret Hoehn, only included stages 1 thru 5. Since then, stage 0 has been added, and stages 1.5 and 2.5 are commonly used (Shulman L.M., Gruber-Baldini A.L., Anderson K.E., Vaughan C.G., Reich S.G., Fishman P.S., & Weiner W.J., 2008).

- Stage 0 - no signs of disease
- Stage 1 - symptoms on one side only (unilateral)
- Stage 1.5 – symptoms unilateral and also involving the neck and spine
- Stage 2 – symptoms on both sides (bilateral) but no impairment of balance
- Stage 2.5 - mild bilateral symptoms with recovery when the 'pull' test is given (the doctor stands behind the person and asks them to maintain their balance when pulled backwards)
- Stage 3 - balance impairment. Mild to moderate disease. Physically independent
- Stage 4 - severe disability, but still able to walk or stand unassisted
- Stage 5 - needing a wheelchair or bedridden unless assisted.

Limit Cycle

A limit cycle is the step cadence or frequency in which a person's gait functions most optimally. As a person gets older, their limit cycle may decrease due to changes in the mechanical properties and morphology of joint structures. In Parkinson's disease it is not uncommon to see a faster than normal limit cycle due to festinating gait patterns, or a decreased limit cycle due to bradykinesia.

Priming

Priming is the ability of an external auditory cue to stimulate recruitment of motor neurons on the spinal cord level, therefore resulting in entrainment of the muscle activation patterns in the legs during walking.

Rhythmic Auditory Stimulation (RAS)

RAS is a neurologic technique used to facilitate the rehabilitation of movements that are intrinsically biologically rhythmical, most importantly gait. RAS can be used as both an immediate entrainment stimulus, providing rhythmic cues during movements and as a facilitating stimulus for training in order to achieve more functional gait patterns (Thaut, 2005).

Rhythmic Entrainment

Rhythmic Entrainment refers to the ability that the motor system has to couple with the auditory system, therefore driving movement patterns.

Step-Wise Limit Cycle Entrainment (SLICE).

SLICE is the process of entraining a patient's current limit cycle and gradually through a stepwise progression, modulating their step cadence to approximate premorbid movement frequencies.

Stride Length

Stride length refers to the length of a stride on one side of the body, from the heel strike of one foot until the next time that same heel hits the ground.

Timed "Up and Go" Test

The Timed "Up-and-Go" Test (Appendix B) quantifies functional mobility through the time (in seconds) in which an individual performs the task (stand up from a standardized chair with back and arm supports, walk three meters, turn around, walk back to the chair and sit down again) (Podsiadlo & Richardson, 1991).

Velocity

Velocity is the speed at which someone walks, and it is measured in meters/minute or feet/minute (feet/min divided by 3.281 = Meter/min).

Delimitations

The results of this study cannot be generalized beyond the following group characteristics: Healthy elderly and patients with Parkinson's disease (2/3 on the Hoehn/Yahr Scale) between the ages of 60 and 85, who have reported 2 or more falls in the past 6 months.

Study Limitation

Due to the varied medical needs and degenerative nature of Parkinson's disease, it is understood that there may be participants who are unable to complete the entire 24 weeks of the study.

While additional factors such as cognition, sensory issues, decreased vision or depth perception, and side effects from medications have been linked to gait and balance problems, outside of physician approval for participation, those variables were not controlled for in this study.

Significance of the Study

There is no single underlying cause or risk factor linked to why elderly people fall, but falling is often a combination of factors (Tinetti, Speechley, & Ginter, 1988). Research has linked many possible factors to an individual's increased risk, including: Muscle weakness, decreased balance during ambulation, blood pressure, slowing of reflexes, cognition, decreased proprioception, decreased vision or depth perception, and side effects from medications.

While there are dangers associated with the physical injuries which result from falling, there are also dangers associated with using excessive caution to avoid falls. Many people who have experienced a fall, regardless of the severity, develop a fear for falling which causes them to limit their activities, resulting in decrease mobility, loss of physical fitness, and decreased social interaction. Therefore, even elderly in good health may reduce their physical activity and

actually increase their risk for future falls (Donald, 1999). While few studies have addressed whether exercise can have an effect on fear of falling, it has been shown that there is a correlation between poor physical function and the fear of falling (Oh, Park, Lee, Oh, Sung, Cho, & Baik, 2012).

Few clinical trials with little evidence for benefit have investigated the effectiveness of interventions to prevent or reduce the risk of falls in Parkinson's disease (Goodwin, Richards, Henley, Ewings, Taylor, & Campbell, 2011). Some recent studies, including a large meta-analysis by Ashburn et al.(2001), have explored the benefit of exercise programs to decrease fall incidences in Parkinson's disease (Allen, Canning, Sherrington, Lord, Latt, Close, O'Rourke, Murray, & Fung, 2010; Goodwin et al., 2011). These studies, found trends towards improvements, but they did not find statistically significant fall reductions, as seen in similar studies with healthy elderly where exercise programs emphasizing strength and balance training resulted in a significant reduction of fall incidents (Sherrington,Whitney, Lord, Herbert, Cumming, & Close, 2008).

Until recently, good predictor variables associated with high risk of falling in PD have not been successfully identified (Bloem, Grimbergen, Cramer, Willemsen, & Zwinderman, 2001). Specifically, associations between increased risks of falling and the three classic signs of Parkinson's disease: rigidity, tremor, and bradykinesia, have not been substantiated (Schaafsma, Giladi, Balash, Bartels, Gurevich, & Hausdorff, 2003). Contreras and Grandas (2012) found an association between falls and Tinetti Balance scores, Hoehn& Yahr stage III or more, and age (exponential increase of falls above age 70); however, the author stated that these metrics are fairly broad, including large subgroups of PD, and are therefore limited in predicting individual fall risks. Pickering, Grimbergen, Rigney, Ashburn, Mazibrada, Wood, Gray, Kerr & Bloem,

(2007), in a meta-analysis of six prospective studies, found that the best predictor was two or more falls in the previous year. This however, does not meet the need to identify risk factors and provide fall prevention programs before falls have occurred.

Theoretical Background

Rhythmic Auditory Stimulation (RAS) is a neurologic technique used to facilitate the rehabilitation of movements that are intrinsically biologically rhythmical, most importantly gait. RAS uses the physiological effects of auditory rhythm on the motor system to improve the control of movement in rehabilitation of functional, stable, and adaptive gait patterns in patients with significant gait deficits due to neurological impairment (Thaut, 2005). RAS accesses biological auditory-motor networks that create fast, temporally precise and stable synchronization mechanisms between sensory input and motor output (Thaut et al., 1998; Stephan, Thaut, Wunderlich, Schicks, Tian, Tellmann, Herzog, MacIntosh, Seitz, & Homberg 2002; Thaut 2003). Auditory -motor pathways have been described on multiple distributed levels from cochlear root neurons synapsing with reticulospinal neurons, to activating corticocerebellar pathways (Fernando del Olmo, Arias, Furio, Pozo, & Cudeiro, 2003; Thaut, Stephan, Wunderlich, Schicks, Tellmann, Herzog, McIntosh, Seitz, & Homberg, 2008), to cortico-striatal loops and fronto-temporal pathways involving the arcuate fasciculus (Schmahman & Pandya, 2008). The evidence for priming and timing of the motor system via reticulospinal pathways has been demonstrated as early as 1967 (Paltsev & Elnor) and 1976 (Rossignol & Melvill Jones).

Several studies have looked at the effects of rhythmic auditory stimulation on gait in persons with Parkinson's Disease, showing that subjects were able to improve their walking patterns through better posture; more appropriate step cadence and stride length; more efficient and symmetric muscle activation patterns (Richards, Malouin, Bedard, & Cioni, 1992; Thaut

McIntosh, Rice, Miller, Rathbun, & Brault 1996; McIntosh, Brown, Rice, & Thaut, 1997; Miller, Thaut, McIntosh, & Rice, 1996); long-term carry-over (McIntosh, Rice, Hurt, & Thaut, 1998), and reduction of freezing episodes (e.g., Thaut et al., 1996; McIntosh et al., 1997; Howe, Lovgreen, Cody, Ashton, & Oldham, 2003; Freedland, Festa, Sealy, McBean, Elghazaly, Capan, Brozycki, Nelson, & Rothman, 2002; Frazzitta, Maestri, Uccellini, Bertotti, & Abelli, 2009; Morris & Schoo, 2004; Willems, Nieuwboer, Chavret, Desloovere, Dom, Rochester, Jones, Kwakkel, & Van Wegen, 2006).

Additionally, studies using RAS with healthy elderly have shown improvements in stride rhythmicity between the left and right legs, delayed onset of the gastrocnemius muscle, shortened duration of muscle activity, decreased variability in EMG, and increased integrated amplitude ratios of EMG (Thaut, McIntosh, Prassas, & Rice, 1992).

Researchers Perspective

The purpose of investigating this research topic was to better understand how neurologic music therapists can best address the needs of elderly and people with Parkinson's disease who are experiencing frequent falls. Standards of best practice require that therapist provide the best available treatment based on research evidence. If a study like this is able to help therapist isolate the key kinematic parameters that are associated with frequent falls in these populations, as well as an effective intervention to improve those kinematic parameters, then this study could take the knowledge of best practice in this area to the next level of understanding.

I have worked as a therapist with these populations for many years, and I have seen how an unintentional fall can have a debilitating effect on a person's life. I have also watched people become increasingly less active socially and physically, because of their fear of falling. An exercise program that targets improvements in the key kinematic parameters that are associated

with falls could have a life changing effect on people and their safety, ability, and confidence to reintegrate into a physically active and social lifestyle.

CHAPTER II: LITERATURE REVIEW

Parkinson's Disease

Parkinson's disease is a degenerative neurologic disease associated with progressive loss of dopaminergic neurons in the basal ganglia, due to the deterioration of the substantia nigra. Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease, and the most common movement disorder. Typical characteristics of Parkinson's disease include progressive loss of muscle control, which leads to bradykinesia (slowing of movements), resting limb tremor (trembling of the limbs and head while at rest), rigidity (stiffness), and gait instability resulting in impaired balance. As symptoms worsen, it may become difficult to walk, talk, and complete simple tasks.

There are over 5 million people affected by Parkinson's disease, with about 1 million people in the United States. Onset of Parkinson's disease typically occurs at 60 years of age or older, with approximately 1% of individuals aged 60 years and in about 4% of those aged 80 years. In general, overall life expectancy continues to rise, so the number of individuals with Parkinson's disease will only continue to increase in the future. Although adult-onset Parkinson's disease is most common, early-onset Parkinson's disease (onset between 21-40 years), and juvenile-onset Parkinson's disease (onset before age 21) may also occur (Sietske, 2013).

A person with Parkinson's disease, presents with very marked gait characteristics including postural instability (stooped posture), decrease arm swing, decreased stride length, shuffling steps (festinating gait), and freezing. Due to postural instability, people with Parkinson's disease have this feeling of falling forward which results in them walking on their toes and taking very short, shuffling steps in order to keep themselves from falling. A key goal

in treatment is to increase heel strike in order to increase stride length and decrease festinating gait patterns which can result in a loss of balance.

The progression of Parkinson's disease and the degree of impairment varies from individual to individual. Many people with Parkinson's disease live long productive lives, whereas others become disabled much more quickly. Premature death is usually due to complications such as falling-related injuries or pneumonia. In 1967, Hoehn and Yahr developed a system commonly used for describing the progression of Parkinson's disease symptoms and the relative level of disability associated with each stage. The stages are not consistent across all patients, and can vary in duration across patients, but are meant to be a general guideline. The original version was published in the journal *Neurology* by Melvin Yahr and Margaret Hoehn (1967), and only included stages 1 thru 5. Since then, stage 0 has been added, and stages 1.5 and 2.5 are commonly used (Shulman, 2008).

Stage 1 The main symptoms- tremor, muscle stiffness, slowness of movement and problems with posture- are only on one side of the body. Problems with balance might also appear.

Stage 2 The disease will be on both sides of the body now and minor symptoms like problems with swallowing, talking and something called "facial masking" (loss of facial expression) may be noticed.

Stage 3 The same symptoms of Stage 2 are still there but may be worse now. Problems with balance will now be noticed for the first time. At this stage, the person with Parkinson's is still independent.

Stage 4 The person with Parkinson's will now be getting more and more disabled and will need help with some or all activities of daily living.

Stage 5 At this stage the person is confined to a wheelchair or bed and needs total assistance.

Risk of Falling in Patients with Parkinson's Disease

Several studies with different sample sizes and various methodologies have assessed risk of falling in patients with PD. Ashburn et al. (2001) found a 40% risk of falling in a 12 month period. In a prospective study by Bloem et al. (2001), 51% of subjects with PD at moderate disease levels were observed experiencing falls over a six month period, whereas only 15% of age-matched normal subjects fell. Gray and Hildebrand (2000) reported 59% of patients falling over a 3month period in a 1-year prospective study. Wood et al. (2002) reported that 68% of observed subjects had at least one fall. Pickering et al. (2007), in a meta-analysis study, found a 3 month fall rate of 46% for patients with previous falls and 21% for patients without prior falls. These numbers, indicate that a very high risk of falling in patients with PD presents not only a serious concern over safety, but also for loss of independence and substantial medical and economic burdens.

Healthy Elderly and Falling

The number of falls among elderly has increased considerably over the last decade. Each year, one in every three adults, age 65 and older, will experience a fall which will cause moderate to severe injuries, such as hip fractures and head traumas (Tromp et al., 2001). In 2010, about 21,700 of those unintentional fall injuries resulted in death (Centers for Disease Control and Prevention, 2014).

While no single underlying cause or risk factor is linked to falls in the elderly, an increase in falling is often caused by a combination of factors related to the normal process of aging. Decreased bone density or osteoporosis not only decreases stability, but also make bones more vulnerable to breaks during a fall. Decreased or lack of physical activity, can result in poor muscle tone, decreased strength, and loss of bone mass and flexibility, putting someone at higher risk for falls and injury. Age related visual impairments such as cataracts and glaucoma can alter depth perception, visual acuity, and peripheral vision, making it more difficult to safely maneuver through ones environment. Medications can reduce mental alertness, impair balance and gait, and cause drops in systolic blood pressure while standing. Additionally, environmental hazards such as poor lighting, loose rugs, lack of grab bars, objects on the floor, or unsteady furniture can cause risks for falling.

Alexander, Rivara, & Wolf (1992), examined 1,989 hospitalizations of older adults with fall-related injuries, finding that hospitalization of elderly patients, ages 65 and older with fall-related trauma, accounted for 5.3 percent of all hospital charges. With the population aging and the rising cost and fees for hospital and nursing home care, doctors and other professional services, rehabilitation, community-based services, use of medical equipment, prescription drugs, changes made to the home, and insurance processing, this number has continued to increase. In 2010, falls among older adults cost the U.S. health care system \$30 billion in direct medical costs. In 2011, emergency departments treated 2.4 million nonfatal fall injuries among older adults; more than 689,000 of these patients had to be hospitalized (Centers for Disease Control and Prevention, 2014).

In an updated Cochrane review, Gillespie, Robertson, Gillespie, Sherrington, Gates, Clemson, & Lamb (2013), assessed the effects of interventions designed to reduce the incidence

of falls in older people living in the community, by examining 159 random control trials with 79,193 participants. The conclusions of his review were that multifactorial assessment and intervention programs such as monitoring medication, treatment of visual problems, fall prevention education, and non-slip shoes reduce the rate of falls, but not the risk of falling. The only interventions which consistently reduced both the rate and risk of falling were group and home-based exercise programs and home safety assessments.

Rhythmic Auditory Stimulation (RAS)

In 1991, Thaut, Schleiffers, & Davis, published the first in a series of research papers which would become the foundation for investigating the effects of a rhythmic auditory stimulus on the motor control of both the upper and lower extremities in normal and neurologically impaired subjects. Since then, basic science and clinical research supporting the use of rhythm in the rehabilitation/habilitation of movement has continued to grow rapidly. As recently identified in by Hurt-Thaut (2014), many recent studies have looked at the effects of rhythmic auditory stimulation on gait with Parkinson's disease (de Bruin, Doan, Turnbull, Suchowersky, Bonfield, Hu, & Brown, 2010; de Dreu, van der Wilk, Poppe, Kwakkel, & van Wegen, 2012; Kadivar, Corcos, Foto, & Hondzinski, 2011; Del Olmo, Aria, Furio, Pozo, & Cudeiro, 2006; Del Olmo, & Cudeiro, 2003), stroke (Prassas, Thaut, McIntosh & Rice, 1997; Thaut, McIntosh, & Rice, 1997), traumatic brain injury (Hurt, Rice, McIntosh, & Thaut, 1998), multiple sclerosis (Baram and Miller, 2007; Conklyn, Stough, Novak, Paczak, Chemali, & Bethoux, 2010), spinal cord injuries (de l'Etoile, 2008), and spastic diplegic cerebral palsy (Kim, Kwak, Park, Lee, Kim, Song, & Cho, 2011; Baram & Lenger, 2012), and continue to show the significant impact of rhythm on gait kinematics through better posture, more appropriate step rates (step cadence) and stride length, and more efficient and symmetric muscle activation patterns in the lower

extremities during walking. A Cochrane review of music therapy for acquired brain injury (Bradt, Magee, Dileo, Wheeler, & McGilloway, 2010) identified the Neurologic Music Therapy (NMT) technique, rhythmic auditory stimulation (RAS) as beneficial with stroke patients for improving gait parameters such as velocity, cadence, stride length and gait symmetry.

As previously identified (Thaut, 2005, Hurt-Thaut, 2014), there are four neurological principles in which the basis for RAS is built upon: rhythmic entrainment, priming, cuing of the movement period, and stepwise limit-cycle entrainment. “**Rhythmic Entrainment** is the ability that the motor system has to couple with the auditory system and drive movement patterns. Central Pattern Generators (CPG) are local spinal cord circuits which help connect incoming sensory information to appropriate motor neurons that enable movement. The CPG is capable of producing coordinated movement of the limbs with no input from the brain. Therefore, this magnet effect of auditory rhythm to synchronize and entrain movement patterns happens even at levels below conscious perception and without cognitive learning”. A simple example of rhythmic entrainment can be seen when two people are walking down the hallway, one in front of the other while one is wearing heels. Even without intentionally trying, the clicking sound of the heels will couple with the motor system and at unconscious levels result in both people walking at the same cadence.

Also described previously by Thaut (2005), “**priming** is the ability of an external auditory cue to stimulate recruitment of motor neurons on the spinal cord level, therefore resulting in entrainment of the muscle activation patterns in the legs during walking”. In 1991, Thaut et al. did a study to analyze auditory rhythm as an external time keeper to modify the onset, duration, and variability of electromyographic (EMG) patterns in the biceps and triceps during the performance of a gross motor task. The results showed that an external auditory cue was

effective in decreasing variability in muscle activation patterns “indicating a more efficient recruitment of motor units necessary in skilled movement”. These results may also imply that when a patient has a more efficient use of their muscles this could lead to the ability to perform a task for a longer period of time. In 1992, another study by Thaut et al. investigated the effect of auditory rhythm on temporal parameters of the stride cycle and electromyographic (EMG) activity in normal gait. Subjects in the rhythmic condition, improved stride rhythmicity between the right and left lower extremities, showed delayed onset and shorter duration of gastrocnemius muscle activity, and increased integrated amplitude ratios for the gastrocnemius muscle. The results in from this study provided evidence that rhythmic cuing creates “more focused and consistent muscle activity during push off when a rhythmic auditory cue is present due to a priming effect”. Similar results were again seen in 1993 by Thaut, McIntosh, Prassas, & Rice with hemiparetic gait and stroke patients.

An additional concept described by Thaut (2005) and Hurt-Thaut (2014), **cueing of the movement period**, came from a 1998 study into rhythmic entrainment and motor synchronization mechanisms. Evidence emerged that “rhythmic motor synchronization is primarily driven by interval adaptation or frequency entrainment rather than event synchronization or phase entrainment between motor response and the rhythmic beat” (Thaut, Miller, & Schauer, 1998). When using rhythm to cue movement, this meant that “time stability is enhanced by rhythmic synchronization throughout the whole duration and trajectory of the movement and not just at the endpoints of the movement coincidental with the rhythmic beat”.

A limit cycle is the step cadence or frequency in which a person’s gait functions most optimally (Thaut, 2005). Limit cycles can change due to neurologic disease or injury, resulting in deficient gait patterns. **Stepwise Limit Cycle Entrainment (SLICE)** is the process of

identifying a patient's current limit-cycle, and gradually through a stepwise progression, modulating their step cadence to a more normal frequency. Although there is no exact normal frequency for every person, Oeberg, Karsznia, & Oeberg (1993), identified guidelines for average norms based on age and gender. The SLICE process is done through 6 steps which make up the protocol for RAS gait training.

RAS Gait Training

Rhythmic Auditory Stimulation (RAS) gait training, as previously defined by Hurt-Thaut (2014) is a technique in neurologic music therapy which follows a sequence of 6 steps, each geared toward gradually shaping a more normal gait pattern. RAS uses stepwise limit cycle entrainment (SLICE) to meet a patient at their current level of functioning, and gradually through a stepwise process, shape their gait to a more normal pattern. The amount of time spent on each step depends on the level of functioning of the client, but based on the protocol that I have identified and defined in *The Handbook for Neurologic Music Therapy* (Hurt-Thaut, C.P., & Rice R. R., 2014), all steps should be considered and carried out in the following order:

- 1) Assessment of current gait parameters
- 2) Resonant Frequency Entrainment and Pre-gait Exercises
- 3) Frequency Modulation at increments of 5-10%
- 4) Advanced Gait Exercises
- 5) Fading of Musical Stimulus
- 6) Re-assessment of gait parameters

Step One- Assessment of Current Gait Parameters

Every RAS gait training session begins with a thorough assessment of the client's gait parameters. This assessment should include, but is not limited to, a 10 meter walk to calculate current cadence (steps/minute), velocity (meters/minute), and stride length (meters). The therapist should also evaluate gait kinematics such as: symmetry of gait, muscle weakness, trunk rotation, arm swing, posture, heel strike, toe off, single and double support time, and effective use of an assistive device. Other assessments commonly used to evaluate additional aspects of balance and functional independence during ambulation include the Berg Balance Scale (Berg, Wood-Dauphinee, Williams, & Gayton, 1992) and the Timed Up and Go (Podsiadlo & Richardson, 1991).

In gait, **Cadence** is defined as the number of steps a person takes per minute. This can be calculated by having someone walk for 30 or 60 seconds while counting the number of steps that they take. For those clients who are unable to walk for the full duration, the 10 meter walk is a standardized assessment which requires the therapist to time how long it takes a patient to walk 10 meters and in how many steps. From those numbers, the therapist can calculate cadence by the following formula: $60/\text{time} \times \text{number of steps}$.

Velocity is the speed at which someone walks, and it is commonly measured in meters/minute or feet/minute (feet/min divided by 3.281 = Meter/min). Velocity can also be calculated in the clinic by using the information collected in the 10 meter walk. Velocity = $60/\text{time (in seconds)} \times 10 \text{ meter (distance)}$.

Stride length refers to the length of a stride on one side of the body, from the heel strike of one foot until the next time that same heel hits the ground. This can also be thought of as two steps. Stride length is a common measurement used to measure functionally of gait, and can be

easily calculated by dividing velocity by the cadence and multiplying by two (Velocity/Cadence x 2= velocity).

Common Deviation of the Ankle, Knee and Hip

In the Oxford Handbook for Neurologic Music Therapy (2014), Thaut and Rice identify common deviations of the ankle, knee, and hip, as they are related to muscle weakness during each event (heel strike, toe off, swing phase, single support, and double support) which takes place in the normal gait cycle (O'Sullivan & Schmitz, 2007).

Ankle

There are several common ankle deviations which may be seen during gait, related to muscle weakness, excessive tone, or limited range of motion in the ankle. Deviations related to weakness in the tibialis anterior muscle may include “foot slap (foot slaps down to the floor) or foot flat (foot is placed flat on the ground) during initial contact. Foot drop and/or toe dragging during swing phase may also occur, resulting in compensation strategies such as increased hip and knee flexion, or hip hiking and circumduction to clear the foot” (Hurt-Thaut, 2005).

Additional deviations may also be seen, related to weakness in the gastrocnemius and soleus. These may include: “increased dorsiflexion and uncontrolled tibial advance during the stance phase, no push off going into swing phase, no heel off and toe off as the whole foot may be lifted off the ground going into swing phase” (Hurt-Thaut, 2014).

Knee

Gait deviations may also be seen at the knee due to quadriceps and hamstring weakness. Common deviations due to quadriceps weakness include excessive knee flexion during initial contact through mid-stance and inadequate knee extension during terminal swing in preparation

for initial contact. Compensations often include knee hyperextension, a forward lean at the trunk, or plantar flexion at the ankle.

Hamstring weakness is commonly characterized by inadequate knee flexion resulting in a toe drag during the swing phase of gait. Compensation patterns often include: increased hip flexion; hip hiking or circumduction; vaulting on the opposite side (O'Sullivan & Schmitz, 2007).

Hip

Gait deviations at the hip are often due to weakness in the gluteus maximus, gluteous medius, hip flexors, and the hamstrings. During stance phase, they are typically characterized by excessive hip flexion with compensation at the trunk leaning backward to prevent further hip flexion. During swing phase, this weakness makes it difficult for the patient to lift their leg for a good heel strike. Weakness in the gluteus medius may result in a Trendelenburg gait pattern in which the pelvis drops on the opposite side. This may result in a trunk lean or shift toward the side of the weakness. Weakness in the hip flexors, primarily the iliopsoas, adductor longus, gracilis, and sartorius make it difficult to initiate hip flexion going into swing phase and can result in hip hiking and/or circumduction to assist forward motion and clearing of the foot during swing phase (O'Sullivan & Schmitz, 2007).

Step Two-Resonant Frequency Entrainment and Pre-gait Exercises

Step two in RAS gait training as defined previously by Hurt-Thaut (2014), involves adding a rhythmic cue through a metronome and/or music with a strong 2/4 meter, set at the same tempo as the client's internal cadence during their assessment. During this step, a metronome is always used in order to make sure that the rhythmic cue is driving the movement and that the therapist is not musically responding to fluctuation in the patient's speed. The

metronome does not need to be audible to the client, but must be audible to the therapist. Initially, the therapist may need to provide verbal cues to help the client entrain, but they should always fade the verbal cuing and allow the rhythmic auditory stimulus to continue to drive the movement pattern. During this step, the therapist should “closely observe any immediate effects that the rhythm may have on the gait kinematics, such as increased step length, symmetry, or changes in single and double support time” (Hurt-Thaut, 2014).

In addition to resonant frequency entrainment, step two also involves pre-gait exercises which are designed to address any additional kinematic deviations and muscle weakness. Pre-gait exercises are designed using the Neurologic Music Therapy techniques Patterned Sensory Enhancement (PSE) to address aspects of gait related to balance, strength and endurance, neuromuscular re-education, and development of normal kinematic patterns.

Pre-gait exercises should include a variety of movements done both sitting and standing, to address all aspects of gait, including: weight shifting, marching, stepping forward and backwards, trunk rotation and arm swing exercises with dowels, heel to toe rocking, long arc quads, and leg abduction/adduction. With some patients, a majority of a session may be spent on this step of the RAS gait training process. For a higher functioning patient, more focus may be put on the advanced adaptive gait exercises in step 4.

Step Three- Frequency Modulation at increments of 5-10%

As the therapist continues to shape and normalize the patients gait patterns they will often notice that the patients step cadence is also beginning to modulate to either a faster or slower step pace. In step three, frequency modulation, the therapist begins to speed up or slow down the rhythmic auditory cue in increments of 5-10% in order to see if the patient can maintain the practiced gait pattern as they work to bring the patient’s limit cycle to a more normal range. In

patients with Parkinson's disease, it is not uncommon that the step cadence needs to slow down in order to increase safety and normalize step length and velocity.

Step Four- Advanced Gait Exercises

The first three steps in RAS gait training address the most basic aspects of gait and mobility under controlled conditions. However, in our everyday life we often encounter situations that require us to change directions, speed up or slow down, walk on uneven surfaces, stop and start movement, walk around obstacles, walk up stairs, or walk with and without an assistive device. Step 4 involves creating exercises using RAS to practice those advanced gait situations that we encounter in our everyday life.

The below examples are taken from Hurt-Thaut, 2014:

- 1) Walking with RAS through an obstacle course with different surfaces and objects to move around;
- 2) walking forward when the music starts and stopping when the music stops;
- 3) walking backwards to a rhythmic cue;
- 4) walking on the beat to music that fluctuates in tempo;
- 5) Walking in a figure eight to practice turning
- 6) Walking outside on different surfaces (i.e., grass, ramps, sidewalk)

Step Five- Fading of Musical Stimulus

The goal in step five of RAS gait training is to fade the use of RAS in order to see if the patient can maintain the changes in their gait patterns without the music present. This is done by gradually fading the music and the metronome as the patient is walking. The patient may need to

use compensatory strategies such as recalling the rhythm in their head or singing a song to recreate the tempo. The therapist should fade the rhythmic cue gradually by starting and stopping the metronome several times as the patient is walking.

Step Six- Re-assessment of gait parameters

The final step in RAS gait training is to reassess the patient's gait parameters using the assessment tools from step one. This step is essential in order for the therapist to have data to quantify the functional changes seen in the patient's gait.

CHAPTER III: METHOD

Participants

Two groups of participants were used in this study. The first group of participants includes 25 patients, ranging in age from 62-82 with a diagnosis of Parkinson's disease at a level 2/3 on the Hoehn/Yahr Scale. Participation in the study was based on physician referral, and all subjects had reported a minimum of 2 falls in the last 6 months. Subjects had to be able to walk independently or with an assistive device (cane, walker), without physical assistance. Patients were randomly assigned to intermittent and continuous treatment conditions using a random number table.

The second group of participants included 20 healthy elderly, ranging in age from 62-82 who had experienced a minimum of 2 falls in the last 6 months. Subjects had to be able to walk independently or with an assistive device (cane, walker), without physical assistance. Healthy elderly participants were also randomly assigned to intermittent and continuous treatment conditions using a random number table.

Measures

The setting for baseline, 8 week, 16 weeks and 24 week data collection was the Center for Biomedical Research in Music at Colorado State University. A computerized stride analysis system was used to collect data related to velocity, stride length, and cadence (B&L Engineering). The system consisted of a portable microprocessor worn on a gait belt by the subject during the assessments, four sensors worn imbedded in the insoles of the subject's shoes, a coupler system to download data from the micro-processor to the computer and data analysis software. Reflective markers on the ankle, heel and toe was used to collect kinematic data

related to dorsiflexion, which was analyzed using the digital PEAK video movement analysis system. The RAS music used for the home walking program was created through FINALE music software, and presented on an MP3 player with a strong 2/4 tempo and a metronome embedded in the music. The number of falls and the severity of the falls were self-reported by the participants.

Validity and Reliability

All parameters assessed have been consistently used in clinical neuro-rehabilitation research and therefore can be considered to possess appropriate internal and external content validity. When examining reliability for the timed “up and go” test (Appendix A) with Parkinson’s disease, Morris, Morris, & Iansek (2001) found agreement in timed scores between raters (intraclass correlation coefficient [ICC] =.99) as well as for the same rater during consecutive clinic visits (ICC=.99). Moreover, the TUG times correlated moderately well with gait speed ($r=-.55$), scores on the Berg Balance Scale ($r=-.72$), and the Barthel Activities of Daily Living Index ($r=-.51$) (Appendix B).

Studies using the Berg Balance Scale (Appendix C) with various elderly populations (N = 31–101, 60–90 + years of age) have shown high intrarater and interrater reliability (ICC =.98, 14, 15 ratio of variability among subjects to total = 0.96–1.0, 16 $r =.8817$). Test-retest reliability in 22 people with hemiparesis was also high (ICC [2, 1] =.98) (Berg, Wood-Dauphinee & Williams,1995). Criterion-related validity has been supported by moderate to high correlations between BBS scores and other functional measurements in a variety of older adults with disability (Berg et al., 1992; Usada, Araya, Umehara, Endo, Shimizu, & Endo, 1988; and Whitney, Wrisley, & Furman, 2003).

Scivoletto, Tamburella, Laurenza, Foti, Ditunno, & Molinari (2011), examined the reliability of the ten meter walk test, finding high inter/intra-rater reliability (ICC=.95 - .99) with comparable results in both dynamic and static starts (Appendix D).

The Fear of Falling Questionnaire is a standardized survey consisting of 16 questions which are intended to measure a person's fear of falling, and the effects that fear has on their participation in social and physical activities outside of the home. Although it is shown to have very strong reliability (Cronbach's alpha=.97) and construct validity (intraclass coefficient=.64), the original questionnaire is long (Kempen, Todd, Van Haastregt, Zijlstra, Beyer, Freiburger, Hauer, Piot-Ziegler, & Yardley, 2007). For the purposes of this study, a shortened version was used, evaluating 10 of the 16 questions (Appendix E).

Procedure

Prior to data collection, human subject approval through Colorado State University and IRB approval through Poudre Valley Hospital were obtained. Data was collected by research associates in the Center for Biomedical Research in Music between 2001 and 2010. All participants were informed of the study procedures, and signed an informed consent prior to begin participation in the study. For the purpose of this dissertation project, the preexisting data set was analyzed. The researcher no longer had access to the subjects, and the data set did not include identifiers, therefore further IRB approval was not required (Appendix F).

Participants were randomly assigned to 2 treatment conditions using a random number table: the continuous treatment condition was the RAS-training group and the intermittent treatment condition was a RAS-training group with intermittent withdrawal. During the first 8 weeks all subjects in both conditions trained daily for 30 minutes in a home based environment. Subjects walked with RAS-metronome imbedded music downloaded to an MP3 player, as

training stimulus. In addition to walking, all subjects trained 3 days/week for 25 minutes with a rhythmically cued exercise training video which consisted of exercises for trunk, upper and lower extremity range of motion, strength in sitting and standing, and standing balance. The exercises on the video were demonstrated by a physical therapist and were rhythmically cued by the neurologic music therapist. Rhythmic Auditory Stimulation (RAS) music was made by the research staff at set cadence rates. The music consisted of instrumental keyboard music (8 pieces per CD) used in previous research. Metronome beats were inserted into the music to enhance beat perception. Subjects received RAS music based on individual cadence assessments so that the beat frequencies of the music matched their step frequencies. Subjects trained with one step frequency per week, which was assessed and adjusted as appropriate by increments of 5% when the participants showed increases in step cadence. Subjects trained for approximately two thirds of session with the RAS music, and the last one third with music which was intermittently faded to train for carry over. All participants were thoroughly instructed of the training procedures prior to training and asked to keep a training log. Weekly home visits were used to assure proper training environments. The training protocols used has been used successfully in previous studies with Parkinson's disease patients.

During the second 8week period, the RAS - group continued to train while the intermittent group stopped training. During the third 8 week period both groups continued/resumed the training for a total of 24 weeks of training.

Testing for all groups was done at the pretest prior to training and at 3 posttest dates at week 8, 16, and 24 weeks. Medication was monitored closely by the medical director of the study to control for influence of change or fluctuations in medication and level of functioning on

outcome measures. Testing for all patients was carried out by a neurologic music therapist and the physical therapist at a set time of ON status after medication intake in the morning.

Design/Analysis

A 2x2x4 factorial design, with repeated measures was used to look at changes in the 11 dependent variables at baseline, 8 weeks, 16 weeks, and 24 weeks between the continuous and intermittent groups. The active independent variables in this study were change over time with 4 levels, and continuous condition vs. intermittent condition. There were two potential attribute independent variables, gender and age; however the researchers tried to control for these variables as much as possible. The dependent variables include: ankle dorsiflexion, number and severity level of falls (1=partial fall, 2=complete fall, 3=complete fall with injury), cadence, velocity, stride length, the Barthel Index, the Berg Balance Scale, the Timed “up and go” test (TUG), and a fear of falling survey. Table 3.1 summarizes the variables in this study; including the number of levels and the level of measurement for each.

Table 3.1*Variable Summary*

Variable	IV or DV	Number of Levels	Description of Variable
Time (test/retest)	change over time	4	Approximately Normal
Intermittent/Continuous	Active IV	2	Approximately Normal
Group	Active IV	2	Approximately Normal
Gender	Attribute IV	2	Dichotomous
Age	Attribute IV	Continuous	Approximately Normal
Dorsiflexion	DV	Continuous	Approximately Normal
Fall Severity 1	DV	Continuous	Ordinal (Skewed)
Fall Severity 2	DV	Continuous	Approximately Normal
Fall Severity 3	DV	Continuous	Approximately Normal
Cadence	DV	Continuous	Approximately Ordinal
Velocity	DV	Continuous	Approximately Ordinal
Stride Length	DV	Continuous	Approximately Normal
Berg Balance Scale	DV	Continuous	Approximately Normal
TUG Test	DV	Continuous	Approximately Normal
Fear of Falling	DV	Continuous	Approximately Normal
Barthel Index	DV	Continuous	Approximately Normal

IV RESULTS

The purpose of this study was to investigate whether an at-home based RAS gait training program would decrease the number of falls in healthy elderly and patients with Parkinson's disease with a history of frequent falls. Additionally, this study evaluated changes in clinical and kinematic parameters commonly used to assess fall risk in these populations. Changes in gait parameters were evaluated including dorsiflexion, cadence, stride length, and velocity, following participation in either an intermittent or continuous RAS-based exercise program. The Berg Balance Test, Barthel Index, TUG test, fear of falling survey, and a self-reported fall scale were also used as kinematic and clinical assessments to search for variables that may be associated with falling and are fall risk predictors.

Research Question One: Can an at-home based RAS gait training and exercise program have an impact on dorsiflexion, velocity, cadence, and stride length; number and severity level of falls; and the Barthel Index, Berg Balance Scale, Fear of Falling Survey and TUG test scores, when comparing intermittent and continuous treatment protocols at baseline and 8 weeks, baseline and 16 weeks, and baseline and 24 weeks, in healthy elderly and patients with Parkinson's disease who have a history of frequent falls?

A repeated measures mixed analysis of variance using the general linear model procedure was conducted to compare all unadjusted means in order to examine whether an at-home based RAS gait training and exercise program had an effect on dorsiflexion, velocity, cadence, and stride length; number and severity level of falls; and the Barthel Index, Berg Balance Scale, Fear of Falling Survey and TUG test scores when comparing intermittent and continuous treatment at

baseline and 8 weeks, baseline and 16 weeks, and baseline and 24 weeks, in healthy elderly and patients with Parkinson's disease who have a history of frequent falls.

Prior to testing the effect of the RAS gait program on the dependent variables, normality of the distribution, homogeneity of variance, and independence of groups were assessed by inspection of the residuals, and found to be met in each of the four groups: 1) Healthy Elderly Intermittent Treatment (HEIT); 2) Healthy Elderly Continuous Treatment (HECT); Parkinson's Disease Intermittent Treatment (PDIT); and Parkinson's Disease Continuous Treatment (PDCT), across the 11 dependent variables (dorsiflexion, velocity, cadence, stride length, the Barthel Index, Berg Balance Scale Scores, TUG test scores, a fear of falling survey scores; and the number of falls at three levels of severity) at baseline. Due to the high number of variables being tested, alpha was set at 0.01 in order to reduce the risk of Type I errors.

Dorsiflexion

A repeated measures mixed ANOVA found significant changes in degrees of dorsiflexion in the HEIT group [$F(3,108)=14.30, p=.0001$]. When examining change scores for the healthy elderly groups, the results for dorsiflexion in the HEIT group indicated a statistically significant increase in degrees of dorsiflexion between baseline and eight weeks ($5.71, p<.0001, d=1.55$), baseline and 16 weeks ($3.70, p<.0003, d=0.96$), and baseline and 24 weeks ($5.63, p<.0001, d=1.32$). The HECT group also showed statistically significant increases in degrees of dorsiflexion [$F(3,108)=42.04, p=.0001$]. Those differences were found between baseline and eight weeks ($7.40, p<.0001, d=1.58$), baseline and 16 weeks ($10.05, p<.0003, d=2.88$), and baseline and 24 weeks ($9.25, p<.0001, d=1.82$). The effect sizes for all time periods in both groups were larger than typical (Table 4.1).

Additionally, A repeated measures mixed ANOVA revealed significant changes in degrees of dorsiflexion in the PDIT group [$F(3,108)=6.81, p=.0003$]. Change scores for dorsiflexion in the Parkinson's disease groups, indicated a statistically significant increase in degrees of dorsiflexion between baseline and eight weeks (4.29, $p<.0001, d=1.89$), and baseline and 24 weeks (2.67, $p<.01, d=0.76$) in the PDIT group. The effect size between baseline and 8 weeks was much larger than typical, and large between baseline and 24 weeks. No statistically significant changes were seen when comparing baseline and 16 weeks (1.27, $p<.21$), however a statistically significant decrease in dorsiflexion was seen between 8 and 16 weeks when treatment was stopped (3.02, $p<.003, d=0.85$), which was also a large effect size. The PDCT group also showed statistically significant increases in degrees of dorsiflexion [$F(3,108)=14.97, p=.0001$]. Those changes were seen between baseline and eight weeks (4.01, $p<.0001, d=1.29$), baseline and 16 weeks (5.20, $p<.0001, d=1.81$), and baseline and 24 weeks (6.26, $p<.0001, d=2.25$), all revealing much larger than typical effect sizes (Table 4.2).

Table 4.1

Means and Standard Deviations for Dorsiflexion over Time in the HEIT and HECT Groups

DF over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
DF0	108	2.71	3.73	2.85	2.73
DF8	108	7.57	2.39	7.46	3.12
DF16	108	5.86	2.79	9.11	1.42
DF24	108	7.50	3.51	8.61	3.57

Table 4.2*Means and Standard Deviations for Dorsiflexion over Time in the PDIT and PDCT Groups*

DF over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
DF0	108	3.75	1.57	2.90	1.78
DF8	108	6.80	2.21	5.75	2.56
DF16	108	4.65	2.79	6.60	2.27
DF24	108	5.65	3.18	7.35	2.16

Velocity

A repeated measures mixed ANOVA found significant changes in velocity in the HEIT group [$F(3,108)=16.43, p=.0001$]. An examination of velocity change scores for the healthy elderly groups, indicated a statistically significant increase in velocity between baseline and eight weeks (5.42, $p<.0001, d=1.43$), baseline and 16 weeks (5.38, $p<.0001, d=1.24$), and baseline and 24 weeks (6.24, $p<.0001, d=2.20$) in the HEIT group, with much larger than typical effect sizes. The HECT group also showed statistically significant increases in degrees of dorsiflexion [$F(3,108)=5.44, p=.0016$]. Significant change scores were seen between baseline and eight weeks (3.09, $p<.002, d=0.33$), baseline and 16 weeks (3.74, $p<.0003, d=0.44$), and baseline and 24 weeks (2.77, $p<.007, d=0.32$), with small effect sizes (Table 4.3).

A mixed ANOVA revealed statistically significant increases in velocity in the PDIT group [$F(3,108)=10.89, p=.0001$]. Statistical analysis of change scores for the Parkinson's disease groups, revealed a statistically significant increase in velocity only between baseline and eight weeks (4.03, $p<.0001, d=0.86$) in the PDIT group, with a large effect size. No statistically significant changes were seen when comparing baseline and 16 weeks (1.49, $p<.14$) and baseline and 24 weeks (0.68, $p<.49$). The PDCT group showed statistically significant increases in degrees of dorsiflexion [$F(3,108)=16.27, p=.0001$]. Those changes were found between

baseline and eight weeks (3.67, $p<.0004$, $d=0.49$) and baseline and 16 weeks (4.97, $p<.0001$, $d=0.71$) with a medium effect size, and baseline and 24 weeks (6.73, $p<.0001$, $d=1.02$) with a much larger than typical effect size (Table 4.4).

Table 4.3

Means and Standard Deviations for Velocity over Time in the HEIT and HECT Groups

Velocity over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
V0	108	61.88	7.80	63.72	14.61
V8	108	74.06	9.20	68.83	16.26
V16	108	73.98	11.34	69.90	13.51
V24	108	75.92	8.59	68.30	14.09

Table 4.4

Means and Standard Deviations for Velocity over Time in the PDIT and PDCT Groups

Velocity over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
V0	108	58.61	8.89	52.88	13.80
V8	108	66.20	8.85	59.79	14.18
V16	108	55.80	8.43	62.24	12.66
V24	108	59.90	7.88	65.56	10.87

Cadence

A mixed ANOVA found significant changes in the HEIT group [$F(3,108)=11.28$, $p=.0001$]. An examination of change scores found a statistically significant increase in cadence between baseline and eight weeks (4.93, $p<.0001$, $d=1.88$), baseline and 16 weeks (3.27, $p<.001$, $d=1.71$), and baseline and 24 weeks (5.14, $p<.0001$, $d=1.83$), all with much larger than typical effect sizes. The HECT group also showed statistically significant increases in degrees of

dorsiflexion [$F(3,108)=3.78, p=.01$] between baseline and eight weeks (2.44, $p<.01, d=0.33$), baseline and 16 weeks (2.83, $p<.006, d=0.41$), and baseline and 24 weeks (2.89, $p<.005, d=0.44$), all revealing small effect sizes (Table 4.5).

Significant changes in cadence were also found in the PDIT group [$F(3,108)=4.13, p=.008$] and the PDCT groups [$F(3,108)=9.93, p=.0001$]. An investigation of change scores showed a statistically significant increase in cadence between baseline and eight weeks (2.85, $p<.005, d=0.50$), and baseline and 24 weeks (2.78, $p<.006, d=0.54$) in the PDIT group, both with typical effect sizes. No statistically significant changes were seen when comparing baseline and 16 weeks (0.78, $p<.44$). The PDCT group showed statistically significant increases in cadence between baseline and eight weeks (4.10, $p<.0001, d=1.13$), baseline and 16 weeks (4.56, $p<.0001, d=1.29$), and baseline and 24 weeks (4.64, $p<.0001, d=1.41$), with much larger than typical effect sizes (Table 4.6).

Table 4.5

Means and Standard Deviations for Cadence over Time in the HEIT and HECT Groups

Cadence over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
C0	108	104.92	6.10	111.40	11.94
C8	108	115.50	5.11	115.24	11.56
C16	108	111.93	10.79	115.86	9.66
C24	108	115.95	5.98	115.96	8.51

Table 4.6*Means and Standard Deviations for Cadence over Time in the PDIT and PDCT Groups*

Cadence over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
C0	108	106.38	9.67	104.82	7.17
C8	108	111.51	10.65	112.18	5.82
C16	108	107.78	9.02	113.01	5.40
C24	108	111.38	8.81	113.15	4.27

Stride Length

An examination of stride length in the healthy elderly groups, revealed statistically significant changes in the HEIT group [$F(3,108)=9.43, p=.0001$] and the HECT group [$F(3,108)=3.24, p=.016$]. Those changes were seen between baseline and eight weeks (3.45, $p<.0008, d=0.71$), baseline and 16 weeks (4.79, $p<.0001, d=1.08$), and baseline and 24 weeks (4.36, $p<.0001, d=0.96$), with large or larger than typical effect sizes. The HECT group did not show statistically significant increases in stride length between baseline and eight weeks (2.24, $p<.03$), baseline and 24 weeks (1.80, $p<.08$), however statistically significant changes were seen between baseline and 16 weeks (3.00, $p<.003, d=0.29$), with a small effect size (Table 4.7).

Significant changes were seen in stride length in both the PDIT group [$F(3,108)=10.20, p=.0001$] and the PDCT group [$F(3,108)=18.37, p=.0001$]. When examining change scores, the results for the PDIT group indicated a statistically significant increase in stride length [$F(3,108)=10.20, p=.0001$]. with a large effect size between baseline and eight weeks (4.31, $p<.000, d=0.85$). No statistically significant changes were seen between baseline and 16 weeks (0.84, $p<.40$) and baseline and 24 weeks (0.99, $p<.32$). Statistically significant increases were seen in stride length between baseline and eight weeks (2.84, $p<.005, d=0.50$) with a medium

effect size, baseline and 16 weeks (5.32, $p<.0001$, $d=0.87$) with a large effect size, and baseline and 24 weeks (6.95, $p<.0001$, $d=1.24$) with a much larger than typical effect size, in the PDCT group (Table 4.8).

Table 4.7

Means and Standard Deviations for Stride Length over Time in the HEIT and HECT Groups

Stride Length over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
SL0	108	1.18	0.14	1.14	0.21
SL8	108	1.28	0.15	1.18	0.22
SL16	108	1.32	0.14	1.20	0.20
SL24	108	1.31	0.14	1.18	0.22

Table 4.8

Means and Standard Deviations for Stride Length over Time in the PDIT and PDCT Groups

Stride Length over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
SL0	108	1.07	0.17	1.02	0.15
SL8	108	1.17	0.09	1.09	0.17
SL16	108	1.04	0.11	1.15	0.17
SL24	108	1.09	0.14	1.19	0.14

Barthel Index

Change scores on the Barthel test, indicated no statistically significant changes at any time points for the HEIT, HECT, or the PDIT. Significant increases were however seen in the PDCT group [$F(3,108)=11.82$, $p=.0001$] between baseline and eight weeks (3.16, $p<.002$, $d=0.62$) and baseline and 16 weeks (3.55, $p<.001$, $d=0.66$) with typical effect sizes; and baseline

and 24 weeks (6.26 $p<.0001$, $d=1.22$) with much larger than typical effect sizes (Table 4.9 and 4.10).

Table 4.9

Means and Standard Deviations for Barthel Index over Time in the HEIT and HECT Groups

Barthel over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
B0	108	100.00	0.00	100.00	0.00
B8	108	100.00	0.00	100.00	100.00
B16	108	99.28	1.89	100.00	0.00
B24	108	100.00	0.00	100.00	0.00

Table 4.10

Means and Standard Deviations for Barthel Index over Time in the PDIT and PDCT Groups

Barthel over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
B0	108	92.00	9.19	90.50	7.97
B8	108	94.00	9.37	94.50	4.38
B16	108	92.00	12.52	95.00	5.77
B24	108	93.50	10.55	98.00	3.50

Berg Balance Scale

An investigation of the Berg Balance Scale change scores for the healthy elderly groups revealed no statistically significant increases in balance in the HEIT group. The HECT group also showed statistically significant increases in degrees of dorsiflexion [$F(3,108)=9.59$, $p=.0001$] between baseline and eight weeks (7.40, $p<.0001$, $d=0.71$) and baseline and 16 weeks (10.05, $p<.0003$, $d=.71$) with medium effect sizes, and baseline and 24 weeks (9.25, $p<.0001$, $d=1.67$) with a much larger than typical effect size (Table 4.11).

Examination of change scores for the Parkinson’s disease groups, indicated a statistically significant increase on Berg Balance scores for the PDIT group [$F(3,108)=10.11, p=.0001$] between baseline and eight weeks (4.29, $p<.0001, d=0.61$), and baseline and 24 weeks (2.67, $p<.01, d=0.72$), with medium effect sizes. No statistically significant changes were seen when comparing baseline and 16 weeks (1.27, $p<.21$), however a statistically significant decrease in dorsiflexion was seen between 8 and 16 weeks when treatment was stopped (3.02, $p<.003, d=0.28$) with a small effect size. The PDCT group showed statistically significant increases in degrees of dorsiflexion [$F(3,108)=17.18, p=.0001$]. between baseline and eight weeks (4.01, $p<.0001, d=0.76$) with a medium effect size, and baseline and 16 weeks (5.20, $p<.0001, d=1.26$), and baseline and 24 weeks (6.26, $p<.0001, d=1.70$), both with larger than typical effect sizes (Table 4.12).

Table 4.11

Means and Standard Deviations for Berg Balance Scale over Time in the HEIT and HECT Groups

Berg over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Berg 0	108	52.57	3.26	50.31	5.04
Berg 8	108	53.14	2.54	53.15	4.18
Berg 16	108	53.57	2.37	53.38	3.45
Berg 24	108	53.71	2.36	53.08	4.21

Table 4.12

Means and Standard Deviations for Berg Balance Scale over Time in the PDIT and PDCT Groups

Berg over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Berg 0	108	47.80	6.63	46.60	3.60
Berg 8	108	51.00	3.40	49.20	3.26
Berg 16	108	49.90	4.33	50.50	2.46
Berg 24	108	51.70	3.77	51.80	2.39

Severity Level 1 Falls

Change scores for the healthy elderly groups, when looking at severity level 1 falls in the HEIT group indicated no statistically significant decreases between baseline and eight weeks (2.33, $p<.02$), baseline and 16 weeks (2.03 $p<.05$), and baseline and 24 weeks (2.03, $p<.05$). The HECT group also showed no statistically significant changes in the number of severity level 1 falls between baseline and eight weeks (0.06, $p<.95$), baseline and 16 weeks (0.00, $p<1.00$), and baseline and 24 weeks (0.44, $p<.66$) (Table 4.13).

A mixed ANOVA revealed significant changes in level 1 falls for both the PDIT group [$F(3,90)=3.44$, $p=.02$] and the PDCT group [$F(3,90)=3.35$, $p=.02$]. Examination of change scores for severity level 1 falls in the Parkinson's disease groups, however, revealed a statistically significant decrease in severity one falls between baseline and 16 weeks (2.92, $p<.004$, $d=0.55$), and baseline and 24 weeks (2.62, $p<.01$, $d=0.54$) for the PDIT group, both with medium effect sizes. No statistically significant changes were seen when comparing baseline and 8 weeks (1.94, $p<.05$). The PDCT group showed statistically significant changes only between baseline and 24 weeks (3.11, $p<.003$, $d=0.74$), with a medium effect size. No statistically significant changes were seen at baseline and 8 weeks (1.99, $p<.05$), or baseline and 16 weeks (1.99, $p<.05$) (Table 4.14).

Table 4.13*Means and Standard Deviations for Severity Level 1 Falls over Time in the HEIT and HECT Groups*

Fall 1 over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Fall1 0	90	3.57	6.73	0.30	1.11
Fall1 8	90	0.00	0.00	0.23	0.83
Fall1 16	90	0.14	0.37	0.15	0.37
Fall1 24	90	0.14	0.37	0.00	0.00

Table 4.14*Means and Standard Deviations for Severity Level 1 Falls over Time in the PDIT and PDCT Groups*

Fall1 over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Fall1 0	90	9.71	24.38	11.00	14.20
Fall1 8	90	1.28	2.56	4.43	7.25
Fall1 16	90	0.28	0.75	4.43	7.25
Fall1 24	90	0.43	0.79	2.00	3.05

Severity Level 2 Falls

A statistical analysis of change scores for the healthy elderly groups, looking at the number of severity level 2 falls in the HEIT group indicated no statistically significant decreases between baseline and eight weeks (2.39, $p < .02$), baseline and 16 weeks (1.96, $p < .05$), and baseline and 24 weeks (1.96, $p < .05$). The HECT group also showed no statistically significant changes in the number of severity level 2 falls between baseline and eight weeks (1.63, $p < .11$), baseline and 16 weeks (2.27, $p < .03$), and baseline and 24 weeks (1.95, $p < .05$) (Table 4.15).

A mixed ANOVA showed significant changes in the PDIT group [$F(3,90)=8.29$, $p=.0001$]. Change scores for severity level 2 falls in the PDIT group, revealed a statistically significant decrease in severity 2 falls between baseline and 8 weeks (3.25, $p < .002$, $d=0.70$),

baseline and 16 weeks (4.50, $p<.0001$, $d=0.81$), and baseline and 24 weeks (4.06, $p<.0001$, $d=0.79$), all with medium effect sizes [$F(3,90)=8.29$, $p=.0001$]. The PDCT group showed no statistically significant changes in the number of severity level 2 falls between baseline and eight weeks (1.33, $p<.19$), baseline and 16 weeks (1.74, $p<.08$), and baseline and 24 weeks (1.83, $p<.07$) (Table 4.16).

Table 4.15

Means and Standard Deviations for Severity Level 2 Falls over Time in the HEIT and HECT Groups

Fall2 over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Fall2 0	90	1.57	2.37	0.85	1.46
Fall2 8	90	0.00	0.00	0.15	0.37
Fall2 16	90	0.14	0.38	0.00	0.00
Fall2 24	90	0.14	0.38	0.08	0.28

Table 4.16

Means and Standard Deviations for Severity Level 2 Falls over Time in the PDIT and PDCT Groups

Fall2 over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Fall2 0	90	6.43	9.54	1.71	1.38
Fall2 8	90	1.57	2.15	1.85	3.18
Fall2 16	90	0.86	1.57	1.57	3.73
Fall2 24	90	1.00	1.53	1.14	2.03

Severity Level 3 Falls

When examining change scores for the healthy elderly groups, the results for the number of severity 3 falls in the HEIT group indicated no statistically significant decreases between baseline and eight weeks (2.28, $p < .02$), baseline and 16 weeks (1.61, $p < .11$), and baseline and 24 weeks (2.28, $p < .02$). The HECT group did however show statistically significant changes in the number of severity level 3 falls [$F(3,90)=30.98$, $p=.0001$] between all-time points; baseline and eight weeks (7.53, $p < .0001$, $d=2.27$), baseline and 16 weeks (8.02, $p < .0001$, $d=2.45$), and baseline and 24 weeks (8.02, $p < .0001$, $d=2.45$), with much larger than typical effects sizes (Table 4.17).

Change scores for severity level 3 falls in the Parkinson's disease groups, indicated a statistically significant decrease in severity 3 falls between baseline and 8 weeks (4.35, $p < .0001$, $d=1.36$) and baseline and 16 weeks (5.30, $p < .0001$, $d=1.80$) with much larger than typical effect sizes, and baseline and 24 weeks (9.96, $p < .0001$, $d=0.87$) with a large effect size, for the PDIT group [$F(3,90)=10.92$, $p=.0001$]. The PDCT group did not show statistically significant changes in the number of severity level 3 falls between baseline and eight weeks (0.00, $p < .1.00$), baseline and 16 weeks (1.34, $p < .18$), and baseline and 24 weeks (2.04, $p < .04$). (Table 4.18)

Table 4.17

Means and Standard Deviation for Severity Level 3 Falls over Time in the HEIT and HECT Groups

Fall3 over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Fall3 0	90	0.57	0.79	1.92	1.11
Fall3 8	90	0.00	0.00	0.08	0.28
Fall3 16	90	0.14	0.38	0.00	0.00
Fall3 24	90	0.00	0.00	0.00	0.00

Table 4.18*Means and Standard Deviation for Severity Level 3 Falls over Time in the PDIT and PDCT Groups*

Fall3 over Time		<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Fall3 0	90	1.86	1.46	0.14	0.38
Fall3 8	90	0.28	0.75	0.14	0.38
Fall3 16	90	0.00	0.00	0.71	0.50
Fall3 24	90	0.57	1.51	1.28	2.63

Fear of Falling Survey

Change scores on the Fear of Falling Survey for the healthy elderly in the HEIT group indicated no statistically significant increases between baseline and eight weeks (1.58, $p < .11$) and baseline and 16 weeks (2.43, $p < .02$) however, significant increases were seen in scores between baseline and 24 weeks (2.43, $p < .01$, $d = 1.38$) with a much larger than typical effect size [$F(3,108) = 11.03$, $p = .0001$]. The HECT group showed statistically significant changes on the fear of falling survey between time points; baseline and eight weeks (3.77, $p < .0003$, $d = 0.61$), baseline and 16 weeks (4.80, $p < .0001$, $d = 1.00$), and baseline and 24 weeks (5.09, $p < .0001$, $d = 0.98$). (Table 4.19)

A mixed ANOVA revealed significant changes in both the PDIT group [$F(3,108) = 8.88$, $p = .0001$] and the PDCT group [$F(3,108) = 27.26$, $p = .0001$]. Fear of Falling Survey change scores in the PDIT group, revealed no statistically significant increases between baseline and eight weeks (.63, $p < .53$) and baseline and 16 weeks (.06, $p < .96$) however, significant increases were seen in scores between baseline and 24 weeks (4.40, $p < .0001$, $d = 1.72$). The continuous treatment group showed statistically significant changes on the fear of falling survey between all-time points; baseline and 8 weeks (2.68, $p < .008$, $d = 0.84$) with a large effect size and

baseline and 16 weeks (5.63, $p<.0001$, $d=1.84$) and baseline and 24 weeks (8.55, $p<.0001$, $d=2.81$), both with a much larger than typical effect (Table 4.20).

Table 4.19

Means and Standard Deviations for Fear of Falling over Time in the HEIT and HECT Groups

Fear of Falling over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
FF 0	108	86.14	10.46	74.38	19.55
FF 8	108	93.00	7.21	86.38	19.60
FF 16	108	96.71	3.03	89.69	9.19
FF 24	108	97.14	4.18	90.61	12.83

Table 4.20

Means and Standard Deviations for Fear of Falling over Time in the PDIT and PDCT Groups

Fear of Falling over Time	<i>df</i>	<u>Intermittent Treatment</u>		<u>Continuous Treatment</u>	
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
FF 0	108	53.80	5.49	48.25	13.71
FF 8	108	56.10	11.98	58.00	8.91
FF 16	108	54.00	4.78	68.70	7.75
FF 24	108	69.80	11.99	79.30	7.47

Timed “Up and Go” (TUG)

Change scores on the TUG test revealed no statistically significant changes between any time points for the HEIT, HECT, PDIT, or PDCT groups.

Research Question Two: Is there a difference between intermittent and continuous participation in at-home based RAS gait training and exercise program, when comparing degrees of dorsiflexion, severity of falls, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, and Timed “Up and Go” score at 16 weeks, and 24 weeks in either of the HE or PD?

A repeated measures mixed ANCOVA, where week 0 acted as the covariate to get the adjusted means, was conducted for each of the dependent variables in order to assess whether there were statistically significant differences between the intermittent and continuous groups when comparing degrees of dorsiflexion, velocity, cadence, and stride length; Barthel Index, Berg Balance Scale, TUG test, and fear of falling survey scores at 16 and 24 weeks in both the HE and PD groups. Prior to testing the differences between intermittent and continuous treatment on the dependent variables, normality of the distribution, homogeneity of variance, and independence of groups were assessed through inspection of the residuals. The differences of least square means at baseline revealed significant differences between the healthy elderly group and the PD group on the Barthel Index (4.44, $p < .0001$), the Berg Balance Test (2.65, $p < .01$), severity two falls (2.36, $p < .025$), fear of falling (6.38, $p < .0001$), and stride length (2.11, $p < .04$). The differences of least square means were also inspected between the intermittent and continuous treatment groups, finding statistically significant differences between the HEIT and the HECT groups (2.64, $p < .01$) and the PDIT and PDCT (2.98, $p < .006$) on severity three falls. The baseline covariate explained the subject within study effect, so it was removed from the model. The Kenward-Roger’s approach (1997) to approximate inference for fixed effects and degrees of freedom methods in mixed linear models were used.

Pairwise comparisons were also used to examine whether there were statistically significant difference in any of the dependent variables when comparing the HEIT and the HECT groups at 16 weeks, and 24 weeks? Results indicated that there were significant differences in dorsiflexion ($p<.002$), when comparing the two treatment groups at 16 weeks (Table 4.21). The effect size ($d=1.47$) was much larger than typical. When examining differences at 24 weeks, statistically significant differences were seen between velocity ($p<.002$). The effect size was typical ($d=0.65$). All results can be seen in Table 4.22.

Pairwise comparisons were used to examine whether there were statistically significant difference in any of the dependent variables when comparing the PD intermittent treatment and the PD continuous treatment groups at 16 weeks, and 24 weeks? Results indicated that there were significant differences in dorsiflexion ($p<.009$), cadence ($p<.009$), velocity ($p<.0001$), stride length ($p<.0003$), severity level 1 falls ($p<.003$), and fear of falling ($p<.0004$), when comparing the two treatment groups at 16 weeks (Table 4.23). The effect size for dorsiflexion ($d=0.77$), cadence ($d=0.80$), velocity ($d=0.60$), and stride length ($d=0.77$) were large. The effect size for severity level 1 falls ($d=1.84$) and the fear of falling survey ($d=2.02$) were much larger than typical. When examining differences at 24 weeks, statistically significant differences were between dorsiflexion ($p<.018$), velocity ($p<.0003$), stride length ($p<.0004$), the Barthel Index ($p<.004$), and fear of falling ($p<.01$) (Table 3.4). The effect sizes for dorsiflexion ($d=0.63$), velocity ($d=0.60$), stride length ($d=0.71$), and the Barthel Index ($d=0.57$) were all medium or typical. The effect size for the fear of falling survey was large ($d=0.95$).

Table 4.21

Pairwise Comparison for Dorsiflexion, Cadence, Severity of Falls, Velocity, Stride Length, Barthel Index, Berg Balance Scale scores, fear of falling, and TUG Score Between HEIT and HECT groups at 16 Weeks

		<i>M</i>	<i>N</i>	<i>Std. Deviation</i>	<i>t</i>	<i>df</i>	<i>p (2 tailed)</i>	<i>d</i>
Pair 1	DF16	5.86	7	2.79	-3.19	77.73	.002	1.47
	DF16	9.12	13	1.42				
Pair 2	Velocity16	73.98	7	11.34	1.97	62.06	.054	0.33
	Velocity16	69.90	13	13.51				
Pair 3	Cadence16	111.93	7	10.79	0.27	72.33	.786	0.38
	Cadence16	115.86	13	9.66				
Pair 4	SL16	1.32	7	.014	2.12	56.77	.038	0.70
	SL16	1.20	13	0.20				
Pair 5	Barthel16	99.29	7	1.89	-0.37	57.33	.714	0.53
	Barthel16	100.00	13	0.00				
Pair 6	Berg16	53.57	7	2.37	-1.17	58.96	.248	0.06
	Berg16	53.38	13	3.45				
Pair 7	Sev 1 Fall16	.14	7	0.38	-0.33	51.52	.745	0.03
	Sev 1 Fall16	.15	13	0.38				
Pair 8	Sev 2 Fall16	.14	7	0.38	0.36	43.99	.717	0.52
	Sev 2 Fall16	0.00	13	0.00				
Pair 9	Sev 3 Fall16	.14	7	0.38	1.12	51.06	.270	0.52
	Sev 3 Fall16	.00	13	0.00				
Pair 10	Fear 16	96.70	7	3.04	0.63	60.84	.532	1.02
	Fear 16	89.69	13	9.20				
Pair 11	TUG 16	8.39	7	1.59	0.28	64.45	.777	0.17
	TUG 16	8.78	13	2.75				

Table 4.22

Pairwise Comparisons for Dorsiflexion, Cadence, Severity of Falls, Velocity, Stride Length, Barthel Index, Berg Balance Scale scores, fear of falling, and TUG Score Between HEIT and HECT groups at 24 Weeks

		<i>M</i>	<i>N</i>	<i>Std. Deviation</i>	<i>t</i>	<i>df</i>	<i>p (2 tailed)</i>	<i>d</i>
Pair 1	DF24	7.50	7	3.51	-1.03	77.73	.305	0.32
	DF24	8.62	13	3.57				
Pair 2	Velocity24	75.92	10	8.59	3.20	62.06	.002	0.65
	Velocity24	68.30	10	14.09				
Pair 3	Cadence24	115.95	7	5.99	1.83	72.33	.071	0.001
	Cadence24	115.96	13	8.51				
Pair 4	SL 24	1.31	10	0.14	2.47	56.77	.017	0.71
	SL24	1.18	10	0.22				
Pair 5	Barthel 24	100.00	7	0.00	-0.00	57.33	1.000	0.00
	Barthel 24	100.00	13	0.00				
Pair 6	Berg 24	53.71	7	2.36	-0.69	58.96	.494	0.18
	Berg 24	53.08	13	4.21				
Pair 7	Sev 1 Fall 24	0.14	7	0.38	0.13	51.52	.895	0.52
	Sev 1 Fall 24	0.00	13	0.00				
Pair 8	Sev 2 Fall 24	0.14	7	0.38	0.12	43.99	.906	0.18
	Sev 2 Fall 24	0.08	13	0.28				
Pair 9	Sev 3 Fall 24	0.00	7	0.00	0.49	51.06	.629	0.00
	Sev 3 Fall 24	0.00	13	0.00				
Pair 10	Fear 24	97.14	7	4.18	0.52	60.84	.602	0.68
	Fear 24	90.61	13	12.84				
Pair 11	TUG 24	8.21	7	1.19	0.17	64.45	.867	0.23
	TUG 24	8.75	13	3.16				

Table 4.23

Pairwise Comparisons for Dorsiflexion, Cadence, Severity of Falls, Velocity, Stride Length, Barthel Index, Berg Balance Scale scores, fear of falling, and TUG Score Between PDIT and PDCT groups at 16 Weeks

		<i>M</i>	<i>N</i>	<i>Std. Deviation</i>	<i>t</i>	<i>df</i>	<i>p (2 tailed)</i>	<i>d</i>
Pair 1	DF16	4.65	10	2.78	-2.68	77.19	.009	0.77
	DF16	6.60	10	2.27				
Pair 2	Velocity16	55.8	10	8.43	-4.09	61.36	.001	0.60
	Velocity16	62.24	10	12.66				
Pair 3	Cadence16	107.79	10	9.02	-2.69	74.11	.009	0.80
	Cadence16	113.01	10	5.40				
Pair 4	SL16	1.04	10	.11	-3.88	56.69	.001	0.77
	SL16	1.15	10	.17				
Pair 5	Barthel16	92.00	10	12.52	-2.18	57.14	.033	0.31
	Barthel16	95.00	10	5.77				
Pair 6	Berg16	49.90	10	4.33	-1.43	59.39	.157	0.43
	Berg16	50.5	10	2.46				
Pair 7	Sev 1 Fall16	.29	10	.76	-3.09	51.7	.003	1.84
	Sev 1 Fall16	4.42	10	7.25				
Pair 8	Sev 2 Fall16	.86	10	1.57	-0.79	42.36	.435	0.25
	Sev 2 Fall16	1.57	10	3.74				
Pair 9	Sev 3 Fall16	0	10	0	-2.16	50.07	.036	0.67
	Sev 3 Fall16	.71	10	1.50				
Pair 10	Fear 16	54.00	10	6.78	-3.74	62.44	.001	2.02
	Fear 16	68.70	10	7.75				
Pair 11	TUG 16	10.89	10	2.76	-0.34	64.75	.737	0.23
	TUG 16	11.62	10	3.63				

Table 4.24

Pairwise Comparisons for Dorsiflexion, Cadence, Severity of Falls, Velocity, Stride Length, Barthel Index, Berg Balance Scale scores, fear of falling, and TUG Score Between PDIT and PDCT groups at 24

		<i>M</i>	<i>N</i>	<i>Std. Deviation</i>	<i>t</i>	<i>df</i>	<i>p (2 tailed)</i>	<i>d</i>
Pair 1	DF24	5.65	10	3.18	-2.41	77.19	.018	0.63
	DF24	7.35	10	2.16				
Pair 2	Velocity24	59.90	10	7.88	-5.24	9	.001	0.60
	Velocity24	65.56	10	10.87				
Pair 3	Cadence24	111.38	10	8.81	-1.22	74.11	.225	0.26
	Cadence24	113.15	10	4.27				
Pair 4	SL 24	1.09	10	0.14	-6.46	9	.000	0.71
	SL24	1.19	10	0.14				
Pair 5	Barthel 24	93.50	10	10.55	-2.99	57.14	.004	0.57
	Barthel 24	98.00	10	3.50				
Pair 6	Berg 24	51.70	10	3.77	-0.87	59.39	.385	0.03
	Berg 24	51.80	10	2.39				
Pair 7	Sev 1 Fall 24	0.43	10	0.79	-1.34	51.7	.188	1.74
	Sev 1 Fall 24	2.00	10	1.00				
Pair 8	Sev 2 Fall 24	1.00	10	1.53	-0.33	42.36	.74	0.08
	Sev 2 Fall 24	1.14	10	2.04				
Pair 9	Sev 3 Fall 24	0.00	10	0.00	-1.65	50.07	.11	0.53
	Sev 3 Fall 24	0.57	10	1.51				
Pair 10	Fear 24	69.80	10	11.99	-2.57	62.44	.013	0.95
	Fear 24	79.30	10	7.47				
Pair 11	TUG 24	11.97	10	5.86	0.11	64.75	.914	0.03
	TUG 24	12.15	10	5.58				

Research Question Three: Is there an association between fear of falling and the level of severity of falls experienced at each of the 4 time points?

A correlation matrix and Spearman Rho statistical analysis were also used to examine the association among fear of falling and the severity level of the falls experienced at baseline, 8 weeks, 16 weeks, and 24 weeks. The results indicated a significant correlation between fear of falling and level 1 falls at 8 weeks (0.48, $p < .004$, $r^2 = .32$). This relationship indicates a medium

effect size, with 32% of the variance explained. A significant correlations between fear of falling and severity level 2 falls was seen over all time periods; baseline (0.42, $p < .01$, $r^2 = .18$), 8 weeks (0.42, $p < .01$, $r^2 = .18$), 16 weeks (0.42, $p < .01$, $r^2 = .18$), and 24 weeks (0.42, $p < .01$, $r^2 = .18$). The effect size of these relationships is small, with 18% of the variance explained. A significant correlation was also seen between severity level 3 falls at 24 week (0.35, $p < .04$, $r^2 = .12$). The effect size of this relationship is also small, with 12% of the variance explained.

Research Question Four: Is there a correlation between dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, or Timed “Up and Go” scores and the level of severity of falls experienced at baseline?

A correlation matrix and Spearman Rho statistical analysis were used to examine the association among the dependent variables and the severity level of the falls in HE and PD participants at baseline in the study. The results for the HE group revealed a statistically significant correlation between severity level 2 falls and the Berg Balance scale (0.65, $p < 0.002$), and severity level 2 and 3 falls (0.65, $p < .002$). Statistically significant correlations were also seen between severity level 3 falls and stride length (0.57, $p < .002$) and velocity (0.65, $p < .002$). The results for the PD groups revealed no statistically significant correlation between severity level of falls and any of the dependent variables.

Research Question Five: Is there a difference in change scores in any of the three fall severity levels for each subject between baseline to twenty-four weeks in any of the dependent variables: dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, or Timed “Up and Go”?

A correlation matrix and Spearman Rho statistical analysis were used to examine differences between dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance

Scale scores, fear of falling, or Timed “Up and Go” individual change scores and the level of severity of falls experienced between baseline and twenty-four weeks. Similar to the previous analysis of correlations between average baseline scores, the results revealed a statistically significant correlation in change scores between baseline and twenty-four weeks in severity level 2 falls and the Berg Balance scale ($0.50, p < 0.002$), and between the severity level 2 falls and severity level three falls ($0.55, p < 0.0008$). A visual representation of these results can be seen in Figures 4.1 and 4.2.

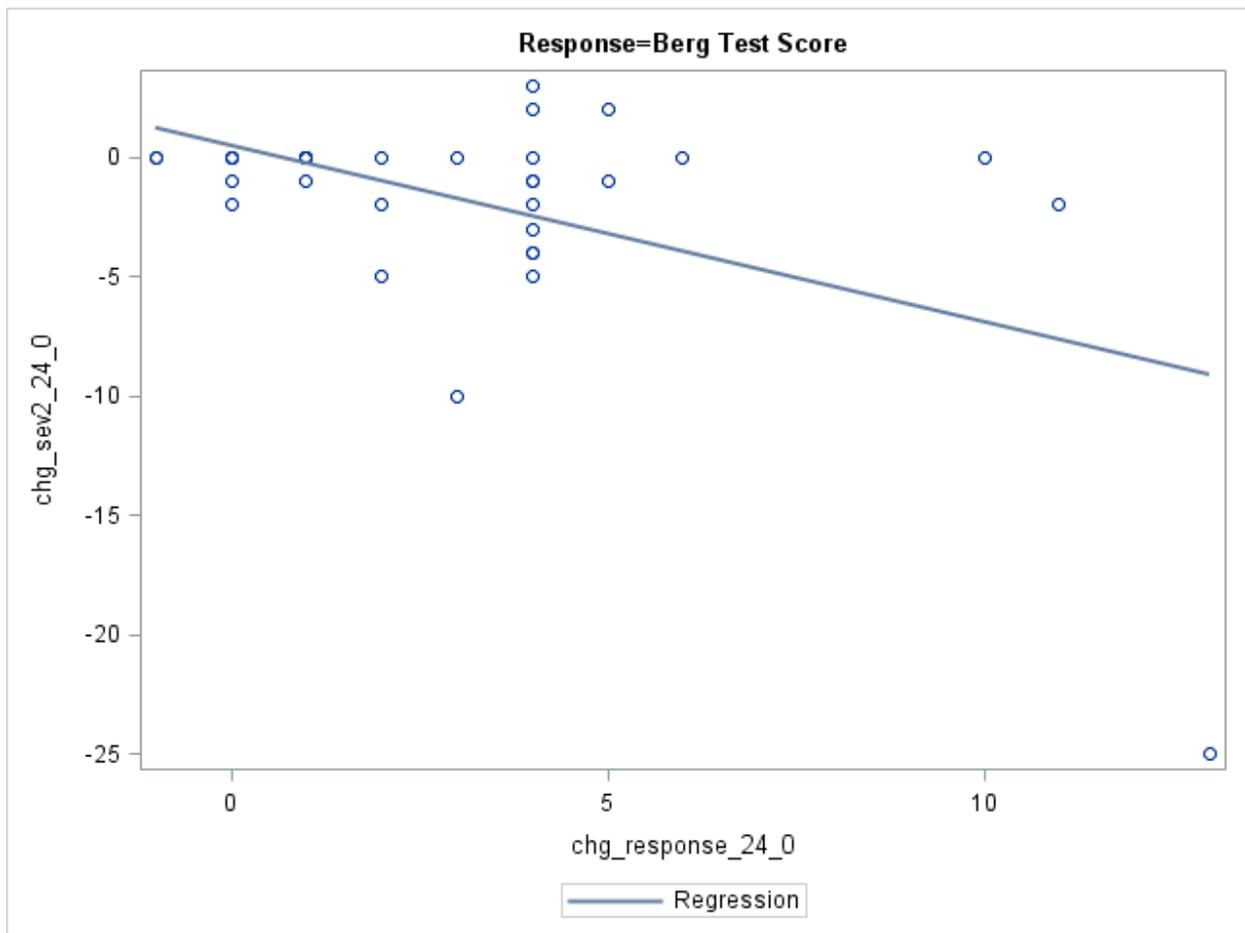


Figure 4.1 A scatterplot of the difference in change scores on the Berg Balance Scale and severity level 2 falls from baseline to week 24.

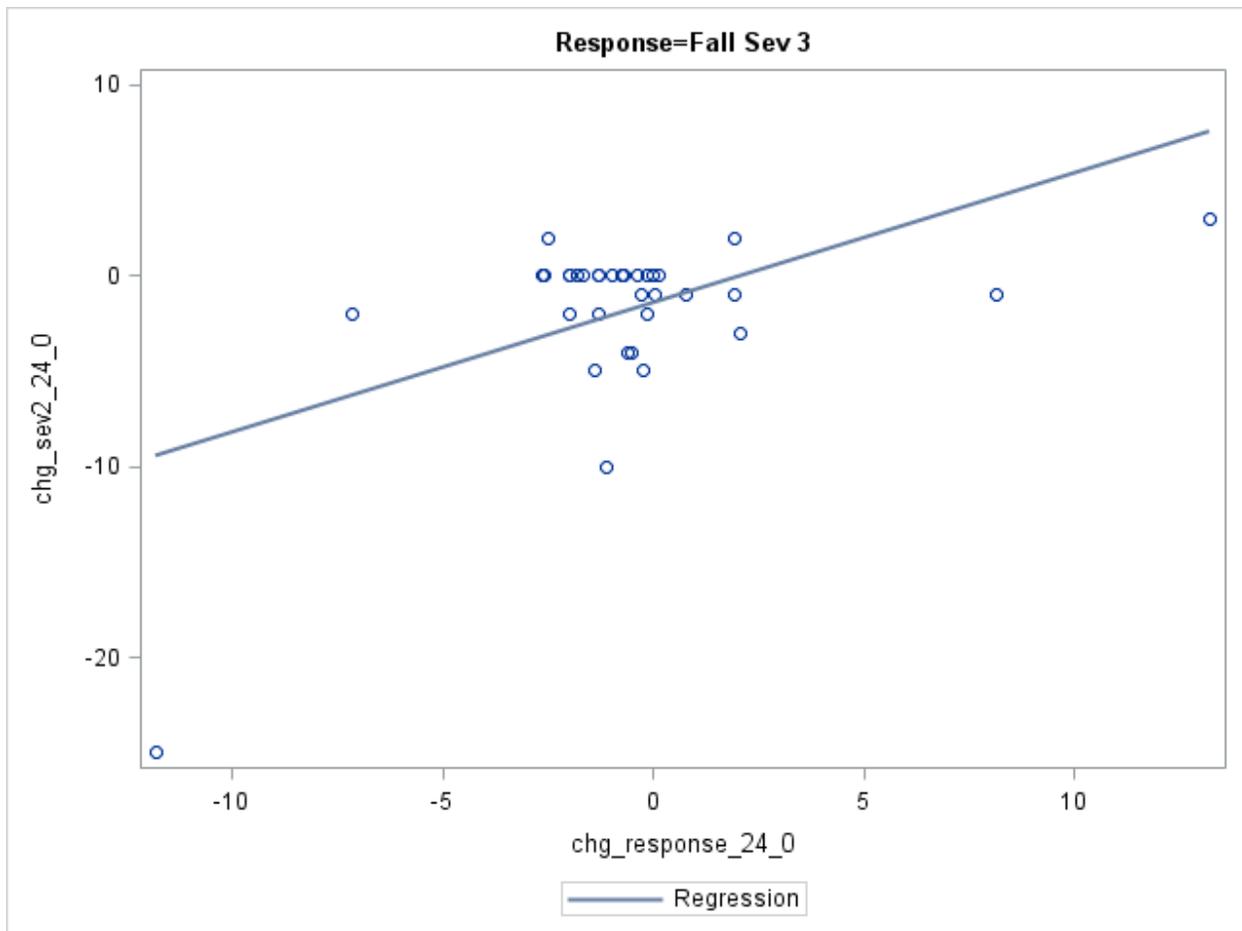


Figure 4.2 A scatterplot of the difference in change scores for severity level 2 and severity level 3 falls from baseline to week 24.

Research Question Six: Is there a statistically significant interaction between intermittent and continuous treatment in the HE or PD group or between the HE and PD groups over time, for any of the dependent variables?

A repeated measures mixed ANCOVA, where baseline acted as the covariate to get the adjusted means, was conducted for each of the dependent variables in order to assess whether there were statistically significant differences between the control and experimental groups when comparing degrees of dorsiflexion, velocity, cadence, and stride length; Barthel Index, Berg Balance Scale, TUG test, and fear of falling survey scores at 8 weeks, 16 weeks, and 24 weeks.

Prior to testing the differences between intermittent and continuous treatment on the dependent variables, the following assumptions were tested for each parameter: (a) independence of observations, (b) normality, and (c) sphericity, through inspection of the residuals. The differences of least square means at baseline revealed significant differences between the healthy elderly group and the PD group on the Barthel Index (4.44, $p < .0001$), the Berg Balance Test (2.65, $p < .01$), severity two falls (2.36, $p < .025$), fear of falling (6.38, $p < .0001$), and stride length (2.11, $p < .04$). The differences of least square means were also inspected between the intermittent and continuous treatment groups, finding significant differences between the HEIT and the HECT groups (2.64, $p < .01$) and the PDIT and PDCT (2.98, $p < .006$) on severity three falls. Therefore, the Kenward-Roger's approach (1997) to approximate inference for fixed effects and degrees of freedom methods in mixed linear models were used.

Dorsiflexion

The results indicated a statistically significant interaction between the degrees of dorsiflexion and continuous vs. intermittent treatment, $F(2,72)=9.54$, $p < .0002$, with a medium effect size ($d=0.64$), but no statistically significant differences between the HE and PD groups $F(2,72)=0.35$, $p < .703$. Table 4.25 provides the means and standard deviations for HE dorsiflexion over 8, 16, and 24 weeks for the intermittent and experimental groups. Table 4.26 provides the means and standard deviations for dorsiflexion between HE and PD over 8, 16, and 24 weeks. Figure 4.3 graphically represents the interaction between dorsiflexion and continuous treatment vs. intermittent treatment in the two groups.

Table 4.25

Adjusted Means and Standard Error for Dorsiflexion Over Time in the HEIT and HECT Groups

DF over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
DF8	77.73	7.81	0.80	7.61	0.59
DF16	77.73	6.10	0.80	9.27	0.59
DF24	77.73	7.74	0.80	8.77	0.59

Table 4.26

Adjusted Means and Standard Error for Dorsiflexion Over Time in the PDIT and PDCT Groups

DF over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
DF8	77.19	6.32	0.67	5.86	0.67
DF16	77.19	4.17	0.67	6.71	0.67
DF24	77.19	5.17	0.67	7.46	0.67

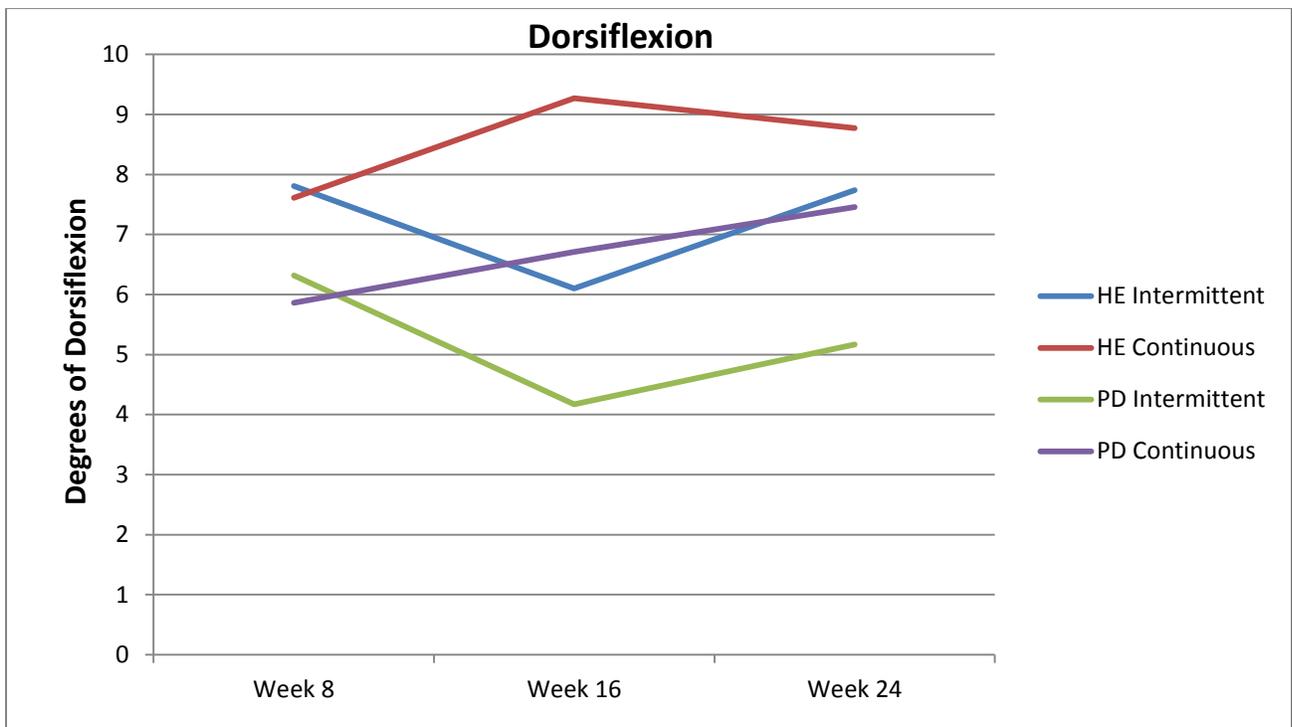


Figure 4.3 Visual representation of the interaction between dorsiflexion and intermittent vs. continuous treatment across healthy elderly and Parkinson’s disease participants over time.

Berg Balance Scale

The results did not reveal a statistically significant interaction between the Berg Balance Scale, and continuous vs. intermittent treatment, $F(2,72)=1.92, p<.15$, however, a statistically significant interaction was seen between the HE and PD groups $F(2, 72)=4.91, p<.01$, with a much larger than typical effect size ($d=3.73$). Table 4.27 provides the means and standard deviations for HE Berg scores over 8, 16, and 24 weeks for the intermittent and experimental groups. Table 4.28 provides the means and standard deviations for Berg scores between HE and PD over 8, 16, and 24 weeks. Figure 4.4 graphically represents the interaction between the HE vs PD groups.

Table 4.27

Adjusted Means and Standard Error of the Berg Balance Scale Scores over, 16, and 24 weeks for the HEIT and HECT Groups

Berg over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
Berg 8	58.96	51.20	0.78	52.50	0.57
Berg 16	58.96	51.63	0.78	52.73	0.57
Berg 24	58.96	51.77	0.78	52.42	0.57

Table 4.28

Adjusted Means and Standard Error of the Berg Balance Scale Scores over 8, 16, and 24 weeks for the PDIT and PDCT Groups

Berg over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
Berg 8	59.39	51.78	0.64	50.65	0.65
Berg 16	59.39	50.66	0.64	51.95	0.65
Berg 24	59.39	52.47	0.64	53.25	0.65

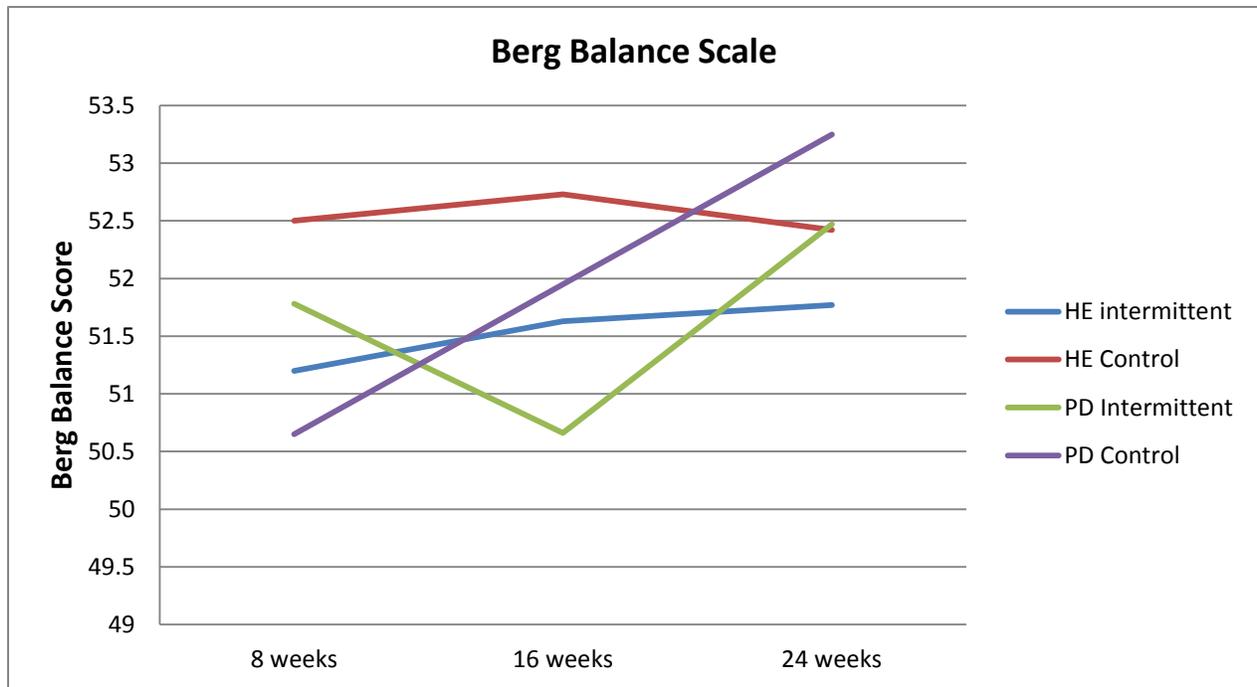


Figure 4.4 Visual representation of the interactions between Berg Balance Scale scores and Intermittent vs. continuous treatment and the healthy elderly and Parkinson’s disease participants over time.

Stride Length

The results for stride length reveal a statistically significant interaction between stride length and continuous vs. intermittent treatment, $F(2,72)=8.17, p<.0006, d=1.00$, HE and PD groups $F(2, 72)=5.03, p<.009, d=2.00$ and between week, group, and population $F(2,72)=15.36, p<.0001, d=3.62$, all with larger than typical effect sizes. Table 4.29 provides the means and standard deviations for HE stride length over 8, 16, and 24 weeks for the intermittent and experimental groups. Table 4.30 provides the means and standard deviations for PD stride length over 8, 16, and 24 weeks. Figure 4.5 graphically represents the interaction between intermittent and continuous treatment and between the HE vs PD groups.

Table 4.29

Adjusted Means and Standard Error of stride length over, 16, and 24 weeks for the HE Intermittent and Continuous Treatment Groups

Stride Length over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
SL 8	56.77	1.21	0.03	1.15	0.02
SL 16	56.77	1.25	0.03	1.17	0.02
SL 24	56.77	1.24	0.03	1.14	0.02

Table 4.30

Adjusted Means and Standard Error of stride length over 8, 16, and 24 weeks for the PD Intermittent and Continuous Treatment Groups

Stride Length over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
SL 8	56.59	1.20	0.03	1.15	0.03
SL 16	56.59	1.07	0.03	1.23	0.03
SL 24	56.59	1.12	0.03	1.27	0.03

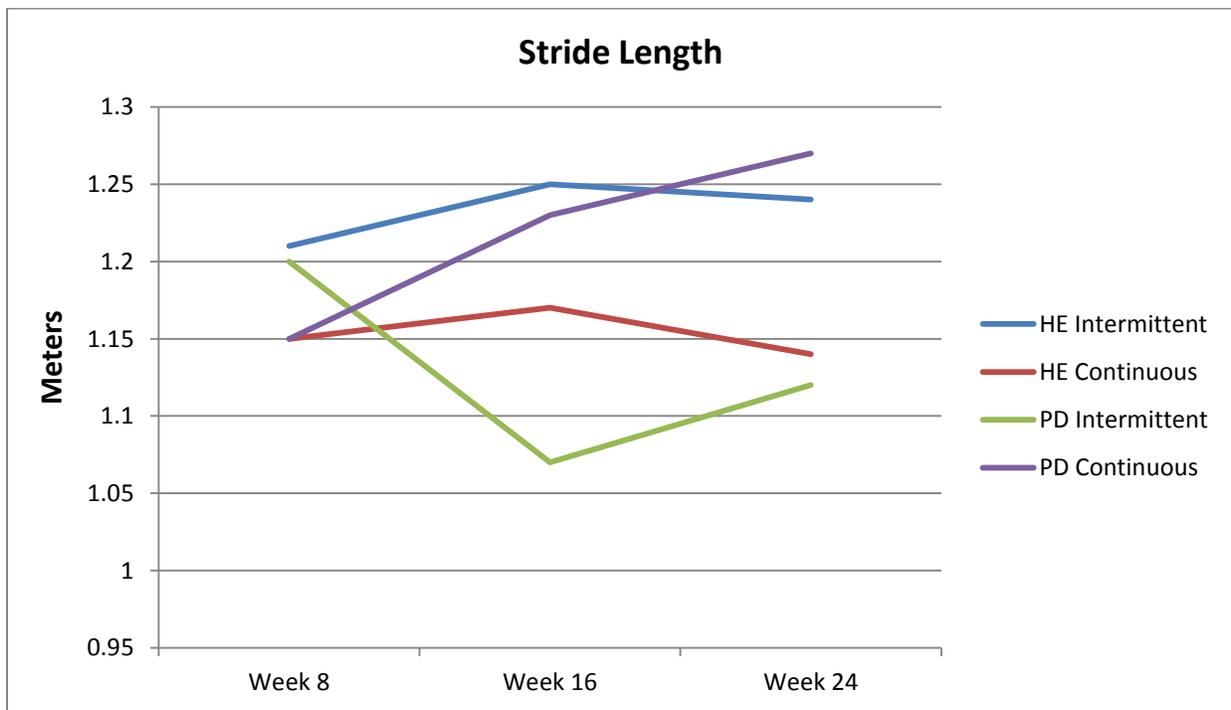


Figure 4.5 Visual representation of the interaction between stride length and intermittent vs. continuous treatment across healthy elderly and Parkinson's disease participants over time.

Velocity

The results for velocity reveal a statistically significant interaction between velocity and continuous vs. intermittent treatment, $F(2,72)=7.92, p<.0006, d=0.70$ with a medium effect size, and between week, group, and population $F(2,72)=9.07, p<.0003, d=2.14$, but not between HE and PD groups $F(2, 72)=3.42, p<.04$. Table 4.31 provides the means and standard deviations for HE stride length over 8, 16, and 24 weeks for the intermittent and experimental groups. Table 4.32 provides the means and standard deviations for PD stride length over 8, 16, and 24 weeks. Figure 4.6 graphically represents the interaction between intermittent and continuous treatment and between the HE vs PD groups.

Table 4.31

Adjusted Means and Standard Error for velocity over, 16, and 24 weeks for the HEIT and HECT Groups

Velocity over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
V 8	62.06	71.96	2.32	65.15	1.73
V 16	62.06	71.88	2.32	66.21	1.73
V 24	62.06	73.82	2.32	64.61	1.73

Table 4.32

Adjusted Means and Standard Error for velocity over 8, 16, and 24 weeks for the PDIT and PDCT Groups

Velocity over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
V 8	61.36	66.88	1.94	65.37	1.99
V 16	61.36	56.48	1.94	67.82	1.99
V 24	61.36	60.58	1.94	71.14	1.99

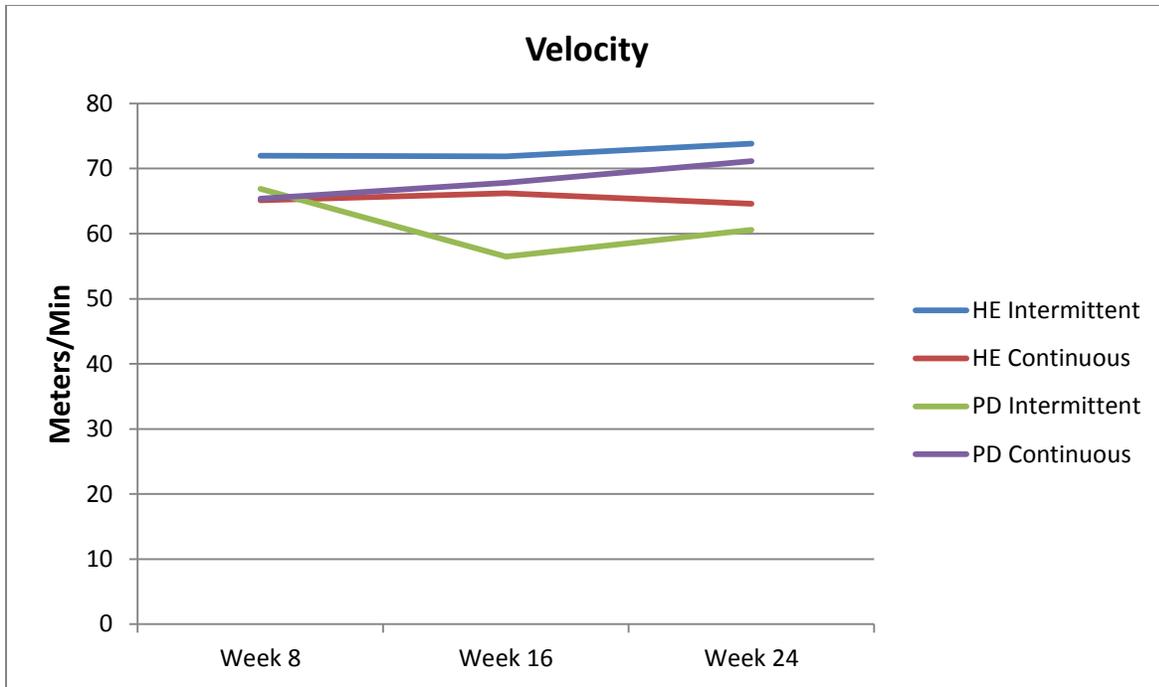


Figure 4.6 Visual representation of the interaction between velocity and intermittent vs. continuous treatment across healthy elderly and Parkinson’s disease participants over time.

Fear of Falling Survey

The results for the fear of falling survey revealed a statistically significant interaction between fear of falling and HE vs. PD over time, $F(2, 72)=12.97, p<.0001, d=3.32$, with a much larger than typical effect size. No statistically significant differences were found between continuous vs. intermittent treatment, $F(2,72)=2.28, p<.11$ and between week, group, and population $F(2,72)=2.55, p<.09$. Table 4.34 provides the means and standard deviations for HE and PD stride length over 8, 16, and 24 weeks Figure 4.7 graphically represents the interaction between the HE vs PD groups.

Table 4.33

Adjusted Means and Standard Error for the fear of falling survey over, 16, and 24 weeks for the HEIT and HECT Groups

Fear of Falling over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
Fear 8	60.84	85.69	4.28	83.09	2.89
Fear 16	60.84	89.39	4.28	86.40	2.89
Fear 24	60.84	89.82	4.28	87.32	2.89

Table 4.34

Adjusted Means and Standard Error for the fear of falling survey over, 16, and 24 weeks for the PDIT and PDCT Groups

Fear of Falling over Time	<u>Intermittent Treatment</u>			<u>Continuous Treatment</u>	
	<i>df</i>	<i>M_{adj}</i>	<i>SE</i>	<i>M_{adj}</i>	<i>SE</i>
Fear 8	62.44	59.85	3.30	63.65	3.52
Fear 16	62.44	57.75	3.30	74.35	3.52
Fear 24	62.44	73.55	3.30	84.95	3.52

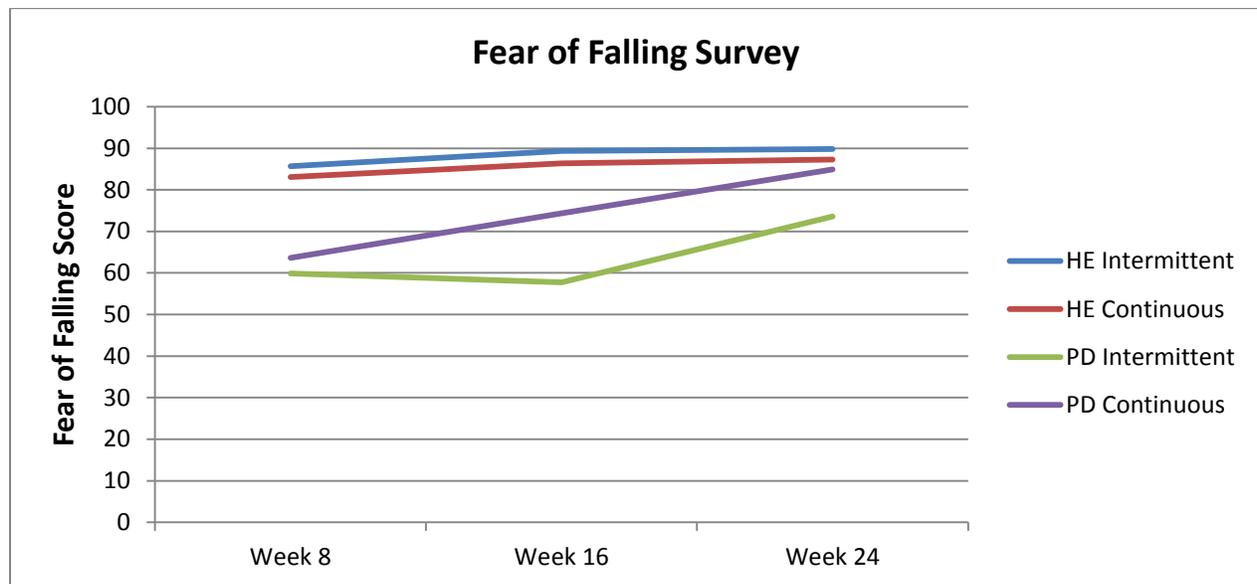


Figure 4.7 Visual representation of the interaction between fear of falling and intermittent vs. continuous treatment across healthy elderly and Parkinson’s disease participants over time.

Barthel Index

No significant interactions were found between intermittent and continuous treatment or between the HE and PD groups on the Barthel Index [$F(2,72)=1.76, p=0.18, F(2,72)=1.56, p<0.22$], cadence [$F(2,72)=3.52, p<0.03, F(2,72)=0.01, p<0.99$], fall severity 1 [$F(2,60)=1.62, p<0.21, F(2,60)=1.84, p<0.17$], fall severity 2 [$F(2,60)=0.06, p<0.94, F(2,60)=1.30, p<0.28$], fall severity 3 [$F(2,60)=0.52, p<0.60, F(2,60)=2.42, p<0.10$], or the TUG test [$F(2,72)=0.08, p<0.92, F(2,72)=1.58, p<0.21$].

Research Question Seven: Are there variables that can predict the risk of falls in a person with HE/ Parkinson's disease?

Simultaneous multiple regression was conducted to investigate whether there were variables or combinations of variables that were the best predictors for the three severities of falls measured at baseline in this study in both healthy elderly and Parkinson's disease subjects. In the healthy elderly group, the Berg Balance Scale Score was a statistically significant predictor of complete falls without injury, $F(1, 18)=13.46, p<.0018$, with an adjusted R^2 value of .428, indicating that 43% of the variance in number of complete falls was explained by the model. Velocity was a statistically significant predictor for complete falls with injuries, $F(1,18)=7.75, p<.0123$, with an adjusted R^2 value of .30. This indicates that 30% of the variance in number of complete falls with injuries was explained by the model. In the Parkinson's group, the Barthel Index was a statistically significant indicator for complete falls $F(1,12)=7.63, p<.0172$, with an adjusted R^2 value of .388, indicating that 39% of the variance in complete falls was explained by the model. According to Cohen (1988), these are large effect sizes.

CHAPTER V: DISCUSSION

Summary of Results

The purpose of this study was to investigate whether an at-home based Rhythmic Auditory Stimulation (RAS) gait training program would decrease the number and severity of falls in healthy elderly and in persons with Parkinson's disease who have a history of frequent falls. Changes in ankle dorsiflexion, a kinematic parameter used to assess fall risk in this population, changes in gait parameters including cadence, velocity and stride length, and the number of falls, following an RAS-based ambulation and exercise program were evaluated. Other kinematic and clinical assessments were also used to search for variables that may be associated with falling and potentially be predictors for fall risks, including the Berg Balance Scale, the Timed Get up and Go Test, and a Fear of Falling Survey. Particular focus was given to: 1) length of treatment, 2) intermittent versus continuous participation, 3) number and severity of falls, 4) impact of fear of falling on falling, 5) correlation of kinematic parameters with falling, and 6) potential predictors for falls.

Length of Treatment

Healthy Elderly

The results of this study revealed many new and clinically important findings related to the use of RAS to improve gait parameters in healthy elderly. When comparing intermittent and continuous treatment over time in the HE group, significant changes in dorsiflexion, velocity, cadence, and the Berg Balance Scale, were seen in both treatment groups at each time point. The changes in velocity and cadence are consistent with results found in other studies using an RAS gait training program with this population (Miller et al., 1996), however this is the first study to additionally address dorsiflexion and balance using the Berg Balance Scale.

Statistically significant changes were also seen in stride length at each time point in the HEIT group, but only between baseline and 16 weeks in the HECT group. When looking at the actual numbers, the changes in stride length were very small overall in both groups, which would be expected since stride length was not significantly impaired in the HE group at baseline. It is difficult to say if it was truly the intermittent treatment or the small sample size that led to the significant changes in stride length in the HEIT group.

When examining the three severity levels of falls, significant changes were not seen in severity one (partial) and severity two (complete without injury) falls in either the continuous or intermittent treatment groups. Additionally, significant changes were not seen in severity level three falls for the intermittent treatment group. However, when looking at severity level three falls which involved a fall with injury, the group that had continuous treatment significantly decreased the number of falls at 8, 16, and 24 weeks. Additionally, falls with injury were completely eliminated after 16 weeks of continuous treatment.

Interestingly, when looking at the HE participant's fear of falling, the participants who only received intermittent treatment did not statistically significantly decrease their fear of falling until they had been participating in the study for 24 weeks. However, those HE subjects who had continuous treatment reported a significant decrease in their fear of falling between baseline and 8 weeks, baseline and 16 weeks, and baseline and 24 weeks. This may indicate that continuous active participation in an exercise program gave healthy elderly more confidence and made them feel less fearful of falling.

The Barthel index and the timed "up and go" test did not reveal any statistically significant changes over time, however the healthy elderly subjects were already performing highly on both of these standardized assessments at baseline so large changes were not expected.

Parkinson's Disease

The results for the participants with Parkinson's disease in this study also revealed many new but very different clinical findings than the HE group. The Parkinson's group showed more significant differences between the intermittent and continuous treatment groups over time. The PDIT group consistently showed significant changes when comparing baseline and eight weeks in dorsiflexion, velocity, cadence, stride length, Berg scores, and severity 2 and three falls. At 16 weeks however, the PDIT participants consistently declined in performance when treatment was taken away. After 24 weeks of intermittent treatment, the PDIT group was able to achieve significant changes in all parameter except velocity, stride length, Berg scores, and the TUG test. These results indicate that intermittent treatment was not as effective as continuous treatment over a 16 week period, however over a longer period of time (exceeding 24 weeks), intermittent treatment may be as effective as continuous treatment. This is particularly interesting, since Parkinson's disease is a degenerative disease and goals are often geared toward adaptive gait to compensate for declines in performance and maintain safety. In this case, RAS gait training resulted in increases in functional gait parameters while decreasing the risk for falls.

When participating in continuous treatment, the PDCT group had significant differences at each time points in dorsiflexion, velocity, cadence, stride length, the Barthel Index, the Berg Scale, and the Fear of Falling survey. The only significant change seen in falls was when comparing level one falls at baseline and 24 weeks.

Intermittent vs Continuous Treatment

Healthy Elderly

This study aimed not only to look at whether the two treatment groups showed significant changes over time, but also whether there were benefits to participating in a treatment continuously versus taking periods of time off. Comparisons showed that both healthy elderly treatment groups were able to maintain gains in most parameters. However, at 16 weeks dorsiflexion decreased significantly when the treatment was taken away, and significant differences were also seen in velocity at 24 weeks. These results are interesting because healthy elderly were able to sustain the gains they made in most parameters, even when treatment was taken away for an 8 week periods. This may suggest that when healthy elderly participate in an RAS intervention program at the intensity level used in this study, the effects can last for eight weeks without significant decline. However, an important point to consider is that a high correlation was seen between dorsiflexion and stride length and velocity; and stride length and velocity are also highly correlated with falls resulting in injury. Therefore, a continuous treatment program would be recommended in order to maintain more normal ranges of dorsiflexion during ambulation in order to support velocity and stride length and therefore reduce the risk of falls with injury.

Parkinson's Disease

Since this study aimed not only to look at whether the two treatment groups showed significant changes over time, but also whether there were benefits to participating in treatment continuously versus taking periods of time off, comparisons were done at 16 and 24 weeks. The results were once again very different for the PD group versus the HE. At 16 weeks, the group

that continued treatment performed significantly better in dorsiflexion, cadence, velocity, stride length, severity level 1 falls, and fear of falling. Additionally, at 24 weeks while the intermittent group caught up in some areas, the continuous treatment group continued to perform better in dorsiflexion, velocity, stride length, the Barthel Index, and fear of falling.

Interaction Between Group, Time, and Treatment

An examination of interaction effects between time, PD versus HE, and intermittent versus continuous treatment also revealed many interesting and some surprising results. Overall, the healthy elderly group was already outperforming the PD group in most parameters at baseline. This is not surprising, since there are many significant motor deficits associated with PD including postural instability (stooped posture), decrease arm swing, decreased stride length, shuffling steps (festinating gait), and freezing.

Both the HE and PD groups showed similar trends in dorsiflexion when comparing intermittent and continuous treatment. When the treatment stopped dorsiflexion decrease, and when treatment resumed dorsiflexion increased again. Both the HE and PD group that received continuous treatment made a steady increase in dorsiflexion over the 24 week period, with the HE group performing slightly higher overall.

The Berg Balance Scale revealed very different results for HE versus PD participants. The HE group showed very similar trends regardless of whether treatment was continuous or intermittent: however the intermittent group did drop slightly at the 24 week time period. The PD group however, showed a dramatic decrease in balance after spending 8 weeks without treatment, while the continuous treatment group continued to show a steady increase in Berg Balance Scale scores surpassing all other treatment groups.

The HE group showed a very similar response patterns for stride length and velocity in the intermittent and continuous treatment groups. Both groups increase slightly between 8 and 16 weeks, and then slightly decreased at the 24 week mark. This seems to indicate that the HE are not only able to sustain the benefits from participating in the initial eight weeks RAS program, but continue to show improvement even when the program is withdrawn. The PD group on the other hand, shows very significant decreases in both stride length and velocity when treatment is withdrawn for the eight week period. Between 16 and 24 weeks they are able to regain some of their improvements, but they are not able to catch up with the continuous treatment group during that time.

The analysis of the of the fear of falling survey revealed that the HE group was overall less fearful of falling than the PD group. The HE group rated their fear of falling very low regardless of whether they were in the intermittent or continuous treatment group, and regardless of what their fall history was. The PD group on the other hand had a very high fear of falling at baseline. Intermittent versus continuous treatment also highly impacted their fear of falling. When PD participants were actively participating in the RAS exercise program they significantly reduced their fear of falling. When required to stop the program for the eight week period their fear did not increased again but plateaued, however the participants who did continuous treatment continued to decrease their fear of falling significantly.

Fear of Falling

Since fear of falling has been identified as being associated with a persons reduced level of activity and therefore an increased risk of falling, this study also looked at whether there was an association between fear of falling and the severity of falls that are experienced. When looking at the overall associations between fear of falling and all levels of falls (partial,

complete, and complete with injuries), there was a relationship between a decrease in falls and a decrease in fear of falling for both groups.

Parameters Correlated with Falls

When looking at the correlations between the severity level of falls and other dependent variables, the HE groups revealed significant correlations between severity level two complete falls and the Berg Balance Scale. This is a logical correlation, because poor balance is a huge risk factor for falling. Severity level 2 falls, were also a strong predictor that a person would have a severity level 3 fall which resulted in injury. Additionally, there was a strong correlation between severity level 3 falls and stride length. Healthy elderly with larger stride lengths also had more falls that resulted in injury. Severity level 3 falls, or falls with injury, were the most common type of fall observed in the healthy elderly group at baseline. These types of falls were completely eliminated by week 16 of the study in both the intermittent and continuous treatment groups. Because many of the parameters in this study proved to be highly correlated, it appeared that an overall improvement in gait parameters had an impact on the frequency and severity of falls. This supports Tinetti's statement (1988) that there is no single underlying cause or risk factor linked to why elderly people fall, but falling is often a combination of factors.

In the PD group, no specific gait parameters were significantly correlated with the severity level of falls, however falls were significantly reduced at all levels of severity by 24 weeks. A statistically significant correlation was seen between dorsiflexion and the Barthel Index, the Berg Balance Scale, and fear of falling. The Berg Balance Scale was also highly correlated with fear of falling, the TUG test, stride length, and velocity; as were velocity, fear of falling, and stride length.

Festinate gait, which results in toe walking instead of a normal heel to toe gait pattern, is a typical characteristic of Parkinson's gait. Festinate gait patterns result in decreased dorsiflexion, i.e. potentially creating a toe drag at heel touchdown, and result in decreased stride length and a higher chance of losing balance or stumbling. A primary focus in gait training with Parkinson's disease is to increase stride length, and therefore increase the distance traveled over time (velocity). Previous studies (Thaut et al., 1995, Richards et al, 1992) have shown significant improvements in stride length and velocity after gait training with a rhythmic cue. The positive correlations between increased dorsiflexion and balance, balance and stride length, and stride length and velocity, are important findings, since the RAS exercise program in this study improved all of these parameters and therefore could have a positive impact on the reduction of falls.

Predictors for Falls

Simultaneous multiple regression was used to examine whether there were variables or combinations of variables that were the best predictors for the three severities of falls measured. In the healthy elderly group, the Berg Balance Scale Score was a statistically significant predictor of complete falls without injury, and velocity was a statistically significant predictor for complete falls with injuries. In the Parkinson's group, the Barthel Index was a statistically significant indicator for complete falls without injury.

Discussion of Research Questions

Research Question One: Can an at-home based RAS gait training and exercise program have an impact on dorsiflexion, velocity, cadence, and stride length; number and severity level of falls; and the Barthel Index, Berg Balance Scale, Fear of Falling Survey and TUG test scores, when

comparing intermittent and continuous treatment protocols at baseline and 8 weeks, baseline and 16 weeks, and baseline and 24 weeks, in healthy elderly and patients with Parkinson's disease who have a history of frequent falls?

Overall, the at-home based RAS gait training and exercise program had a very large impact on many of the independent variable measured in this study in both the HE and PD groups. In the HE group, stride length, the Barthel Index and the TUG test did not show significant changes; but given that most healthy elderly do not show a substantial problem with stride length and are able to independently perform activities of daily living, these variables would be expected to be in fairly normal ranges at baseline. Therefore, fairly small changes would be expected.

The at-home based RAS gait training and exercise program also had a significant impact on the PD groups. After 24 weeks of intermittent treatment, the PDIT group was able to achieve significant changes in all parameter except velocity, stride length, Berg scores, and the TUG test. all time points in dorsiflexion, velocity, cadence, stride length, the Barthel Index, the Berg Scale, and the Fear of Falling survey.

Research Question Two: Is there a difference between intermittent and continuous participation in at-home based RAS gait training and exercise program, when comparing degrees of dorsiflexion, severity of falls, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, and Timed "Up and Go" score at 16 weeks, and 24 weeks in either of the HE or PD?

Intermittent versus continuous treatment did not have as big of an impact on the healthy elderly as it did on the PD groups. Outside of dorsiflexion, the HE participants were able to maintain the gains that they achieved during the initial eight week training program, even when

the treatment was taken away for 8 weeks. While decreased muscle strength and balance are a natural part of the aging process and the leading risk factors for falls in the elderly, an intermittent exercise program was able to improve and maintain those parameters with minimal decline over eight weeks. At 24 weeks it was interesting to see that both HE groups began to plateau or in some situations, slightly decline in their performance. The decrease in dorsiflexion when the RAS treatment was stopped may be a direct reflection of the need for regular practice with audio-spinal facilitation in order to consistently see more efficient recruitment of motor neurons on the spinal cord level. While EMG information was not collected in this study, it appears that increased integrated amplitude ratios, in this case in the tibialis anterior muscle resulting in increased dorsiflexion when treatment was continuous (Thaut, 1992).

Although all participants did not come into the study performing at the same level, the trends for improvements were similar across subjects over time, with participants who were already performing at normal levels showing minimal gain and other participants showing gradual increase across time depending on continuous or intermittent participation. Figures 5.1 and 5.2 are visual representations of dorsiflexion in the intermittent and continuous groups across all HE subjects over time.

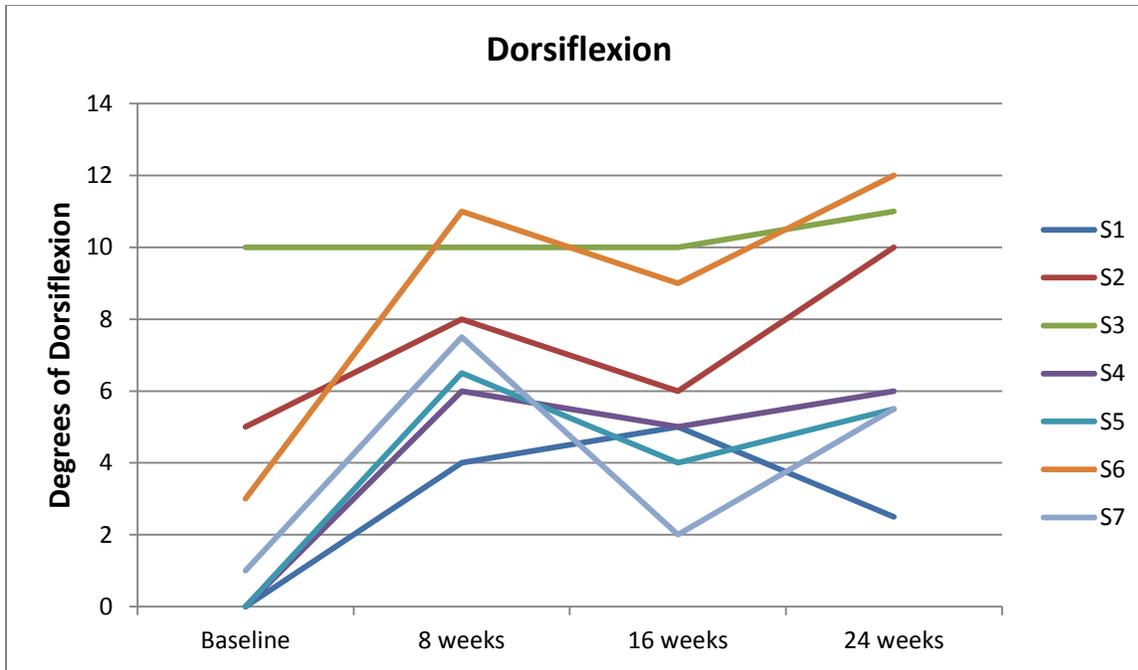


Figure 5.1 Above is a visual representation of the changes in dorsiflexion for the healthy elderly intermittent treatment group across all subjects over time.

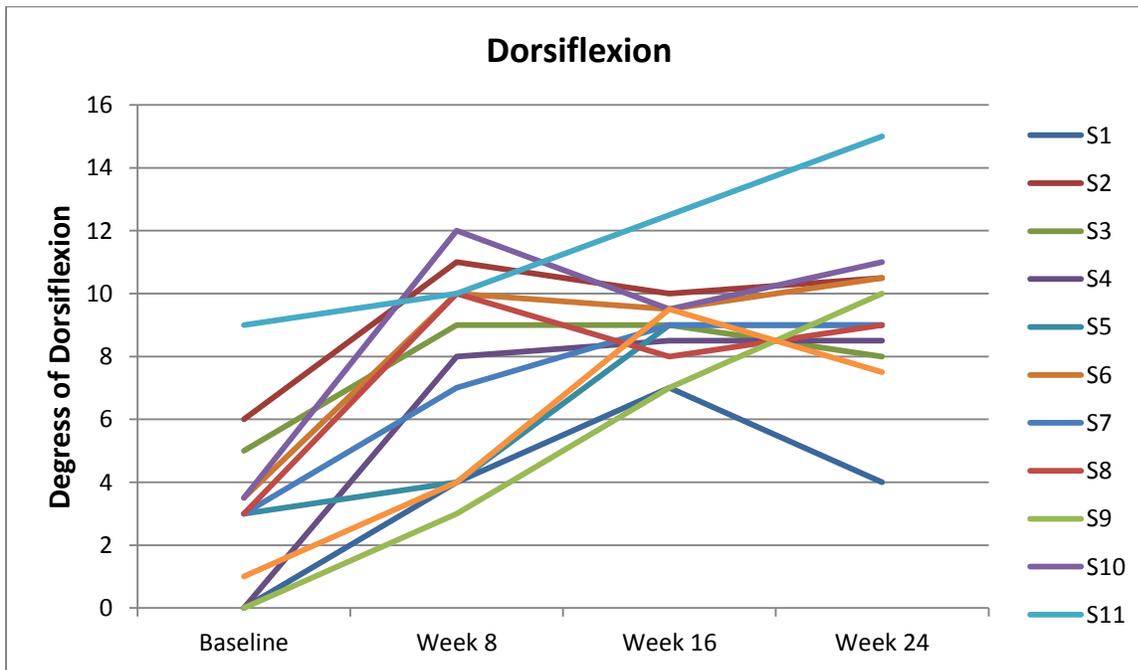


Figure 5.2 Above is a visual representation of the changes in dorsiflexion for the healthy elderly continuous treatment group across all subjects over time.

The PD group revealed a much more direct relationship between intermittent and continuous treatment. When treatment was stopped, PD patients consistently declined in all parameters over the eight week period without treatment. When treatment was resumed the PD subjects were able to continue to make improvements, but not at the same rate as those subjects who participated in continuous treatment. These results are consistent with finding by McIntosh et. al.(1998) in a Parkinson decline study. Participants who participated in a 6 week RAS training program made significant increases in cadence, velocity, and stride length. When treatment was taken away, it took about 5 weeks for all subjects to return to baseline performance on these parameters. A graph of the results for velocity in this study can be seen in Figure 5.3.

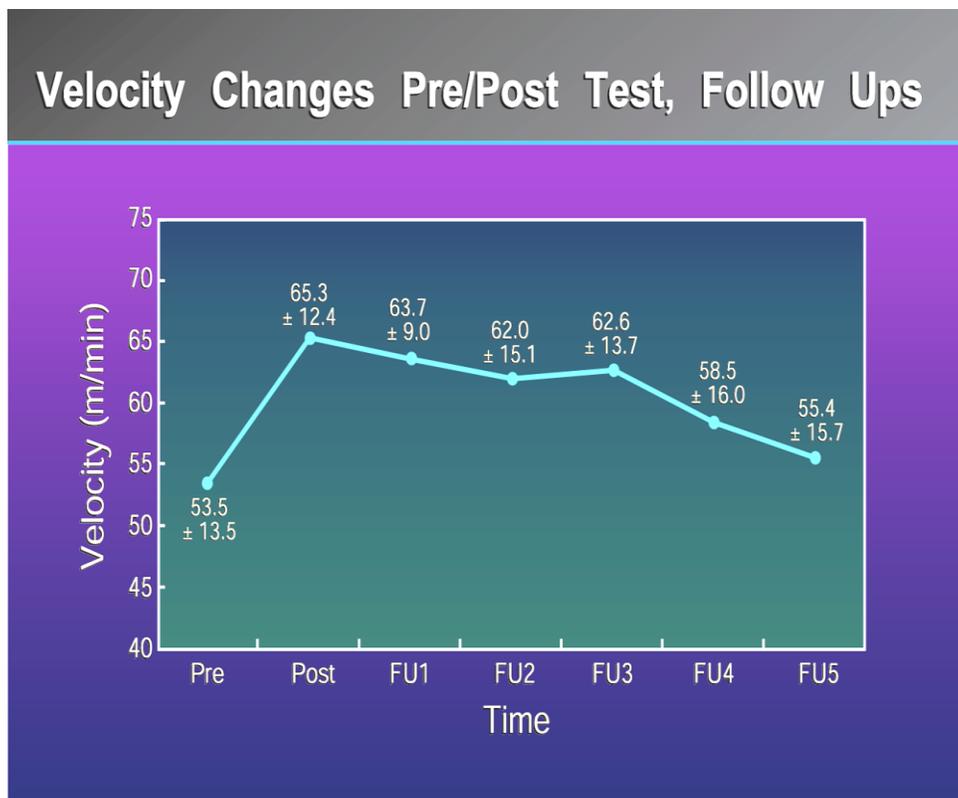


Figure 5.3 The above figure demonstrates the mean velocity and standard deviations at pretest, posttest, and weekly after treatment was stopped in a study by McIntosh et. al. (1998).

Similarly to the HE group all of the participants did not come into the study performing at the same level, however, the trends for improvements were similar across subjects over time. Overall, gradual increases were seen across time varying in significance depending on continuous or intermittent participation. Figures 5.4 and 5.5 are visual representations of dorsiflexion in the intermittent and continuous groups across all PD subjects over time.

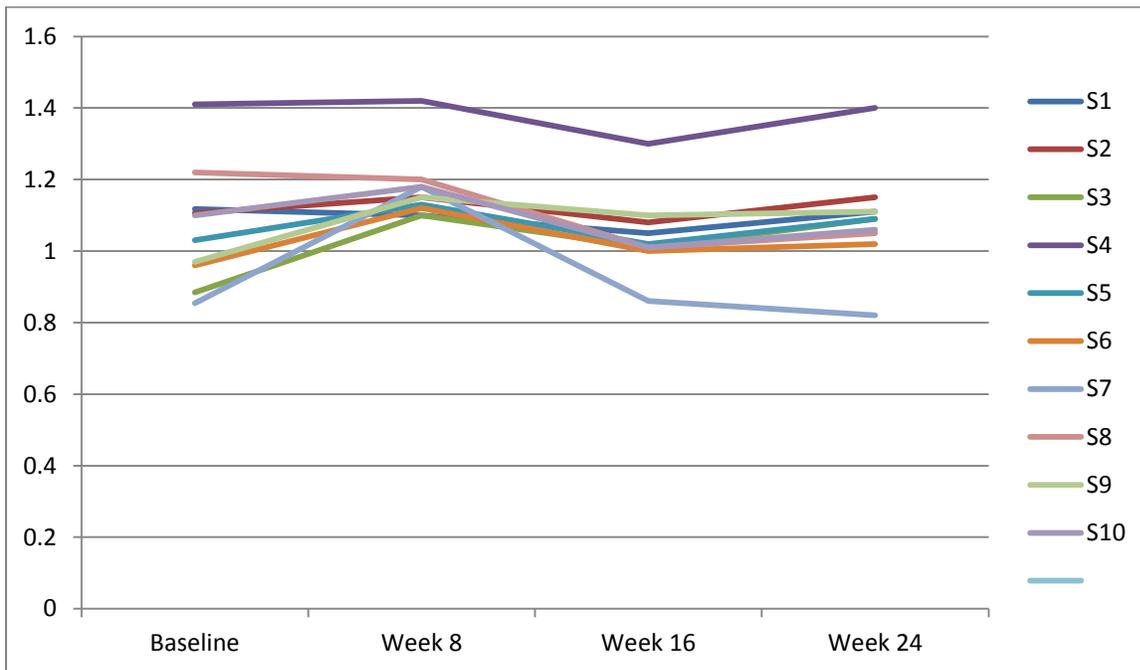


Figure 5.4 Above is a visual representation of the changes in stride length for the Parkinson's disease intermittent treatment group across all subjects over time.

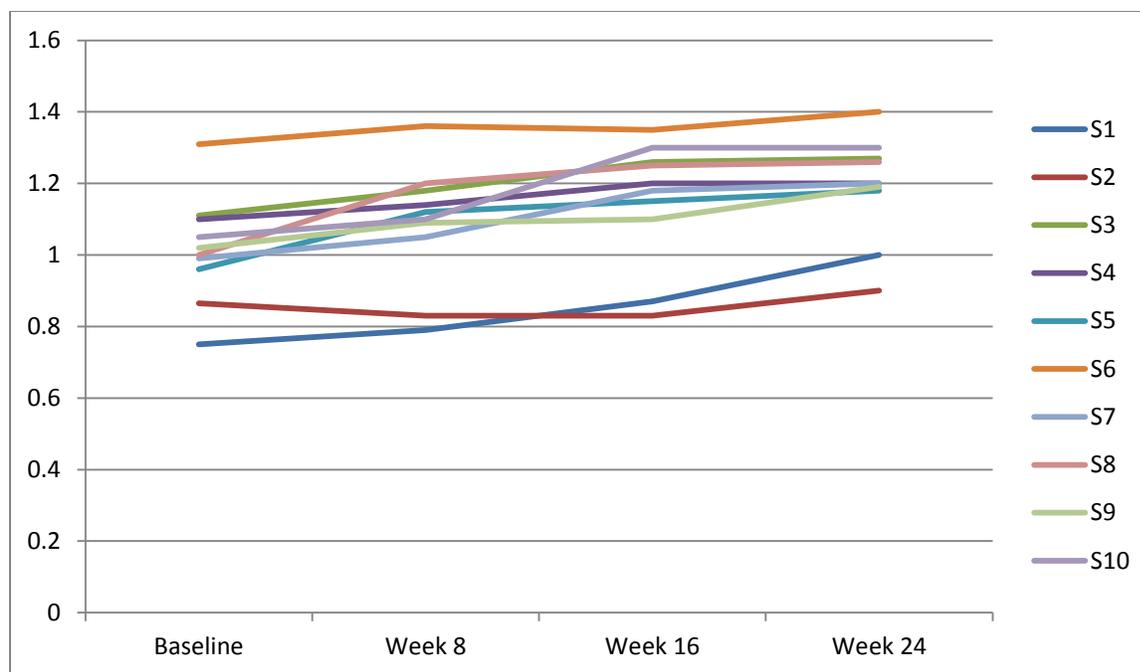


Figure 5.5 Above is a visual representation of the changes in stride length for the Parkinson’s disease continuous treatment group across all subjects over time.

Research Question Three: Is there an association between fear of falling and the level of severity of falls experienced at each of the 4 time points?

When looking at the overall associations between fear of falling and all levels of falls (partial, complete, and complete with injuries), the results varied between PD and HE and between the intermittent and continuous treatment groups. The strongest association was seen between complete falls without injury and increased fear of falling, however overall the participants with PD had a much greater fear of falling than the HE participants. This makes sense since people with PD are most likely conscious of the progression of the disease and realize that falling is always a risk, particularly as their motor abilities may vary throughout a typical day.

This may suggest that not just inactivity, but a lack of fear of falling may also be associated with an increased risk of falling since HE overall appears to not realize that they are at risk. While HE did show significantly less fear of falling than PD, this study also showed that continuous exercise did indeed decrease the number of falls experienced by healthy elderly, which should provide them with an increased confidence when ambulating

Research Question Four: Is there a correlation between dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, or Timed “Up and Go” scores and the level of severity of falls experienced?

No significant correlations were seen between falling and any of the dependent variables in the PD group, however, there were a few correlations between the dependent variables and the level of severity of falls in the HE group. Complete falls that did not result in injury were highly correlated with the Berg Balance Scale. Participants, who scored lower on the Berg Balance Scale, also had a higher number of complete falls. Complete falls without injury were also highly correlated with have a complete fall with an injury. This makes sense that if someone is experiencing frequent falls they are at a higher risk of getting hurt when falling. Stride length and velocity were both highly correlated with complete falls that resulted in injury. Unlike the PD group, the HE participants who had greater stride length and higher velocity showed an increase risk of falling and getting hurt.

Research Question Five: Is there a difference in change scores in any of the three fall severity levels for each subject between baseline to twenty-four weeks in any of the dependent variables: dorsiflexion, cadence, velocity, stride length, Barthel Index, Berg Balance Scale scores, fear of falling, or Timed “Up and Go”?

An analysis of change scores in the 3 fall severity levels and the other dependent variables, for each of subjects between baseline and twenty-four weeks revealed similar results to the correlations at baseline for all subjects. These results are strong support that the Berg Balance Scale is a consistent predictor of complete falls as well as the fact that treatment produces consistent changes across subjects.

Research Question Six: Is there a statistically significant interaction between intermittent and continuous treatment in the HE or PD group or between the HE and PD groups over time, for any of the dependent variables?

There were several significant interactions between the PDIT group and the PDCT group including dorsiflexion, the Berg Balance Scale, stride length, velocity, and fear of falling. When treatment was taken away, the PD patients consistently declined in their performance, and when treatment resumed they were able to make further gains.

There was also a significant interaction between the HE and the PD groups on the fear of falling survey. The HE groups did not identify a significant fear of falling, even at baseline in this study. The PD groups started with a severe fear of falling at the baseline and significantly decreased their fear over the 24 weeks.

However, when looking at the HE vs. PD group, the healthy elderly had an overall very low fear of falling, even at baseline in this study, while subjects with PD were statistically significantly more fearful of falling at baseline. This may suggest that not just inactivity, but a lack of fear of falling may also be associated with an increased risk of falling since HE overall appears to not realize that they are at risk. While HE did show significantly less fear of falling than PD, this study also showed that continuous exercise did indeed decrease the number of falls

experienced by healthy elderly, which should provide them with an increased confidence when ambulating.

Research Question Seven: Are there variables that can predict the risk of falls in a person with HE/ Parkinson's disease?

It is difficult to identify single predictors for falls in healthy elderly and people with Parkinson's disease due to the complex combination of factors that often contribute to the risk for falls. It also appears that fall predictors may be very different between HE and PD. Although simultaneous regression showed these three variables to be statistically significant, it would be necessary to have a larger sample size to more accurately determine good predictors for falls in these populations.

Limitations and Directions for Future Research

There are two main limitations to the interpretation of the data in this study: 1) a small sample size in each of the four groups limits the interpretation and generalizability of the data, and 2) the length of the study and the vulnerability of the participants.

It is hoped that this study has provided preliminary insights into the effect of a home-based RAS program on the reduction of falls in both healthy elderly and persons with Parkinson's disease. The following suggestions are recommended for future research:

- 1) Additional controlled research studies with larger sample sizes to further explore the relationship of dorsiflexion, cadence, velocity, and stride length; and their ability to predict people who may be at more of a risk of falling.
- 2) Exploration muscle strength and activation patterns in the tibialis anterior.

- 3) Examine other kinematic parameters such as hip or knee angles and acceleration patterns.
- 4) Increased length of the study to see how long it takes for the PD participants to plateau.
- 5) Add an additional individual or group treatment component which targets specific problematic parameters in each of the populations.
- 6) Follow up studies to check maintenance of the treatment success

Clinical Relevance

This study revealed many important findings relevant to Neurologic Music Therapist and Physical Therapist working with healthy elderly and patients with Parkinson's disease.

Important findings to be considered when implementing treatment are:

- 1) The use of Rhythmic Auditory Stimulation can be an effective tool for gait and balance training in both healthy elderly and patients with Parkinson's disease.
- 2) Educating healthy elderly about their risk of falls, not to create fear of falling, but to create awareness of risk factors.
- 3) The Berg Balance Test is a good predictor for fall risk in healthy elderly.
- 4) RAS is an effective tool to increase dorsiflexion, which is associated with an increased risk for falls, in both healthy elderly and PD.
- 5) Continuous treatment is more effective than intermittent treatment to maintain functional mobility and reduce the risk of falls.
- 6) Most importantly taking into consideration whether increasing stride length and velocity are decreasing or increasing the risk for falls.

Conclusion

Although research has frequently looked at falling statistics in HE and PD populations, few studies have examined specific programs and interventions to reduce the risk of falls before they happen. This study investigated an RAS-based exercise program which was designed to target the key kinematic parameters associated with falling in these populations and therefore reduce or eliminate falls.

The results revealed that although both populations have frequent falls, healthy elderly tend to fall for different reasons than people with Parkinson's disease. The biggest predictor for falls in HE was decreased functional balance in everyday activities of daily living. HE did not identify a high fear of falling, which perhaps made them less cautious when performing everyday task. Prior to participation in the study, HE with increased stride length and velocity tended to have a higher frequency of falls. After participation in the study regardless of whether they had intermittent or continuous treatment, HE decreased their number of falls while maintaining and in some cases increasing their speed and stride length. This may indicate that an overall improvement in key kinematic parameters can result in increased functional balance in everyday life and therefore reduce falls.

In the PD groups, continuous treatment was a key factor in the overall functional improvement in all gait parameters. Subjects who experienced continuous treatment for the 24 week period consistently made steady gains, while those who stopped treatment at 8 weeks consistently declined back to baseline until treatment resumed at 16 weeks again. Overall, the PD participants had a very high fear of falling at the beginning of this study. As they participated in treatment and reduced their number of falls, that fear decreased substantially. Dorsiflexion showed great improvement in both the HE and PD groups, however decreased dorsiflexion and

toe walking are typical characteristics of PD gait and often associated with falling. In this study, an increase in dorsiflexion was typically accompanied by increased heel strike, stride length, and velocity. These more normal gait kinematics resulted in a reduction of falls.

This study provides the first supportive evidence that RAS gait training is not only an effective tool to increase and maintain gait kinematics in healthy elderly and Parkinson's disease patients, but also to decrease the risk of falling which is of great concern in these population. The consistent improvements in gait parameters and decrease in the number of falls seen across subjects could have a significant impact on health care cost and provide a valuable tool in the maintenance of patient safety, independence, quality of life, and the ability and confidence to reintegrate into a physically active and social lifestyle.

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APPENDIX A: TIMED GET ‘UP AND GO’ TEST

Measures mobility in people who are able to walk on their own (assistive device permitted)

Name _____

Date _____

Time to Complete _____ **seconds**

Instructions:

The person may wear their usual footwear and can use any assistive device they normally use.

1. Have the person sit in the chair with their back to the chair and their arms resting on the arm rests.
2. Ask the person to stand up from a standard chair and walk a distance of 10 ft. (3m).
3. Have the person turn around, walk back to the chair and sit down again.

Timing begins when the person starts to rise from the chair and ends when he or she returns to the chair and sits down.

The person should be given 1 practice trial and then 3 actual trial. The times from the three actual trials are averaged.

Predictive Results

Seconds Rating

<10 Freely mobile

<20 Mostly independent

20-29 Variable mobility

>20 Impaired mobility

APPENDIX B: BARTHEL INDEX OF ACTIVITIES OF DAILY LIVING

Instructions: Choose the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the patient's self-report, from a separate party who is familiar with the patient's abilities (such as a relative), or from observation. Refer to the Guidelines section on the following page for detailed information on scoring and interpretation.

The Barthel Index

Bowels

0 = incontinent (or needs to be given enemata)

1 = occasional accident (once/week)

2 = continent

Patient's Score:

Bladder

0 = incontinent, or catheterized and unable to manage

1 = occasional accident (max. once per 24 hours)

2 = continent (for over 7 days)

Patient's Score:

Grooming

0 = needs help with personal care

1 = independent face/hair/teeth/shaving (implements provided)

Patient's Score:

Toilet use

0 = dependent

1 = needs some help, but can do something alone

2 = independent (on and off, dressing, wiping)

Patient's Score:

Feeding

0 = unable

1 = needs help cutting, spreading butter, etc.

2 = independent (food provided within reach)

Patient's Score:

Transfer

0 = unable – no sitting balance

1 = major help (one or two people, physical), can sit

2 = minor help (verbal or physical)

3 = independent

Patient's Score:

Mobility

0 = immobile

1 = wheelchair independent, including corners, etc.

2 = walks with help of one person (verbal or physical)

3 = independent (but may use any aid, e.g., stick)

Patient's Score:

Dressing

0 = dependent

1 = needs help, but can do about half unaided

2 = independent (including buttons, zips, laces, etc.)

Patient's Score:

Stairs

0 = unable

1 = needs help (verbal, physical, carrying aid)

2 = independent up and down

Patient's Score:

Bathing

0 = dependent

1 = independent (or in shower)

Patient's Score:

Total Score:

Scoring:

Sum the patient's scores for each item. Total possible scores range from 0 – 20, with lower scores indicating

increased disability. If used to measure improvement after rehabilitation, changes of more than two points in the

total score reflect a probable genuine change, and change on one item from fully dependent to independent is also

likely to be reliable.

Guidelines for the Barthel Index of Activities of Daily Living

General

- The Index should be used as a record of what a patient **does**, NOT as a record of what a patient **could do**.
- The main aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason.
- The need for supervision renders the patient not independent.
- A patient's performance should be established using the best available evidence. Asking the patient, friends/relatives, and nurses will be the usual source, but direct observation and common sense are also important. However, direct testing is not needed.
- Usually the performance over the preceding 24 – 48 hours is important, but occasionally longer periods will be relevant.
- Unconscious patients should score '0' throughout, even if not yet incontinent.

- Middle categories imply that the patient supplies over 50% of the effort.
- Use of aids to be independent is allowed.

Bowels (preceding week)

- If needs enema from nurse, then 'incontinent.'
- 'Occasional' = once a week.

Bladder (preceding week)

- 'Occasional' = less than once a day.
- A catheterized patient who can completely manage the catheter alone is registered as 'continent.'

Grooming (preceding 24 – 48 hours)

- Refers to personal hygiene: doing teeth, fitting false teeth, doing hair, shaving, washing face. Implements can be provided by helper.

Toilet use

- Should be able to reach toilet/commode, undress sufficiently, clean self, dress, and leave.
- 'With help' = can wipe self and do some other of above.

Feeding

- Able to eat any normal food (not only soft food). Food cooked and served by others, but not cut up.
- 'Help' = food cut up, patient feeds self.

Transfer

- From bed to chair and back.
- 'Dependent' = NO sitting balance (unable to sit); two people to lift.
- 'Major help' = one strong/skilled, or two normal people. Can sit up.
- 'Minor help' = one person easily, OR needs any supervision for safety.

Mobility

- Refers to mobility about house or ward, indoors. May use aid. If in wheelchair, must negotiate corners/doors unaided.
- 'Help' = by one untrained person, including supervision/moral support.

Dressing

- Should be able to select and put on all clothes, which may be adapted.
- 'Half' = help with buttons, zips, etc. (*check!*), but can put on some garments alone.

Stairs

- Must carry any walking aid used to be independent.

Bathing

- Usually the most difficult activity.
- Must get in and out unsupervised, and wash self.
- Independent in shower = 'independent' if unsupervised/unaided.

APPENDIX C: BERG BALANCE SCALE

The Berg Balance Scale (BBS) was developed to measure balance among older people with impairment in balance function by assessing the performance of functional tasks. It is a valid instrument used for evaluation of the effectiveness of interventions and for quantitative descriptions of function in clinical practice and research. The BBS has been evaluated in several reliability studies. A recent study of the BBS, which was completed in Finland, indicates that a change of eight (8) BBS points is required to reveal a genuine change in function between two assessments among older people who are dependent in ADL and living in residential care facilities.

Description: 14-item scale designed to measure balance of the older adult in a clinical setting.

Equipment needed: Ruler, two standard chairs (one with arm rests, one without), footstool or step, stopwatch or wristwatch, 15 foot walkway.

Completion Time: 15-20 minutes

Scoring: A five-point scale, ranging from 0-4. "0" indicates the lowest level of function and "4" the highest level of function. Total Score = 56

Interpretation:

41-56 = low fall risk

21-40 = medium fall risk

0 -20 = high fall risk

A change of 8 points is required to reveal a genuine change in function between 2 assessments.

Berg Balance Scale

Name: _____ Date: _____

Location: _____ Rater: _____

ITEM DESCRIPTION SCORE (0-4)

Sitting to standing _____

Standing unsupported _____

Sitting unsupported _____

Standing to sitting _____

Transfers _____

Standing with eyes closed _____

Standing with feet together _____

Reaching forward with outstretched arm _____

Retrieving object from floor _____

Turning to look behind _____

Turning 360 degrees _____

Placing alternate foot on stool _____

Standing with one foot in front _____

Standing on one foot _____

Total _____

GENERAL INSTRUCTIONS

Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item. In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches. Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

Berg Balance Scale

SITTING TO STANDING

INSTRUCTIONS: Please stand up. Try not to use your hand for support.

- () 4 able to stand without using hands and stabilize independently
- () 3 able to stand independently using hands
- () 2 able to stand using hands after several tries
- () 1 needs minimal aid to stand or stabilize
- () 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED

INSTRUCTIONS: Please stand for two minutes without holding on.

- () 4 able to stand safely for 2 minutes
- () 3 able to stand 2 minutes with supervision
- () 2 able to stand 30 seconds unsupported
- () 1 needs several tries to stand 30 seconds unsupported
- () 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported.

Proceed to item #4.

SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL

INSTRUCTIONS: Please sit with arms folded for 2 minutes.

- () 4 able to sit safely and securely for 2 minutes
- () 3 able to sit 2 minutes under supervision
- () 2 able to sit 30 seconds
- () 1 able to sit 10 seconds
- () 0 unable to sit without support 10 seconds

STANDING TO SITTING

INSTRUCTIONS: Please sit down.

- () 4 sits safely with minimal use of hands
- () 3 controls descent by using hands
- () 2 uses back of legs against chair to control descent
- () 1 sits independently but has uncontrolled descent
- () 0 needs assist to sit

TRANSFERS

INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

- () 4 able to transfer safely with minor use of hands
- () 3 able to transfer safely definite need of hands
- () 2 able to transfer with verbal cuing and/or supervision
- () 1 needs one person to assist
- () 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED

INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.

- () 4 able to stand 10 seconds safely
- () 3 able to stand 10 seconds with supervision
- () 2 able to stand 3 seconds
- () 1 unable to keep eyes closed 3 seconds but stays safely
- () 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER

INSTRUCTIONS: Place your feet together and stand without holding on.

- () 4 able to place feet together independently and stand 1 minute safely
- () 3 able to place feet together independently and stand 1 minute with supervision
- () 2 able to place feet together independently but unable to hold for 30 seconds
- () 1 needs help to attain position but able to stand 15 seconds feet together
- () 0 needs help to attain position and unable to hold for 15 seconds

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

- () 4 can reach forward confidently 25 cm (10 inches)
- () 3 can reach forward 12 cm (5 inches)
- () 2 can reach forward 5 cm (2 inches)
- () 1 reaches forward but needs supervision
- () 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet.

- () 4 able to pick up slipper safely and easily
- () 3 able to pick up slipper but needs supervision
- () 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
- () 1 unable to pick up and needs supervision while trying
- () 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)

- () 4 looks behind from both sides and weight shifts well
- () 3 looks behind one side only other side shows less weight shift
- () 2 turns sideways only but maintains balance
- () 1 needs supervision when turning
- () 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

- () 4 able to turn 360 degrees safely in 4 seconds or less
- () 3 able to turn 360 degrees safely one side only 4 seconds or less
- () 2 able to turn 360 degrees safely but slowly
- () 1 needs close supervision or verbal cuing
- () 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

- () 4 able to stand independently and safely and complete 8 steps in 20 seconds
- () 3 able to stand independently and complete 8 steps in > 20 seconds
- () 2 able to complete 4 steps without aid with supervision
- () 1 able to complete > 2 steps needs minimal assist
- () 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

- () 4 able to place foot tandem independently and hold 30 seconds
- () 3 able to place foot ahead independently and hold 30 seconds

- () 2 able to take small step independently and hold 30 seconds
- () 1 needs help to step but can hold 15 seconds
- () 0 loses balance while stepping or standing

STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding on.

- () 4 able to lift leg independently and hold > 10 seconds
- () 3 able to lift leg independently and hold 5-10 seconds
- () 2 able to lift leg independently and hold L 3 seconds
- () 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
- () 0 unable to try or needs assist to prevent fall
- () TOTAL SCORE (Maximum = 56

APPENDIX D: TIMED 10-METER WALK TEST

General Procedure:

Individual walks without assistance 12 meter and the time is measured for the intermediate 10 meters to allow for acceleration and deceleration

- o start timing when the toes of the leading foot crosses the 1-meter mark
- o stop timing when the toes of the leading foot crosses the 11 meter mark
- o assistive devices can be used but should be kept consistent and documented from test to test
- o if physical assistance is required to walk, this should not be performed
- o can be performed at preferred walking speed or fastest speed possible
- o documentation should include the speed tested (preferred vs. fast)

Set-up (derived from the reference articles):

- measure and mark a 12-meter walkway
- add a mark at 1-meters
- add a mark at 11-meters

Instructions:

Normal comfortable speed: *“I will say ready, set, go. When I say go, walk at your normal comfortable speed until I say stop”*

Maximum speed trials: *“I will say ready, set, go. When I say go, walk as fast as you safely can until I say stop”*

10 Meter Walk Testing Form

Name: _____

Assistive Device _____

Date: _____

Normal Walk:

Seconds to ambulate 10 meters _____

of steps _____

Velocity _____

Cadence _____

Stride Length _____

Fast Walk:

Seconds to ambulate 10 meters _____

of steps _____

Velocity _____

Cadence _____

Stride Length _____

APPENDIX E: FEAR OF FALLING QUESTIONNAIRE

Subject name: _____

Tester name: _____

Date: _____

FEAR OF FALLING QUESTIONNAIRE

On a 10 scale please rate how confident you feel doing each of the following activities. 0 corresponds to "not at all confident", and 10 is "completely confident".

	Not confident at all							Completely confident			
	0	1	2	3	4	5	6	7	8	9	10
1) Cleaning house											
2) Getting dressed and undressed	0	1	2	3	4	5	6	7	8	9	10
3) Preparing simple meals	0	1	2	3	4	5	6	7	8	9	10
4) Taking a bath or shower	0	1	2	3	4	5	6	7	8	9	10
5) Simple shopping	0	1	2	3	4	5	6	7	8	9	10
6) Getting in and out of a chair	0	1	2	3	4	5	6	7	8	9	10
7) Going up and down stairs	0	1	2	3	4	5	6	7	8	9	10
8) Walking around the neighborhood	0	1	2	3	4	5	6	7	8	9	10
9) Reaching into cabinets or closets	0	1	2	3	4	5	6	7	8	9	10
10) Hurrying to answer the phone	0	1	2	3	4	5	6	7	8	9	10

APPENDIX F: RESEARCH INTEGRITY AND COMPLIANCE REVIEW



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Research Associate II & Doctoral Candidate
Music, Theatre, and Dance Department

From: Evelyn Swiss, CIP, IRB Coordinator 

Re: *RAS To Reduce Falls in Healthy Elderly and Patients With Parkinson's Disease: A Randomized Control Trial*

After review of information regarding the secondary anonymous data that will be analyzed, it was determined that the data did not meet the requirements of the federal definition of human subject research. "Human subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information" (45CFR46.102(f)).

Living individual – Y
About Whom – Y
Intervention/Interaction – N
Identifiable Private Information – N

Thank you for submitting this information. If you have more projects that are similar, please contact us prior to submission. The IRB must determine whether a project needs to have IRB approval.