PHYSICAL ACTIVITY AND SELF-EFFICACY IN INDIVIDUALS WITH PARKINSONS DISEASE WITH A HISTORY OF FALLS

A dissertation submitted to the Kent State University College and Graduate School of Education, Health and Human Services in partial fulfillment of the requirements for the degree of Doctor of Philosophy

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BACKGROUND: Parkinson’s disease (PD) is characterized by motor and non-motor symptoms that predispose individuals to fall, which negatively impacts physical activity behavior. Dual-task (i.e., simultaneous training of gait and cognition) and single-task training (training gait and cognition separately) has been shown to be efficacious in improving PD function; however, the effects of these interventions on physical activity and factors related to physical activity has yet to be assessed. PURPOSE: The aim was to determine the effects of dual-task and single-task interventions on physical activity behavior, fall frequency, PD motor symptoms, exercise self-efficacy, and balance confidence in individuals with PD with a history of falls. METHODS: Twenty-one individuals with PD were randomized into a single-task (n = 11) or dual-task (n=10) group and trained three times/week for eight-weeks for 40 minutes each session. Physical activity, 30-day fall frequency, self-efficacy for exercise (SEE), balance confidence, and PD motor symptoms were assessed at three time points (baseline, end of treatment and four-week follow up). RESULTS: Physical activity and motor symptoms significantly (p ≤ 0.04) improved for both groups. Fall frequency decreased for the dual-task group only (p ≤ 0.02). SEE only increased from end of treatment to four-week follow up for single-task group (p = 0.02) and balance confidence remained unchanged for both groups (p ≥ 0.25). DISCUSSION: Overall, both the single-task and dual-task
groups were successful in increasing physical activity behavior, which may have been a result of the improvement in motor symptoms shown in both groups. The dual-task group was able to decrease fall frequency from baseline levels, while, relative to baseline, neither group improved self-efficacy or balance confidence.
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CHAPTER I
INTRODUCTION

Parkinson’s disease (PD) is a chronic, neurodegenerative disease that affects approximately one million Americans with annual medical treatment costs estimated at $14.4 billion (Kowal, Dall, Chakrabarti, Storm, & Jain, 2013; Zigmond & Burke, 2002). The cardinal signs of PD include resting tremor, bradykinesia (i.e., slowed movement), rigidity (i.e., stiffness), and postural instability and gait dysfunction (i.e., poor balance and walking disturbances). Postural instability and gait dysfunction are associated with cognitive declines and cognitive dysfunction, and coupled with balance problems, this predisposes an individual with PD for falls (Bartels & Leenders, 2009; Gray & Hildebrand, 2000). Falling is of particular concern as both falling and fear of falling have been shown to decrease engagement in physical activity behaviors (Nilsson, Drake, & Hagell, 2010). Also, a decrease in physical activity behavior is of particular concern as decreased physical activity increases risk for comorbidities related to hypokinetic diseases such as cardiovascular disease and diabetes (Haskell et al., 2007).

Sedentariness can be combatted with participation in regular physical activity and has been shown to increase quality of life and decrease overall morbidity and mortality risk (Haskell et al., 2007). However, it is estimated that less than half of American adults meet the recommended requirements for physical activity for health benefits (Haskell et al., 2007). Approximately only 39% of adults over 65 years, meet the recommended daily requirement of physical activity, and those with PD are 29% less active than healthy age-matched peers (Haskell et al., 2007; van Nimwegen et al., 2011). Therefore,
interventions aimed at increasing physical activity in all age groups and special populations may optimize health benefits derived from regular participation in physical activity.

Gait, or walking, is not purely a motor task as it involves planning, navigating and reacting to the environment to result in successful and appropriate motor behavior (Yogev-Seligmann, Hausdorff, & Giladi, 2008). Executive function and attention are two higher-order cognitive processes that are active during normal walking, and dysfunction to these domains have been linked to gait and balance impairment (Bridenbaugh & Kressig, 2015; Yogev-Seligmann et al., 2008). To combat gait dysfunction, gait training and cognitive training interventions have been employed. Gait training has been successful in improving walking performance in individuals with PD, and cognitive training has resulted in increased executive function and attention in individuals with PD (Fisher et al., 2008; Goodwin, Richards, Taylor, Taylor, & Campbell, 2008; Petzinger et al., 2013; Sammer, Reuter, Hullmann, Kaps, & Vaitl, 2006; Sinforiani, Banchieri, Zucchella, Pacchetti, & Sandrini, 2004). Therefore, training both (i.e., gait and cognition) should result in further gains.

Dual-task constructs (or simultaneous performance of a cognitive-motor task) are required in daily tasks (e.g., walking while talking), and it is known that individuals with PD have greater difficulty while performing a dual-task when compared to their healthy peers (Bastiaan R Bloem, Grimbergen, Dijk, & Munneke, 2006; Rochester et al., 2004). Both dual-task training (i.e., gait and cognitive training performed simultaneously) and single-task training (i.e., separate training of gait and cognition) have resulted in
improvement in gait function in individuals with PD (Conradsson et al., 2015; Strouwen et al., 2017), but the impact of single-task and dual-task training on physical activity behavior, and the factors that affect physical activity behavior (e.g., fall frequency, exercise self-efficacy, and balance confidence) have yet to be assessed.

**Focus of the Study**

The focus of this study is to determine the effects of an eight-week gait and cognitive training intervention administered two ways on physical activity behavior, fall frequency, exercise self-efficacy, and balance confidence in individuals with Parkinson’s disease who have a history of falls. Participants will be randomized into either a single-task or dual-task training group and both groups will be time-matched. The dual-task training group will perform gait training while simultaneously performing cognitive tasks during the training session. The single-task group will also engage in gait training and cognitive tasks; however, these tasks will be performed separately, not simultaneously, during the training session. Assessments of physical activity behavior (steps), fall frequency (30-day fall recall), self-efficacy for exercise, and balance confidence will be made at three time points: baseline (one week prior to the start of the intervention), end of treatment (within one week post intervention), and four-week post intervention.

**Hypothesis**

It is hypothesized that physical activity behavior, fall frequency, self-efficacy, and balance confidence will increase in both training groups after the eight-week intervention when compared to baseline, but the dual-task group will exhibit greater increases when compared to the single-task group. It is hypothesized that the
improvements observed in both groups will diminish at the four-week follow up but only the dual-task group will maintain some improvements over baseline levels.
CHAPTER II
LITERATURE REVIEW

Chronic Conditions

Chronic medical conditions are widely prevalent in the United States, and projections estimate that by 2020, 164 million Americans will have at least one chronic condition (Anderson & Horvath, 2004). Over 75% of total health care costs are associated with management of chronic conditions (e.g., home-health care, prescription medication, physician visits, hospital stays). Eighty-five percent of individuals age 65 years and older have at least one chronic medical condition, and the prevalence of individuals with multiple chronic medical conditions increases with age (Anderson & Horvath, 2004). Parkinson’s disease (PD) is an example of a chronic and progressive medical condition, which affects approximately one million Americans. It is estimated that the annual medical treatment cost of PD is $14.4 billion, and projections increase with the United States’ aging population (Kowal et al., 2013; Zigmond & Burke, 2002). Because of high current and further projected increases in the cost of health care, low-cost treatment alternatives or programs to prevent or delay the development of chronic conditions are attractive additions to health communities.

Parkinson’s Disease Overview

PD was first described in 1817, by James Parkinson as the “Shaking Palsy”. The early crude description has since evolved with the increase in knowledge of the disease. Today, PD is the second most common neurodegenerative disease, affecting
approximately one million people in the United States (Zigmond & Burke, 2002). PD is characterized by the cardinal motor symptoms of resting tremor, bradykinesia, rigidity and postural instability and gait dysfunction. At disease onset, symptoms present unilaterally, with symptoms becoming bilateral as the disease progresses (Bartels & Leenders, 2009).

**PD and the Basal Ganglia**

The basal ganglia is the primary brain structure that is affected in PD, but many other structures are involved. The hallmark pathological feature of PD is the loss of dopaminergic neurons in the substantia nigra within the basal ganglia (Zigmond & Burke, 2002). At the time of diagnosis, there is roughly an 80% loss in dopamine, and when the availability of dopamine drops to levels where compensatory methods cannot keep up with demands, the clinical features of resting tremor, bradykinesia, rigidity and postural instability and gait dysfunction develop (Zigmond & Burke, 2002). The basal ganglia aids in overall motor learning, motor control, and the discrimination of sensory feedback to allow for motor inhibition (Bartels & Leenders, 2009; Xu, Wang, Lalchandani, & Ding, 2017). The basal ganglia is comprised of five subcortical nuclei: the putamen, nucleus caudate, globus pallidus, subthalamic nucleus and substantia nigra.

The classical model of basal ganglia function involves a direct and indirect pathway. The model involves a series of loops between central structures in the brain that allow for either inhibition of inhibitory neurons, which ultimately allows for increases in movement, or increased inhibition that suppresses movement (Bartels & Leenders, 2009). The direct pathway involves information being sent to the putamen,
which then travels to the substantia nigra and globus pallidus. This pathway has D1 dopamine receptors, and the resultant signal that is sent to the thalamus is an inhibition of inhibitory neurons, which ultimately helps to facilitate movement. Like the direct pathway, the indirect pathway also begins with information being sent from the putamen, but in the indirect pathway, the signal goes to the globus pallidus and subthalamic nucleus. This pathway has D2 dopamine receptors, and the resultant signal that is sent to the thalamus enhances inhibition of movement, which ultimately suppresses movement (Bartels & Leenders, 2009). With PD, the direct and indirect pathways are disrupted through the selective loss of neurons.

While the cause of PD remains unknown, a generally accepted theory is that the disease is a result of a combination of both a genetic and environmental factors (Bartels & Leenders, 2009). A genetic predisposition in combination with environmental factors, such as an increased exposure to toxins, lead to oxidative stress and disruption of mitochondrial respiration, which results in cell death in nigral neurons. There are a small percentage of PD cases that are believed to be familial PD. PD is more common in males compared to females, and as age increases from 41 to 80 years, the prevalence of PD increases from 41 in 100,000 to 1,903 in 100,000 diagnosed cases (Pringsheim, Jette, Frolikis, & Steeves, 2014).

**Current PD Treatment**

Current therapies for PD target symptom management rather than delaying or halting disease progression. Pharmacological interventions, and in more severe cases, neurosurgery, are the current medical treatment options for symptom reduction in
individuals with PD. Levodopa is the most commonly prescribed medication for PD, and is a dopamine precursor that is converted to a usable form of dopamine in the brain. It is considered to be the most common and effective form of antiparkinsonian prescription medication (Nutt & Wooten, 2005), even though it remains rather ineffective in reducing symptoms of postural instability and gait dysfunction (Marsden, 1994). Postural instability and gait dysfunction have been found to have greater impact on quality of life than other motor features (Hariz & Forsgren, 2011). Therefore, increasing postural stability and gait function remains an unmet need in the PD community. Recent research suggests that exercise could serve as an adjunct to traditional antiparkinsonian therapies as it has been shown to improve motor symptoms (Alberts, Linder, Penko, Lowe, & Phillips, 2011; Goodwin et al., 2008), although the effectiveness of exercise on improving postural instability and gait dysfunction specifically is not well understood.

**PD Postural Instability and Gait Dysfunction**

The most visible symptom of PD is tremor, but only about 70% of those with PD have resting tremor (Marsden, 1994). The Movement Disorders Society Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) is commonly used to rate PD symptoms (Goetz et al., 2008). The UPDRS scores can be used to classify individuals with PD as being tremor dominant, or postural instability and gait dysfunction dominant based on individual’s rating on a zero-to-four scale, with zero indicating no symptoms present and four indicating severe symptoms (Bartels & Leenders, 2009; Stebbins et al., 2013). The hallmark features of postural instability and gait dysfunction are shuffling, small steps, decreased arm swing and stooped posture, overall resulting in disturbances in
walking and maintenance of balance (Bartels & Leenders, 2009). Declines in posture, balance and gait are associated with decreased mobility, decreased quality of life, and increased overall disability in individuals with PD (Allen, Sherrington, Paul, & Canning, 2011). In self-reports from mild-moderate PD patients (Hoehn-Yahr II-III), over 50% report balance problems or falling (Whitson et al., 2009; Wielinski, Erickson-davis, Wichmann, Walde-douglas, & Parashos, 2005). Individuals with postural instability and gait dysfunction are at risk for falling because of impairment of postural reflexes and decreased reaction time which is needed to correct imbalances when they occur (Allen et al., 2011; Marsden, 1994).

In individuals with PD who fall, approximately 65% result in moderate to severe injuries that require medical attention (e.g. bone fractures or surgery) (Wielinski et al., 2005). As previously mentioned over 50% of individuals with PD report falling at least once over a two-year period. In a shorter time period of three months, over 30% of Parkinson’s patients, Hoehn and Yahr II-III, a staging scale for clinical description of PD, report at least one fall (Hoehn & Yahr, 1967; Matinolli et al., 2009; Wielinski et al., 2005). Fear of falling ranges anywhere from 35-59% in individuals with PD (Nilsson, Hariz, Iwarsson, & Hagell, 2012). Difficulties in walking and increases in other motor symptoms are associated with fear of falling in PD, with gait dysfunction being the strongest factor in fear of falling (Jonasson, Ullen, Iwarsson, Lexell, & Nilsson, 2015).

Fear of falling is important in health and wellness because it can reduce participation in physical activity in both older adults and individuals with PD (Howland et al., 1998; Murphy, Williams, & Gill, 2002; Nilsson et al., 2010). Seventy percent of individuals
with PD and a fear of falling have reduced physical activity because of their fear of falling (Nilsson et al., 2012).

Motor features of PD are visually apparent, but non-motor features also accompany the disease (Marsden, 1994). The basal ganglia functions in both motor and cognitive processes, and dysfunction to this brain structure, as occurs in PD, leads to declines in function in both areas (Bartels & Leenders, 2009; Middleton & Strick, 2000). With disease progression, cognitive declines can become more pronounced (Bartels & Leenders, 2009). Executive function is a domain of cognition that is responsible for planning and coordinating complex actions (Bridenbaugh & Kressig, 2015). Deficits of executive function, episodic memory impairment, visuospatial dysfunction, and decreases in mental flexibility are associated with PD, and approximately 30% of those diagnosed with PD eventually develop dementia (Bartels & Leenders, 2009). Cognitive changes associated with PD do not respond well to pharmaceutical and surgical interventions, and cognitive declines can further affect an individuals ability to maintain postural control under multi-tasking conditions (Stegemoller et al., 2014).

Falling in PD has been linked to impaired executive function (Mak, Wong, & Pang, 2014). In PD, those with a history of falls had lower scores on both the Activity-specific Balance Confidence (ABC) scale, which measures balance confidence (Powell & Myers, 1995), and the Mattis Dementia Rating Scale, which measures cognitive function (Mak et al., 2014). This is evidence that walking is not simply a motor task. Gait is a complex activity that involves cognition, and impairment to cognitive function could lead to impairment in walking activity (Bridenbaugh & Kressig, 2015). Mild cognitive
impairment is defined as cognitive declines that are greater than expected for a certain age and does not affect activities of daily living (Gauthier et al., 2006). Mild cognitive impairment in PD is estimated to be present in 20% of those diagnosed, and of the 20% that have mild cognitive impairment, about 40% of the impairment is related to executive dysfunction (Caviness et al., 2007; Goldman & Litvan, 2011). If both cognitive and motor dysfunction is present in those with PD, it is reasonable to suggest that treatment to both systems should result in increased gait function.

**Aging, Gait and Balance Changes**

The normal, healthy aging process involves decreases in proprioception, vestibular function, vision and cognition, which all contribute to gait and balance (Sturnieks, St George, & Lord, 2008). Proprioception is the sensory information from receptors in muscles, tendons and joints, and provides information regarding where limbs are in space, joint movement and touch (Sturnieks et al., 2008). The sensory input from the body to the central nervous system requires monitoring for appropriate responses to the surrounding environment (Cameron & Monroe, 2011). The integration of sensory input and the resultant response involves the use of executive function. Tasks that require executive function tend to have the largest declines with aging (Smiley-Oyen, Lowry, Francois, Kohut, & Ekkekakis, 2008). Since gait is not simply a motor task (Bridenbaugh & Kressig, 2015; Yoge-Seligmann et al., 2008), even small declines in executive function result in declines in gait (i.e., slowed walking and increased gait variability) (Bridenbaugh & Kressig, 2015). Improvement in executive function could
result in improvement in executing complex tasks as in under dual-task constructs (i.e. completing a motor and cognitive task simultaneously).

Dual-task conditions are present in activities of daily living. Therefore, the successful and appropriate completion of a dual-task is required. An example of dual-task conditions in daily life is when an individual is walking while having a conversation with their companion. Successful completion of this dual-task requires maintenance of balance and normal gait patterns while simultaneously processing information and responding to the person with whom they are conversing with. One explanation for diminished performance under dual-task conditions is the Limited Resource Hypothesis (Wickens & Kessel, 1980). The Limited Resource Hypothesis suggests that within the central nervous system there is a limited capacity, or resources, for processing stimulus information, and if two tasks are completed simultaneously, there is competition for resources. If cognitive load exceeds available capacity, the result is diminished performance in one or both of the tasks being performed (Faulkner et al., 2007). Deterioration of performance during the execution of a motor and cognitive task suggests that both motor and cognitive processes share the same neural circuitry (Ruthruff, Pashler, & Klaassen, 2001). In older adults, research supports training that targets improving dual-tasking to improve postural stability (Agmon, Belza, Nguyen, Logsdon, & Kelly, 2014).

**Physical Activity in Older Adults**

The benefits of regular participation in physical activity and aerobic exercise are well documented in adults, and since physical inactivity is a modifiable risk factor for
many health related conditions, engaging in physical activity could ease the burden of health care costs. In liberal terms, exercise has been described as the “Polypill” due to the incidence of the reduction of HbA1c levels, decrease in triglycerides, reduced blood pressure and risk of cardiovascular events, improvement in endothelial dysfunction that is associated with aging, and proliferation of neuronal stem cells (Fiuza-luces, Garatachea, Berger, & Lucia, 2013). Chronic physical activity also increases the expression of brain neurotransmitters, such as brain-derived neurotrophic factor (BDNF), as seen in animal models, with potential to increase brain neurotransmitters in humans as well (Dishman et al., 2006). BDNF is a neurotrophic factor that functions in neuronal proliferation, survival and plasticity, and it is suppressed in those with PD (Baquet, Bickford, & Jones, 2005). Increases in BDNF could promote to neuroplasticity and neuroprotection in both healthy and diseased populations. Neuroplasticity is the brain’s ability to respond to stimuli through reorganization of structure, function and connections of neural networks (Cramer et al., 2011), and neuroprotection is the promotion of neuronal survival. In rodent models, in as little as one week of treadmill running, neuroplasticity was observed, as increases in learning were concomitant with decreases in brain plaque formations, which are similar to those in Alzheimer’s disease (Dishman et al., 2006). Increases in BDNF levels in PD could be beneficial as neuroprotection and neuroplasticity has the potential to aid in the decrease of symptoms and slowing the progression of the disease.

There is evidence that regular participation in physical activity has a positive effect on cognition, fall frequency and neuroprotection on cognitive function in an aging population (Colcombe et al., 2004; Dishman et al., 2006; Sherrington et al., 2008;
Smiley-Oyen et al., 2008). One of the first studies to research the effect of physical activity on brain function was by Rogers et al., in 1990. It is known that cerebral blood flow decreases with age, and decreases in cerebral blood flow is a risk factor for not only stroke and heart disease, but also, the onset of dementia (R. Rogers, Meyers, Mortel, Mahurin, & Judd, 1986). Engagement in physical activity helps to minimize the effects of aging. In a group of 62 to 70 year old individuals, cerebral blood flow was maintained over a four-year period in those who participated in regular physical activity, but significantly decreased over time in those who did not participate in regular physical activity (R. L. Rogers, Meyers, & Mortel, 1990). Additionally, older adult exercisers exhibit greater executive function and focused attention, both of which are active in multi-tasking, and improvements to executive function can be made through the use of physical activity. In older adults, increases to executive function, as measured by the Stroop Word-Color test, were found after a ten month aerobic exercise intervention (Arthur F Kramer, Erickson, & Colcombe, 2006; Smiley-Oyen et al., 2008). The effects of exercise in improving normal aging and cognition, are not limited to healthy, older adults. Individuals with cognitive impairment can also benefit cognitively from regular aerobic exercise (Arthur F Kramer et al., 2006).

Mild cognitive impairment is a condition in which cognitive declines are not accounted for by the normal aging process, but do not impact activities of daily living (Gauthier et al., 2006). Prevalence of mild cognitive impairment in older adults is estimated between 3-19% and can affect different aspects of cognition including executive function and attention (Gauthier et al., 2006). Cognitive training in both
healthy older adults, and older adults with mild cognitive impairment, both improve aspects of cognition. However, according to the 2011 Cochrane Review on cognition-based interventions, intensity, type and duration of the cognitive therapy has yet to be determined (Martin, Clare, Altgassen, Cameron, & Zehnder, 2011). Improvements in executive function have been noted in healthy older adults in as few as ten cognitive therapy sessions (Lustig, Shah, Seidler, & Reuter-Lorenz, 2009). The improvements in cognitive function can lead to improvements in gait function even in the absence of gait-specific training (Verghese, Mahoney, Ambrose, Wang, & Holtzer, 2010). When gait and cognitive training are coupled (i.e., dual-task training) improvements to global cognitive function in older adults with mild cognitive impairment resulted after a 21-week intervention (Gill et al., 2016).

**Physical Activity Recommendations**

Sedentariness (i.e., sitting) of 12 or more hours per day is associated with a 40-55% increase in cardiovascular mortality (Matthews et al., 2015). In contrast, increasing exercise and non-exercise physical activity (e.g., walking for transportation), can decrease the risk of all-cause mortality (Matthews et al., 2015). The National Health and Nutrition Examination Survey (NHANES) included over 3,000 older adults, and it was found that those with the lowest physical activity levels, had the greatest mortality rates (Fishman et al., 2016). The results of the NHANES study found that simply replacing 30 minutes per day of sedentary time with light physical activity resulted in reductions of mortality risk by 20% and replacing 60 minutes of sedentary behavior with physical activity decreased mortality risk by 39% (Fishman et al., 2016).
Regular physical activity is associated with enhanced overall health and increased quality of life; however, physical inactivity and sedentariness is a growing public concern. It is estimated that less than half of Americans meet the daily physical activity recommendations from the Center of Disease Control (CDC) and American College of Sport Medicine (ACSM) (Haskell et al., 2007). The CDC/ACSM’s most updated physical activity recommendations for healthy adults ages 18-65, includes moderate intensity exercise for 30 minutes five days/week, or vigorous intensity exercise for 20 minutes three days per week (Haskell et al., 2007). Moderate intensity exercise (three to six times the resting metabolic rate (METs)) is similar to a brisk walk that elevates heart rate. Vigorous intensity (> six time resting METs) would be similar to jogging. There is a dose-response relationship between physical activity and health-related benefits for both men and women (Lee & Skerrett, 2001) with the greater the dose of physical activity resulting in a greater decrease in all-cause mortality rate. Simply reaching the minimum of the physical activity guidelines result in 20-30% reductions in all-cause mortality (Lee & Skerrett, 2001).

The number of individuals meeting the physical activity requirements declines with increasing age, and for adults 65 and older, only 39% meet the recommendations (Haskell et al., 2007). Surprisingly, physical activity recommendations do not change for older adults (age 65 and older) and for those ages 50-64 with clinically significant chronic conditions and/or functional limitations. The physical activity recommendations are the same as healthy younger adults; however the type of exercise for certain intensities may not be the same. For example moderate intensity for an older adult may
be slow walk, but for healthy younger adults, moderate intensity would be the equivalent of a brisk walk (King, Rejeski, & Buchner, 1998; Nelson et al., 2007). Engagement in the minimum requirement of physical activity in older adults, and also those with chronic medical conditions, has the potential to improve management of existing conditions and prevent additional health conditions related to sedentariness from developing (Nelson et al., 2007). The 65 and older age group is associated with the largest medical costs, and with the baby boomers aging, the numbers in this segment of the population are expected to grow (Nelson et al., 2007). Physical activity could be utilized to offset medical costs, and should be considered as an adjunct to traditional medical interventions due to both the health benefits associated with regular participation in physical activity and also the cost effectiveness of lifetime engagement in physical activity (Roux et al., 2008).

Ten thousand steps/day is an alternative physical activity threshold that represents a reasonable amount of steps to take per day that elicits health benefits (Tudor-Locke & Bassett, 2004). It is reported that healthy older adults take on average 6,000-8,500 steps/day and it is estimated that 2,500 steps/day are the basal steps/day needed to perform activities of daily living (Tudor-Locke et al., 2011). Further classification on the number of steps per day can place older adults in physical activity level classification of sedentary (<5000 steps/day), low active (5,000-7,499 steps/day), somewhat active (7,500-9,999 steps/day), or active (10,000 steps/day) (Tudor-Locke et al., 2011). Fluid movement between classifications can be made through changing the amount of physical or steps/day. A meta analysis reported that older adults, ages 55-95 years, steps/day were increased by 775 after an exercise intervention ranging from structured aerobic exercise
classes to a home-based walking program, with a small average effect size (Cohen’s $d$) of 0.26 (Tudor-Locke et al., 2011). Comparatively, in special populations, ranging from cancer to COPD, average change in steps/day were 2,215 with a moderate effect size of 0.67 (Tudor-Locke et al., 2011). A separate meta analysis reported that by simply providing an activity monitor that displayed steps/day, the number of steps/day increased by 2,183 compared to baseline (Bravata et al., 2007). Regardless of the intervention, in older adults, where sedentary tendencies increase with age, even small increases in steps/day can result in increases in health related benefits. Improvements in health-related quality of life measures are seen through a 2,000 step/day increase. A 1,000 step/day increment is equivalent to a ten minute bout of moderate-vigorous physical activity (Tudor-Locke et al., 2011). In older adults, those who minimally achieved 4,227 steps/day had lower blood pressure and fasting blood glucose levels when compared to those who had fewer steps (Tudor-Locke et al., 2011). This suggests that although more steps/day are recommended for optimal health benefits, some steps are better than none, and attaining a lower number of steps/day than the recommended amount could still result in some health-related benefits. The idea that some health benefits, such as lowered blood pressure and fasting blood glucose, can be gained even with less than recommended steps/day, supports the idea that an active lifestyle should be promoted across ages and disability levels, even when activity guidelines for health cannot be met.

**Activity Monitors**

Mobility and independence are associated with increases in quality of life (Gabriel & Bowling, 2004; Rejeski & Mihalko, 2001). Quality of life is a term to
describe the conscious judgment of one’s life (Rejeski & Mihalko, 2001). Walking is the simplest form of mobility and can be directly measured by activity monitors, (i.e., pedometers and accelerometers) and results in the number of steps taken or activity counts per day. Activity monitors are superior to self-reports of physical activity, as individuals tend to overestimate their physical activity on questionnaires (Fishman et al., 2016). Commercially available, wearable activity monitors, both worn on the wrist and waist, have moderate acceptability in older adults with chronic disease (Mercer et al., 2016). In addition to being acceptable to older adults, wearable activity monitors have wireless transmission of data that is time-stamped, making them attractive for researchers.

**Neuroplasticity and Motor Learning**

Neuroplasticity and neuroprotection through exercise have the potential to aid in the preservation and improvement of cognitive function, and blunt disease progression in PD. Neuroplasticity after aerobic exercise may be a result from increases in neurotrophins and growth factors that are associated with neuronal growth, neurogenesis, angiogenesis, and overall and neuroprotection (Cramer et al., 2011). Upregulation of neurotrophic factors, like BDNF, could provide resistance to further degeneration (Kleim, Jones, & Schallert, 2003). It is proposed that not all exercise is the same. To capitalize on neuroplasticity properties of exercise, the exercise must fall under the following categories: intense practice, complexity of practice, saliency of treatment, and timing of treatment (Fox et al., 2006). A proposed schematic of how exercise acts on the central nervous system is shown in Figure 1.
According to Fitts and Posner (1967), there are three main phases to motor learning and behavior: cognitive phase, associative phase, and an autonomic phase (Fitts & Posner, 1967). Part of the associative phase involves practice of the new skill. Two main strategies have emerged from dual-task training literature: Part-task strategy and whole-task strategy (A. F. Kramer, Larish, & Strayer, 1995). Part-task strategy training is breaking down dual-task into the two separate parts, motor and cognitive, and then training those components separately before completing the whole task. Whole task strategy training is training both the motor and cognitive components of a dual-task simultaneously. To test for the permanent transfer or acquiring of the new skill in daily life requires a sufficient rest period in which no formal practice takes place. After the rest period, a new skill can be tested to study the permanent effects of the new acquired skill (Salmoni, Schmidt, & Walter, 1984).

Management of gait dysfunction in mild-moderate PD through physical therapy currently focuses on three areas: to teach individuals to move more easily through strategy training, to manage any secondary conditions that occur as a result of the disease or deconditioning, and to promote a physically active lifestyle for overall health and the prevention of falls (Morris, Martin, & Schenkman, 2010). Strategy training focuses on compensatory strategies to surpass basal ganglia dysfunction and gait practice and exercises are recommended three times per week for 6-8 weeks, and if cognitive impairments are noted, to avoid multi-tasking (Morris et al., 2010). However, avoidance to multi-tasking is not practical in daily life, as even walking relies on some aspects of executive function and attention (Bridenbaugh & Kressig, 2015; Yogev-Seligmann et al.,
Therefore, training individuals to multi-task could promote an increase in gait function.

Figure 1. Schematic of proposed neurobiology of exercise on the central nervous system. Engagement in exercise results in both intrinsic and extrinsic feedback, which may result in release of neurotrophic factors (i.e. brain-derived neurotrophic factor). Brain structures involved are pictured, and increase in stimulation may allow for changes in function. Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2016. All Rights Reserved

Physical Activity in PD

There is a general trend from the results of exercise research studies which suggests benefits to those with PD who participate in regular exercise (Goodwin et al., 2008). However, perhaps, in part due to the manifestation of impaired motor control, sedentariness is common among those with PD. Individuals with mild-moderate PD who wore an physical activity monitor (accelerometer) for one-week averaged 4,700 steps/day, which is less than 50% of the recommended 10,000 steps/day for health
benefits (Wallén, Franzén, Nero, & Hagströmer, 2015). In those with mild to moderate PD, there is a 29% decrease in physical activity time compared to age-matched controls, as measured by self-report activity questionnaires (van Nimwegen et al., 2011). The time spent in physical activity further decreases when history of falls are present. Within mild-moderate PD, “fallers” spent 32% less time engaging in physical activity when compared to those without a history of falls (van Nimwegen et al., 2011). Individuals with PD report some of the same barriers to exercise as those without PD, such as lack of time and poor weather conditions. However, some differences between healthy older adults and those with PD are noted as barriers to engage in physical activity (Ellis et al., 2013). Low outcome expectation from exercise engagement and fear of falling has been found to be significant barriers to exercise in those with PD (Ellis et al., 2013; Jonasson et al., 2015), where these barriers to physical activity are typically absent in healthy adults.

**Exercise Interventions in PD**

It has been established that in healthy older adults, regular participation in physical activity and increases in current levels of physical activity result in improved health variables, however, in those with PD, additional benefits specific to PD may be gained. A meta-analysis of exercise in the prevention of falls in older adults report that exercise interventions can have nearly a 20% reduction in fall frequency (Sherrington et al., 2008). As gait dysfunction has been shown to be a strong factor in fear of falling, perhaps an exercise intervention that targets improving gait function may result in a decrease in falls in individuals with PD (Jonasson et al., 2015). Additionally, since
chronic physical activity has the potential to promote neuroplasticity, perhaps this could be harnessed to improve both motor and cognitive function in those living with PD (see Figure 1.).

Treadmill gait training has been found to improve the gait parameters of stride length, walking speed (Bello & Fernandez-Del-Olmo, 2012; Mehrholz et al., 2010; Pelosin et al., 2009) and stride variability (Pelosin et al., 2009) in those with PD. After a four-week treadmill training intervention, improvements on the Timed Up and Go test, 6-minute walking test, and 10-minute walk test were found, and these improvements were maintained up to 30 days post intervention (Pelosin et al., 2009). A 12-week treadmill training program had similar results with increased gait speed and 6-minute walking test distance (Shulman et al., 2013).

Since higher order cognitive centers are active during gait, cognitive training may be of benefit to those with PD. Similar to healthy older adults, in as few as ten, 30-min cognitive training sessions that focused on executive function, improvements in executive function in mild-moderate PD has been shown (Sammer et al., 2006). If cognitive training improves cognition and gait training improves gait function, than training both (i.e. dual-task training) should result in greater improvements in postural instability and gait dysfunction in those with PD.

PD and Dual-task Conditions

Under dual-task conditions, gait parameters of stride length and gait speed decline and step variability increases in those with PD (Stegemoller et al., 2014; Yogevel-Seligmann, Rotem-Galili, Dickstein, Giladi, & Hausdorff, 2012). Understanding
Decrement in gait function in those with PD under dual-task conditions provides groundwork for the development of dual-task interventions aimed at improving postural function.

Even with the knowledge of the declines in performance under dual-task conditions understood, little has been researched in terms of dual-task interventions in PD. The research that has been done in dual-task interventions and PD have had relatively small sample sizes and longer-term effects of interventions are not well documented (Brauer & Morris, 2010; Canning, Ada, & Woodhouse, 2008; Yogev-Seligmann, Giladi, Brozgol, & Hausdorff, 2012). Improvements in step length and gait speed are noted in as little as a one-time, 20 minute dual-task intervention in mild-moderate PD, however, the duration of these benefits are, however, unknown (Brauer & Morris, 2010). In a longer, four-week dual-task training intervention, improvements in gait parameters of walking speed and step variability were found in a similar mild-moderate population of PD (Yogev-Seligmann, Giladi, et al., 2012; Yogev-Seligmann, Rotem-Galili, et al., 2012). Despite the improvements noted in these dual-task and PD studies, it is unknown whether these improvements translate to increases in physical activity behavior outside of the laboratory and therapy setting. Therefore, more research examining the effects of dual-task training on daily physical activity behavior is warranted.

**Self-Efficacy**

Self-Efficacy is the belief that one can successfully engage in a certain behavior (Bandura, 1977). Self-efficacy can be used to predict behaviors and influence the activities or behaviors one chooses to engage in and also the amount of time and effort
devoted to a specific activity or behavior (Higgins, Middleton, Winner, & Janelle, 2014). Increases in self-efficacy result in increases in engagement of the behavior that one has confidence in (B H Marcus & Simkin, 1994). Self-efficacy is believed to be influenced by four primary factors: performance accomplishments, vicarious experiences, verbal persuasion and emotional arousal (Bandura, 1977). Performance accomplishments are based on an individual’s personal experiences, and efficacy can be increased through personal success, or decreased through personal failure. Performance accomplishments are considered the strongest influence on self-efficacy (Bandura, 1977). Vicarious experience can influence self-efficacy and is related to modeling behavior. In other words, seeing another person perform a task or behavior successfully can increase one’s own personal self-efficacy by increasing expectations that they will have the same successful result (Bandura, 1977). Verbal persuasion is trying to convince someone to successfully engage in a certain behavior. Although this method has been shown to have weaker results in influencing self-efficacy than other methods discussed, it still can influence self-efficacy (Bandura, 1977). Emotional arousal is related to stress, and increases in stress levels, physical or emotional, decreases self-efficacy.

Self-efficacy theories can be applied to different types of health-related behaviors, and can be used for predictors of behavior change (Warner et al., 2014). Physical activity self-efficacy is an individual’s confidence that they can successfully engage in physical activity. Physical activity self efficacy scores can be applied to the Transtheoretical Model for resultant stages of behavior change (B H Marcus & Simkin, 1994; Bess H. Marcus, Selby, Niaura, & Rossi, 1991). The Transtheoretical Model helps to explain the
stages of change that individual’s progress through during the changing of a behavior. The stages of change according to this model are: Precontemplation, Contemplation, Preparation, Action and Maintenance (B H Marcus & Simkin, 1994; Bess H. Marcus et al., 1991). Self-efficacy scores, as measured through questionnaires, are related to the stages of behavioral change, and can be used to predict behavior. Individuals with the lowest self-efficacy scores are more likely to be in the Precontemplation stage, in contrast to those with the highest self-efficacy scores are most likely in the Maintenance stage (B H Marcus & Simkin, 1994; Bess H. Marcus et al., 1991). Therefore, if you can increase an individual’s self-efficacy, they may progress further in the stages of change and can potentially adopt a healthy behavior.

**Physical Activity Self-Efficacy and PD**

Relatively little is known about physical activity self-efficacy in those with PD, but perceptions of health status could affect their physical activity self-efficacy. It is known that fall self-efficacy in PD deters participation in physical activity (Nilsson et al., 2010). So, perhaps, if balance confidence can be increased, physical activity self-efficacy can be increased and vice versa; If physical activity self-efficacy can be increased, balance confidence can likewise increase. In healthy adults, self-efficacy is an important factor in physical activity behavior (Higgins et al., 2014; Bess H. Marcus et al., 1991), and due to its dynamic nature, self-efficacy can be changed over time. Self-efficacy changes with experiences, persuasion and emotion in healthy adults (Bandura, 1977), and the same principles could be applied to individuals with PD for increasing physical activity self-efficacy. Applying the four factors that are known to influence self-efficacy
to those with PD and gait dysfunction has the potential to increase physical activity self-efficacy. Application of Bandura’s self-efficacy principles can be accomplished by providing individuals with PD with successful experiences in walking, watching others (e.g., physical therapists and other patients) have successful experiences with walking, being persuaded to try new walking exercises and providing a supportive and positive environment.

**Purpose of the Study**

The purpose of the study is to examine the effects of an eight-week single-task and dual-task intervention on physical activity behavior, fall frequency, PD motor symptoms, exercise self-efficacy and balance confidence in those with PD with a history of falls.

**Specific Aims**

**Specific Aim 1:** To determine the effects of an eight-week dual-task and single-task training program on physical activity behavior and fall frequency in individuals with PD with a history of falls.

It is known that a history of falling and fear of falling decreases engagement in physical activity. Decreases in physical activity are associated with increases in all-cause morbidity and mortality risk. In older adults, pedometer-based interventions can change physical activity behavior, and the mean change in steps per day was 775 after adjusted for sample size (Tudor-Locke et al., 2011). Previous research suggest that in special populations where mobility may be limited, an average of 3,500-5,500 steps/day is a normative value, which is well below the recommended amount of steps/day of 10,000,
for health benefits (Tudor-Locke et al., 2011). Although 10,000 steps/day are recommended for maximum health benefits, literature suggests that increasing the number of steps/day in smaller increments results in some increases in health (Tudor-Locke et al., 2011). There is limited research in special populations studying the effects of interventions on change of steps/day. Specifically, direct measurement of physical activity in those with PD before and after a gait-training program has yet to be assessed.

The primary outcome will be average steps/day. This will be measured using a wearable activity monitor (i.e. accelerometer). Participants will be asked to wear the activity monitor throughout the research study, beginning one week prior to the start of training and continual wear up through four weeks post intervention.

**Specific Aim 2:** To determine the effects of an eight-week dual-task and single-task intervention on exercise self-efficacy and balance confidence in individuals with Parkinson’s disease with a history of falls.

Self-efficacy is a primary determinant of whether or not an individual will engage in a behavior, and also the amount of effort and time devoted to a specific behavior. The primary contributor to self-efficacy is mastery experience, or having experiencing success (Bandura, 1977). Assessment of physical activity self-efficacy and balance confidence after a dual-task training program in those with PD and a history of a fall have yet to be assessed. The primary outcomes will be the Self-Efficacy for Exercise Scale and the Activities-specific Balance Confidence Scale. The secondary outcome will be a report of falls for the past 30 days, six months and one year at baseline, end of treatment, and four weeks post treatment.
Hypothesis

It is hypothesized that both the single and dual-task training groups will increase physical activity and reduce fall frequency after an eight-week intervention when compared to baseline physical activity and fall frequency, but only the dual-task group will maintain the increase in physical activity and reduced fall frequency at four weeks post treatment. It is hypothesized that both the single and dual-task training groups will increase exercise self-efficacy and balance confidence when compared to baseline physical activity level at end of treatment, but only the dual-task group will have an increase in self efficacy at four weeks post treatment. Finally, it is hypothesized that both the single and dual-task training groups will decrease fall frequency of 30 days at end of treatment when compared to baseline 30 day fall frequency, but only the dual-task group will continue to have a decreased fall frequency at four weeks post treatment. The dual-task treatment group is expected to have longer effects than the single-task group because dual-task training is a more complex task which may provide an environment necessary for motor skill acquisition and retention more than single-task training (Simon and Bjork, 2001, Xu et a., 2017).
CHAPTER III
RESEARCH METHODS

Participant Sampling and Recruiting

Sample size validation was computed through a priori power analysis using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) and Tudor-Locke et al., (2011), meta-analysis examining changes in steps per day in special populations after exercise interventions (Tudor-Locke et al., 2011). The difference between controls and exercise groups from the meta-analysis yielded an effect size of 0.67. Given that effect size and an a-priori $\alpha = 0.05$ and a power $= 0.8$, a sample size of $N = 20$ is needed to achieve statistical significance. As a result, a total of 20 participants with idiopathic PD will be recruited from the Cleveland Clinic and surrounding area. Physician and physical therapy referrals will serve as the primary recruitment method. Prior to the start of the study, Cleveland Clinic Movement Disorder specialists (e.g., neurologists and physical therapists that primarily care for PD) will receive information regarding study participation and inclusion and exclusion criteria. Inclusion criteria for participation will include:

- A clinical diagnosis of PD
- History of at least two falls within the last 12 months
- Ability to provide informed consent
- Ability to ambulate a minimum of 300ft with or without the use of assistive walking device

Exclusion criteria for participation will include:

- Any medical or musculoskeletal contraindication to exercise
- History of stroke
- High risk exerciser as defined by the American College of Sports Medicine
- Diagnosis of dementia
- Inability to follow two step commands
- Undergone any surgical procedure for the treatment of PD (i.e., deep brain stimulation)

Methods

Participants will be initially phone screened for study participation, to ensure that all participants meet inclusion and exclusion criteria. Those that meet inclusion requirements will be asked to come to the main campus of the Cleveland Clinic in Cleveland, Ohio for an informed consent interview. All procedures and informed consent documents were approved by The Cleveland Clinic Institutional Review Board, and all participants signed the informed consent form prior to the start of study participation (see Appendix A). Participants will be enrolled for a total of 13 weeks, which includes one week for baseline assessments, eight-weeks of training, and four-weeks of a follow-up phase (see Figure 2). After consent, participant demographics and medical history will be obtained. Baseline assessments include the MDS-UPDRS Motor-III, self-report of history of falls, the Self-Efficacy for Exercise Scale and the ABC balance scale (see Figure 2). All assessments and training will be completed with participants ‘on’ their anti-parkinsonian medication as prescribed by their neurologist. Participants are permitted to miss a training session due to life events (i.e., illness, vacation, previous
appointment), however the session will be rescheduled, and all 24 sessions will be completed within 12 weeks from the date of the first intervention session.

Figure 2. Study flow chart
Participants will be fitted with an activity monitor (accelerometer), and given instructions of its use. The activity monitor will be worn throughout research participation beginning one week prior to the start of the training intervention, through four weeks post the end of the intervention. The initial week of activity monitor wear will serve as individual’s baseline physical activity level. Participants will be instructed to wear the activity monitor during all waking hours each day of the week, except for when showering, bathing or swimming, throughout the duration of the research study. Valid days of wear will consist of at least being worn for ten hours or more for at least four days out of the seven days of the week in accordance with previous research (Wallén et al., 2015). Participants will be asked to sync their activity monitor daily to software provided with the activity monitor, and also to report if activity monitor was not worn for ten hours. This will be confirmed in the wireless transmission of data through daily activity monitor syncs. The activity monitor will measure steps/day.

Participants will then be randomized into either a single-task ($n=10$) or dual-task training group ($n=10$). All training will be supervised by a physical therapist that specializes in PD at the main campus of the Cleveland Clinic. Training will occur three times a week for eight weeks for 40 minutes each session. All intervention sessions will take place in a traditional outpatient rehabilitation environment. Training will be adjusted based on individual’s baseline assessments. The assessments completed at baseline will be repeated at the end of treatment and at a four-week post treatment follow-up.
The single-task training group will consist of 20 min of gait training and 20 min of cognitive training in a seated position for a total of 40 min of intervention. Each task (i.e., gait and cognitive) will be preformed separately, where attention will be focused on one task at a time. Examples of single-task gait training are walking on a treadmill while focusing on long strides. All single-task cognitive training will be preformed in the seated position, and will include memory tasks (e.g., recall of meals eaten the day prior), attention tasks (e.g., focusing attention on auditory or visual cues), and general thinking tasks that will tax executive function (e.g., continuous subtraction by 7’s from a given number).

The dual-task training group will consist of gait training while simultaneously completing a cognitive task for a total of 40 minutes of intervention. Dual-task training will include the same activities as the single-task group, but performance of tasks will be completed simultaneously. An example of a dual-task activity would be recalling meals eaten the day prior while walking at a constant pace on a treadmill.

**Measurements**

**MDS-UPDRS Motor III**- The MDS-UPDRS is the most commonly utilized scale to clinically assesses motor symptoms of PD (Goetz et al., 2008). There are four components of the MDS-UPDRS, with the Motor III section used to rate motor symptoms of PD. The MDS-UPDRS Motor III will be completed by a Movement Disorders specialist. The exam consists of 18-items that are rated on a scale from zero to four, with lower scores indicating lesser impairment.
**Activity Monitor** - The activity monitor is a wrist worn accelerometer that measures steps/day. A wrist worn activity monitor was chosen as it has acceptability among older adults (Mercer et al., 2016), and wrist worn activity monitors has higher compliance rates of wear time (Fairclough et al., 2016).

**Self-efficacy for Exercise Scale (SEE)** - The SEE is a valid and reliable self-reported measure of physical activity self-efficacy in older adults (Appendix B) (Resnick & Jenkins, 2000). The SEE is a nine-item questionnaire in which responses range on a scale from 0-10. The scale is anchored by not confident (0) and very confident (10), with greater scores indicating greater self-efficacy for physical activity.

**Activities-specific Balance Confidence Scale (ABC)** - The ABC scale is a 16-item questionnaire that identifies balance confidence, which is related to fall self-efficacy, in specific functional activities (Appendix C) (Powell & Myers, 1995). The scale consists of percentages in increments of 10, and is anchored by not confident (0%) and completely confident (100%) with greater scores indicating more confidence in balance related activities. This scale was chosen as the Falls Self-Efficacy Scale was shown to have a ceiling effect for active community-dwelling older adults (Legters, 2002; Tinetti & Powell, 1993).

**30-Day Fall Recall** - Participants will be asked to recall how many times they have fallen over the past year and how many times they have fallen in the past 30 days. They will be asked by study personnel and prompted by the Kellogg International Working Group’s definition of falling which is well accepted in assessment of falls in literature: “How many times have you come to rest inadvertently on the ground or other
lower level other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis or a seizure?” (Gibson, 1987).

**Statistical Analysis**

Four separate, two-group (dual-task and single-task) by three time point (Baseline, end of treatment and four-week follow up) Repeated Measures Analysis of Variance (ANOVA) will be completed to compare average steps/day, mean score on the SEE Scale, 30-day fall frequency and mean ABC scale scores. If significant main effects are found, post hoc analysis will be performed using t-tests with the Benjamini–Hochberg correction for multiple comparisons. The relationship between the change in physical activity, as measured in steps/day, and change in exercise self-efficacy, as measured by the Self-Efficacy for Exercise Scale, will be assessed through correlation analysis. Correlation analysis will also be completed to study the relationship between the change in physical activity, as measured in steps per day, and change in balance confidence, as measured by the ABC scale.
CHAPTER IV.

DUAL-TASK TRAINING INCREASES PHYSICAL ACTIVITY BEHAVIOR AND DECREASES FALL FREQUENCY IN INDIVIDUALS WITH PARKINSON’S DISEASE

Parkinson’s disease (PD) is the second most common movement disorder with healthcare costs in the United States estimated at $14.4 billion annually, and the cost are expected to rise over the next ten years (Kowal et al., 2013). PD is characterized by both motor and non-motor features (Bartels & Leenders, 2009). The motor feature of postural instability and gait dysfunction is described as shuffling, small steps, decreased arm swing and stooped posture, which overall, result in disturbances in walking, maintenance of balance, and an increase in falling (Bartels & Leenders, 2009; Gray & Hildebrand, 2000). As a result of postural instability and gait dysfunction, over 50% of individuals with PD report falling within the previous two years, of which 65% result in injury requiring medical intervention (Wielinski et al., 2005).

Greater fall frequency and fear of falling not only leads to greater injury risk which in turn increase health care costs, it also reduces engagement in physical activity behavior in individuals with PD (Nilsson et al., 2012). Reduced physical activity is of concern as decreases in physical activity in older adults are associated with increases in all-cause morbidity and mortality risk (Fishman et al., 2016). To decrease mortality risk, the National Health and Nutrition Examination Survey found that simply by replacing 30 minutes/day of sedentary activity with light physical activity, older adults exhibited a 20% reduction of overall mortality risk in older adults (Fishman et al., 2016).
Furthermore, there is evidence which suggests participation in exercise may have therapeutic benefits in alleviating motor symptoms of PD (Alberts et al., 2011; Goodwin et al., 2008; Ridgel, Vitek, & Alberts, 2009).

Measurement of physical activity behavior as captured in average steps/day via pedometers and accelerometers has become increasingly common as usage of low-cost, easy-to-use activity monitors has increased (Fairclough et al., 2016; Mercer et al., 2016; Thompson, 2016). A goal of 10,000 steps/day is a widely accepted threshold for the quantity of physical activity recommended to elicit health benefits (Tudor-Locke & Bassett, 2004). Older adults without a chronic condition take between 6,000-8,500 steps/day, while older adults with chronic conditions, such as PD, accumulate approximately 50% fewer steps/day than their healthy peers (Tudor-Locke et al., 2011). For example, Wallén et al (2015) demonstrated that individuals with mild-moderate PD averaged only 4,700 steps/day over a one-week bout (Wallén et al., 2015). Therefore, PD steps/day are not only less than healthy adults (6,000-8,500 steps/day) but also well below the recommended 10,000 steps/day. Although 10,000 steps/day are recommended for maximum health benefits, previous research suggests that increasing the number of steps/day in smaller increments still results in reduced morbidity and mortality risks (Tudor-Locke et al., 2011). Despite the health benefits of increasing physical activity behavior, there are limited studies examining the efficacy of interventions designed to increase physical activity in a PD population for which falling is a significant concern.

While impairments in motor function may partially explain PD patients lower walking behavior, the lower activity level may be exacerbated as a result of non-motor
PD features such as cognitive dysfunction. Specifically, individuals with PD have greater gait dysfunction under dual-task conditions (e.g., carrying on a conversation while walking) (Bastiaan R Bloem et al., 2006; Rochester et al., 2004). Individuals with PD exhibit gait and posture dysfunction while cognitive function is maintained under dual-task constructs greater than their healthy older peers, (Bastiaan R Bloem et al., 2006; Rochester et al., 2004). Bloem et al (2006) refers to the preservation of cognitive performance while simultaneously gait function declines under dual-task conditions as a ‘posture second’ strategy (Bastiaan R Bloem et al., 2006). Posture second strategy is more prevalent in individuals with PD and places individuals at a greater fall risk (Bastiaan R Bloem et al., 2006; Heinzel et al., 2016; Stebbins et al., 2013). Healthy adults display the opposite of ‘posture second’ strategy under dual-task conditions, with prioritization given to maintenance of balance and gait over the secondary task (B R Bloem, Valkenburg, Slabbekoorn, & Willemsen, 2001). The greater dual-task gait interference in individuals with PD compared to healthy adults is related to the disruption of basal ganglia function in the monitoring of voluntary movement and cognitive processes (Iansek, Bradshaw, Phillips, Cunnington, & Morris, 1995). In PD, the selective loss of dopaminergic projections places individuals at a deficit for resources available under dual-task conditions (Iansek et al., 1995). Thus placing individuals with PD at a greater risk for falling while performing a secondary, cognitive task (e.g. carrying on a conversation) while walking.

In animal models of PD, motor learning is impaired, but learning and neuroplasticity is still possible (Xu et al., 2017). To improve performance under dual-task
constructs, motor training is warranted. To refine and retain motor skills under dual-task constructs, there is conflicting evidence whether part-task training or whole-task training is most effective (A. F. Kramer et al., 1995). Part-task strategy training is the equivalent of single-task training, and it involves training motor and cognitive components separately. Whole-task strategy training involves training both the motor and cognitive components simultaneously. The differential effects of single-task (i.e., part-task) and dual-task (i.e., whole task) training on physical activity behavior and falls in PD remain unknown. One study, utilizing a combination of single-task and dual-task training showed a 6% increase in steps/day from baseline levels in individuals with PD following a ten week intervention, but the direct comparison of the effects of single-task and dual-task interventions on physical activity behavior was not performed (Conradsson et al., 2015).

Studies of interventions incorporating both therapeutic cognitive and motor components (e.g., single-task and dual-task training) in individuals with PD are limited. Existing research incorporates both single-task and dual-task training within the same intervention, or only include one type of training (single-task or dual-task) into the intervention (Conradsson et al., 2015; Protas et al., 2005; Strouwen et al., 2017). All studies, that have been completed in single-task and dual-task training in PD result in gait improvements such as increased gait velocity and balance scores for individuals with PD although direct comparison of the effects of purely single-task training versus dual-task training upon physical activity and fall behavior has yet to be assessed in individuals with PD (Conradsson et al., 2015; Strouwen et al., 2017).
The purpose of this study was to determine the effects of two, separate, eight-week interventions that utilized either single-task or dual-task training on physical activity behavior, fall frequency, and PD motor symptoms in individuals with Parkinson’s disease with a history of falls. It is hypothesized that both the single-task and dual-task training groups will improve motor symptoms, increase physical activity and reduced fall frequency at the completion of the intervention, but only the dual-task training group will maintain the improvement in motor symptoms, increase in physical activity and reduced fall frequency at four-weeks post treatment. The hypothesis that only the dual-task group will have lasting effects of training is due to the assumption that dual-task training is more complex which may provide the environment for motor skill acquisition and retention greater than single-task training (Simon & Bjork, 2001; Xu et al., 2017)

**Methods**

**Participants**

Twenty-one participants between the ages of 43 and 77 years (mean 61.75 ± 8.76 years) with mild-moderate idiopathic PD were recruited from the Cleveland Clinic and surrounding area. Sample size validation was computed through a-priori power analysis using Tudor-Locke et al., 2011, meta-analysis examining changes in steps/day in special populations after exercise interventions. Power was set at 0.80, with \( \alpha = 0.05 \). Given the effect size from Tudor Locke and an alpha of 0.05, a sample size of 20 would be needed to achieve a power \( \geq 0.80 \). Therefore, a sample of 21 was deemed to be adequate.
Inclusion criteria included a clinical diagnosis of PD, a history of at least two falls within the last 12 months, and ability to ambulate a minimum of 300 feet with or without the use of assistive walking device. Exclusion criteria included any medical or musculoskeletal contraindication to exercise, a history of stroke, diagnosis of dementia, inability to follow two-step commands, and having undergone any surgical procedure for the treatment of PD (e.g., deep brain stimulation). Participants were initially phone screened to insure inclusion and exclusion criteria were met, and medical records were obtained to verify PD diagnosis. Within medical records, disease duration and levodopa equivalent daily dose (LEDD) was obtained for study demographics. All participants read and signed an informed consent document that was approved by the Cleveland Clinic (Cleveland, OH, USA) Institutional Review Board.

**Intervention**

This study was part of a larger, randomized trial, and all participants were randomly allocated using sealed envelopes with group names labeled inside each envelope to a single-task ($n = 11$) or dual-task intervention group ($n = 10$). All training was supervised by a licensed physical therapist that specialized in PD at the main campus of the Cleveland Clinic. Both single-task and dual-task interventions were administered three times per week, for 40-min sessions, for eight-weeks. The single-task group consisted of 20 minutes of gait training and 20 minutes of cognitive training during each session. Each task (i.e., gait and cognitive) was preformed separately in the seated position, focusing on one task at a time. The dual-task group consisted of 40 minutes of gait training while simultaneously completing a cognitive task. Cognitive training for
both groups involved executive function, attention, memory, and language tasks. Gait training in both groups focused on improving the quality of gait (e.g., gait velocity, step length).

**Clinical and Physical Activity Assessment**

Clinical and physical activity assessments were completed three time points: baseline (i.e., one week prior to the start of the intervention), post intervention (i.e., one week post intervention), and again four weeks post intervention for a follow up. For clinical assessments, participants were instructed to take their antiparkinsonian medication one hour prior to the start of their appointment to ensure evaluations were completed during peak levodopa response (Nutt, Woodward, Hammerstad, Carter, & Anderson, 1984). Testing was performed by a single, blinded rater and PD motor symptoms were assessed utilizing the Movement Disorders Society Unified Parkinson’s Disease Rating Scale Motor III (MDS-UPDRS). The MDS-UPDRS Motor-III is the most commonly utilized rating exam to classify and assesses motor symptoms of PD (Goetz et al., 2008). Fall frequency over the past 30 days were assessed via participant recall, and individuals were prompted by study personnel asking, “How many times have you come to rest inadvertently on the ground or other lower level surface in the past 30 days?” (Gibson, 1987).

Physical activity was assessed utilizing a valid, wrist-worn activity monitor (Movband 3, DHS Group, Houston, TX) (Newton, Glickman, Fennel, Gunstad, & Barkley, 2017). Participants were fitted with the activity monitor and given instructions for its use. Participants were instructed to wear the activity monitor during all waking
hours with the exception of bathing or participation in water sports (monitor is not waterproof) during study participation. Duration the activity monitor was worn daily was confirmed using the activity monitor’s online software (Movband 3, DHS Group, Houston, TX). Activity monitor outcome variables of steps/day and steps/hour the device was worn (to account for varying wear times) were assessed at all three time points. In accordance with previous studies, a valid activity monitor wear day consisted of ≥10-hour of wear, and valid wear weeks consisted of at least four valid wear days out of the seven days of the week (Trost, Mciver, & Pate, 2005; Wallén et al., 2015). Activity monitors were downloaded each time the participant came to the clinic for intervention.

**Statistical Analysis**

Independent samples t-tests were completed to assess for differences in age, MDS-UPDRS Motor-III scores, fall frequency, disease duration, and LEDD between groups. Tests of normality were then performed for baseline measure for all dependent variables (steps/day, steps/hr, fall frequency, and UPDRS Motor-III). UPDRS Motor-III scores (Shapiro-Wilk = 0.93, p = 0.20) were normally distributed, but steps and falls were not (Shapiro-Wilk ≤ 0.84, p ≤ 0.005), therefore, UPDRS Motor-III scores were analyzed using a mixed factorial, two-group (single-task, dual-task) by three time (baseline, post and 4-weeks post) analysis of variance (ANOVA) with repeated measures on time. Post hoc analyses on any significant effects from the ANOVA were performed using t-tests. Because they were not normally distributed, non-parametric Wilcoxon signed rank tests were utilized to compare both 30-day falls and steps (steps/day and steps/hour) across the three time points (baseline, end of training and four-weeks post) with all participants in a
single group and then again for each group (single task, dual task) separately. Data was analyzed using IBM SPSS Statistics version 24 and significance level was set at $p \leq 0.05$.

**Results**

Two participants failed to comply with activity monitor wear time guidelines (i.e., did not wear the monitor requisite days/times) and were excluded from the final analyses. Therefore, the final sample size was $N = 19$ (single-task $n=10$, dual-task $n=9$). There were no significant differences between groups for baseline demographics of age, disease duration, UPDRS Motor-III score, and LEDD ($p > 0.05$). Participant characteristics are provided in Table 1.

Table 1

*Participant demographics and clinical scores at baseline ($N=19$)*

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age (yr)</th>
<th>Disease Duration (yrs)</th>
<th>UPDRS Motor-III Score</th>
<th>H &amp; Y Stage</th>
<th>LEDD</th>
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*Mean ± SD*  
13 M 61.37 ± 8.83 6.47 ± 4.48 36.47 ± 11.54 2.26 ± 0.45 741.53 ± 581.83
When comparing UPDRS Motor-III scores between the groups and across the three time points, no significant group and time interaction effects were found ($F= 0.37$, $p= 0.60$). However, there was a significant main effect of time ($F= 5.68$, $p= 0.007$) as UPDRS scores significantly ($p \leq 0.04$) decreased from baseline (34.90 ±11.24) to end of treatment (32.75 ±11.63) and baseline to the four-week follow up (31.90 ± 10.45) with no difference ($p = 0.23$) from end of treatment to four-week follow up. There was no significant main effect of intervention group ($F= 1.02$, $p = 0.325$). Figure 3 illustrates the change in UPDRS Motor-III over time.

Figure 3. Change in MDS-UPDRS Motor-III scores over time (N=19). UPDRS significantly decreased ($p \leq 0.04$) in both the single-task and dual-task groups from baseline to end of treatment, and the lower UPDRS was maintained through the 4-week follow up. Data are reported as mean ± SE.
When comparing 30-day fall frequency across the three time points for all participants simultaneously, there were no significant difference ($Z \leq 1.85, p \geq 0.07$) in falls at any time point (1.45 ± 2.3 falls at baseline, 0.80 ± 1.32 falls at end of treatment, 0.70 ± 1.42 falls at the four-week follow up). However, when analyzing the single-task and dual-task groups separately, the dual-task group had a significant ($Z \geq 2.21, p \leq 0.02$) reduction in fall frequency from baseline (2.30 ±3.02 falls) to end of treatment (0.80 ± 1.14 falls) and baseline to the four-week follow up (0.70 ± 1.57 falls) with no difference ($Z = 0.33, p = 0.74$) from end of treatment to the four-week follow up. There were no significant ($Z \leq 1.00, p \geq 0.32$) differences in falls across the three time points for the single-task group (0.60 ± 0.84 falls at baseline, 0.80 ± 1.14 falls at end of treatment, 0.70 ± 1.57 falls at the four-week follow up). Changes in fall frequency across the three time points, for each group separately are illustrated in Figure 4.
Figure 4. Change in fall frequency over time. Only the dual-task group significantly ($p \leq 0.02$) decreased their number of 30-day falls from baseline to end of treatment and the decrease in fall frequency was maintained during the 4-week follow-up. Data are reported as mean ± SE.

When comparing steps/day across all three time points for all participants simultaneously, there was a significant increase ($Z = 2.17, p = 0.03$) from baseline (4,942 ± 4,415 steps/day) to end of treatment (5,914 ± 5,425 steps/day) as steps/day increased by approximately 16%. Even though, steps/day at the four-week follow up (5,339 ± 5,211 steps/day) were still approximately 8% greater than baseline level, there was no significant difference between baseline and the four-week follow up steps/day ($Z = 1.00, p = 0.31$). There was also no difference in steps/day from end of treatment to the four-week follow up ($Z = 1.19, p = 0.23$). When analyzing the single-task and dual-task groups separately there were no significant ($Z \leq 0.05, p \geq 0.07$) differences in steps/day.
across the three time points for either the single-task (baseline 3,814 ± 2,742 steps/day, 
end of treatment 4,525 ± 3,827 steps/day, four-week post 3,778 ± 2,910 steps/day) or 
dual-task (baseline 6,195 ± 5,661 steps/day, end of treatment 7,690 ± 6,849 steps/day, 
four-week post 7,459 ± 6,735 steps/day) groups. Figure 5 illustrates the steps/day 
increase over time for both the single-task and dual-task intervention groups.

When comparing steps/hr the accelerometer was worn across all three time points 
for all participants simultaneously, there was a significant 15% increase (Z = 2.21, \( p = 
0.03 \)) in steps/hr from baseline (349 ± 316 steps/hr) to end of treatment (408 ± 340 
steps/hr). Although the four-week follow up steps/hr (394 ± 295 steps/hr) were still 13% 
greater than baseline physical activity, this difference was not significant (Z = 1.49, \( p = 
0.14 \)). Step/hr at the end of treatment were also not significantly different from the four- 
week follow up steps/hr (Z = 0.85, \( p = 0.40 \)). When analyzing the single-task and dual- 
task groups separately there were no significant (Z ≤ 0.06, \( p ≥ 0.11 \)) differences in 
steps/hr across the three time points for neither the single or dual-task groups.
Figure 5. Change in steps/day over time. Both the single-task and dual-task groups significantly increased their steps/day after the intervention ($p = 0.03$). Data are reported as mean ± SE.

Discussion

The results of this study show a 972 step/day or nearly a 20% increase in physical activity behavior after an eight-week intervention, regardless of the mode of intervention utilized (single-task or dual-task). In PD, gait dysfunction is the strongest contributor to fear of falling. The improvement in PD motor symptoms (i.e., reduced MDS-UPDRS Motor-III scores) seen in all participants combined, may have enabled individuals to increase their physical activity behavior (Nilsson et al., 2012). The reduction in MDS-UPDRS Motor-III score from baseline (36.55 ± 11.24) to end of training (32.75 ± 11.63) in both groups reached and exceeded the minimal clinically important difference of 3.25 on the MDS-UPDRS Motor-III (Horvath et al., 2015). The PD motor symptom reduction
was maintained during the four-week follow up period for both the single-task and dual-task groups. Additionally, the dual-task group significantly decreased fall frequency after the eight-week intervention, while the single-task group did not. The reduction in fall frequency was maintained during the four-week follow up for the dual-task group, indicating that dual-task training was successful in reducing fall frequency in individuals in PD who have a history of falls.

Physical activity is modifiable behavior that is associated with morbidity and mortality risk. Current American Heart Association and American College of Sports Medicine physical activity recommendations for older adults include 30 min of moderate intensity aerobic physical activity at least five days/week (Nelson et al., 2007). A 1,000 step/day increase is equivalent to a ten-min bout of moderate-vigorous physical activity (Tudor-Locke et al., 2011). In our study, the single-task group nearly reached a 1,000 step increase (771 steps), and the dual-task group exceeded the 1,000 steps, taking an additional 1,495 daily at the end of the intervention. It was found that in older adults, those who minimally attained 4,227 steps/day had lower blood pressure and fasting blood glucose levels when compared to those with fewer average daily steps (Tudor-Locke et al., 2011). Baseline average steps/day in this study for the combined groups, 4,942 steps/day, was similar to the 4,700 PD steps/day from Wallen et al., (2015) (Wallén et al., 2015). The single-task group’s baseline steps were 3,814 steps/day and increased to 4,525 steps/day at end of treatment, which suggests they reached the threshold for health gains. While the near-1,000 step/day increased shown for all aggregated participants in this study did not move these participants to fully meet the physical activity guidelines
(i.e., 10,000 steps/day), the increase in physical activity does provide evidence that although more steps/day are recommended for optimal health benefits, some steps are better than none, and prevention of comorbidities may result even in smaller increases in activity (Tudor-Locke et al., 2011).

While our study showed nearly a 1,000 step/day increase when combining the single-task and dual-task groups, Conradsson et al (2015) showed an increase of only 282 steps/day following a 10-week combined single-task and dual-task intervention in individuals with PD (Conradsson et al., 2015). The outcomes of the studies may differ for a number of reasons. The present intervention may have provided greater individualized attention to participants and as the intervention was administered to one participant at a time and only included gait training for the motor portion of the intervention. Conversely, the intervention employed by Conradsson et al utilized a group setting of four-seven participants and included both gait and balance training (Conradsson et al., 2015). Conradsson et al (2015) also did not separate out single-task training and dual-task training, but rather used both training methods during their ten-week intervention (Conradsson et al., 2015).

Another important finding of this study was that only the dual-task group significantly decreased their fall frequency after the eight-week intervention, and the reduction in falls was maintained at the four-weeks follow up. The reduction in fall frequency in the dual-task group only indicates a training effect occurred in individuals with PD who have a history of falls. The decreased fall frequency noted in the dual-task group suggests dual-task training may provide greater transfer of training during
activities of daily living resulting in an overall decreased fall frequency. The greater transfer of training may be due to dual-task training being more complex, which would provide an environment needed for motor skill acquisition and retention (Simon & Bjork, 2001; Xu et al., 2017). While dual-task training may be superior in fall frequency reduction, both single-task and dual-task training groups increased their physical activity and decreased PD motor symptoms at an equivalent rate. The equivalent change suggests that while dual-task training may promote a reduction in fall frequency, both single-task and dual-task training have the efficacy to promote physical activity behavior and reduce PD symptoms.

While this investigation was the first to report that both single-task and dual-task training resulted in an increase physical activity behavior and decrease PD motor symptoms, and dual-task training may reduce fall frequency, it is not without limitations. The sample size was small and baseline data for the dependent variables of steps/day and fall frequency were not normally distributed. The actual observed power for average steps/day was small to detect change at 0.16. A larger sample size may allow for normal data distribution and greater statistical power. Also, while baseline fall frequency were not statistically different between the single-task and dual-task groups, the dual-task group did have a greater fall frequency at baseline, which may have allowed for a greater improvement than the single-task group post intervention.

**Conclusion**

Both single-task and dual-task training resulted in an improvement in PD motor symptoms and increased physical activity behavior. These are important outcomes as
greater physical activity and reduced PD motor symptom severity likely both have a positive impact upon the quality of life in individuals with PD. While both single-task and dual-task training resulted in greater physical activity and lower UPDRS scores, only dual-task training was successful in decreasing fall frequency in individuals with PD with a history of falls. It is unclear why only dual-task training reduced reported fall frequency. It is possible the reduction in fall frequency was due to a non-significant group difference of fall frequency at baseline, and/or that dual-task training resulted in greater motor and/or cognitive benefits than single-task training, although the difference in single-task and dual-task improvements were not manifested in UPDRS scores or physical activity behavior. Therefore, while we have provided evidence of the potential utility of gait and cognitive training in individuals with PD, additional research is warranted to determine the most efficacious mode for training.
CHAPTER V.

SELF-EFFICACY FOR EXERCISE IS DELAYED AFTER COGNITIVE AND GAIT TRAINING IN INDIVIDUALS WITH PARKINSON'S DISEASE WHO FALL

Parkinson’s disease (PD) is a neurodegenerative movement disorder that affects over 4.1 million individuals worldwide, with the prevalence projected to more than double over the next ten years (Dorsey ER, Constantinescu R, Thompson JP & al., 2007). Healthcare costs associated with PD in the United States account for approximately $14 billion annually (Kowal et al., 2013). One contribution to the high cost of care is related to falling. Postural instability and gait dysfunction, one of the cardinal motor features of PD, places individuals at a greater risk for falls (Gray & Hildebrand, 2000). Falling in PD is of particular concern as 55% of individuals with PD report falling, compared to 32% in healthy peers (Tinetti, Speechley, & Ginter, 1988; Wielinski et al., 2005). Furthermore, 65% of falls in PD require medical intervention which further inflates medical cost associated with the disease (Wielinski et al., 2005).

Falls not only directly impact the cost of healthcare in PD, but falling and fear of falling has been shown to limit participation in physical activity (Jonasson et al., 2015; Nilsson et al., 2010, 2012). This likely occurs as individuals who have a high fear of falling likely have reduced confidence in their ability to be physically active safely. In other words, individuals with PD likely have lower self-efficacy for physical activity than their healthy peers. Previous research has found that in both older adults and individuals with PD low exercise adherence is associated with low self-efficacy for exercise (Cox et
This reduced physical activity is problematic as engagement in physical activity and exercise has the potential to increase balance confidence and reduce fear of falling (Legters, 2002). Furthermore, greater participation in physical activity has a myriad of health benefits including evidence of motor symptom relief in individuals with PD (Alberts et al., 2011; Petzinger et al., 2010; Ridgel et al., 2009).

In addition to lower physical activity participation, postural instability and gait dysfunction in individuals with PD contributes to greater difficulty, relative to their healthy peers, while performing a dual-task (i.e. simultaneous completion of a motor-cognitive task), such as walking while talking (Bastiaan R Bloem et al., 2006; Rochester et al., 2004). In PD, Basal ganglia dysfunction result in motor skill dysfunction which may impact the functional performance in activities of daily living (ADL) (Hariz & Forsgren, 2011). As a result, individuals with PD often have difficulty performing a dual-task, such as walking while talking (Bastiaan R Bloem et al., 2006; Rochester et al., 2004). Even with dysfunction of the corticostriatal circuit, motor-skill acquisition is still possible in PD (Doyon, 2008). Motor skills are acquired through learning and practice, and maintenance of skilled motor tasks involve automaticity and retention of the task (Doyon, 2008; Simon & Bjork, 2001). Practice, or training, in the same mode that is used in ADL’s may improve retention of self-efficacy and confidence. There are two primary modes to acquire or refine a new motor skill under dual-task constructs (i.e. simultaneous completion of a motor-cognitive task): part-task training and whole-task training and there is contradicting evidence as to which mode is superior in motor-cognitive learning (A. F. Kramer et al., 1995). Part-task training, or single-task training
involves dividing the dual-task into separated components (motor and cognitive), and then training these components separately. Whole task training, or dual-task training, involves training both the motor and cognitive components of a dual-task simultaneously. Part-task training may allow for greater skill acquisition, while whole-task training may allow for greater skill retention (Simon & Bjork, 2001).

While there is limited evidence, both dual-task training and single-task training have shown the ability to increase gait performance as measured by increased gait velocity and step length in individuals with PD (Conradsson et al., 2015; Strouwen et al., 2017). However, while both single-task and dual-task training may have utility in improving motor and balance confidence in individuals with PD, no study that we are aware of has directly compared these two interventions to determine if one is more effective than the other in altering balance confidence and/or self-efficacy for exercise (SEE). Balance confidence, fear of falling, physical activity behavior and SEE are all fluid and dynamic inter-related constructs. A change to one has a cascade effect on the others. As balance confidence has the potential to decrease fear of falling and promote physical activity, SEE has also been found to be a significant predictor of physical activity behavior. Increasing SEE raises the likelihood of participation in a specific type of behavior (Higgins et al., 2014; B H Marcus & Simkin, 1994; Warner et al., 2014).

It is possible that increasing balance confidence decreases fear of falling, which could increase SEE potentially leading to an increase in engagement in physical activity. However, the ability of an exercise intervention to enhance SEE in PD patients has not been previously assessed. If such an intervention was able to increase SEE and promote
balance confidence it may promote an increase in physical activity. This is potentially important as increased physical activity behavior in individuals with PD has been shown to result in greater mobility, quality of life, overall health, and decrease symptoms as measured by the Unified Parkinson’s disease rating scale (UPDRS) (Goodwin et al., 2008; Speelman et al., 2011).

The purpose of this study was to evaluate SEE, balance confidence, and PD motor symptoms before and after a dual-task or single-task training intervention in individuals with PD with a history of falls. It was hypothesized that both the single-task and dual-task training groups will increase SEE, balance confidence, and decrease PD motor symptoms when compared to baseline at end of treatment, but only the dual-task group will maintain this increase in SEE and balance confidence and improvement in PD motor symptoms at four weeks post treatment due to the ability of dual-task training to allow for greater motor skill retention (Simon & Bjork, 2001).

Methods

Participants

Twenty-one, community-dwelling, individuals with moderate idiopathic PD (Hoehn-Yahr II-III) were recruited from the Cleveland Clinic and surrounding area to participate in this study. Inclusion criteria consisted of a clinical diagnosis of PD, a history of at least two falls within the last 12 months, and ability to ambulate a minimum of 300ft independently with or without the use of an assistive device (e.g. walker). Exclusion criteria included any medical or musculoskeletal contraindication to exercise, diagnosis of dementia, inability to follow two-step commands, a history of stroke, and
having undergone any surgical procedure for the treatment of PD (e.g. deep brain stimulation). To verify inclusion and exclusion criteria were met, participants were initially phone screened, and medical records were obtained to confirm PD diagnosis and levodopa equivalent daily dose (LEDD) was calculated. All participants read and signed an informed consent document that was approved by the Cleveland Clinic (Cleveland, OH, USA) Institutional Review Board.

**Intervention**

Participants were randomly assigned to interventional groups using sealed envelopes with group names labeled inside each envelope, to a single-task \( (n = 11) \) or dual-task intervention group \( (n = 10) \). All training was supervised by a licensed physical therapist that specializes in PD and completed at the main campus of the Cleveland Clinic (Cleveland, OH). Both single-task and dual-task training were time-matched (40 min) and were administered three times a week for eight weeks.

The single-task group consisted of 20 minutes of gait training and 20 minutes of cognitive training with each task (i.e., gait and cognitive) preformed separately. Cognitive training included attention, memory, language, and executive function tasks. An example of cognitive task includes performing mathematical equations or recalling letters in an order they were presented. Gait training focused on improving the quality of gait (e.g. increasing step length or gait velocity). An example of a task used in gait training is walking with long strides in different directions (e.g. forward, sideways or backwards). The dual-task group also consisted of gait training and cognitive training, but the tasks (i.e., gait and cognitive) were performed simultaneously. An example of
dual-task training would be walking backwards while simultaneously performing mathematical equations.

**Clinical Assessment and Outcomes**

Clinical assessments and study outcomes were completed at baseline (one week prior to the start of the intervention), end of treatment (post intervention), and four weeks post intervention. For all assessments, participants were instructed to take their antiparkinsonian medication one hour prior to the start of their appointment to ensure evaluations were during peak levodopa response (Nutt et al., 1984). Motor symptoms were assessed utilizing the UPDRS by a single, blinded rater. The UPDRS is the most commonly used scale to clinically assesses motor symptoms of PD (Goetz et al., 2008). The intraclass correlation coefficient for test for reliability for UPDRS Motor-III is 0.89, which is well above the accepted 0.70 (Steffan & Seney, 2008).

Exercise self-efficacy was assessed using the Self-efficacy for Exercise Scale. The SEE scale is a nine-item questionnaire in which responses range on a scale from zero to ten, with greater scores indicating greater self-efficacy for exercise. The SEE is a valid and reliable self-reported measure of physical activity self-efficacy in older adults (Resnick & Jenkins, 2000). The scale was validated in older adults (age 81± 7.2 yrs) living in a retirement community, and an alpha coefficient of 0.92 was found in the internal consistency of the SEE score. A significant, positive correlation between SEE score and participating in exercise at least 20 min/day, three days/wk was also previously reported (Resnick & Jenkins, 2000).
The Activities-specific Balance Confidence Scale (ABC) was utilized to assess balance confidence. The scale consists of confidence percentages, with greater scores indicating more confidence, and less fear of falling, during balance-related activities. The ABC scale is a valid 16-item questionnaire for older adults that identifies balance confidence, which is related to fear or falling, during specific functional activities (Powell & Myers, 1995). In PD, the intraclass correlation coefficient to test for reliability is 0.94, (Steffan & Seney, 2008).

**Statistical Analysis**

Independent sample t-tests were completed to assess for differences in baseline measures of age, UPDRS Motor-III scores, fall frequency, disease duration, and LEDD across the two groups. Tests of normality were performed for baseline measures for dependent variables (mean SEE score, mean ABC score, and UPDRS Motor-III score). It was found that UPDRS Motor-III scores were normally distributed (Shapiro-Wilk = 0.93, \(p = 0.20\)), but SEE and ABC scores were not (Shapiro-Wilk \(\leq 0.78\), \(p \leq 0.04\)). Therefore, UPDRS Motor-III scores were analyzed using mixed factorial, two-group (single-task, dual-task) by three time (baseline, end of treatment and 4-week follow-up) analysis of variance (ANOVA) with repeated measures on time. Post hoc analyses of any significant effects from the ANOVA were performed using t-tests. Non-parametric analyses were then utilized to assess effects of the interventions on SEE and ABC scores as they were not normally distributed at baseline. Wilcoxon signed rank tests were utilized to compare both SEE and ABC scores across the three time points (baseline, end of training and four-
weeks post) with all participants in a single group and then again for each group (single-task, dual-task) separately.

**Results**

One participant failed to complete follow up assessments and was excluded from the final analyses. Therefore, final sample size was N = 20 (single-task group n = 10, dual-task group n=10). Participant demographics are provided in Table 2. There were no significant differences between groups for baseline demographics of age, disease duration, UPDRS Motor-III score or LEDD (p > 0.05).

Table 2

*Participant demographics and clinical scores at baseline (N=20)*

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age (yr)</th>
<th>Disease Duration (yrs)</th>
<th>UPDRS Motor-III Score</th>
<th>H &amp; Y Stage</th>
<th>LEDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>68</td>
<td>6.5</td>
<td>31</td>
<td>2</td>
<td>713</td>
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*Mean ± SD* 14 M 61.75 ± 8.76 6.43 ± 4.47 36.55 ± 11.24 2.3 ± 0.47 725.45 ± 570.86
The ANOVA used to assess UPDRS Motor-III scores between the groups and across the three time points revealed no significant group and time interaction ($F= 0.37$, $p= 0.60$). However, there was a significant main effect of time ($F= 5.68$, $p = 0.007$) as UPDRS scores significantly ($p \leq 0.04$) decreased from baseline (36.55 ±11.24) to end of treatment (32.75 ±11.63) and baseline to the four-week follow up (31.90 ± 10.45) with no difference ($p = 0.23$) from end of treatment to the four-week follow up. The change in UPDRS Motor-III score for both single-task and dual-task groups are illustrated in Figure 6. There was no significant main effect of intervention group ($F= 1.02$, $p = 0.325$).

Figure 6. Change in MDS-UPDRS Motor-III scores over time ($N=20$). UPDRS significantly decreased ($p \leq 0.04$) in both the single-task and dual-task groups from baseline to end of treatment, and the lower UPDRS was maintained through the 4-week follow up. Data are reported as mean ± SE.
When comparing mean SEE score across all three time points for all participants simultaneously, there were no significant differences ($Z \leq 1.14, p \geq 0.26$) in SEE score at any time point (8.09 ± 2.18 SEE score at baseline, 7.72 ± 2.14 SEE score at end of treatment, 7.81 ± 2.14 SEE score at the four-week follow up). When analyzing the SEE score for the single task and dual task groups separately, the single-task group had a significant ($Z = 2.32, p = 0.02$) increase in SEE score from end of treatment (7.50 ± 2.38) to the four-week follow up (7.92 ± 1.98 SEE score), but no significant difference ($Z \leq 1.00, p \geq 0.12$) between baseline (8.56 ± 2.11 SEE score) and any other time point. There were no differences ($Z \leq 0.30, p \geq 0.77$) at any time point for the dual task group (7.63 ± 2.27 SEE score at baseline, 7.83 ± 1.96 SEE score at end of treatment, 7.70 ± 2.38 SEE score at the four-week follow up). The SEE scores are illustrated in Figure 7.
Figure 7. SEE score response over time. Only the single-task group significantly increased their SEE score from end of treatment to 4-week follow up ($p = 0.02$). Data are reported as mean ± SE.

When comparing mean ABC scores across all three time points for all participants simultaneously, there were no significant differences ($Z \leq 0.35$, $p \geq 0.25$) at any time point (mean ABC score at baseline 76.94 ± 20.71, end of treatment 80.06 ± 17.72, four-week follow up 81.59 ± 13.57). When analyzing the mean ABC score for single-task (mean ABC score at baseline 75.44 ± 22.94, end of treatment 76.44 ± 18.64, four-week follow up 79.38 ± 15.90) and dual-task (mean ABC score at baseline 78.44 ± 19.34, end of treatment 83.69 ± 16.92, four-week follow up 83.81 ± 11.19) groups separately there still
was no significant difference for either group ($Z \leq 0.30, p \geq 0.30$). ABC scores are illustrated in Figure 8.

*Figure 8.* ABC score response over time. There were no significant differences ($p \geq 0.25$) in mean ABC score at any time point. Data are reported as mean ± SE.

**Discussion**

The primary aim of this study was to determine the effects of single-task and dual-task training on balance confidence and SEE. Although single-task and dual-task training did not alter ABC score, actual balance may have still been improved as the UPDRS Motor-III scores improved post intervention. The UPDRS improvement from baseline ($36.55 \pm 11.24$) to end of training ($32.75 \pm 11.63$) reached the minimal clinically important difference of 3.25 on the MDS-UPDRS Motor-III, and this was maintained
during the four-week follow up period for both the single-task and dual-task group (Horvath et al., 2015).

The mean ABC score cutoff score used to predict individuals that would be classified as “fallers” is <67% (Lajoie & Gallagher, 2004). The mean ABC score in this current sample was 76.9% at baseline, which indicates the present PD sample, would not meet the ABC scale threshold to be categorized as “fallers”. Since the present PD cohort had ABC balance scores at baseline above that of “fallers,” perhaps the ABC questionnaire was not sensitive enough to detect subtle changes in balance confidence presently. Haas et al (2011) found that the ABC questionnaire was successful at detecting large differences in balance confidence in individuals with PD, but was unable to discriminate subtle differences (Bello-Haas, Klassen, Sheppard, & Metcalfe, 2011). Given the high balance confidence at baseline in the current sample, it stands to reason that improvements the current intervention elicited in balance confidence, if there were any, were subtle. Furthermore, previous studies have found that balance confidence scores in both older adults and individuals with PD do not always correlate with actual balance ability (Cyarto, Brown, Marshall, & Trost, 2008; Lohnes & Earhart, 2010). This may explain the discordance between the findings of improved UPDRS scores with no improvement in ABC scores. The improvement in UPDRS scores may have resulted from a decrease in motor symptoms other than postural instability and gait dysfunction (i.e. tremor, rigidity, bradykinesia).

An unexpected finding in the present study was that mean SEE scores did not significantly change immediately after the completion when the data from both single-
task and dual-task training groups were combined. This lack of a change may be due to the fact that the individuals in the present study had SEE scores, which were relatively high at baseline (mean of 8.09 out of 10). In general, this was similar to what was observed with balance confidence. These high baseline SEE scores limited the ability of the present sample to significantly improve their SEE score (i.e., a possible ceiling effect). It is also possible that, much like the balance scale, the SEE questionnaire may not have been sensitive enough to detect subtle changes in SEE, if there were any, in the current PD sample.

While the lack of an increase in SEE for the combined sample was unexpected, the increase in SEE score in the single-task group only from end of treatment to the four-week follow up was quite surprising. SEE scores in the single-task group were, like the combined sample, high at baseline (mean of 8.56 out of 10). SEE then decreased, albeit non-significantly, at the end of treatment (mean of 7.50 out of 10). The significant increase from the end of treatment to the four-week follow up (mean of 7.92 out of 10) represented a return towards the baseline SEE score. It is unclear why SEE would decrease from baseline to the end of treatment and then rebound to baseline four-weeks later. Perhaps individuals in the single-task group were more aware of their gait dysfunction at the end of treatment, which would negatively impact SEE, and then their awareness decreased again by the four-week follow-up assessments. Additional research examining the effect of exercise interventions on PD patients is warranted. Future studies should target a PD cohort with lower baseline SEE scores (mean of ≤ 5 out of 10) thus allowing room for improvement in this variable.
While this study revealed improvements in motor symptoms after a single-task and dual-task intervention, it was not without some limitations. The sample size was relatively small thus limiting our ability to generalize and detect significant changes in the variable of interest. While it was large enough to detect a significant improvement in UPDRS scores and to a lesser extent SEE scores, it may not have been able to detect the small changes in balance confidence scores. More importantly, both the single-task and dual-task groups reported high SEE and balance confidence scores at baseline which, regardless of sample size, limits the possibility of the hypothesized increases in these variables. Future studies should prescreen for SEE and balance confidence to target individuals with PD who have lower SEE and balance confidence so improvements in these domains may be more easily detected.

Conclusion

Both single-task and dual-task training was successful in decreasing actual motor symptoms of PD, and reached the minimal clinically important difference of 3.25 on the MDS-UPDRS Motor-III (Horvath et al., 2015). While actual motor symptoms were decreased in both groups, neither single-task nor dual-task training significantly changed balance confidence or SEE from baseline levels in individuals with PD with a history of falls. The PD cohort in this study had high balance confidence and SEE at baseline, indicating a ceiling effect may have occurred, and continued research is warranted to study how balance confidence and fear of falling affects actual physical activity behavioral response to a physical therapy intervention, specifically in individuals who have lowered balance confidence and SEE.
CHAPTER VI.

SUMMARY

Motor learning is impaired in individuals with PD however learning is still possible (Xu et al., 2017). Dual-task (i.e., the simultaneous completion of a motor-cognitive task) and single-task (the separate completion of a motor task and cognitive task) training are two modalities that have emerged as promising adjunct therapeutic interventions in individuals with PD as they may enhance motor learning in gait therapy (Conradsson et al., 2015; Arthur F Kramer et al., 2006; Strouwen et al., 2017). The present study aimed at investigating the effects of two separate eight-week single-task and dual-task interventions on physical activity behavior and factors that may affect physical activity behavior (i.e., motor symptom severity, fall frequency, balance confidence, and exercise self-efficacy) in individuals with PD who have a history of falls.

Baseline activities levels of individuals with PD in the present study were similar to what others have reported (Wallén et al., 2015). Both the single-task and dual-task intervention were successful in increasing baseline physical activity levels by 16% by the end of treatment. Additionally, activity levels were still 8% greater than baseline physical activity levels at the four-week follow up, although this difference was not statistically significant. The increase in physical activity behavior provides evidence that gait and cognitive training administered by either single-task or dual-task training may be efficacious in promoting physical activity behavior in individuals with PD who fall.
Motor symptoms also significantly improved to an extent that reached clinical relevance in both the single-task and dual-task intervention groups over the course of the intervention. By the end of treatment motor symptoms exceeded the minimal clinically important difference of 3.25 on the MDS-UPDRS Motor-III, and the improvement in motor symptoms was sustained at the four-week follow up, as motor symptom improvement was still statistically and clinically significant at the four-week follow up assessment (Horvath et al., 2015). It is unclear whether the improvement in motor symptoms allowed individuals to ambulate with less impairment, which may have contributed to the increase in physical activity observed or whether the increase in physical activity caused the decrease in observed motor symptoms.

A significant reduction in 30-day fall frequency from baseline to end of treatment was observed in the dual-task group only. The decrease in fall frequency in the dual-task group suggests that dual-task training may be superior to single-task training in fall prevention. Although the reduction in fall frequency is promising, the results should be interpreted with caution. There appeared to be a non-significant difference in baseline fall frequency, with the dual-task group having greater fall frequency at baseline, perhaps limiting the improvements possible in the single-task group.

Self-efficacy for exercise and balance confidence outcomes was contrary to the hypotheses in this study. It was hypothesized that both exercise self-efficacy and balance confidence would improve following both the single-task and dual-task interventions. Presently, no significant improvements over the course of the intervention were observed for either of these variables following single-task and dual-task training. Upon further
inspection of baseline self-efficacy for exercise and balance confidence scores, it was found that the PD sample in this study had relatively high exercise self-efficacy and balance confidence. Baseline exercise self-efficacy as measured by the Self-Efficacy for Exercise score were found to have a mean of 8.09 out of 10, and baseline balance confidence as measured by Activities-specific Balance Confidence scale was found to be 76.9%. An Activities-specific Balance Confidence scale score of 76.9% does not meet the threshold for prediction of fallers which is < 67% (Bello-Haas et al., 2011). These high baseline scores for self-efficacy and balance confidence likely limited the ability of either of the two interventions to elicit improvements in these variables (i.e., possible ceiling effect).

Before concluding, it is important to note that UPDRS scores were the only normally distributed dependent variable in this study. A larger sample size may allow for a normal distribution of data, which would allow for the use of parametric statistics (e.g., ANOVAs) when analyzing all dependent variables. Also, the unexpected outcomes for self-efficacy for exercise and balance confidence may be related to the relatively high baseline scores for these values. Future studies that include self-efficacy for exercise and balance confidence would benefit from screening for these variables at baseline to ensure a deficit exists in the targeted group. This would increase the likelihood that improvements in these variables were achievable.

In conclusion, it was found that both single-task and dual-task training is efficacious in improving motor symptoms and physical activity behavior in individuals with PD who fall. This study revealed that dual-task training reduced fall frequency to a
greater extent than single-task training, and self-efficacy for exercise and balance confidence remained unchanged from baseline levels. Future research evaluating factors that affect physical activity behavior (e.g., self-efficacy for exercise) and interventions that aim to improve physical activity behavior is warranted in individuals with PD who fall.
APPENDIX A

INFORMED CONSENT
Appendix A

Informed Consent

Cleveland Clinic
Consent to Participate in a Research Study

**Study Title:** The Effects of Dual Task Training on Motor and Non-Motor Function in Individuals with Parkinson’s disease (Phase 2)

**Principal Investigator:** Jay Alberts, PhD

**Sponsor:** Davis Phinney Foundation

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:
- You are being asked to participate in a research study
- Carefully consider the risks, benefits and alternatives of the research
- Your decision to participate is completely voluntary

1. **INFORMATION ON THE RESEARCH**

You are being asked to participate in the research entitled, “The Effects of Dual Task Training on Motor and Non-Motor Function in Individuals with Parkinson’s Disease (Phase 2)” because you have been diagnosed with idiopathic Parkinson’s disease (PD). The purpose of this study is to gain a better understanding of how performing two tasks simultaneously affects individuals with PD.

**How Many People Will Take Part In The Study?**

Approximately 20 people will take part in Phase 2 of this research study at the main campus of the Cleveland Clinic. The study consists of the following steps:

1. Screening & consent
2. Baseline clinical testing including gait analysis on the CAREN system
3. Randomization
4. Intervention performed 3x/week for 8 weeks
5. End of treatment clinical testing including gait analysis on the CAREN system
6. Four week follow up clinical testing including gait analysis on the CAREN system

1. **Screening & Consent**

   The screening will take place over the phone to ensure you meet all the criteria to participate and the study and to ensure your safety during participation. You will be asked various questions about your medical history and your level of physical functioning. If you meet eligibility requirements and agree to consent with the study protocol, you will proceed with the testing.

2. **Baseline clinical testing including gait analysis on the CAREN system**

   Baseline testing is performed to gather information about your current level of function. You will complete several tests and questionnaires as described below.

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
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<tr>
<td>Unified Parkinson’s Disease Rating Scale</td>
<td>Movement assessment to assess rigidity, speed of movement, and tremor</td>
</tr>
<tr>
<td>Tests using an iPad</td>
<td>Assessing information processing, vision, and balance</td>
</tr>
<tr>
<td>Questionnaires</td>
<td>Assessing falls, physical activity behavior, and quality of life</td>
</tr>
</tbody>
</table>

   You will perform several cognitive tasks in a seated position. The cognitive tasks will assess specific domains of cognition such as executive function, memory, language, and attention. You will then perform these cognitive tasks again while you are walking. You will be asked to walk both over a flat ground surface and on the Computer Assisted Rehabilitation Environment (CAREN) system. The CAREN system is a treadmill surrounded by a virtual reality system with 3-D motion capture analysis. During the CAREN system testing, you will wear markers on your body in order for the computer to track the way you are walking and the angle of your joints. There is a safety harness attached to the treadmill to prevent falls.

   You will also be asked to wear a wrist worn activity monitor to assess your physical activity behavior during the study. The monitor will be worn for approximately one week prior to the start of the exercise intervention, and be worn throughout your study participation until the study is complete during all waking hours. You will be shown how to wear the monitor and how to use it.

3. **Randomization**
Participants will be randomized through envelope selection to 1 of the following 2 groups:

   a) Single Task Intervention
   b) Dual Task Intervention

**Single Task Intervention:** A 45 minute training session consisting of: 1) Gait training; and 2) Cognitive training in a seated position. The gait and cognitive training are not performed together. An equal amount of time will be spent on the walking and the cognitive tasks.

**Dual Task Intervention:** A 45 minute training session consisting of gait and cognitive training simultaneously.

4. *Intervention performed 3x/week for 8 weeks*

Individuals in both groups exercise 3x/week for a total of 8 weeks at the Main Campus of the Cleveland Clinic. If you miss a session, you will be required to make it up in order to complete all 24 sessions.

5. *End of treatment clinical testing including gait analysis on the CAREN system*

An identical testing protocol that was performed at baseline will be repeated after the intervention has ceased to determine the immediate effects of the intervention.

6. *Four week follow up clinical testing including gait analysis on the CAREN system*

An identical testing protocol that was performed at baseline and end of treatment will be repeated 4 weeks after the intervention has ceased to examine long term effects of the intervention.

2. **RISKS AND DISCOMFORTS**

   **Skin irritation or inflammation:** You may experience a temporary redness under the markers that you will wear during the virtual reality testing.

   **Sprains, falls or mechanical trauma:** These activities may be challenging to your balance and there is a risk of losing your balance while performing these exercise activities or stepping on/off of the virtual reality system that could lead to a stumble.
or fall. Sprains or other injuries to your joints or lower extremities are also possible. This risk is minimized by having a member of the study team supervise your activities as well as by wearing a harness on the virtual reality system.

**Exercise:** The exercise may be slightly uncomfortable at times. The appropriate intensity level will be personalized to your age and general activity level. Please request to rest if you are feeling uncomfortable or unreasonable tired. You may also feel tired or have muscle soreness up to several days following the exercise. There is a small risk of experiencing a cardiovascular event during any type of exercise, although that risk is minimized by this submaximal intervention. All exercise staff are trained in Basic Cardiac Life Support including emergency resuscitation and life sustaining techniques.

3. **BENEFITS**

There is a chance that your gait and cognitive abilities may improve with the intervention. From this study, the scientific community and the PD community hopes to gain a better understanding of the role that dual tasking plays in the lives of individuals with the disease.

4. **ALTERNATIVES**

The alternative to study participation is to simply NOT participate in this investigation. Your decision to participate or not will not affect treatment you are receiving now or in the future.

5. **PRIVACY AND CONFIDENTIALITY**

The medical and research information recorded about you for this research will be used within the Cleveland Clinic. If you have established medical care at the Cleveland Clinic, there will be a note placed in your electronic medical record that you are participating in the study, but results will not be posted in the record. Protected health information will be stored on a secured electronic database accessible only to research personnel. There will be no personal identifiers stored on the activity monitor or the iPad. You will be videotaped while on the CAREN system for the purpose of data analysis. This video will not leave the computer of the CAREN system without further written consent from you. The information recorded about you as part of this research will be maintained in a confidential manner.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.
Upon completion of the study, you may have access to the research information if contained in the medical record. During the study, your access to research information about you will be limited. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information to assist in treating you.

Federal regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, Cleveland Clinic monitors/auditors and IRB, the study Sponsor and its agents, the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), other governmental agencies from foreign countries. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. The Cleveland Clinic also may use and disclose this information for treatment and payment reasons. The Cleveland Clinic must comply with legal requirements that mandate disclosure in unusual situations. Once your personal health information is released, it may be re-disclosed and no longer protected by federal privacy laws. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to Dr. Jay Alberts at The Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio 44195. If you do so, your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of the research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. Even if you ask us to stop outside disclosures, information collected about you will be disclosed as required by state and federal law.

The Cleveland Clinic will not use or disclose the information collected in this study for another research purpose without your verbal or written permission unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is protects the safety and welfare of research subjects.

6. RESEARCH RELATED INJURIES

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form.
Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. COSTS

The study intervention or other study related tests/procedures/visits will be provided at no cost to you. You will be provided with a parking voucher to cover your costs for parking during your visits to the main campus. The cost for routine tests and services that would normally be performed even if you don’t participate in the study will be billed to you or your insurance provider.

8. VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled.

9. QUESTIONS

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr. Jay Alberts at 216.445.3222 or Anson Rosenfeldt at 216-445-3277. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. SIGNATURE

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

________________________________________________________________________
Printed name of Participant Date

________________________________________________________________________
Participant Signature Date
Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

______________________________  ________________________________
Printed name of person obtaining consent  Date

______________________________  ________________________________
Signature of person obtaining consent  Date
APPENDIX B

SELF-EFFICACY FOR EXERCISE SCALE
Appendix B

Self-efficacy for Exercise Scale

<table>
<thead>
<tr>
<th></th>
<th>Not Confident</th>
<th>Very Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The weather was bothering you</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>2. You were bored by the program or activity</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>3. You felt pain when exercising</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>4. You had to exercise alone</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>5. You did not enjoy it</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>6. You were too busy with other activities</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>7. You felt tired</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>8. You felt stressed</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
<tr>
<td>9. You felt depressed</td>
<td>0 1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX C

ACTIVITIES-SPECIFIC BALANCE CONFIDENCE SCALE
Appendix C

Activities-specific Balance Confidence Scale

The Activities-specific Balance Confidence (ABC) Scale
For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:
0%  10  20  30  40  50  60  70  80  90  100%
no confidence  completely confident

“How confident are you that you will not lose your balance or become unsteady when you…
1. …walk around the house? ____%
2. …walk up or down stairs? ____%
3. …bend over and pick up a slipper from the front of a closet floor ____%
4. …reach for a small can off a shelf at eye level? ____%
5. …stand on your tiptoes and reach for something above your head? ____%
6. …stand on a chair and reach for something? ____%
7. …sweep the floor? ____%
8. …walk outside the house to a car parked in the driveway? ____%
9. …get into or out of a car? ____%
10. …walk across a parking lot to the mall? ____%
11. …walk up or down a ramp? ____%
12. …walk in a crowded mall where people rapidly walk past you? ____%
13. …are bumped into by people as you walk through the mall? ____%
14. …step onto or off an escalator while you are holding onto a railing? ____%
15. …step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%
16. …walk outside on icy sidewalks? ____%
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