EFFECT OF NON-MOTORIZED TREADMILL TRAINING ON GAIT, BALANCE, AND QUALITY OF LIFE MEASURES IN INDIVIDUALS WITH PARKINSON'S DISEASE

A DISSERTATION

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BY

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DEDICATION

For those who have encouraged, supported, and loved me throughout this journey.

I am forever grateful.

Thank you Jason, Jackson, Sam, Mom, and Dad

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ABSTRACT

ANNE BODDY

EFFECT OF NON-MOTORIZED TREADMILL TRAINING ON GAIT, BALANCE, AND QUALITY OF LIFE MEASURES IN INDIVIDUALS WITH

PARKINSON'S DISEASE

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Parkinson's disease (PD) is a complex disorder characterized by non-motor and motor impairments. Within the motor-impairments, mobility deficits resulting from postural instability and gait abnormalities are some of the challenging characteristics that are associated with PD. Physical therapists often use outcome measures to determine if an individual is considered a fall risk. The modified four square step test (mFSSTT) was designed to assess standing dynamic balance by replacing the canes used in the traditional four square step test with 2-inch tape. Without intervention from physical therapy, those with PD are at risk for rapid decline in function. Motorized treadmill (MT) training is the most frequently used exercise modality in those with PD, as it is comparable to daily ambulation. Recently, non-motorized treadmill (NMT) training has become a point of interest among clinicians attempting to increase intensity while treadmill training. The three purposes of this project were to evaluate the interrater reliability and validity of the mFSST, the relationship between the mFSST and outcome measures related to fall risk and quality of life, and determine the immediate effects of MT and NMT on gait parameters and fall risk after one 10-minute session in individuals with PD. The participants were tested for one day to collect data for study one and two. While those participating in study three attended two treadmill training sessions over one week. The results revealed excellent interrater and excellent test-retest reliability of the mFSST. Additionally, this study found a strong correlation between the mFSST and FSST for assessment of dynamic standing balance. To assess the effects of NMT training, the Zeno Electronic Walkway was used to measure the spatial-temporal parameters of gait. Despite there being no significant difference in gait parameters or fall risk assessments between the two types of treadmills. There was a significant difference in perceived exertion between the treadmills during the treadmill training protocol. The results indicated the mFSST is a feasible assessment to assess dynamic standing balance in individuals with PD. Additionally, NMT was found to be a feasible therapeutic intervention to increase intensity demands with treadmill training individuals with PD.

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CHAPTER I

EFFECT OF NON-MOTORIZED TREADMILL TRAINING ON GAIT, BALANCE, AND QUALITY OF LIFE MEASURES IN INDIVIDUALS WITH PARKINSON'S DISEASE

Parkinson's disease (PD) is a progressive disease that is one of the most prevalent diseases involving the central nervous system (CNS), estimated to affect more than 1 million people in the United States.[1-4] The pathology involves a depletion of neurotransmitter dopamine (DA), within the substantia nigra of the basal ganglia.[1-4] As a result, individuals with PD have postural instability and gait abnormalities such as gait hypokinesia starting in the early stages of this progressive disease.[5,6] It is estimated that 60.5% of persons with PD report a fall history, with 39% experiencing frequent falls.[7] Subsequently, those with PD often restrict activity due to fear of falling (FOF) and report a decreased quality of life (QOL).[8]

Fall risk and FOF often limit participation in life activities for those with PD, leading to decreased independence. When compared to healthy individuals of similar age, FOF is more prominent in the PD population.[8] With a variety of assessments available to clinicians to determine fall risk and fear of falling, clinicians often must determine the most valuable assessments to perform within time constraints. The Four Square Step Test (FSST) was developed to assess dynamic balance while stepping over obstacles in multiple directions.[9] FSST demonstrates moderate sensitivity (0.78) in capturing fall risk in individuals with PD, with a score greater than 9.68 seconds indicating a fall risk.[10] The modified Four Square Step Test (mFSST) was developed to assess dynamic balance while stepping over tape lines in multiple directions.[11] Roos et al. found a higher percentage of those with stroke were able to complete the mFSST when compared to the FSST ($p < 0.04$).[11] Although the reliability of the mFSST has not been studied within the PD population, Roos et al. found the test-retest, intrarater, and interrater reliability to be excellent with an ICC range from 0.81-0.99 for individuals with stroke.[11]

Walking ability contributes to FOF in individuals with PD; hence improving walking ability may help improve fall risk, perceived confidence, and QOL in those with PD.[13] Paker et al. found gait speed to significantly correlate with FOF ($p = 0.001$) and risk of falling ($p \leq 0.001$) in patients with PD.[5] As a result, physical therapists (PT) focus on gait speed training as it plays a role in one's ability to perform activities of daily living (ADL), FOF, and ultimately QOL.[5]

Motorized treadmill (MT) training is frequently used by PTs to improve strength, endurance, balance, and spatial-temporal parameters of gait.[16] In PD, the repetitive stimulus of treadmill training helps promote a reciprocal gait pattern.[17] Suggesting that external rhythmic cues provided by treadmill training may improve the rhythmicity and speed of gait and balance reactions.[17] Mishra et al. found statistically significant ($p \leq 0.002$) improvements in gait speed as a result of MT training.[17] By varying traditional treadmill training, such as the addition of multi-directional treadmill training by Smith et al, improvements have been noted in both balance and gait parameters in persons with PD.[16]

Recently, non-motorized treadmills (NMT) have become a point of interest amongst clinicians in hopes of increasing intensity demands while treadmill training. Morgan et al. found when testing at matched speeds between non-motorized and motorized treadmill training there was a 67% greater heart rate (HR) in the non-motorized treadmill at submaximal levels.[18,19] During NMT training the participant must generate power to move themselves vertically, and dynamically control belt speed.[18,20] Thus, the intensity requirements while participating in NMT training is higher as compared to MT training. The potential benefits of NMT on the spatial-temporal parameters of gait has not been studied in the PD population.[21]

PURPOSE

The primary purpose of this dissertation is to assess if the mFSST is reliable and valid for assessing fall risk; and to explore the effectiveness of a new strategy in NMT training on gait pattern and fall risk in individuals with PD. The first study determines the test-retest and interrater reliability of the mFSST to determine fall risk. Simultaneously, the second study investigates the relationship between fall risk and commonly used outcome measures for individuals with PD. The final study will compares two gait training interventions: NMT and MT training in individuals with PD.

PARTICIPANTS

To determine sample size for Study One and Two, an *a priori* power analysis using G*Power[1] for a Pearson correlation test with a large effect size of $p = 0.7$,

[1] G*Power Version 3.0.10, Franz Faul, Universitat Kiel Germany’

power = 0.8, and alpha = 0.05 reveals a sample size of 12 participants. For a linear regression, a sample of 27 will be required. Therefore, for Study One and Two, the sample size will be 30. Based on previous literature, for Study Three an *a priori* power analysis using G*Power for a repeated-measures analysis of variance for within-between interaction with an effect size of f = 0.35 (estimated from previous literature)[17,22,23] power = 0.8 and alpha = 0.05 reveals a sample size of 16 participants. Participants were recruited from local PD support groups. To be included in all three studies, participants must be between ages 55-85 years old, diagnosed with PD Hoehn and Yahr (H&Y) I-III, and able to walk 10 meters without assistive device. To detect cognitive impairment, the participants were screened with Montreal Cognitive Assessment (MoCA) and must score >26/30 on this measure. Participants were excluded if they have a history of a neurological condition other than PD or have cardiovascular, orthopedic, and/or metabolic condition that would make moderate to vigorous aerobic exercise unsafe. To control for medication, all participants started testing within 60-120 minutes of taking their prescribed medication on testing days.

INSTRUMENTATION

The primary outcome measures used throughout this study will be the FSST and mFSST. The FSST requires a participant to step over a low obstacle while changing directions and has been deemed reliable Intraclass Correlation Coefficient (ICC) (ICC = 0.78-0.99) [9,10] The mFSST replaces the low obstacle with tape on the floor to permit those unable to clear obstacles to still perform the assessment.[11] Both assessments are measured using time and recorded in seconds.

Assessing perceived confidence in balance and QOL is important when working with individuals with PD due to their postural instability.[8] Therefore, the relationship between mFSST and additional measures of fall risk and QOL will then be explored in study two. Additional fall risk and QOL assessments will include: gait speed, step length, stride length, base of support, Timed Up and Go (TUG), Freezing of Gait Questionnaire (FOGQ), Parkinson's Fatigue Scale (PFS-16), Parkinson's Disease Questionnaire-39 (PDQ-39), and Activities-specific Balance Confidence scale (ABC).

A Zeno Walkway System (Zeno) with ProtoKinetics Movement Analysis software (PKMAS)[2] was used to assess spatial-temporal parameters of gait.[24] The Zeno 20' Walkway System is a computerized gait analysis system will account for height and weight parameters when calculating gait parameters. The reliable and valid PKMAS (ICC = 0.84-0.99)[25], enables data collection and analysis for static and dynamic balance along with gait tests.[25]

In Study Three, the Woodway Curve™ and Cybex 625T was used for treadmill training. The Woodway Curve™ design is a curved non-motorized treadmill; designed to permit runners to attain full velocity and facilitate increased stride length and longer swing phases.[18,19] The Woodway has a running surface of 17" W x 67" L, walking weight capacity of 800 lb., and 112 precision ball bearings with 12 roller guides.[26] The Cybex 625T served as the motorized treadmill in this study. All participants was used the NxStep™ Unweighing System harness to allow for a safe environment.

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[2] ProtoKinetic, LLC
60 Garlor Dr., Haverton, PA 19083
610.449.4879

PROCEDURES

Approval through University of St. Augustine for Health Sciences and Texas Woman's University Institutional Review Boards (IRB) will be obtained prior to recruitment and data collection. Individuals interested will be informed of the purpose and all parts associated with the study (fall risk, gait parameters, and perceived QOL) and asked to participate in the IRB-approved consent process. Throughout all three studies, participants were asked to wear athletic shoes and wore a gait belt for safety. The data collection period will involve three separate assessment time points.

STUDY ONE: Reliability of Modified Four Square Step Test (mFSST) performance in people with Parkinson disease.

This was a methodological study to assess the test-retest and interrater reliability between FSST and mFSST in the PD population.

Specific Aims and Hypotheses

- The first assessed the interrater reliability of the mFSST and FSST in individuals with PD by two PTs. The hypothesis was that there will be a significant correlation $r \geq 0.90$ between assessors on the first trial.
- The second aim assessed the test-retest reliability of the mFSST in individuals with PD. The hypothesis was that there will be a significant correlation $r \geq 0.80$ between the first and second trial.

- The third aim assessed the concurrent validity of the mFSST with the FSST in individuals with PD. The hypothesis was that there will be a significant correlation $r \geq 0.70$ between FSST and mFSST.

Procedure

Participants were instructed to perform the FSST and mFSST two consecutive times for test-retest reliability after one practice trial. To decrease the risk of a carryover effect, the participants were randomized to one of two groups, either to perform FSST first or mFSST first during first session. While performing each trial, two licensed PTs with more than three years of experience timed the duration required to complete the assessment for interrater reliability. Licensed PTs also provided stand by assist (SBA) for safety during assessment. A graduate assistant observed and counted any freezing episodes during performance of FSST and/or mFSST.

Data Analysis

All statistical analyses were calculated using SPSS Statistics version 23 software.[3] To determine reliability, Pearson's correlation and intraclass correlation coefficients (ICC) were used to determine the both test-retest reliability and interrater reliability ICC (2,1).

[3] IBM Corporation
1 New Orchard Rd., Armonk, NY 10504
914.449.1900

STUDY TWO: The relationship between mFSST and outcome measures related to fall risk and quality of life in individuals with Parkinson's disease.

Data was collected to assess fall risk using the mFSST, gait parameters, freezing of gait, and balance confidence.

Specific Aims and Hypotheses

- The first aim determined the correlation between fall risk and recommended outcome measures for individuals with PD. The hypothesis was that the mFSST will significantly correlate $r \geq 0.70$ with fall risk and QOL outcome measures (gait speed, stride length, step length, base of support, TUG, FOGQ, PFS-16, PDQ-39, and ABC) in individuals with PD.
- The second aim determined if there is a predictive relationship between mFSST and outcome measures related to fall risk and QOL from aim 1 for individuals with PD. The hypothesis was that there will be a significant relationship ($p < 0.05$) between fall risk and recommended balance and QOL outcome measures in people with PD.

Procedure

During the initial assessment session, participants completed multiple fall risk and QOL outcome measures (TUG, ABC, FOGQ, PFS, and PDQ-39) in a randomized order. Participants also traversed the Zeno at both self-selected (SS) speed and fastest comfortable (FC) speed three consecutive times for average gait velocity. Assessments were performed by three licensed PTs with more than three years of experience working with the neurologic population. Licensed PTs also provided SBA for safety throughout all outcome measures. Prior to the study, the PTs met with the primary investigator to review outcome measure procedures and receive training to ensure consistency.

Data Analysis

Using SPSS, correlational in addition to a regression analysis was used to determine if a relationship exists of the measures. Descriptive statistics (mean, standard deviation) reflecting the participants will be included along with Pearson correlation value (*r*) and R^2 will explain the predictor variable. The level of significance for this study will be set at alpha ≤ 0.05.

STUDY THREE: Effects of non-motorized treadmill training for one session on laboratory measures of gait in Parkinson disease.

This is a study with a randomized one-group pretest-posttest-posttest design.

Specific Aims and Hypotheses

- The first aim of this study was to assess the immediate effects of NMT training versus MT training on gait parameters in individuals with PD. The hypothesis was that there will be a significant difference ($p < 0.05$) in gait speed following one session of NMT training when compared to one session of MT training.
- The second aim of this study was to assess the immediate effects of NMT training versus MT training on fall risk using the mFSST in individuals with PD. The hypothesis is that there was a significant difference ($p < 0.05$) in fall risk following one session of NMT training when compared to MT training.

Procedure

Each participant completed two sessions, one with the NMT training and one with the MT training. The order of the NMT and MT training sessions was randomized amongst the participants. Initially, participants traversed the Zeno at both SS speed and FC speed three consecutive times for gait parameters (pretest). After completing the intervention, the participant again traversed the Zeno for immediate posttest measurements and again 20 minutes later for additional posttest measures. Following the last walk over the Zeno for posttest measurements, participants performed the TUG and mFSST with SBA of a licensed PT. The participant then returned 5-7 days later to complete the same protocol with the other intervention.

To begin treadmill training, participants received a training session to inform them about both treadmills. This included how to safely get on/off treadmill and performed 1 minute of treadmill training prior to beginning protocol. Baseline assessment of blood pressure (BP) and heart rate were measured prior to treadmill training. During treadmill training sessions, the participant's BP, HR (Polar, Polar Electro, Bethpage, NY) and Borg Rating of Perceived Exertion were monitored at 2 minutes, 8 minutes, and 10 minutes. Treadmill speed was documented every 30 seconds throughout the duration of the 10-minute session (see Appendix A). The treadmill training protocol utilized the SS and FC gait speed collected from the Zeno. The treadmill began with 2 minutes of the participants SS gait speed, then 6 minutes of training within a range of 110% of the SS speed up to FC gait speed, followed by 2 minutes at SS gait speed. This totaled up to 10 minutes of treadmill training for each session. To ensure patient safety, the NxStep harness was used, however was not support the participant (0% body weight support). Licensed PTs acted as blinded assessors for posttest measurements.

Using SPSS, a 2 x 3 repeated measure of analyses of variance (ANOVA) for intervention x time was used to analyze the significance of change in gait speed of each time point (pre, immediate posttest, and 20-minutes later) amongst two different conditions of NMT and MT treadmill training. The level of significance was set at alpha $\leq$ 0.05.

CHAPTER II

FALL RISK ASSESSMENT AND TREADMILL TRAINING STRATEGIES IN INDIVIDUALS WITH PARKINSON'S DISEASE

A LITERATURE REVIEW

RESEARCH PURPOSE

Parkinson's disease is a complex disorder marked with non-motor impairments and motor impairments. Within the motor impairments, gait abnormalities and postural instability are some of the challenging characteristics that are associated with PD. Postural instability is frequently associated with PD and results in an increased fall risk. For individuals diagnosed with PD, this instability often results in limited participation in life activities due to a fear of falling. The fear of falling and frequency of falling diminishes the quality of life for those diagnosed with this progressive disease. Physical therapists play an important role in aiding those diagnosed with PD through the assessment and implementation of evidence-based treatment strategies to improve postural stability and promote independence with the goal to improve quality of life.

Physical therapists work to delay the effects of PD; however, continue to struggle with the most effective way to improve gait abnormalities such as the spatial-temporal parameters of gait. Spatial-temporal parameters of gait include gait speed, step length, stride length, and cadence and can all be affected by Parkinson's disease. As a result, those with PD are at risk for rapid decline in function without intervention.

One common intervention is treadmill training with a physical therapist to enhance function. Motorized treadmill training is often utilized to improve spatial-temporal parameters of gait during physical therapy. Readily available, motorized treadmills are often used clinically and can be used upon discharge from physical therapy. Non-motorized treadmill training has become a point of interest as a more intense form of treadmill training. Frequently used with athletes, it is used to challenge gait speed through self-propulsion. Currently, limited research is available regarding non-motorized treadmill training to improve spatial-temporal parameters of gait in PD.

This research study investigated the relationship of a fall risk assessment tool and the effects of non-motorized treadmill training in individuals with PD. Quantitative data were collected using assessment tools and a computerized gait mat, while qualitative and quantitative data were collected through self-reported questionnaires.

The purpose of this literature review is to provide an overview of PD and describe current methods for assessing fall risk in individuals with PD using standardized outcome measures. Additionally, this review will include current treatment strategies using treadmill training to improve gait parameters and their effects on fall risk assessment.

METHODOLOGY OF REVIEW

An extensive review of literature occurred between 2016-2018, and included research studies that discussed pathology and presentation of signs and symptoms of PD. Once the foundational knowledge of PD was reviewed, the review expanded to include current assessment tools used to determine fall risk and treatment strategies specifically treadmill training for individuals diagnosed with PD. To find the most appropriate articles for this study, the following databases were used: CINAHL Complete, PubMed, ERIC, and Cochran Database of Systematic Reviews. The key words used to search the literature for fall risk assessment tools were "Parkinson's disease," "fall risk," "fear of falling," "outcome measures," "falls," and "assessment tools." To search for quality of life measures, the key words included "quality of life," "activity," "physical therapy," and "ICF." The key words for the intervention section include; "physical therapy," "treadmill," "non-motorized treadmill," "physical therapy and gait," "gait and Parkinson's disease," "gait parameters and Parkinson's disease," "intensity," "Tai Chi," "heart rate," "Borg," "cycling and Parkinson's disease," "boxing and Parkinson's disease," "high-intensity training," "speed training and Parkinson's disease," and "treadmill and Parkinson's disease."

After reviewing over 198 articles, there were a total of 165 used; which included those focusing on fall risk within PD, quality of life self-reported questionnaires, and treadmill training interventions. All articles included in this literature review were written in English and include the Parkinson's disease population, with an emphasis on fall risk and rehabilitation. Also included in this literature review, were some studies regarding fall risk outcome measures and rehabilitation strategies within other neurologic populations that have yet to be studied in the Parkinson's population.

INTRODUCTION TO PARKINSON'S DISEASE

Parkinson's disease is a progressive disease that is a one of the most prevalent diseases involving the CNS, estimated to be affecting more than 1 million people in the United States.[1-4] The disease can be idiopathic with an unknown cause, or considered to be secondary parkinsonism from other identifiable causes.[2.] The diagnosis of PD often occurs later in life, however there a diagnosis of early-onset PD that frequently occurs when an individual is in their 40s. Those diagnosed with early-onset PD, often have a familial history of PD.

The pathology of PD involves a depletion of the neurotransmitter dopamine (DA), within the substantia nigra of the basal ganglia.[1-4] The basal ganglia consists of the caudate nucleus, putamen, globus pallidus, subthalamic nucleus, and substantia nigra.[2] The excitatory pathway within the basal ganglia assists in the initiation of voluntary movement.[2,4] As a result of the depletion of dopamine, the pathways that are responsible for inhibition become overactive and result in the signs and symptoms associated with PD. The phenomenon known as "rebound firing" is an example of this overactive process, in which there is a transient increase in the firing rate. The common impairments associated with decreased dopamine may include a flexed posture, diminished equilibrium reactions, and decreased trunk rotation.[1,2] There are two distinct subgroups noted in those diagnosed with PD; those with postural instability and gait disturbances and those with a tremor dominant presentation.[2] Often times those with tremor dominant PD, may experience fewer difficulties with hypokinesia and postural instability.[1-4] For those diagnosed with PD, this progressive disease may have a relatively long subclinical period of at least 5 years, before clinical manifestations appear.[2] With the mean duration of the disease lasting around 13 years.[2]

Non-motor and motor symptoms will challenge those diagnosed with Parkinson's disease daily.[1,2,5] Macphee et al describes PD as a non-motor disorder as they discuss the progression in symptoms such as dementia, depression, and falls.[4] Non-motor symptoms often precede onset of motor symptoms, and include loss of smell, constipation, rapid eye movement sleep behavior disorder, altered cognition, and orthostatic hypotension.[2] Additional symptoms include difficulty speaking and swallowing, which becomes detrimental to those with Parkinson's disease.[2]

Motor symptoms are often considered the "entry point" for diagnosis, with pathology being the "arbiter" of PD diagnosis.[6] Parkinson's disease is characterized by four cardinal motor features: bradykinesia, resting tremor, rigidity of muscles, and impaired posture.[1-4,7] These motor impairments progressively compromise balance, mobility, and participation in functional activities. As a result of balance dysfunction and postural instability, falls and injuries are common composite symptoms of Parkinson's disease.[8] As a result, there is an inherent increased risk of falls that is associated with the diagnosis of PD. Weaver et al found 61% of falls in those with Parkinson's compared to 46% in those without PD were due to incorrect weight shift.[7] In addition, in individuals diagnosed with PD, the common symptoms of postural instability and gait disorders affect their ability to safely perform ADL.

MEDICAL MANAGEMENT

Medical management uses neuroprotective strategies and treatment of non-motor and motor symptoms to slow down disease progression.[2] Medical management of symptoms is complex due to potential side effects of the medication. To determine the diagnosis of PD, physicians look for a consistent response to Levodopa accompanied with two of the four cardinal motor signs.[4] Shin et al reported that Levodopa is the most effective medicine to manage the motor symptoms of Parkinson's disease.[10] Levodopa/Carbidopa has been considered the gold standard drug for PD since the late 1960s.[2] Carbidopa (inhibitor of aromatic amino acid decarboxylation) is usually taken with Levodopa to "prevent conversion to dopamine before entering the brain."[1] When combined, Levodopa and Carbidopa are known as Sinemet. Sinemet has been proven to be helpful in reducing bradykinesia and rigidity, however not as effective in decreasing tremor and postural instability.[1]

Medical management often results in the "on-off" phenomenon, which is the short-duration benefit of improved symptoms followed by rapid decline in symptoms and appearance of dyskinesias.[1,2] In a study by Bryant et al, Levodopa increased mean gait speed ($F(1,20)=15.98$), $p \leq 0.05$ during the "on" phase, however during the "off" phase mean gait speed was slower ($F(1,20)=146.87$), $p \leq 0.05$.[8] Levodopa has been found to improve gait speed and stride length, however does not improve cadence.[8]

Unfortunately, due to risk factors of motor fluctuations and dyskinesia (involuntary movements of limbs, face or trunk), physicians have concerns with long-term use of Levodopa.[1,2,10] At around the six-year mark, the patients tend to receive the optimal benefits of the medications. However, prolonged use (over 10 years) results in decreased sensitivity of receptors and decreased effectiveness.[1] Physical therapists must consider pharmacological timing when assessing gait speed in PD and while providing daily interventions.[11]

To monitor the progression of PD, the Unified Parkinson's Disease Rating Scale (UPDRS) was developed. The UPDRS consists of 50 questions using a four-point scale, with 0 representing no problem and 4 representing severe impairments.[2] Within this assessment tool, there are some "yes" or "no" questions, which are included in the score. The maximum total points being 199 points on the UPDRS indicating severe problems. The UPDRS consist of six-subsections including: cognition, mood, ADL, motor function, complications of therapy, and a modified Hoehn and Yahr classification. The UPDRS has excellent test-retest reliability (ICC = 0.91) and a MDC of 13.[12] The UPDRS focuses mostly on the non-motor symptoms of PD and can be completed in approximately 30 minutes.[2] Due to the high cost of this assessment tool, it is utilized in clinical trials more than clinically by physical therapists.

The Movement Disorder Society (MDS) developed a modified version (MDS-UPDRS) to include the non-motor impairments frequently seen in PD. This version uses an ordinal score, 0 to 4 with a total max score of 200 indicating severe problems. The MDS-UPDRS is subdivided into 4 parts; Part 1 – non-motor aspects of daily living, Part 2 – motor aspects of daily living, Part 3 – motor examination, and Part 4 – motor complications. There is a strong correlation (r = 0.96) between the UPDRS and MDS-UPDRS demonstrating strong concurrent validity.[12] Within each part of the MDS-UPDRS, there is strong internal consistency with a Cronbach's alpha ranging from (0.79-0.93).[12]

CLASSIFICATION

The H&Y classification of disability scale is used to estimate the stage and severity of the disease.[2,12,13] Designed after studying 802 patients from 1949-1964, this descriptive scale included functional deficits and objective signs.[12,13] Ranging from I to

V, values increase as symptoms increase in severity (see Table 2.1).[2,12,13] In 2004, Goetz et al reviewed the strengths and weaknesses of the H&Y scale, revealing simplicity and easy application as strengths.[12] Due to the simplistic nature, the H&Y scale is not inclusive of symptoms such as tremor and bradykinesia revealing limitations in classification.[12] However, a modified H&Y scale was developed which adds 0.5 increments to be more inclusive (see Table 2.2), Goetz et al recommend continued use of the original H&Y scale due to the lack of clinimetric testing.[12]

Clinically, H&Y classification provides clinicians with a broad measurement of disease progression while developing plan of care. In early stages of PD, patients are functional with minimal impairments.[2,13] As the disease progresses, activity limitations and symptoms become more apparent during the middle stages.[2] Finally, during the late stages of the disease, patients become dependent in functional mobility and ADLs.[2] Ideally, patients seek physical therapy during initial stages (Stages I-III) of the disease to improve or maintain function and quality of life. A study by Dipasquale et al found that those at H&Y stage 2 who received specific physiotherapy improved more in functional mobility when compared to those who received general exercise.[14] However, in 2015 Hoskovcová et al[15] found there to be no significant difference in H&Y stage when comparing fallers to non-fallers ($p < 0.001$) .

Table 2.1: Hoehn & Yahr Classification of Disability

Stage	Disability
Stage I	minimal /absent or unilateral involvement
Stage II	Minimal bilateral or midline involvement balance not impaired
Stage III	Impaired righting reflexes
Stage IV	All symptoms present and severe, standing only possible with assistance
Stage V	Confined to bed or wheelchair

Table 2.2: Modified Hoehn & Yahr Classification of Disability

Stage	Disability
Stage 1	Unilateral Involvement
Stage 1.5	Unilateral and axial involvement
Stage 2	Bilateral involvement without impairment of balance
Stage 2.5	Mild bilateral disease with recovery on pull test
Stage 3	Mild to moderate bilateral disease; some postural instability; physically independent
Stage 4	Severe disability; still able to walk or stand unassisted
Stage 5	Wheelchair bound or bedridden unless aided

PARKINSON'S DISEASE AND FUNCTIONAL LIMITATIONS

Functional limitations that occur as a result of motor symptoms in PD, include difficulty with writing, transfers, turning directions, and gait.[16] As PD progresses, patients progress to the final stages in H&Y (IV and V) resulting in a significant decline in independence and functional ability. Initially, functional limitations in early/mild PD may result in changes noted in posture and gait.[2] Movement symptoms may be minimal, and intervention strategies are focused on prevention and restoration with regular exercise and community classes for social interaction.[2] During the middle / moderate stage of PD, individuals should expect increasing number and severity of impairments, and additional assistance with ADL.[2] Patients with PD demonstrating bilateral involvement and postural instability, respectively H&Y stage II or III, have been found to require assistance with ADLs such as dressing and walking.[17]

Initially, intervention strategies will include regular exercise and community classes as previously stated for those in H&Y I-III. However; compensatory strategies will be necessary with use of assistive devices and home modifications as the disease progresses.[2] Finally, during the late/advanced stages of PD, functional limitations are apparent in most activities such as difficulty with walking, often resulting in a patient becoming wheelchair bound.[2] At this point, interventions are focused on participation in ADLs, prevention of contractures/wounds, and education in importance of proper positioning.[2]

Gait speed and balance often play strong roles in one's ability to perform ADLs and ultimately quality of life. Weaver et al. found walking (36.3%) followed by standing still (24.2%) as the most common activities resulting in falls in people with Parkinson's disease.[7] Hass et al found that participants with H&Y 1 and 2 walked significantly faster than those at H&Y stage 2.5, 3, and 4.[11] In 2014, Combs et al found that significant declines in gait speed occur beyond H&Y stages 1 and 2.[18] Paker et al found most PD patients with H&Y stage 2 and 3 require assistance with ADLs such as dressing and walking.[17]

Accompanying the physical changes and debilitation, changes in cognition and psychosocial symptoms such as depression is often seen in those with PD.[2,19,20] In 2014, Park et al found non-motor symptoms such as depression and anxiety are more bothersome than motor symptoms.[20] In a study by Soleimani et al,[19] those experiencing Parkinson's disease reported their primary concern to be "becoming disabled" in all 17 participants. With no cure for PD at this time, management of symptoms via medicine and physical activity become even more imperative to improve quality of life for those with Parkinson's disease.[21]

FALL RISK AND FEAR OF FALLING

FOF and fall risk are common issues noted in individuals with postural instabilities.[22] In 1990, Tinetti et al published an article describing FOF as the lack of self-confidence in performing normal activities without falling.[23] Eight years later, Howland et al[24] published a study that described FOF as a rational and cautious response to a potentially dangerous event and it could be viewed as a form of fall prevention.

Furthermore, while it is a reasonable response, too much FOF may compromise an individual's well-being.[24] In the geriatric population, even those who did not experience a fall over a 1-year time reported FOF.[25] Cummings et al[25] found that in the geriatric population, 40% reported falling in the past year. Additionally, of those who had not fallen over the year, 23% reported a FOF.[25]

The impact of these deficits may result in activity avoidance and diminished quality of life.[22,24,26-28] Similarly in 2009, Brozova et al[30] found that FOF had the higher impact on QOL when compared to the impact of falls. Therefore, Cummings et al[25] concluded that FOF is as serious a health problem as experiencing falls in both fallers and non-fallers.

Adkin et al found that FOF was more evident in individuals with PD when compared to age matched healthy individuals.[22] Also, in a study that looked at falls and FOF in individuals with PD, 62% of the participants reported a fall or frequent falls.[8] Allen et al[29] discussed how fear of falling is found to be high when compared to actual fall risk. Interestingly, community dwelling individuals that report a FOF, when tested are not always characterized as a fall risk.[27]

Determination of an individual's fall risk involves multiple factors that contribute to the likelihood that an individual will fall.[31] Hausdorff et al.[31] found that when compared to healthy controls, those with PD experience more falls within a 6-month timeframe (0.9 ± 1.0, $p < 0.05$). In a study by Allen et al[33], around 70% of individuals with PD who experience a fall will experience recurrent falls. Fall frequency has been found to significantly correlate ($r = -0.396$, $p < 0.001$) with daily activity limitations within their home.[8]

Potential factors associated with recurrent falls include cognitive impairments[34,35] freezing of gait[36], fear of falling[37], and balance impairment.[29] Therefore, individuals will often restrict their participation in life activities due to a debilitating FOF. The role of the clinician is to evaluate functional mobility, improve safety with balance and gait to improve their QOL through participation in activities.

CLINICAL FRAMEWORK

Due to the underlying causes of falls in individuals with PD, appropriate assessments of fall risk are necessary. Clinicians depend on the use of outcome measure assessments to determine a patient's status regarding fall risk. Outcome measure assessments are organized based on the International Classification of Functioning, Disability and Health (ICF) framework. The ICF is a decision-making process that is patient-centered, emphasizing the patient's roles and functions while identifying limitations.[38] Within the framework there are three domains; body structure/impairment, activity limitations, and participation restriction.[38,39] When properly used, the ICF provides clinicians a mechanism for making clinical decisions, developing clinical hypotheses, and developing a plan of care.[38] To begin the assessment process, clinicians must determine a patient's cognitive status before proceeding with additional tests and measures.

Cognitive Assessment Tools

Mild **c**ognitive impairment is extremely common in PD, and the rate increases as the disease progresses. Found even during early stages of PD, mild cognitive impairment may only become apparent during neuropsychological tests.[40,41] When comparing individuals recently diagnosed with PD (*n* = 117) to healthy control (*n* = 70), 24% of those diagnosed with PD showed evidence of cognitive dysfunction compared to 4% of healthy controls.[40] Muslimović et al[40] found that when assessing cognitive function in individuals with PD, the areas of attention and executive functions were most frequently impaired.

It is important for clinicians to assess an individual's cognitive ability at evaluation, as it will greatly affect participation in rehabilitation. Since PTs are not experts in cognitive functioning, they will often use screening tools and refer out as appropriate. The two most common cognitive screens used clinically within the Parkinson's population include the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA).

Mini-Mental State Examination. The MMSE consists of 11 simple questions that break down to 7 domains (orientation to time, place, registration of three words, attention and calculation, word recall, language and visual construct.**).** The MMSE takes approximately 10 minutes to complete and a maximal score of 30/30 indicates no cognitive impairment. In a study by Dick et al[42] the cut off score of < 24 indicated the presence of cognitive impairment in neurologically involved individuals. A cut-off score was found to be 29/30 (sensitivity = 0.90, specificity = 0.38) on the MMSE for mild cognitive impairment in individuals diagnosed with PD.[43] To determine dementia in individuals with PD, a cut-off score of 24/25 (sensitivity = 0.82, specificity = 0.63).[43]

Montreal Cognitive Assessment. Designed to improve upon the limitations of the MMSE, the MoCA **c**onsists of 16-items, this cognition screening tool assesses 11 domains including: visuo-spatial and executive functions, naming, memory, attention, language, abstraction, and orientation.[43] This screening tool requires minimal equipment including: stop watch, pencil, paper and takes around 10-15 minutes to complete.

A study by Chou et al[44], recommend the MoCA to be the most suitable cognition screening measure for clinical trials in individuals diagnosed with PD. A maximum score of 30, with a score of ≥ 26 indicates that an individual is cognitively intact based on this screening tool. Hoops et al[43] determined the cut-off score for increased fall risk is <26/30 in individuals diagnosed with PD. The MoCA demonstrates good test-retest reliability (ICC = 0.79) and interrater reliability (ICC = 0.81) in individuals diagnosed with PD.[45] In 2015, a study by Hoskovcová[15] found there to be no significant difference in MoCA scores between fallers and non-fallers (p = 0.544) in individuals diagnosed with PD. Caetano et al[46] found no significant difference in MoCa score between those diagnosed with PD (26.3±2.8) when compared to healthy controls (27.2±2.4). Recently in a study by Biundo et al[47], it was suggested that the MoCA was a superior cognitive screening tool due to the lack of ceiling and floor effects in individuals diagnosed with PD.

Postural Stability and Balance Assessment Tools

Postural instability is one of the four cardinal signs of Parkinson's disease and remains one of the most limiting symptoms, with a significant difference ($p < 0.05$) between those diagnosed with PD compared to healthy control experiencing falls.[46] To determine if an individual is a fall risk, physical therapists often utilize postural stability and balance assessments. With a range of outcome measures available to assess postural instability and fall risk, clinicians must consider multiple factors when selecting proper assessment tools. Factors such as time, equipment, use of assistive devices, and environment all contribute to the selection of assessment tools. Once the assessment tools are selected, patients will often be assessed throughout a plan of care to determine the effectiveness of selected interventions.

Four Square Step Test. The FSST was developed to assess dynamic balance while stepping over sticks in multiple directions.[48] The FSST requires stepping forward, sideways and backward and is scored based upon the time it takes to complete the entire sequence.[48-50] The total time required to complete the assessment is recorded, with the faster the time indicating less risk of falling.

In 2002, Dite et al[48] determined the FSST to have excellent interrater reliability (n = 30, ICC = 0.99) and excellent test-retest reliability (n = 20, ICC = 0.98) in older community dwelling adults. In 2013, 53 individuals diagnosed with PD participated in a study looking at the performance of the FSST.[50] Participants ranged in H&Y from stage I-V with an average age of 70 ± 7.4.[50] For this study, both interrater reliability (ICC = 0.99) and test-retest reliability (ICC = 0.78) were high while participants were

on-medication.[50] In 2014, McKee et al[51] assessed the FSST reliability over three trials in individuals with PD demonstrating a range of ICC = 0.543-0.876 between trials. During this study, the FSST was determined to strongly correlate with the TUG
($r = 0.734$, $p < 0.01$).[51]

It was determined the FSST demonstrates moderate sensitivity (0.78) in capturing fall risk in individuals with PD, with a score greater than 9.68 seconds indicating a fall risk.[50] A cut off score was determined to be 15 seconds, with scores greater than 15 seconds categorizing older adults as a fall risk.[48]

Dite et al[48] assessed the FSST in community dwelling older adults including those with multiple falls (> 2 in 6 months), non-multiple fallers (< 2 falls in 6 months) and a comparison group. The FSST was determined to be significantly different ($p < 0.001$) between the three groups.[48] In a different study, the FSST was not significantly different between falls and non-fallers ($p = 0.133$) or between freezers and non-freezers ($p = 0.524$) in individuals diagnosed with PD.[51] It was determined, however that there was a significant difference ($p = 0.026$) between those with some cognitive impairment when compared to those without cognitive impairment.[51] In 2015, Duncan et al[52] found a significant difference ($p = 0.03$) between FSST while on-medication versus off-medication However; it is was not significantly different between freezers and non-freezers ($p = 0.08$) or between fallers and non-fallers ($p = 0.06$).[52]

Modified Four Square Step Test. In 2008, Blennerhassett et al[53] reported that between 40-62% of individuals post stroke were unable to successfully complete the FSST. As a result, in 2016 Roos et al[54] developed the mFSST to assess dynamic balance while stepping over tape lines in multiple directions. Designed to permit those unable to successfully complete the FSST, the mFSST requires subjects to perform the same sequence as the FSST without having to step over raised obstacles. Similarly, the score of the mFSST is the time required to complete the assessment with the faster the time indicating a decreased risk of falling. Roos et al[54] found the test-retest, intrarater, and interrater reliability to be excellent with an ICC range from 0.81-0.99 for individuals with stroke and highly correlated to the FSST (Spearman $\rho = 0.954$, $p < 0.001$).[54] The mFSST was also found to have a strong correlation between time to complete the mFSST and TUG (Spearman $\rho = 0.726$, $p < 0.001$).[54] Concurrent validity was determined using the Berg Balance Scale (BBS), with a moderate negative correlation (Spearman $\rho = - 0.616$, $p < 0.001$) and ABC (Spearman $\rho = -0.449$, $p < 0.004$).

While performing fall risk testing, a higher percentage of those with stroke were able to complete the mFSST when compared to the FSST ($p < 0.04$).[54] When comparing the completion rate of the FSST to the mFSST in individuals with a stroke, 11% more were able to complete the mFSST.[54] Resulting in the completion rate of the mFSST being significantly greater ($p = 0.04$) than the completion rate of the FSST.[54] Out of the total participants (n =55), seven were unable to complete the FSST yet able to complete the mFSST.[54]

Timed Up and Go. In 1991, Podsiadlo et al[55] described the TUG as a simple clinical tool to assess lower limb function, mobility and fall risk. TUG is an outcome measure that assesses functional mobility, by measuring the time required for one's ability to stand up from a chair, walk 3 meters, turn around, walk back and sit down.[18,56]

The TUG has demonstrated excellent interrater reliability (ICC = 0.99) and intrarater reliability (ICC = 0.99) in frail elderly patients.[55] Steffen et al[57] found the TUG demonstrated excellent test-retest reliability (ICC = 0.85) in individuals with parkinsonism.[57] In individuals with PD, the TUG demonstrates excellent interrater reliability (ICC = 0.99) between experienced and inexperienced raters.[58] Morris et al[58] also found that individuals with PD even when “on-medication” were slower than age matched counterparts. In a study by Del-Ballo Haas[59], the TUG demonstrated moderate test-retest reliability (ICC = 0.69) in individuals with PD ranging from H&Y 1-3.

In 2010, Kerr et al[28] studied 101 participants diagnosed with PD ranging from H&Y 1-4, with the mean stage 2.1 (*SD* ± 0.8). As a result of this study, Kerr et al[28] found there was no significant difference ($p = 0.053$) in TUG between fallers and non-fallers based on H&Y stage. The average time for the TUG for all participants with PD was 10.1 seconds (*SD* ± 2.7), non-fallers 9.4 seconds (*SD* ± 2.2), and fallers 10.8 seconds (SD ± 3).[28] When compared to non-fallers, fallers performed worse on the TUG ($p < 0.010$).[28] Likewise, Mak and Pang[60] found a significant difference between fallers and non-fallers ($p < 0.05$) for TUG time in individuals with PD. Later in 2011, Foreman et al[61] found the TUG was able to differentiate between fallers and non-fallers ($p < 0.006$) only when off-medication. With the mean score for fallers on-medication 12.21 (*SD* ± 7.42) and off-medication 15.5(*SD* ± 11.03).[61] In 2015, Vance et al[62] found a significance difference between fallers and non-fallers ($p = 0.005$) in individuals with PD during TUG test. The TUG median range for non-fallers 10.12 seconds (SD ± 6.6) and fallers 13.01 seconds (*SD* ± 1.0).[62] In a study by Steffen et al[57], 37 participants with parkinsonism performed the TUG. The mean time was 15 seconds with a 10 second standard deviation. With the aim of the study to determine predictability of falls in PD, the TUG demonstrated moderate sensitivity (0.69) and moderate specificity (0.62).[28] Mak and Pang[60] increased fall risk was significantly associated (p = 0.028) with a longer TUG time. Recently, O'Connell et al[63] found that there was a significant difference (p = 0.04) in performing the TUG between those with a high FOF and those with a low FOF in individuals diagnosed with PD. Thus, suggesting that those with a higher FOF may walk more cautiously requiring a longer time to complete activites.[63]

Berg Balance Score (BBS). This 14-item scale was designed to measure functional standing balance and is often used for clinical and research purposes.[64] Each item-level consists of a score ranging from 0-4, with a potential overall score up to 56 indicating no balance impairments.[65] This static and dynamic balance assessment takes about 15-20 minutes to complete and includes activities such as picking up an object from the floor, sit-to-stand, and turning 360 degrees. Steffen et al[65] found good test-retest reliability (ICC = 0.94) and MDC of 5 points in individuals with PD. In 2011, Leddy et al[66] found excellent interrater reliability (ICC = 0.95) of the BBS for individuals with PD. A cut-off score of 47/56 was determined to identify fallers in individuals with PD.[66]

In 2015, Duncan et al[52] monitored balance changes over one-year, with assessment points at baseline, six-months, and one-year in individuals with PD. There was no significant change from baseline at six- months (mean raw change: -0.25 ± 4.16; p = 0.66; 95% CI [-1.39, 0.89]) and at one-year (mean raw change: -0.32 ± 4.77;

p = 0.62; 95% CI [- 1.73, 1.09]).[52] Duncan et al[52] concluded that the BBS may not be the best assessment tool to monitor postural changes overtime in individuals with PD.

BESTest. The BESTest is a measure that assesses balance control using 36-items that consists of six subcategories (biomechanical constraints, stability limits and verticality, anticipatory postural adjustments, postural responses, sensory orientation, and stability in gait). Each item is graded based on a 0 to 3 scale, with a maximum score of 108 points. The total score is then converted to a percentage, the higher the percentage the better balance. This test requires numerous pieces of equipment and can take up to 30 minutes to complete.

The BESTest has high interrater reliability (ICC = 0.96, 95% CI [0.89-0.99]) with excellent test-retest reliability (ICC = 0.88).[66] Excellent correlations have been found between the BESTest and ABC (*r* = 0.757) and BBS (*r* = 0.873).[66] Leddy et al[66] reported the cut-off score of 69% on the BESTest indicates increased fall risk in individuals diagnosed with PD. The BESTest has demonstrated higher sensitivity to balance deficits compared to BBS and Functional Gait Assessment.[66] Due to the administrative time and extensive equipment required to complete the BESTest, the application of the BESTest within the clinic is limited.

Self-Reported Questionnaires

To assess the participation level of the ICF, clinicians frequently use self-reported questionnaires. Self-reported measures are used to provide the individual the opportunity to assess their symptoms, functional status, and quality of life. Varying in format, questionnaires may involve a Likert scale, be multiple choice, or require participants to provide an estimated percentage of balance confidence. Initially completed at baseline, these questionnaires can also be used to assess an individual's perceived quality of life following therapeutic intervention. Therefore, providing clinicians valuable insight into the individuals response to intervention regarding quality of life and perceived participation in daily activities.

Activities-specific Balance Confidence scale. Perceived confidence in performing ADLs can be assessed through the ABC. Consisting of 16- items, the ABC scale assesses ones perceived ability to maintain balance while performing various activities on a scale of 0%-100% with 100% representing full confidence.[11,57,59,67,68] The ABC was also developed to assess balance confidence in individuals at varying functional levels.[69] Adkin et al[69] assessed FOF by using the ABC in those with PD, and found those with greater balance and gait impairments reported less confidence in avoiding falls during ADLs.

In a study by Steffen et al[65], the ABC scale demonstrated excellent test-retest reliability (ICC =0.94) with a mean score of 70% (*SD* ± 19) in individuals with parkinsonism. In 2011, Dal-Bello Haas et al[59] found the ABC scale to demonstrate test-retest reliability (ICC =0.79) in individuals with PD. The MDC for the ABC ranges from 11.2% to 13% in individuals with PD and parkinsonism.[59,65] A score of < 69 on the ABC qualifies a high FOF, while a score of ≥ 69 indicates a low FOF in individuals with PD.[70] Fall frequency has been shown to significantly correlate with the ABC

(r = -.332, p = 0.003) in individuals with PD.[70] The ABC also significantly correlates with the TUG (r = -0.44, p = 0.03) a psychomotor assessment of fall risk.[59] Similarly, Lohnes et al[71] found the ABC to significantly correlate with TUG fall risk assessment (r = -.372, p = 0.01) in individuals with PD.

As PD progresses, the ABC scale has been shown to significantly differentiate between H&Y stage 1 and 3 (p = 0.007), however is unable differentiate between H&Y stage 1 and 2 (p = 0.56).[59] Therefore, Dal-Bello Haas et al[59] concluded the ABC is a valid assessment for earlier stages of PD, and can detect the onset of postural instability as the disease progresses to stage 3. In a study by Almeida et al[67], the ABC significantly differentiated (p <0.001) between nonrecurrent fallers (0 to 1 falls in 12 months) and recurrent fallers (2 or more falls in 12 months) in individuals diagnosed with PD. Similar results were found in a study by Mak and Pang[60] in which there was a significant difference in ABC score between falls and non-fallers diagnosed with PD. When compared to control subjects, non-fallers diagnosed with PD had significantly lower (p < 0.05) ABC scores.[60] In 2014, Bryant et al[70] studied 83 persons with PD and classified them into three categories: non-fallers (n = 31), rare fallers (n = 35), and frequent fallers (n = 17). As a result of a one-way ANOVA, there was found to be a significant difference between H&Y groups (F = 6.58, p = 0.002), and the ABC (F = 5.74, p = 0.05). A score of 69% or below on the ABC can correctly identify recurrent fallers in people with Parkinson's disease.[60] A score of at least 80% on the ABC was significantly (p = 0.013) associated with a reduction in falls.[60] Meanwhile, a score ranging between 50-80% on the ABC was not associated with a reduced fall risk

(p = 0.078), suggesting that self-perceived balance confidence is a significant predictor for fall risk when evaluating individuals with PD.[60]

Parkinson's Fatigues Scale. Fatigue is often reported by individuals with PD, it frequently impacts quality of life and can contribute to apathy and depression. In 2018, Chong et al[72] found that when compared to caregiver's perception, those with PD perceived fatigue to be more bothersome than symptoms of bradykinesia and freezing of gait.[72] Fatigue has been shown to significantly correlate with fall frequency (r = 0.254, p = 0.021) in individuals with PD.[60] Consisting of 16-items, the PFS-16 encourages the participants to rate their feelings and experienced of fatigue over the prior 2 weeks. The scoring includes a range from 1 "strongly disagree" to 5 "strongly agree" with the total score then representing a sum of the 16-items. A high overall score on the PFS-16, indicates that fatigue is more severe. Within the 16-items, seven of the questions assess the physical effects and nine assess the impact on daily functioning and socializing. This screening questionnaire only takes about five minutes to complete and only requires paper and pen.

The PFS-16 was determined to have excellent reliability (ICC = 0.83) and excellent internal consistency (Cronbach's α = 0.98).[73] In 2018, the PFS-16 was found to have excellent internal consistency for each item ranging from Cronbach's α = 0.967-0.968.[72] When compared to other measures of fatigue (Fatigue Severity Scale and a fatigue rating question) all three measures were strongly correlated (r = 0.84), suggesting all are valid measures of fatigue.[74] In a study by Grace et al[74], the mean PFS-16 in individuals with PD was 54.34(34.81) and was significantly higher (p < 0.001) than a control group at 15.03(15.53). In this study, all questions except question five "I feel completely exhausted" were able to significantly differentiate individuals with PD compared to healthy control group.[74]

Freezing of Gait questionnaire. Freezing of gait (FOG) is a disabling clinical symptom that is episodic in nature resulting in the inability to step during initiating gait or when turning while walking.[75] To assess freezing of gait, the freezing of gait questionnaire was developed and involves 6-items with a total score ranging from 0-26; a higher score indicates more FOG severity.[52] The FOGQ was validated with the Unified Parkinson's Disease Rating Scale revealing a moderate correlation ($r = 0.74$) between the two assessments.[76,77] Over a 10 week period, in 2009 Giladi et al[77] assessed the test-retest reliability of the FOGQ, which demonstrated excellent reliability ($r = 0.84$). When comparing baseline characteristics of individuals who experience movement freezing and those who do not, those who experienced freezing of gait were significantly older ($p = 0.0145$), had a longer duration of symptoms ($p = 0.0010$), and more advanced disease in H&Y staging ($p = 0.0004$).[77] The FOGQ demonstrated a significant correlation between FOGQ and H&Y ($r = 0.66$, $p = 0.01$), revealing that as the disease progresses through the H&Y staging there is an increase in number of freezing episodes.[77]

Duncan et al[52] reported that individuals with PD who report FOG (PD + FOG) reported a significantly different score ($p < 0.001$) on the FOGQ compared to those who do not report freezing of gait (PD-FOG). The average FOGQ score for PD + FOG was 12.88(±3.86) while the PD – FOG average score was 2.96(±2.49).[52] Amongst individuals with PD those who were categorized as fallers when compared to non-fallers scored higher on the freezing of gait questionnaire.[28] Within the 6-items of the FOGQ, a score >1 on question 3 has been deemed a good question to identify individuals with freezing tendencies, when compared to non-freezers.[77] In 2009, Giladi et al[77] found the FOGQ to be an appropriate tool to assess treatment intervention in individuals with PD.

Parkinson's Disease Questionnaire - 39. The PDQ-39 is the most widely used self-reporting questionnaire consisting of 39-items and can take up to 20 minutes to complete.[78] This questionnaire was designed to reflect QOL over the last month in eight different domains. The eight domains include: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. This questionnaire uses an ordinal scale from 0 to 4, 0 = never and 4 = always, with the lower the score indicating a better quality of life. Each separate domain can be scored or there can be an overall PDQ-39 summary index (PDQ-SI).

In a study by Jenkinson et al[79], the PDQ-39 was completed by patients through a postal survey and at a clinic; the PDQ-39 SI was found to have high internal reliability of Cronbach's alpha ($\alpha = 0.84$-0.89). For those assessed at a clinic ($n = 127$), there was a significant correlation between the PDQ-39 SI and the H&Y ($r = 0.51$, $p < 0.001$).[79] Therefore, Jenkinson et al[79] concluded the PDQ-39 SI is useful in determining the impact of PD, with a score closer to 100 representing more health problems.[78] Margolius et al[80] found when assessing the change in PDQ-39 total score there was an increase in worsening of health-related quality of life (HRQL) with 47.9% reporting worsening (visit two compared to visit one) to 52.15% reporting worsening (visit five compared to visit four).[80] Specifically noting that the mobility and cognitive subscales of the PDQ-39 most likely deteriorate over time.[80] A multiple regression analysis evaluating how gait disorders relate to QOL revealed a significant relationship between PDQ-39 total score and FOF ($r = 0.32$, $p < 0.001$) and falls ($r = 0.15$, $p = 0.006$).[30] The PDQ-39 total score was significantly different between those with minimal gait disturbances and those with moderate gait disturbances ($p < 0.01$).[30] Likewise, the PDQ-39 total score was significantly different between those with moderate gait disturbances and those with severe gait disturbances ($p < 0.01$).[30] In a study by Rose et al[81] there was a significant ($p < 0.005$) improvement of 8.3 points in the PDQ-39 total score following motorized treadmill training. To reflect a meaningful change, the effect size was assessed for each domain of the PDQ-39 ranging in value from 0.10-0.43 over a 6-month time period.[82] After a 6-month follow-up, a moderate effect size ($d = .43$) was noted within the social support domain of the PDQ-39.[82]

PARKINSON'S DISEASE AND GAIT

Walking is a complex functional activity with numerous variables that influence ones walking ability.[83,84] In a study by Brozova et al[30], of the 491 participants diagnosed with PD, 79% experienced moderate to severe gait disturbances. Parkinsonian gait characteristics may comprise of small shuffling steps, stooped posture, and reduced arm swing.[11] Impairments such as decreased spatial, temporal, and stability-related measures increase ones' disability with Parkinson's disease.[11,85] In PD, gait abnormalities such as gait hypokinesia (decreased gait speed and decrease stride length) are present starting in preliminary stages of the progressive disease and often restrict functional independence.[11,18,85-87] As PD, the gait impairments were found to be strongly correlated ($r = 0.4$-0.64, $p < 0.001$) with disease severity.[88] A systematic review and meta-analysis by Tan et al[88] found a moderate to strong correlation ($r = 0.39$-0.67, $p < 0.001$) between gait impairments and activity limitations.[88] Noting that freezing of gait, postural instability, and hypokinesia (determined by gait speed) were the main gait disorders associated with activity limitations.[88]

RELATIONSHIP BETWEEN FEAR OF FALLING AND GAIT

Walking ability contributes to FOF in individuals with PD; hence improving walking ability may help improve fall risk, perceived confidence and QOL in those with PD.[89] Paker et al[17] found gait speed to significantly correlate with FOF ($p = 0.001$) and risk of falling ($p \leq 0.001$) in patients with PD. In 2014, Bryant et al[70] found that the spatial-temporal parameters (gait speed and stride length) were significantly different ($p < 0.002$ and $p < 0.0005$) between those with a low FOF and those with a high FOF. In addition to these findings, the significant difference between those with a low FOF and those with a high FOF was present during both forward and backward walking.[70] As a result of these findings relating FOF and its effects on mobility in individuals with PD. Thus, leading clinicians to focus on improving the spatial-temporal parameters of gait, such as gait speed training as it plays a role in individuals' ability to perform ADLs, FOF, and ultimately QOL.[17]

Gait Assessment Measures

Gait impairment is a significant feature of PD requires a physical therapist assessment to monitor functional mobility and disease progression.[11] Paker et al[17] found that "unchangeable factors" such as age, height, gender, and clinical severity can affect gait speed in those with Parkinson's disease.[17] In 2014, Hass et al[11] found age was correlated with gait speed (r = -0.33) indicating a weak negative correlation. Nonetheless, physical therapists strive to improve gait impairments such as gait speed in patients with PD to improve functional mobility.

10 Meter Walk Test. Clinically, physical therapists will use outcome measures as tools to assess gait speed, gait symmetry, and gait adaptability. To assess gait speed, clinicians often use the 10 MWT.[17,30] As described by Paker et al[17], the 10 MWT allows for participants to attain their normal gait speed as they traverse the center 10 meters over a total 14 meters. The 10 MWT is a reliable test for fast walking tests ($ICC_{2,1}$ = 0.99) and comfortable walking test ($ICC_{2,1}$ = 0.98), that can be used to test gait speed in Parkinson's disease.[18] Combs et al found the 10 MWT to be a valid measurement to assess decline in walking speed across stages of disease progression in persons with PD.[18]

Functional Gait Assessment (FGA). The FGA is a 10-item assessment tool that assesses postural stability while performing a variety of walking tasks. This assessment uses an ordinal scale for each item ranging from 0-3, with a maximal score of 30 indicating normal ambulation. Activities performed during the FGA include walking with head turns, changing speeds while walking, and stepping over an obstacle.[93] A benefit of the FGA is that participants may utilize an assistive device while performing this assessment. There is minimal equipment needed to complete this tool and can take around 10 minutes to complete. The FGA exhibits excellent test-retest reliability (ICC = 0.91, 95% CI[0.80-0.96]).[66] Wrisley et al[93] found the FGA to have excellent interrater reliability (ICC = 0.86) in individuals diagnosed with PD. Similarly to Wrisley et al, in 2016 Yang et al[94] found the FGA to have excellent intrarater reliability (ICC = 0.99) in individuals diagnosed with PD. The FGA has been found to have excellent correlations with the BBS ($r = 0.84$, $p < 0.01$) and TUG ($r = 0.84$, $p < 0.01$) in community dwelling older adults.[95] Excellent correlations have been found between the FGA and BESTest ($r = 0.882$) in individuals with PD.[66] In 2010, the a cut-off score of 22/30 was effective in classifying older adults as a fall risk.[95] In 2011, Leddy et al[66] found a cut-off score of 15/30 to be indicative of increased fall risk in individuals with PD.

Six – Minute Walk Test (6 MWT). The 6 MWT is an outcome measure that assesses the distance an individual can walk in a six -minute allotted time. The assessment tool has been deemed useful for measuring exercise capacity and endurance.[57,65,96,97] While performing the 6 MWT, participants can take rest breaks and utilize assistive devices as needed, however documentation must reflect these adaptions. In older adults, the 6 MWT has a MDC of 58.21 meters and 50 meters for the MCID.[98] In individuals diagnosed with PD, the 6 MWT has excellent test-retest reliability (ICC = 0.96) with an MDC of 82 meters.[65]

Dynamic Gait Index (DGI). The DGI is an assessment tool that assesses gait adaptability. Involving six-items, the DGI uses a 4-point scale ranked on impairment from severe impairment to no gait dysfunction. A maximum possible score of 24 indicates no gait dysfunction. This assessment tool includes items such as walking while changing speeds and stair climbing. In 1997, Shumway-Cook et al[99] determined a cut-off score of <19 to indicate a fall risk in community dwelling elderly adults. Similarly; in 2008, Dibble et al[100] found the cut-off score of < 19 to indicate an individual diagnosed with PD is a fall risk. In 2011, Romero et al[101] determined the MDC at 2.9 on the DGI in community dwelling older adults. Additionally, in 2011 Huang et al[102] found the MDC Elon the DGI to be 2.9 points for individuals diagnosed with PD. The DGI demonstrates high test-retest reliability (ICC = 0.84) in individuals with PD.[102]

To determine a baseline, these assessment tools are used initially during the physical therapy evaluation to assess the individual's mobility and potential fall risk. Inclusive of all levels of the ICF framework, assessment tools can be used to illustrate a clear picture of a patient's presentation to justify therapy services. Throughout the plan of care, physical therapists will reassess the individuals using the selected outcome measures to determine the effectiveness of interventions and modify the plan of care as needed.

Computerized Electronic Walkways. To attain precise spatial-temporal measurements of gait, clinicians may use a computerized electronic walkway to fully assess gait parameters and resultant impairments. While the use of outcome measures such as the DGI, 6 MWT, and FGA provide clinicians with useful information about gait ability there is still a chance of human error in testing. Additionally, when specifically assessing the spatial parameters of gait such as step and stride length, these widely used outcome measures do not provide sufficient data. Therefore, clinicians may utilize computerized electronic walkways to attain accurate assessment of an individual's spatial-temporal parameters of gait.

Assessment of spatial-temporal parameters using a computerized gait analysis walkway such as GAITRite electronic walkway when compared to three - dimensional motion analysis demonstrated high levels of concurrent validity.[17] The Zeno with PKMAS is a computerized mat that assess both static and dynamics balance along with gait.[103] Improving upon some of the processing issues noted with the GAITRite, the Zeno uses the same PKMAS system with updated improvements. The Zeno is a 20-foot gait mat that enables data collection and demonstrates reliability and validity of the PKMAS system (ICC = 0.84 - 0.99).[103] The Zeno is a low profile gait mat consisting of a three-layer surface embedded with 16 levels of pressure that uses a sampling rate of 60Hz to 120Hz to assess dynamic gait.[104]

In 2004, the GAITRite electronic walkway was determined to have excellent test-retest reliability for gait speed (ICC = 0.95), stride length (ICC = 0.97) and step length (ICC = 0.097).[105] Likewise, Menz et al[106] found excellent reliability for the spatial-temporal parameters of gait ranging from ICC = 0.82-0.92 in older adults. In 2017, a study by Vallabhajosula, determined the Zeno Walkway to have excellent concurrent validity (ICC = 0.854 to 0.976) when compared to the GAITRite walkway while testing gait spatial-temporal parameters of gait (comfortable and fast speeds) in healthy older adults and those considered high fall risk.[107]

The Functional Ambulation Performance (FAP) is a quantitative means of assessing gait spatial-temporal parameters, which is occasionally used to assess gait characteristics in early stages of PD.[108] Nelson et al[108] found that the GAITRite system provided a more detailed analysis of gait components when compared to the FAP. The GAITRite was able to differentiate between healthy age matched individuals and those diagnosed with PD by assessing preferred and fast walking speed.[108] The relationship between the spatial-temporal parameters of gait in individuals with PD is often studied in hopes of finding treatment strategies to improve functional mobility and QOL.

SPATIAL-TEMPORAL PARAMETERS OF GAIT

Classic characteristics of parkinsonism gait may consist of a hypokinetic gait, shuffling gait pattern, and freezing episodes. One's ability to increase or decrease their walking speed permits them to adapt to environment and task constraints.[57] Shuffling gait pattern is a common symptoms of PD, which results in a shortened stride length and reduced gait speed.[109] In 2017, Morris et al[110] found that a decline in cognition was predicted by speed [$\beta = 4.05$, $p < .01$]; reduced step length [$\beta = 8.64$, $p < .01$]; and step length variability [$\beta =115.68$, $p < .01$]. To improve functionality in individuals with PD, clinicians frequently target the improvement of these spatial-temporal parameters and the resultant gait abnormalities.

Temporal Parameters. Gait speed may be the most frequently used primary outcome measure in rehabilitation.[11] Fast and comfortable walking speeds are often assessed to ensure one's ability to change walking speed.[65] Gait speed has been deemed the only significant predictor of actual walking mobility, especially self-selected gait speed as a partial predictor of community ambulation.[90] Self-selected gait speed is often used by physical therapists to determine plan of care in patients with neurological diagnoses. In 2002, Steffen et al[57] found the mean comfortable (self-selected) gait speed in elderly community dwelling adults to range from 1.15m/s to 1.59 m/s. While the mean fast gait speed ranged from 1.59 m/s to 2.05 m/s in elderly community dwelling older adults aged 60-89.[57] This study demonstrated that individuals were able to increase their gait speed 28%-38% beyond their comfortable gait speed to attain their fast gait speed.[57]

In a study by Hausdorff et al[32], both elderly fallers and individuals diagnosed with PD demonstrated reduced gait speeds ($p < 0.05$) when compared to healthy controls. In 2013, a study involving 153 participants diagnosed with PD determined that a gait speed of 0.88 m/s (sensitivity 0.67, specificity 0.75) correctly predicted 70% as community ambulators.[111]

In 2013, Nemanich et al[112] studied gait speed and falls in 78 individuals diagnosed with PD. It was determined that the average self-selected gait speed was 1.10 m/s (SD±0.29), while the fast-as-possible was 1.53 m/s ($SD \pm 0.47$).[112] Interestingly, a focus in this study was to assess the difference between the self-selected and fast-as-possible gait speed. The average difference was 0.43 m/s ($SD \pm 0.26$), with a significant difference ($p = 0.008$) noted between male and females diagnosed with PD.[112] Based on a regression model, Nemanich et al[112] found that this model was able to predict 51.9% (self-selected) and 54.1% (fast) and only 20.2% was determined based upon the difference between gait speeds. In conclusion, it was found that self-selected (AUC = 0.803, $p < 0.001$; sensitivity = 0.800, specificity = 0.717) and fast gait speeds (AUC= 0.811, $p < 0.001$; sensitivity = 0.840, specificity = 0.755) are both predictive of falls.[112]

Assessment of gait spatial-temporal parameters is necessary to develop an efficient treatment strategy to improve gait speed in those with Parkinson's disease. Hass et al[11] found that physical therapy significantly improved gait speed (mean difference of 0.05 m/s) resulting in a difference in gait speed that is small but clinically important. The smallest amount of change in an outcome measure that is perceived as valuable is known as the Minimal Clinically Important Difference (MCID).[11] In 2014, Hass et al found in individuals with PD a 0.06 m/s improvement in gait velocity while on-medication met MCID noted by a 6-point change in UPDRS score.[11]

In 2008, Steffen et al[65] tested comfortable gait speed in 36 participants diagnosed with parkinsonism. Gait speed was determined through the 10 MWT and demonstrated excellent test-retest reliability (ICC ≥ .96).[65] The minimal detectable change (MDC) was determined to be 0.18 m/s for comfortable gait speed and 0.25 m/s for fast gait speed.[65] In a case series, Smith et al[49] found that three of the four participants exceeded the MDC (0.18m/s) following an 8-week treadmill training study.

As PD progresses, individuals will progress through the H&Y scale, which is used to determine the stage and severity of the disease. In 2014, Hass et al found a range of H&Y 1 mean gait speed was 1.11 m/s (*SD* ± 0.27) while H&Y 4 mean gait speed was

0.70 m/s (*SD* ± 0.27).[11] Recently, Caetano et al[46] found those with an average H&Y 2.1 classification, demonstrated an average of usual gait speed of 1.26 m/s (*SD* ± 0.24).[46] In 2015 Cavanaugh et al,[113] studied ambulatory activity individuals diagnosed with PD over a two-year time period. Cavanaugh et al[113] determined that gait speed declined with the significant change ($p = 0.005$) occurring at the end of the 2 years when compared to baseline. At both the 1-year and 2-year assessment points, it was also noted that daily steps were significantly different ($p < 0.05$) when compared to baseline measures.[113] Thus, confirming that as the disease progresses the propensity for gait speed to decrease is reinforced by previous literature.

Spatial Parameters. Stride length is considered one full gait cycle, beginning with initial contact of one limb and ending with initial contact of the same limb. While step length is considered the distance from the initial contact of one limb to initial contact of the other limb. Decreased stride length is attributed to hypokinetic movement, which in conjunction with decreased cadence, are associated with reduced overall gait speed.[85] In individuals diagnosed with PD, increased cadence can result in freezing of gait, which when accompanied with decreased step length produces an ineffective stepping strategy.[114]

In 1986, Mathias et al[115] found a strong correlation ($r = 0.95$) between gait speed and step length in elderly adults. When compared to age matched controls, those with PD demonstrated a 23% reduction in stride length.[109] In 2018, Caetano et al[116] found a trend for decreased step length in meters (0.67 ± 0.11) in those diagnosed with PD compared to control (0.69 ± 0.07). Morris et al found an association between decreased step length and poor coordination, which may promote FOG.[117,118]

A study by Chee et al[117] compared individuals diagnosed with PD who experience FOG (PD + FOG), those without FOG (PD – FOG) and a control group. Step length was significantly different ($p < 0.05$) in PD + FOG (37.76 cm ± 18.18) and PD – FOG (64.40 cm ± 5.86) during their preferred speed.[117] After calculating normal step length (0.8 x leg length), markings were made at 25%, 50%, 75%, and 100% and participants were asked to take steps.[117] When assessing the preferred step length, PD + FOG's preferred step length mean was similar to 50% of normal step length, PD – FOG preferred step length was between 75% -100% normal step length, and control group preferred step length was almost exactly at 100% normal step length.[117] Concluding that those who experience FOG, often prefer a decreased stride length.[117]

Gait analysis provides physical therapists with gait impairments such as decreased step length, decreased stride length, and decreased speed. These gait impairments along with results of other assessment tools allow clinicians to develop a holistic plan of care for individuals diagnosed with PD. Such as treatment strategies that have been found to improve stride length include stepping over certain types of cues.[109] The plan of care will include evidence-based interventions to reduce impairments and improve functionality in individuals diagnosed with PD.

Effects of Medications on Gait Parameters. The neurotransmitter imbalance that occurs within the basal ganglia results in major spatial and temporal parameter constraints in individuals with PD.[118] This imbalance affects the ability to perform sequential movements such as walking and turning.[118] Thus, medications such as Levodopa are used to improve movement speed and amplitude.[118] While taking medication, those diagnosed with PD experience "on" and "off" medication phenomenon. Throughout this continuous cycle, there will be a "peak – dose" time, which occurs approximately 1 hour after administration of medication.[118] In a case study by Morris et al[118] stride length varied based upon medication. During the end-of-dose period stride length measured at 0.972 meters, while at peak- dose it increased to 1.061 meters.[118] The addition of verbal cues during peak- dose increased the stride length to maximal value of 1.29 meters.[118] In 2015, a study by Hoskovcová et al[15] found there to be no significant difference (p = 0.902) in gait speed when ON-medication between fallers and non-fallers diagnosed with PD.

Ellis et al[119] found that there was a significant difference (p = 0.12) in comfortable walking speed in a group taking medication and receiving physical therapy compared to a control medication only group. Thus, supporting the short-term benefits from physical therapy in addition to medication treatment to improve mobility and function. When treating individuals with PD, clinicians must communicate the importance of medication dosage and timing and how it relates to function. Allowing clinicians to provide patients with the support and knowledge to optimally benefit from physical therapy sessions.

BALANCE AND GAIT INTERVENTIONS

In a systematic review of exercise interventions for people with PD, Goodwin et al[120] found that exercise benefits physical functioning, health-related quality of life, strength, and balance in individuals with PD. The motor symptoms of PD often include postural instability and postural rigidity that often restrict one's desire to participate in activities. King et al[121] found that those participating in group therapy sessions demonstrated the most improvement in gait measures (gait variability, stride, and freezing of gait) compared to those receiving individual treatment sessions or performing a home exercise program. Those receiving individual care did show the most improvements in balance, apathy, self-efficacy, and depression.[121] The acknowledgement of the isolation seen in PD and benefits of group therapy, has resulted in the development a variety of group classes and alternative therapies for individuals diagnosed with PD.

Recently, boxing, cycling, Lee Silverman Voice Treatment (LSVT), and Tai Chi have been utilized as therapeutic modalities to improve gait and balance in PD. These evidence-based strategies often incorporate activities that are salient and enjoyable to encourage participation. Performed in individual sessions or group sessions, these strategies often provide both physical and emotional support for those diagnosed with PD.

Boxing. Recently, Rock Steady has become a popular program that utilizes boxing as an approach to improve PD. Boxing incorporates the entire body, in which both upper extremity and lower extremity movements are performed in an explosive manner.[122] The explosive high-speed arm motions in conjunction with trunk rotations challenge anticipatory postural control.[121] In a case series by Combs et al[122], those with moderate to severe (H&Y 3 and 4) improved their BBS following 12- weeks of boxing improving their score by 5 points to meet MDC. Those with mild PD, showed little improvement following 12-week boxing intervention due to scoring high on the BBS at baseline.[122] Improvements were also made on the ABC, with five of the six participants maintaining or increasing their score upon completion of the boxing intervention.[122] Boxing further improved gait and mobility, with improvements in TUG score and gait speed by all six participants.[122] Specifically improving gait speed by 23% in those with mild (H&Y 1 and 2) PD.[122] With improvements noted in balance and gait, boxing seems to feasible regardless of stage of PD. However, a point of contention is the positioning often seen with boxing, which involves a flexed position reinforcing the slumped and flexed posture associated with PD.

Cycling. Cycling is thought to provide a safe intervention for individuals with PD with a reduced risk of injuries. In 2009, Ridgel et al[123] looked at forced exercise (FE) and voluntary exercise (VE) in individuals with PD. Ten participants completed 8 weeks of cycling of FE at a rate 30% greater than voluntary rate, while those pedaling at VE performed at preferred rate.[123] Upon completion of the 8 week cycling program, those who performed at FE saw a 35% improvement in the UPDRS motor score.[123] Meanwhile, those who performed at VE saw no difference in the UPDRS motor score.[123] In 2012, Ridgel et al[124] found that after a single bout of active-assisted cycling, there was an improvement in tremor during “off-medication” that was similar to tremor during “on-medication.” In 2015, Ridgel et al[125] studied the effects of dynamic cycling on gait and balance in individuals with PD. Dynamic cycling was defined as a motor speed output speed between 75-85 rpm.[125] During dynamic cycling, the motor did the majority of the work, while cyclists were encouraged to actively pedal during training.[125] While static cycling involved the cyclist pedaling at a self-select speed without motor assist.[125]

Upon completion of three sessions of cycling intervention, there was a significant difference ($p < 0.05$) in overall UPDRS motor score between dynamic and static cycling.[125] Specifically, those participating in dynamic cycling improved their overall UPDRS motor score by 13.9% compared the 0.9% experienced by those performing static cycling.[125]

In 2015, Arcolin et al[126] compared the effects of cycle ergometer training to treadmill training in individuals with PD. Participants also performed common exercises such as “sit-to-stand” and “get in/out of bed” daily. Following three weeks of training at 60-minutes a day there was a 4% increase in cadence for both groups.[126] Further gait analysis revealed the treadmill training increased their stride length (13%) and gait speed (19%) compared to those in the cycling group’s stride length (7%) and gait speed (12%).[126] For both groups gait speed and stride length were both significantly different ($p < 0.005$) from pre-intervention to post-intervention assessments.[126] The 6 MWT distance was significantly different ($p < 0.0005$) for all participants.[126] Cadence was not significantly different for the treadmill group ($p < 0.07$) yet was significantly different for the cycling group ($p < 0.05$).[126] Finally, there was a significant improvement in the TUG ($p < 0.05$) for both groups.[126] As a result of this study, Arcolin et al[126] reported that cycle ergometer training improved in gait impairments and is a safe alternative to treadmill training for individuals with PD.

LSVT. Derived from the Lee Silverman Voice Treatment, LSVT BIG was developed to improve motor performance in individuals with PD. LSVT exercises include sitting and standing movement patterns to create high-amplitude movements, improve initiation of movement, and improve motor control.[127] In a study by Millage et al[127], participants (*n* = 9) received four days a week for four weeks of LSVT BIG, which resulted in improvements in gait speed and balance measures. Specifically, all participants met MCID in at least one of the primary measures in this study (gait speed, FGA, BBS, and UPDRS) upon completion of LSVT intervention.[127] A case series by Janssens et al[128] found that after the four times a week for four weeks of LSVT BIG, participants did improve their TUG and FGA scores. These improvements, however, did not meet the MDC.[128] One of the three participants did however reveal a considerable improvement in the FOGQ from 12/24 at baseline to 4/24 at post training measurement.[128] In 2010, Ebersbach et al[129] compared three groups of interventions; LSVT BIG, Nordic pole walking, and home exercise program. Upon completion of the study, there was a significant difference noted between groups on the UPDRS (p , 0.001), TUG ($p < 0.033$), and 10 MWT ($p = 0.05$).[129] Greatest improvements for all three measures were noted within the LSVT BIG group.[129] However, there was no significant difference ($p = 0.264$) in quality of life measure (PDQ-39) between groups.[129]

Tai Chi. Individuals diagnosed with PD have significantly impaired balance and often seek out exercise programs within the community. Tai Chi is a balance-based exercise program that improves strength and balance in older adults.[130-132] In 2012, Li et al[131] compared three groups of exercise: Tai Chi, Resistance training, and stretching. From baseline measurements to a six-month assessment, there was a significant difference ($p < 0.01$) in gait speed between Tai Chi and stretching groups.[131] However, there was no significant difference noted in gait speed between Tai Chi and resistance training group at six-month assessment.[131] Likewise, when testing the TUG there was a significant difference ($p < 0.01$) between Tai Chi and stretching group and no significant between Tai Chi and resistance training group.[131] Over the six-month study, 76 of the 195 participants experienced 381 falls, with the Tai Chi group experiencing the least compared to the other groups.[131] As a community program, Tai Chi offers those with early stages of PD an exercise program that will improve their balance and provide a social support to improve their QOL.

TREADMILL TRAINING FOR PARKINSON'S DISEASE

There are complications related to a sedentary lifestyle in those with PD; therapeutic interventions such as physical activity aid in reducing symptoms and improving gait and balance.[108] Gait training in those with PD, often uses verbal and visual cues or auditory cueing via metronome. These approaches, while beneficial, have inconsistent carryover effects and are not always retained once the cue is withdrawn.[133] Delineating the most beneficial interventions to improve gait impairments in PD, becomes a crucial step in the management of this progressive disease.

Treadmill training is the most frequently used exercise modality in those with PD, as it is comparable to daily ambulation.[108] Treadmill training has been found to improve both gait speed and stride length in older frail adults.[134] Improvements in gait impairments following treadmill training, may be due to stimulating neuroplasticity, thus improving motor function in individuals with PD.[135] Recently, Thumm et al[136] found that prefrontal lobe activation was significantly different ($p < 0.01$) while performing treadmill training when compared to overground walking. Supporting the notion that improved cognitive processing occurs during externally paced treadmill training.

Treadmill training individuals diagnosed with PD can promote physical activity, aerobic capacity, and improve the motor symptoms of PD.[134-136] However, there are unique considerations such as training intensity, heart rate, and perceived exertion that must be consider prior to initiating a treadmill training program in individuals with PD.

Training Intensity. Training at higher intensity may result in greater improvements in symptom reduction and cognitive function when compared to training at lower intensities.[137,138] Developing a plan of care that provides enough intensity to make neuroprotective changes without harming the patient is always a challenge for clinicians. Often under the assumption that those diagnosed with neurologic diagnoses cannot tolerate vigorous exercise, clinicians may not challenge their patients enough. Clinicians whom strive to challenge their patients for optimal improvement, will consider factors such as heart rate, perceived exertion, and speed when performing treadmill training.

Heart Rate. When deciding on exercise prescription, clinicians must consider cardiovascular dysfunction in PD and how it can make it difficult to assess exercise tolerance.[139] According to the AHA/ACSM guidelines, treadmill training within the range of 50% - 90%HR_{max}, specifying the ranges for light intensity (57% - 63%HR_{max}), moderate-intensity (64% - 75%HR_{max}), and vigorous intensity (76% - 95%HR_{max}).[140] Within these guidelines, it can be difficult to monitor HR responses to exercise leading to the use of rate of perceived exertions scales (RPE) scales. In 2016, Bryant et al[141] cardiovascular response to treadmill exercise did not vary based on disease severity

(H&Y 2, 2.5, or 3). In conclusion, Bryan et al[141] stated that treadmill training is a safe therapeutic modality for individuals diagnosed with PD.

Clinicians must always be cognizant of potential compensations while treadmill training. Berling et al[142] found that if an individual is holding onto the handrail while treadmill training, it results in a reduction in heart rate and cardiopulmonary effort. Resulting in a potentially inaccurate representation of intensity based on heart rate while treadmill training.[108] Therefore, simply instructing an individual to use external support such as a handrail, may provide an inaccurate depiction of the intensity level and therapists must use other forms such as perceived exertion to determine intensity.

Borg Rate of Perceived Exertion (Borg). Common symptoms of idiopathic hypotension such as dizziness and lightheadedness are often seen as cardiac dysfunction in individuals with PD. Therefore, it is extremely important to monitor exercise intensity through tools such as heart rate and rate of perceived exertion (RPE). The Borg was developed to monitor and quantify perceived effort during exercise.[143] The 15-grade scale (6-20) for perceived exertion was developed to denote heart rate ranges from 60-200 beats*min^{-1}.[143] In a study by Penko et al[139] there was a significant relationship between heart rate and RPE ($r = 0.61$, $p < 0.001$) and between workload and RPE ($r = 0.77$, $p < 0.001$).[139] In a study involving 38 participants diagnosed with PD, both heart rate and workload were considered significant predictors of the RPE score ($p < 0.001$), indicating concurrent validity of the Borg scale as a measure of exertion in individuals with PD.[139] Penko et al[139] determined the Borg RPE scale an appropriate tool to monitor intensity when heart rate monitoring is not permissible in individuals with PD.

Clinicians often utilize a RPE scale such as the Borg scale to assess exercise tolerance during aerobic activity. In the study by Nelson et al[108], RPE is considered a consistent indicator of self-reported training intensity in individuals diagnosed with PD. Nelson et al[108] determined the minimum detectable change (MDC) for RPE (1.0) and test-retest reliability (ICC = 0.9) and MDC for heart rate (4.9) and test-retest reliability (ICC = 1.0) during forward treadmill training in individuals with PD. Penko et al[139] found a positive relationship between RPE and HR, (r =0.61, $p \leq 0.001$) and a strong, positive correlation between RPE and workload ($r = 0.77$, $p \leq 0.001$).[139] Validity of RPE scale use was found by Penko et al[139] as HR was a significant predictor of RPE ($p \leq 0.001$) and workload ($p \leq 0.001$). Training at a higher intensity, determined by a higher RPE is a promising approach to promote neuroplastic changes in individuals diagnosed with PD. High-intensity exercise on a motorized treadmill has been shown to have dopamine sparing qualities and improve motor function in rodents.[144,145]

Speed. During the evaluation process, physical therapists will assess gait speed using assessment tools or computerized gait mats. These tools provide us with helpful data, such as overground gait speed. In 2012, Earhart et al[146] discussed the benefits of treadmill training at the same speed as self-selected overground speed, suggesting it may be more effective and tolerable than high-intensity treadmill training. With little research including treadmill training protocols for individuals diagnosed with PD, clinicians often use their own discretion. Recently, in a study by Schenkman et al[147] the feasibility of high-intensity treadmill training was studied in individuals with PD. High-intensity treadmill training was defined as four days per week at 80-85% maximum heart rate, while moderate-intensity training was four days per week at 60-65%.[147] Of the participants in this study, those in the high-intensity group on average attended 2.8 (95% CI, 2.4-3.2) days per week and trained at an average of 80.2% (95% CI, 2.8-3.6; $p = 0.13$).[147] Compared to those in the moderate-intensity group, which on average attended 3.2 (95% CI, 2.8-3.6) and trained at 65.9% (95% CI, 64.2-67.7%) maximum heart rate.[147] Following the high-intensity training there was an increase in VO_2max of 1.9 mL/min/kg (8%) compared to the usual care group which experienced a decline of 1.3 mL/min/kg (5%).[147] Of the 128 participants in this study, only 2 serious adverse events occurred within the moderate-intensity group and were unrelated to exercises, providing support to clinicians that high-intensity if prescribed appropriately is tolerable within this patient population.[147]

TREADMILL TRAINING STRATEGIES

When developing a treadmill program for individuals with PD, physical therapists consider aspects such as frequency and duration as well as mode of treadmill. The benefits from treadmill training have been found from varying frequencies ranging from the immediate effects to long-term effects. In a study by Pohl et al[148] the researchers found the immediate effects of a single intervention of speed-dependent treadmill training and progressive treadmill training significantly improved ($p < 0.05$) all basic gait parameters including gait speed and stride length.[148] In contrast, these improvements in immediate effects of conventional gait training were not significant. While traditional frequency may include two to three times a week for at least four weeks, it is encouraging to know that the benefits of treadmill training can be immediate in individuals with PD.

To improve endurance, treadmill training often lasts 30 minutes[147-149] to achieve benefits of cardiovascular per American College of Sports Medicine (ACSM) guidelines.[150] Recently, high-intensity interval training (HIT) has become a point of interest in treadmill training. Within the stroke population, several studies have looked at the benefits of HIT noticing the benefits are superior to low-intensity training.[151] When training at the high-intensity levels, the goal is not endurance. The goal of HIT is to improve strength and has been found to benefit patients with cardiac and pulmonary disease.[152] In individuals with stroke, HIT treadmill training duration can vary between 30 seconds to four-minute bursts of high-intensity speed.[152,153] Askim et al[152] found that high-intensity aerobic interval training is feasible for treadmill training in the stroke population. HIT treadmill training has not been studied within the PD population.

To ensure safety, clinicians frequently use a harness system during treadmill training sessions. Toole et al154 found that the effects of unloading and loading during treadmill training were compared. The unloading group experienced 25% body weight reduction from a Biodex Unweighing system.[154] This study compared the unloading group to a loading group, which wore a scuba belt (increase 5% body weight) and a control treadmill group. All groups increased stride length (4.5 cm) and gait velocity (2.5 cm/sec).[154] In conclusion, this study revealed the benefits of treadmill training regardless of the weight bearing in individuals with PD.

Motorized Treadmill. Numerous treatment strategies are available to facilitate safety with gait and balance, thus improving independence with functional mobility. Motorized treadmill training is frequently used by physical therapists to improve strength, endurance, balance, and spatial-temporal parameters of gait. Motorized treadmill training has the potential to restore the rhythmicity and impact fall risk, with benefits noted following intensive treadmill training.[135]

In 2014, Harro et al[155] found speed-dependent treadmill training resulted in a statistically significant ($p = 0.045$) reduction in falls based on the Sensory Organization Test. In the early stages of PD, treadmill training is a promising approach for treatment of gait dysfunction.[156] In PD, external sensory cues help with transitional movements, therefore the repetitive stimulus of treadmill training helps promote a reciprocal gait pattern.[156] Mishra et al[156] suggested that external rhythmic cues provided by treadmill training may improve the rhythmicity and speed of gait and balance, and found statistically significant ($p \leq 0.002$) improvements in gait speed as a result of treadmill training. In this study, the pre-treadmill training gait speed mean estimated was 0.46m/s (*SD* ± 0.155) and post-treadmill training mean gait speed was 0.736 (SD±0.205).[156] Along with improvements in specific spatial-temporal parameter of stride length was also statistically significant ($p \leq 0.05$).[156]

In a systematic review by Merholz et al[157] eight treadmill-based studies involving individuals diagnosed with PD were reviewed. Improvements were noted following treadmill training in gait speed (mean difference 0.21 m/s, 95% CI = 0.71-0.84, $p = 0.003$, 7 studies) and stride length (mean difference 0.07m, 95% CI = 0.00- 0.84, $p = 0.05$, 5 studies) and walking distance (mean difference 358 meters, 95% CI = 289-426, $p < 0.0001$). Of all the treadmill studies review by Merholz et al[157] they report that treadmill training did not increase drop-out rate amongst individuals with PD.

In 2013, Rose et al[81] found walking distance improved significantly ($p = 0.013$) by 10.6% following treadmill training when compared to the control group without treadmill training in individuals with PD. In 2012, a case series by Oh-Park et al[134] found an improvement in gait speed (18.8%) and stride length (22%) from baseline over an 8-week training session. These results were similar to a study by Patterson et al[158] which found an increase of gait speed of 22% and stride length increased by 13% in individuals with chronic stroke at a 6-month follow-up. Short-term benefits of gait speed significantly improved ($p = 0.014$) from a pre-treadmill training speed of 1.17 m/s ($SD \pm 0.17$) to a post-treadmill training gait speed of 1.25 m/s ($SD \pm 0.16$) following a 6-week intensive treadmill training program.[135] When assessed 4 to 5 weeks later for long-term effects, those improvements in gait speed remain significant (1.16±0.024 m/s, $p = 0.28$) when compared to baseline.[135]

Treadmill training traditionally involves forward treadmill training; however, clinicians are incorporating various directions of treadmill training during treatment sessions. In a case series involving individuals diagnosed with PD, their normal (self-selected) gait speed increased by 10.0% following forward treadmill training and continued to improve it even more by an additional 10.8% following 4 weeks of multi-directional treadmill training.[49] In contrast, when looking at fastest gait speed, Smith et al[49] found the greatest change (11.7%) following the multi-directional treadmill training. In 2015, Smith et al[49] found that with the addition of multi-directional treadmill training (backward and side stepping) in addition to forward treadmill training resulted in larger stride lengths with a change of 4.1% in contrast to 0.2% with only forward treadmill training in individuals with PD.

In 2015, Smith et al[49] looked at the effects of treadmill training with individuals diagnosed with PD. The four participants ranged in H&Y 2-4 and performed 4 weeks of forward treadmill training and followed with 4 weeks of multi-directional treadmill training (backward and side stepping).[49] At the mid-intervention assessment, the Mini-BESTest revealed a percent change of 21.8%, with no significant improvement for the last 4 weeks.[49] Once the addition of the multi-directional treadmill training was added, there was an improvement of the fall risk assessments iTUG (14.9%) and FSST (10.6%) from Week 5-8.[49]

A randomized clinical trial by Trigueiro et al[159] performed treadmill training under three separate conditions, 0%, 5%, and 10% additional load at three times a week for one month. Upon completion of the treadmill training, there was a significant improvement in postural instability ($F = 11.23$; $p = 0.002$) and motor function ($F = 12.92$; $p < 0.01$) regardless of the additional load percentage.[159] Ganesan et al[160] found that partial weight-supported treadmill gait training resulted in significantly better ($p < 0.05$) motor score on the UPDRS when compare to a conventional gait training group.

In 2007, Herman et al[135] developed an intensive six-week treadmill training program for individuals diagnosed with PD. Initially, the protocol began treadmill training at 80% of the overground comfortable walking speed.[135] Progressing weekly in speed, by week three the treadmill reached a goal of 5-10% above that week's overground comfortable walking speed.[135] Designed to replicate the rehabilitation environment, physical therapists provided positive feedback and reinforcement. Completion of the 6-week intensive treadmill training program has been found to significantly increase ($p = 0.012$) stride length from a pre-treadmill stride length of 1.17m ($SD \pm 0.22$) to a post-treadmill training of 1.25m ($SD \pm 0.22$) in individuals with PD.[135] At a 4 to 5 week follow-up, the stride length remained significant ($p = 0.043$) with a mean of 1.26m ($SD \pm 0.21$).[135]

Non-Motorized Treadmill. Recently, NMT have become a point of interest amongst clinicians in hopes to drive intensity while treadmill training. Morgan et al[161] found a significant increase in RPE with an increase of 25% of the time during non-motorized treadmill training ($r^2 = 0.81$) as opposed to motorized treadmill training. In 2016, Morgan et al[161] found graded exercise testing with NMT in VO_2, HR, RPE ($p \leq 0.05$). Consisting of two distinctive designs, non-motorized treadmills can be flat or curved as seen with the Woodway Curve™ design. The curved design is to permit runners to attain full velocity and facilitate increased stride length and longer swing phases.[161,162] In a study by Hachett et al[163] there was a significant difference in stride length ($p = 0.033$) and step length ($p = 0.039$) following training on a NMT compared to a MT. Training on a NMT results in a more natural and efficient gait pattern and improved quality of life.[161,162]

Current literature supports the use of non-motorized treadmill training for cardiorespiratory benefits in healthy individuals. Morgan et al[161] found when testing at matched speeds between NMT and MT training there was a 67% greater HR in the non-motorized treadmill at submaximal levels. A potential benefit of the non-motorized treadmill training is the participant generates the propulsion on their own, permitting control over the velocity. During non-motorized treadmill training the participant must generate power to move themselves vertically, and dynamically control belt speed, thus increasing the intensity requirements while participating in non-motorized treadmill training when compared to motorized treadmill training.[161,164] Potentially improving gait speed thru application of principles of neuroplasticity such as intensity, specificity, and repetition through NMT.[165] Treadmill training using a NMT has yet to be studied within the PD population.

In conclusion, gait speed remains one of the most frequently used outcome measurements in physical therapy.[11] There is potential for an associated relationship between gait difficulty and worsening QOL in Parkinson's disease.[87] Limited research has explored the effects of non-motorized treadmill training on the spatial-temporal parameters of gait in those with neurologic diagnoses, especially PD. A study by Combs et al[18] found both comfortable and fast walking speeds were moderately associated with perceptions of QOL related to mobility on the PDQ-39. Reiterating the importance of developing interventions to decrease the burden of gait difficulty in Parkinson's disease.[87]

Park et al[20] found that when comparing early start exercise group versus delayed start exercise group there was no statistically significant difference ($p = 0.86$) between groups on timed walking. Suggesting initiation of an exercise program is beneficial throughout the stages of PD, positive influencing both cognitive and motor impairments.[20] Due to motor impairments having a such an impact on quality of life in PD, it should continue to be a focus in research. Therefore, to continue to positively impact quality of life in PD, research should assess the potential benefits of NMT training to improve gait speed and quality of life.

The first purpose of this study is to determine the test-retest reliability and interrater reliability of the mFSST to determine fall risk in individuals diagnosed with Parkinson's disease. The second purpose of this study was to determine the relationship of the fall risk and commonly used outcome measure for individuals with PD. Lastly, the third purpose of this study will compare two gait training interventions; non-motorized and motorized treadmill training in individuals with PD.

Through assessment of a fall risk measure in individuals diagnosed with Parkinson's disease, we can provide clinicians with the reliability of a tool that may improve efficiency of fall risk testing. This assessment tool may have a relationship with other outcome measures that validate it as a beneficial tool for assessing fall risk. Finally, to connect the relationship of fall risk and gait adaptability, we can assess if non-motorized treadmill training is superior to motorized treadmill training on gait parameters and fall risk.

CHAPTER III

RELIABILITY AND VALIDITY OF MODIFIED FOUR SQUARE STEP TEST (mFSST) PERFORMANCE IN PEOPLE WITH PARKINSON'S DISEASE

INTRODUCTION

Parkinson's disease is a progressive disease that is one of the most prevalent diseases involving the CNS and is estimated to affect more than 1 million people in the United States.[1-4] The pathology of PD involves a depletion of DA, within the substantia nigra of the basal ganglia.[1-4] This complex disorder is marked with non-motor and motor impairments, including gait abnormalities and postural instability. As a result of balance dysfunction and postural instability, falls and injuries are common composite symptoms of PD.[5] It is estimated that 60.5% of individuals with PD report a fall history, with 39% reporting frequent falls.[6] Subsequently, those diagnosed with PD often restrict activity participation due to FOF and report a decreased QOL.[5]

Fall risk and FOF are common issues noted in individuals with postural instabilities.[7] In 1990, Tinetti et al[8] published an article describing FOF as the lack of self-confidence in performing normal activities without falling. Eight years later, Howland et al[9] published a study that described FOF as a rational and cautious response to a potentially dangerous event and could be viewed as prevention. Also stating that while it is a reasonable response, excessive FOF may compromise an individual's well-being.[9] Adkin et al[7] found that FOF was more evident in individuals with PD when compared to age matched healthy individuals. Recently in a study that looked at falls and

FOF in individuals with PD, 62% of the participants experienced a fall or frequent falls.[5] Allen et al[10] discussed how fear of falling is found to be high when compared to actual fall risk in individuals with PD.

Determination of an individual's fall risk involves multiple factors that contribute to the likelihood that an individual will fall.[11] Hausdorff et al[11], found that when compared to healthy controls, those with PD experience more falls within a 6-month timeframe (0.9±1.0, $p < 0.05$). In a study by Allen et al[33], around 70% of individuals with PD who experience a fall will experience recurrent falls. Physical therapists play an important role in determining if an individual diagnosed with PD is considered a fall risk. With numerous assessment tools available to determine if an individual is a fall risk, there is a significant challenge in selecting the best tool to assess balance. Factors such as time, equipment, use of assistive devices, and environment all contribute to the selection of assessment tools.

The FSST assesses dynamic balance by requiring individuals to step over obstacles in multiple directions.[12-14] The FSST was found to have high interrater reliability (ICC = 0.99) in individuals with PD.[13] In 2013, with a moderate sensitivity (0.78) of capturing fall risk in individuals with PD, a score of greater than 9.68 seconds is considered a fall risk.[13] While the FSST is a quick fall assessment tool, with minimal equipment (four canes) and minimal space required to complete, these can be considered limitations in some settings. Individuals occasionally are not able to complete the FSST due to their inability to step over raised obstacles. So, in 2016, Roos et al[12] designed the mFSST by simply replacing the canes with 2-inch tape. Roos et al[12] found excellent interrater, intra rater, and test-retest reliability (ICC =0.81-0.99) in individuals post stroke. Roos et al[12] found that individuals post stroke were able to successfully complete the mFSST at a higher percentage than the FSST. The purpose of this study is to determine the reliability and validity of the mFSST in individuals with PD.

METHODS

Participants

Twenty-eight community dwelling people with PD were recruited from a local Parkinson's disease support group through an advertisement in a support group email list. Sample required to demonstrate adequate power was calculated using G*Power and determined to be 17 participants for the interrater and test-retest reliability. Inclusion criteria included: age 55-85, diagnosed with PD Hoehn & Yahr I-III, and able to walk 10 meters with assistive device. To detect cognitive impairments, the participants were screened using the MoCA and must receive a score ≥ 26/30.[15,16] Individuals were excluded if they had a diagnosis of a neurological condition other than PD or had uncontrolled cardiovascular, orthopedic, and/or metabolic condition that would make moderate to vigorous aerobic exercise unsafe. Participants were asked to take their medication one to two hours prior to testing, to ensure they were tested while on-medication. All participants signed informed consents that had been approved by the Institutional Review Boards at Texas Woman's University in Houston, Texas and the University of St. Augustine for Health Sciences in St. Augustine, Florida. Demographic information is presented in Table 3.1.

Table 3.1 Participant Demographics (*n* = 27)

Characteristic	Mean (*SD*)	
Gender (male, female)	15, 12	
Age (years)	73.07 (6.3)	
MoCA	27.81(1.3)	
Hoehn & Yahr		
I		9
II		9
III		9

Abbreviations:
SD- Standard Deviation
MoCA- Montreal Cognitive Assessment

Instruments

Four Square Step Test. To complete the FSST, participants performed the test as described by Dite et al.[14] Single point canes laid flat on the ground and placed in a cross position resulting in four separate squares. Participants complete the test by stepping into each square with both feet while facing forward throughout the entire test. The stepping sequence for this test included a specific sequence: forward, right, backward, left, right, forward, left, backward.[13,14] Timing begins when the participant steps forward and makes foot contact within square 2 and ends when the subject steps backwards and returns to square 1 with both feet. To successfully complete this test, participants are instructed to complete this entire sequence as quickly and safely as possible, without touching the canes and if possible and to face forward throughout the entire sequence. The FSST has been shown to have high interrater, intrarater, and test-retest reliability in individuals with PD.[13,14,17]

Modified Four Square Step Test

Similar to the FSST, the mFSST requires participants to perform the same sequence; with the modification of replacing canes with 2 inch tape.[12] Timing of the mFSST is the same as the FSST beginning with the first foot in square 2 and ending when both feet return to square 1. The mFSST has been deemed a reliable and valid tool to assess fall risk in individuals post stroke.[12]

PROCEDURES

Participants attended one testing session, in which they completed the FSST and mFSST. To complete the FSST, participants stepped over canes in a standardized sequence. To complete the mFSST, participants stepped over two-inch tape in the same standardized sequence as the FSST. To decrease practice effect, participants randomly selected a card which would determine the test to perform first.

Participants completed the FSST and mFSST by facing forward while standing in quadrant 1, then completing the sequence in a clockwise manner though quadrant 4. Once the subject returns to quadrant 1, they then go counterclockwise stepping into quadrant 4 to end the test returning to quadrant 1 (see Figure 3.1). Participants were asked to "complete the sequence as fast and safe as possible without touching the cane/tape. Both feet must make contact with each square and if possible, face forward throughout the entire sequence. The clock will begin when I say go and will end when both feet return to square 1. Are you ready?" For both tests, participants were permitted to have one practice trial before beginning testing. During that time, assessors provided feedback as needed to ensure correct test performance. Once testing began, participants performed both tests two times and the score was averaged. Participants completed the mFSST a total of four repetitions, beginning with the first two trials and waiting at least 20 minutes before completing the last two trials. If participants experienced a mistrial during testing, an additional trial was performed. Two PT students provided stand by assist for safety during the assessment. Participants wore a gait belt and took rest breaks as needed to prevent any fatigue.

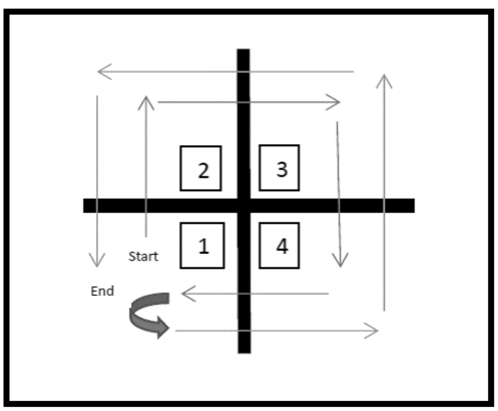

Figure 3.1: mFSST and FSST testing sequence

Reliability

To ensure consistency of timing the mFSST/FSST, assessors completed a 10-minute training session in which the testing procedures, instructions, and scoring were discussed. Assessors were deemed appropriate after assessing a volunteer's completion of the mFSST/FSST, which included a demonstration, verbalizing instructions, and correct timing of the mFSST/FSST.

To determine interrater reliability of the mFSST, two licensed PTswith greater than three years of experience treating patients simultaneously timed the test. During the test, assessors determined if the test was successfully completed and recorded the time. The same assessors with more than three years of experience of treating patients established the test-retest reliability during the session, which were separated by at least 20-60 minutes. Timed results of both trials for the mFSST were averaged and recorded.

Validity

To determine concurrent validity in this study, the mFSST and the FSST were assessed during the same testing session.

Data Analysis

Descriptive statistics were calculated using the average of the two trials for both the mFSST and FSST. Pearson's correlation was used to determine the interrater and test-retest reliability of the mFSST. In addition, the ICCs model 2,2 was used to evaluate interrater reliability, and test-retest reliability of the mFSST. To determine the validity of the mFSST and the FSST, a Pearson's correlation was performed. For all analyses, the average of two trials the FSST and mFSST were used while the participant was on-medication. Statistical significance was set at $\alpha \leq 0.05$ for all analyses. All statistical analyses were calculated using SPSS 25 software (SPSS, INC, Chicago, IL).

RESULTS

A total of 28 participants were tested and 27 completed this study, see Table 3.1. One participant received a score < 26/30 on the MoCA and was not included in this study. To account for any practice effect between FSST and mFSST, participants randomly selected a card to determine which test was performed first (mFSST = 12, FSST = 15). The primary investigator and one additional consistent assessor completed the interrater and test-retest reliability assessments. For the interrater reliability, the subject's average of the first two trials were used in this study. For the test-retest reliability, the subject's average of the first two trials were compared to the average of the latter two trials that were completed 20-60 minutes following first assessment. To determine the validity of the mFSST, the average of the mFSST and the FSST were calculated.

The mean FSST performance was 10.91 ± 4.05 seconds, while the mean mFSST was 9.37 ± 2.24 seconds. There was a total of three mistrials for both the mFSST and the FSST. A mistrial was considered a trial in which the participant was unable to successfully complete with entire sequence. See Table 3.2 for mean mFSST and FSST per H&Y and MoCA score.

Table 3.2: Average mFSST and FSST time per H&Y and MoCA score

H&Y	n	mFSST	FSST
I	9	8.89 (1.88)	9.71 (1.69)
II	9	9.53 (2.41)	10.85 (2.90)
III	9	9.55 (2.71)	12.28 (6.63)
Overall		9.37 (2.24)	10.91 (4.05)
MoCA Score	n	mFSST	FSST
26	4	11.37 (1.75)	12.58 (0.77)
27	9	9.97 (2.87)	12.65 (6.38)
28	7	8.61 (1.34)	8.96 (1.38)
29	2	8.59 (1.09)	10.46 (1.34)
30	5	8.05 (1.57)	9.40 (1.42)

Abbreviations:
H&Y- Hoehn & Yahr
MoCA- Montreal Cognitive Assessment
mFSST- modified Four Square Step Test
FSST- Four Square Step Test

Reliability

To assess the relationship between assessors while timing the mFSST, a Pearson's correlation was calculated. The interrater reliability was excellent with a Pearson's correlation of $r = 0.999$, $p = 0.001$ ($ICC^{(2,2)} = 0.99$). To measure the relationship between two different assessment times, a Pearson's correlation was calculated. Test-retest reliability of the mFSST was excellent with a Pearson's correlation of $r = 0.916$, $p = 0.01$ ($ICC^{(2,2)} = 0.96$). See Table 3.3.

Validity

To validate the relationship between mFSST and FSST utilization for fall risk, Pearson's correlation was calculated. The average of the first two trials of the mFSST and FSST were high correlated with a Pearson's correlation of $r = 0.805$, $p = 0.01$.

See table 3.3. Figure 3.2 shows the mean differences between to mFSST and the FSST in Bland-Altman plot.

Table 3.3: Reliability and Validity of the mFSST in individuals with Parkinson's disease

	n	Pearson's correlation	$ICC_{2,2}$	95% CI of ICC	SEM
Interrater	27	0.999	0.999	0.999-1.00	0.07
Test-Retest	27	0.916	0.956	0.916-0.98	0.49
Concurrent Validity	27	0.805			

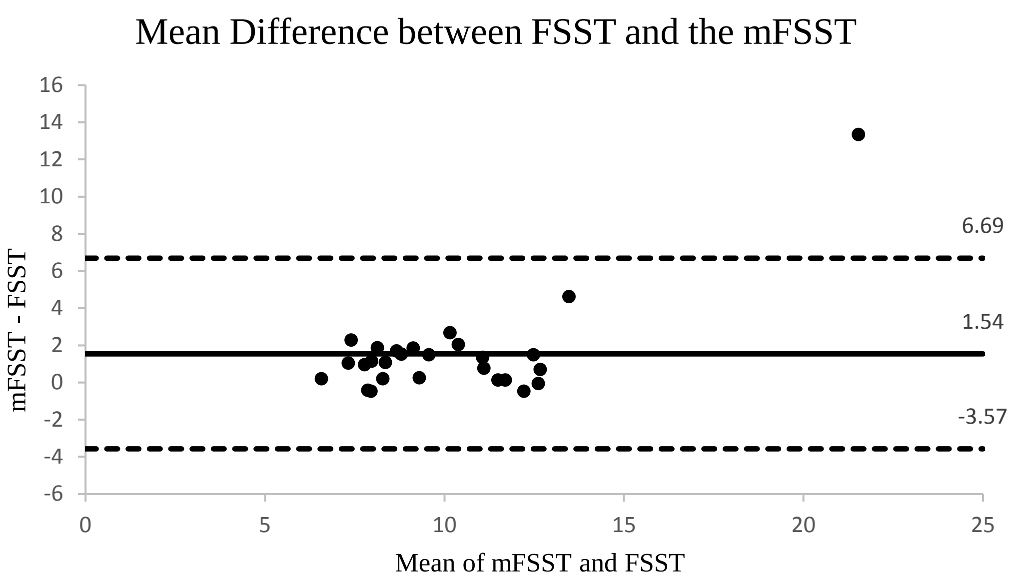

Figure 3.2: Bland-Altman plot for mean difference between FSST and the mFSST

DISCUSSION

This study describes the reliability and validity of an assessment tool of dynamic balance for individuals with PD. As a modified version of the highly reliable and valid FSST[13,14] the simple modification of replacing canes with tape has potentially made the assessment tool more feasible. To our understanding, this is the first study of the reliability and validity of the mFSST for individuals with PD. Previously studied by Roos et al[12] the mFSST has been shown to be a measure dynamic balance in individuals with stroke. With a successful completion rate of the mFSST 11% higher when compared to the FSST in individuals with stroke. Thus, making it a positive choice to assess dynamic balance for individuals with PD.

Ultimately, the interrater reliability, test-retest reliability and validity of the mFSST were excellent, matching the finding by Roos et al.[12] These preliminary findings suggest the mFSST as a reliable and valid assessment tool for individuals with PD while on-medication.

In this study, as the H&Y classification increased, the mFSST and FSST completion time similarly increased. Thus, suggesting that as the disease progresses there is a correlation with increased fall risk using the mFSST and FSST. Duncan et al[13] found the cut-off score of 9.68 seconds indicating a fall risk using the FSST in individuals with PD. As noted in table 3.2, the mean score for the FSST for H&Y stages I-III were all above the recommended cut-off score for FSST in individuals with PD.

Likewise, as cognitive ability decreased according to the MoCA, the mFSST score increased. With the max score on the MoCA (30) representing the fastest mean score for the mFSST (8.05 seconds) and the lowest score on the MoCA (26) at the slowest score (11.37 seconds). Similar to the findings by Hoops et al[15] that as the MoCA score decreased the risk of fall increased in individuals with PD.

The results of this study suggest that there is a strong correlation between the mFSST and the FSST for assessment of dynamic standing balance. The FSST is used to assess dynamic standing balance while avoiding obstacles.[12-14] Clinicians can feasibly assess dynamic standing balance while simply stepping over tape in multiple directions using the mFSST. In this study, the primary reason participants experienced a mistrial was due to incorrectly performing the correct sequence. Participants who experienced any mistrials during testing were provided an additional trial. While there were exactly three mistrials for both the mFSST and the FSST, there was no difference in successful completion rate of the assessment tools. In contrast, to the study by Roos et al[12] that revealed a successful completion rate of the FSST (60%) and mFSST (71%) in individuals with stroke.[12] Finding a statistically significant improvement (*p* = 0.04) in completion of the mFSST by individuals with stroke. No freezing episodes were noted throughout the testing of the mFSST or FSST. This may be due to the visual cue promoting a step over compensatory strategy.

As demonstrated in this study, the mFSST is an easy assessment tool to measure dynamic balance in multiple directions for individuals with PD. No adverse events occurred while testing standing dynamic balance using the mFSST during this study. This measure requires minimal space and minimal equipment and can be completed in a short amount of time. Thus, indicating the mFSST is feasible for physical therapists to implement in a variety of settings when working with individuals with PD.

Limitations

Participants in this study were community dwelling individuals from a local PD support group. Those who volunteered to participate in this study, may not fully depict a comprehensive representation of individuals with PD at varying levels of activity and participation. As those with an increased fall risk may not voluntarily participate in a study assessing fall risk due to fear of falling.

Additionally, the current study only assessed the mFSST while participants were on-medication. Thus, a limitation in this study includes testing only while on-medication, while participants may be at a higher fall risk while off-medication.

To determine test-retest reliability, the mFSST was re-administered at least 20-60 minutes after the initial assessment. To prevent any practice effect, future studies may increase the time between testing to at least one day.

Finally, while performing the mFSST mistrials were noted by assessors for each trial. However, assessors did not describe the cause of the mistrial including direction of stepping or confusion of sequence. Future studies should describe what causes a mistrial while performing the mFSST, to explore the role cognition has on completing the mFSST.

CONCLUSION

The mFSST is an assessment tool that measures the dynamic standing balance while stepping over tape in multiple directions. The mFSST demonstrates excellent interrater and test-retest reliability and excellent concurrent validity. As PD progresses, postural instability becomes a debilitating and activity restricting symptom that prevents participation in daily activities due to fear of falling. Therefore, identification of fall risk for individuals with PD is important as this disease progresses. The mFSST can be completed by a large percentage of individuals with PD with ease and little equipment in a variety of settings. This tool can provide clinicians insight into an individual's dynamic standing balance. This study supports the use of the mFSST for assessing dynamic standing balance in individuals with PD.

CHAPTER IV

THE RELATIONSHIP BETWEEN MODIFIED FOUR SQUARE STEP TEST (mFSST) AND OUTCOME MEASURES RELATED TO FALL RISK AND QUALITY OF LIFE IN INDIVIDUALS WITH PARKINSON'S DISEASE

INTRODUCTION

Parkinson's diseases is a progressive disease that is a one of the most prevalent diseases involving the CNS, estimated to be affecting more than one million people in the United States.[1-4] The pathology of PD involves a depletion of DA, within the substantia nigra of the basal ganglia.[1-4] As a result of the depletion of dopamine, the pathways that are responsible for inhibition become overactive and result in the signs and symptoms associated with PD. The common signs and symptoms associated with decreased dopamine may include a flexed posture, diminished equilibrium reactions, and decreased trunk rotation.[1,2]

Parkinson's disease is characterized by four cardinal motor features: bradykinesia, resting tremor, rigidity of muscles, and impaired posture.[1-5] These motor impairments progressively compromise balance, mobility, and participation in functional activities. As a result of balance dysfunction and postural instability, falls and injuries are common composite symptoms of PD.[6] As a result, there is an inherent increased risk of fall that is associated with the diagnosis of PD.

Fall risk and FOF are common issues noted in individuals with postural instabilities.[7] In 1990, Tinetti et al[8] published an article describing FOF as the lack of self-confidence in performing normal activities without falling. Eight years later, Howland et al[9] published a study which described FOF as a rational and cautious response to a potentially dangerous event that could be viewed as prevention. Adkin et al[7] found that FOF was more evident in individuals with PD when compared to age matched healthy individuals. Recently in a study that looked at falls and FOF in individuals with PD, 62% of the participants experienced a fall or frequent falls.[6] Allen et al[10] discussed how fear of falling is found to be high when compared to actual fall risk.

Potential factors that are associated with falls include cognitive impairments[11,12] freezing of gait[13], fear of falling[14], and balance impairment.[10] When these factors combine, individuals will often restrict their participation in life activities due to a debilitating FOF. Physical therapists often utilize outcome measures to determine if an individual is a fall risk. Outcome measure assessments are organized based on the International Classification of Functioning, Disability and Health (ICF) framework. The ICF is a decision-making process that is patient-centered, emphasizing the patient's roles and functions while identifying limitations.[15] Within the framework there are three domains; body structure/ impairment, activity limitations, and participation restriction.[15,16] To capture a holistic view of an individual's impairments and quality of life, it is important to address all three domains of the ICF. When properly used, the ICF provides clinicians a mechanism for making clinical decisions, developing clinical hypotheses, and developing a plan of care.[15] The purpose of this study is to determine the relationship between the mFSST and outcome measures related to fall risk and quality of life in individuals with PD.

METHODS

Participants

Twenty-eight community dwelling people with Parkinson's disease were recruited from local PD support group through advertisement in support group email list. Sample required to demonstrate adequate power was calculated using G*Power and determined to be 27 participants for the linear regression. Inclusion criteria included: age 55-85, diagnosed with PD Hoehn & Yahr (H&Y) I-III, and able to walk 10 meters with assistive device. To detect cognitive impairments, the participants were screened using the MoCA and must have received a score $\geq$ 26/30 on this measure.[17,18] Individuals were excluded if they had a diagnosis of a neurological condition other than PD or had uncontrolled cardiovascular, orthopedic, and/or metabolic condition that would make moderate to vigorous aerobic exercise unsafe. Participants were asked to take their medication one to two hours prior to testing, to ensure they were tested while on-medication. All participants signed informed consents that had been approved by the Institutional Review Boards at Texas Woman's University in Houston, Texas and the University of St. Augustine for Health Sciences in St. Augustine, Florida. Demographic and clinical characteristics information is presented in Table 4.1.

Table 4.1 Participant Demographics and Clinical Characteristics (*n* = 27)

Characteristic	Mean (*SD*)
Gender (male, female)	15, 12
Age (years)	73.07 (6.3)
Hoehn & Yahr	
I	9
II	9
III	9
MoCA (0-30)	27.81 (1.3)
TUG (sec)	9.35 (2.5)
FSST (sec)	10.92 (4.05)
mFSST (sec)	9.37 (2.24)
SS gait speed (m/s)	1.10 (0.21)
FC gait speed (m/s)	1.50 (0.38)
PFS-16 (16-80)	49.41 (14.53)
FOGQ (0-24)	5.63 (5.26)
ABC (0-100)	76.16 (18.55)
PDQ-SI (0- 156)	24.99 (12.30)

Abbreviations:
SS- self-selected
FC- fastest comfortable
Sec- seconds
m/s- meters/second
MocA- Montreal Cognitive Assessment
TUG- Time Up and Go
FSST- Four Square Step Test
mFSST- Modified Four Square Step Test
PFS-16- Parkinson’s Fatigue Scale -16
FOGQ- Freezing of Gait questionnaire
ABC- Activities-specific Balance Confidence scale
PDQ-39 SI- Parkinson’s disease questionnaire-39 Summary Index

Instruments

Zeno Walkway System

A Zeno with PKMAS[4] will be used to assess spatial-temporal parameters of gait.[19] The Zeno is a low profile gait mat consisting of a three-layer surface embedded with 16 levels of pressure that uses a sampling rate of 60Hz to 120Hz to assess dynamic gait.[19]

This 20-foot gait mat enables data collections and demonstrates reliability and validity of the PKMAS system (ICC = 0.844-0.99).[20] In 2017, a study determined the Zeno Walkway to have excellent concurrent validity (ICC = 0.854 to 0.976) when compared to the GAITRite walkway while testing adults at high fall risk gait spatial-temporal parameters of gait (comfortable and fast speeds).[21]

Four Square Step Test

To complete the FSST, participants performed the test as described by Dite et al.[22] Single point canes laid flat on the ground and placed in a cross position resulting in four separate squares. Participants complete the test by stepping into each square with both feet while facing forward throughout the entire test. The stepping sequence for this test include a specific sequence: forward, right, backward, left, right, forward, left, backward.[22,23] Timing begins when the participant steps forward and makes foot contact within square 2 and ends when the subject steps backwards and returns to square 1 with both feet. To successfully complete this test, participants are instructed to complete this

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entire sequence as quickly and safely as possible, without touching the canes and if possible, face forward throughout the entire sequence. The FSST has been shown to have high interrater, intrarater, and test-retest reliability in individuals with PD.[22-24]

Modified Four Square Step Test

Similar to the FSST, the mFSST requires participants to perform the same sequence; with the modification of replacing canes with 2-inch tape.[24] Timing of the mFSST is the same as the FSST beginning with the first foot in square 2 and ending when both feet return to square 1. The mFSST has been deemed a reliable and valid tool to assess fall risk in individuals post stroke.[24]

Timed Up and Go

In 1991, Podsiadlo et al[25] described the TUG as a simple clinical tool to assess lower limb function, mobility and fall risk. TUG is an outcome measure that assesses functional mobility, by measuring the time required for one's ability to stand up from a chair, walk 3 meters, turn around and sit down.[26,27] The TUG demonstrates excellent interrater reliability (ICC = 0.99) and test-retest reliability (ICC = 0.85) in individuals with parkinsonism.[28,29] Foreman et al[30] found the TUG was able to differentiate between PD fallers and non-fallers ($p < 0.006$) only when off-medication. With the mean score for fallers on-medication 12.21(*SD* ± 7.42) and off-medication 15.5(*SD* ± 11.03).[30]

Parkinson's Fatigue Scale

Fatigue is often reported by individuals with PD, it frequently impacts quality of life and can contribute to apathy and depression. The PFS-16 consists of 16-items, while encouraging the participants to rate their feelings and experience of fatigue over the prior 2 weeks. The scoring includes a range from 1 "strongly disagree" to 5 "strongly agree" with the total score then representing a sum of the 16-items. The higher the overall score of the PFS-16, indicates that fatigue is more impactful on an individual's life. Within the 16-items, seven of the questions assess the physical effects and nine assess the impact on daily functioning and socializing. This screening questionnaire takes about five minutes to complete and only requires paper and pen. In a study by Grace et al[31] the mean PFS-16 in individuals with PD 54.34(34.81) was significantly higher ($p < 0.001$) than a control group at 15.03(15.53). In 2018, Chong et al[32] found that when compared to caregiver's perception, those with PD perceived fatigue to be more bothersome than symptoms of bradykinesia and freezing of gait.[32] Fatigue has been shown to significantly correlate with fall frequency ($r = 0.254$, $p = 0.021$) in individuals with PD.[33]

Freezing of Gait Questionnaire

Freezing of gait is a disabling characteristic that is episodic in nature resulting in the inability to step during initiating gait or when turning while walking.[34] To assess freezing of gait, the FOGQ was developed and involves 6-items with a total score ranging from 0-26, the higher the score results in more FOG severity.[35] The FOGQ demonstrated a significant correlation between FOGQ and H&Y (r =0.66, $p = 0.01$), revealing that as the disease progresses through the H&Y staging there is an increase in freezing episodes.[36] Duncan et al[35] found that when individuals with PD who report freezing of gait (PD + FOG) reported a significantly different score ($p < 0.001$) on the FOGQ compared to those who do not report freezing of gait (PD-FOG). The average FOGQ score for PD + FOG was 12.88(±3.86) while the PD – FOG average score was 2.96(±2.49).[35]

Parkinson's Disease Questionnaire-39

The PDQ-39 is the most widely used self-reporting questionnaire consisting of 39-items and can take up to 20 minutes to complete.[37] This questionnaire was designed to reflect quality of life over the last month in eight different domains. The eight domains include: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. This questionnaire uses an ordinal scale from 0 to 4, 0 = never and 4 = always, with the lower the score indicating a better quality of life. Each separate domain can be scored or there can be an overall PDQ-SI.

In a study by Jenkinson[38] the PDQ-39 was completed by patients through a postal survey and at a clinic, the PDQ-39 SI was found to have a high internal reliability of Cronbach's alpha ($\alpha = 0.84$-0.89). For those assessed at a clinic ($n = 127$), there was a significant correlation between the PDQ-39 SI and the H&Y ($r = 0.51$, $p < 0.001$).[38] Concluding; the PDQ-39 SI to be useful in determining the impact of PD[38], with a score closer to 100 representing more health problems.[37]

Activities-specific Balance Confidence scale

Perceived confidence in performing ADLs can be assessed through the ABC. Consisting of 16- items, the ABC scale assesses ones perceived ability to maintain balance while performing various activities on a scale of 0-100%, with 100% representing full confidence.[28,39-42] The ABC was also developed to assess balance confidence in individuals at varying functional levels.[43] In a study by Steffen et al[28], the ABC scale demonstrated excellent test-retest reliability (ICC = 0.94) with a mean score of 70% (*SD* ± 19) in individuals with parkinsonism.[28] A score of $< 69\%$ on the ABC qualifies a high FOF, while a score of $\geq 69\%$ indicates a low FOF in individuals with PD.[45]

PROCEDURES

Participants attended one testing session, in which they completed the mFSST, FSST, TUG, and QOL measures (PFS-16, FOGQ, PDQ-39, and ABC). To begin the study, participants completed the mFSST and FSST. Participants completed the FSST and mFSST by facing forward while standing in quadrant 1, then completing the sequence in a clockwise manner though quadrant 4. Once the subject returns to quadrant 1, they then go counterclockwise stepping into quadrant 4 to end the test returning to quadrant 1. Participants were asked to "complete the sequence as fast and safe as possible without touching the cane/tape. Both feet must contact each square and if possible, face forward throughout the entire sequence. The clock will begin when I say go and will end when both feet return to square 1. Are you ready?" For both tests, participants were permitted to have one practice trial before beginning testing. During that time, assessors provided feedback as needed to ensure correct test performance. Once testing began, participants performed both test two times and the score was averaged. If any mistrial occurred, such as incorrect sequence, an additional trial was performed. Two physical therapy students provided stand by assist for safety during the assessment. Participants wore a gait belt and took rest breaks as needed to prevent any fatigue.

Upon completion of the mFSST and FSST, participants traversed the Zeno at both self-selected (SS) speed and fastest comfortable (FC) speed three consecutive times to assess average gait velocity. Participants were instructed to "walk at a safe and comfortable speed" (SS) and "walk at their fastest and safest speed" (FC) across the Zeno. The participant then completed the TUG assessment for fall risk. A gait belt and SBA were provided during the fall risk and gait assessments by a licensed physical therapist or physical therapy student. Participants were provided rest breaks between all fall risk and gait assessments as needed. Lastly, the participant and a licensed physical therapist went into a private space to complete the QOL outcome measures (ABC, FOG, PFS-16 and PDA-39) in a randomized order.

Assessments were performed by three licensed PTs with more than three years of experience working with the neurologic population. Physical Therapy students provided SBA as needed under the supervision of a licensed physical therapist. Prior to the study, the PTs met with the primary investigator to receive training for fall risk assessments and review outcome measure procedures to ensure consistency.

DATA ANALYSIS

Descriptive statistics were calculated to determine the mean and standard deviation (SD) for all variables. Pearson's correlation (*r*) and regression analyses were used to determine the relationship of the measures. For all analyses, participants were assessed while on-medication. Statistical significance was set at $\alpha \leq 0.05$ for all analyses. All statistical analyses were calculated using SPSS 25 software
(SPSS, INC, Chicago, IL).

RESULTS

A total of 28 participants were tested and 27 completed this study, see Table 4.1 for participants demographics. One participant received a score < 26/30 on the MoCA and was not included in this study. To determine the relationships among mFSST and additional measures, linear regression were performed (see Table 4.2). Of the demographic variables, the strongest relationships were between the FSST and mFSST at 0.81 and TUG at 0.65. For all of the gait parameters, increased parameters were significantly negatively correlated with mFSST. However, none of the QOL measures were significantly correlated with the mFSST.

Finally, to determine the predictability of the mFSST hierarchical multiple regression was performed using the enter method (see Table 4.3). The correlation coefficient resulting from the multiple regression analysis with all the significant variables (Model 1), showed a strong correlation (R = 0.82) between the mFSST and the seven variables (TUG, SS gait speed, FC gait speed, average stride length SS, average step length SS, average stride length FC, and average step length FC); see Table 4.3. The coefficient of determination for Model 1 was moderate (R^2 = 0.55) and shows moderate strength in predicting mFSST. Thus, after entry of the seven significant variables, the total variance explained by the model as a whole was 55%, $F(7,19) = 3.271$, $p = 0.02$. The overall model 1 regression equation for mFSST = 4.66 + (0.93 TUG) + (-6.39 SS gait speed) + (2.03 FC gait speed) + (1.46 step length SS) + (-1.55 step length FC) + (-0.63 stride length SS) + (-0.63 stride length FC). Model 2 included 11 variables (TUG, SS gait speed, FC gait speed, average stride length SS, average step length SS, average stride length FC, average step length FC, and QOL measures) resulting in a strong correlation (R = 0.82). While the coefficient of determination for Model 2 (R^2 = 0.67) revealed moderate strength for predicting mFSST. Thus, after entry of all seven variables, the total variance explained by the model as a whole was 67%, $F(11,15))$ = 2.751, p = 0.04. The overall model 2 regression equation for mFSST = -2.687 + (0.91 TUG) + (-10.41 SS gait speed) + (0.001 FC gait speed) + (-0.26 step length SS) + (-1.62 step length FC) + (0.27 stride length SS) + (0.78 stride length FC) + (-0.21 FOGQ) + (0.03 PFS-16) + (0.02 ABC) + (0.01 PDQ-39 SI). See Table 4.3 for Model 1 and 2 regression results. To ensure the models predict the mFSST, the FSST was not used in the multiple regression models as it highly correlates with the mFSST. Additionally; age and the MoCA scores were not included as they were part of the screening for inclusion criteria in this study.

Table 4.2: Results of linear regression for independent variables

Variable	*B* (SE)	*p*	F	R	R^2	Adjusted R^2
Demographics and Fall Risk Assessments						
Age	0.11 (0.07)	0.14	2.345	0.29	0.09	0.05
MoCA	-0.79 (0.30)	0.01	6.945	0.47	0.22	0.19
TUG	0.59 (1.38)	<0.01*	18.247	0.65	0.42	0.40
FSST	0.45 (0.07)	<0.01*	46.025	0.81	0.65	0.63
Gait Parameters						
SS gait speed	-5.87 (1.84)	<0.01*	10.179	-0.54	0.29	0.26
FC gait speed	-3.06 (1.00)	<0.01*	9.349	-0.52	0.27	0.24
SS step length	-0.11 (0.40)	0.01*	7.665	-0.48	0.24	0.20
SS stride length	-0.06 (0.02)	<0.01*	7.978	-0.49	0.24	0.21
FC step length	-0.07 (0.03)	0.01*	7.049	-0.47	0.22	0.19
FC stride length	-0.04 (0.01)	0.01*	7.083	-0.47	0.22	0.19
Quality of Life Measures						
PFS-16	0.03 (0.03)	0.28	1.220	0.22	0.05	0.00
FOGQ	0.01 (0.09)	0.88	0.025	0.03	0.00	-0.04
PDQ-39 SI	0.03 (0.04)	0.43	0.648	0.16	0.03	-0.01
Mobility	0.04 (0.02)	0.06	4.011	0.37	0.14	0.10
ADLs	0.04 (0.020	0.10	2.940	0.32	0.11	0.07
ABC	-0.03 (0.02)	0.18	1.921	0.27	0.07	0.03

*Correlation is significant at the ≤ 0.05 level
Abbreviations:
MocA- Montreal Cognitive Assessment
TUG- Time Up and Go
FSST- Four Square Step Test
mFSST- Modified Four Square Step Test
SS- Self -selected
FC- Fastest comfortable
PFS-16- Parkinson’s Fatigue Scale -16
FOGQ- Freezing of Gait questionnaire
PDQ-39 SI- Parkinson’s disease questionnaire-39 Summary Index
ABC- Activities-specific Balance Confidence scale

Table 4.3: Results of the regression for Model 1 and Model 2

	Model 1			Model 2		
Variable	B (SE)	t	*p*- value	B (SE)	t	*p*- value
TUG	0.93 (0.35)	2.67	0.15	0.91 (0.41)	2.24	0.04
SS Gait Speed	-6.39 (5.79)	-0.59	0.28	-10.41 (6.17)	-1.69	0.11
SS Step Length	1.46 (1.15)	1.27	0.22	-0.26 (1.35)	-0.19	0.85
SS Stride Length	-0.63 (0.59)	-1.08	0.29	0.27 (0.69)	0.40	0.70
FC Gait Speed	2.03 (3.53)	0.57	0.57	0.001 (3.75)	<0.01	1.00
FC Step Length	-1.55 (1.15)	-1.35	0.19	-1.62 (1.25)	-1.29	0.22
FC Stride Length	-0.63 (0.59)	1.37	0.19	0.78 (0.61)	1.27	0.22
FOGQ	-	-	-	-0.21 (0.12)	-1.68	0.11
PFS-16	-	-	-	0.03 (0.04)	0.70	0.50
PDQ-39 SI	-	-	-	0.01 (0.04)	0.12	0.90
ABC	-	-	-	0.02 (0.03)	0.68	0.51
R	0.74			0.82		
R^2	0.55			0.67		
Adjusted R^2	0.38			0.43		

Abbreviations:
TUG- Time Up and Go
FSST- Four Square Step Test
SS- Self-selected
FC- Fastest comfortable
mFSST- Modified Four Square Step Test
PFS-16- Parkinson’s Fatigue Scale -16
FOGQ- Freezing of Gait questionnaire
ABC- Activities-specific Balance Confidence scale
PDQ-39 SI- Parkinson’s disease questionnaire-39 Summary Index

DISCUSSION

This study describes the relationship of the mFSST in relation to additional fall risk measures, gait parameters, and QOL measures for individuals with PD. As a modified version of the reliable and valid FSST, the simple modification of replacing canes with tape has potentially made the assessment tool more feasible. Previously studied by Roos et al,[24] the mFSST has been shown to measure dynamic balance in individuals with stroke. To our understanding this is the first study to determine the relationship between the mFSST and additional fall risk measures, gait parameters, and QOL measures for individuals with PD.

The relationship between H&Y stage and fall risk assessments in this study demonstrated a linear relationship. As the H&Y stage progressed from H&Y I to III, all the fall assessments (mFSST, FSST, and TUG) increased in time required to complete the assessments. As previously determined by Duncan et al[23] the cut-off score of 9.68 seconds on the FSST categorizes individuals with PD as a fall risk. In this study the mean score for the FSST for H&Y stages I-III (9.71 to 12.28), which is above the recommended cut-off score for FSST in individuals with PD. In a study by Mak and Pang[33] increased fall risk was significantly associated ($p = 0.028$) with a longer TUG time. In 2010, Kerr et al[45] studied 101 participants diagnosed with PD ranging from H&Y 1-4; those who reported falling had a mean score of 10.8 ± 3 on the TUG. In the current study, the TUG increased from H&Y I (8.25 ± 1.98) to H&Y III (10.87 ± 2.94). Reaching a similar mean TUG score (10.87 seconds) as reported by Kerr et al[45] to be associated with those reporting falls.

The relationship between H&Y and QOL measures demonstrated a decline in ABC score from stage H&Y II (82.40% ± 14.23) to H&Y III (58.60 ± 19.22). Likewise, there was an increase in mean score on FOGQ from H&Y I (3.89 ± 3.82) to III (9.13 ± 6.64), which represents an increased report of freezing episodes as the disease progresses. However, with the max score of 26 on the FOGQ indicating increased severity of freezing episodes, the mean score of 5.63 represented in this study indicates this sample reports minimal freezing of gait complaints. Supporting the findings by Giladi et al[46], the FOGQ demonstrated a significant correlation between FOGQ and H&Y (r = 0.66, p = 0.01), revealing that as the disease progresses through the H&Y staging patients may experience an increase in freezing episodes. In a study by Grace et al[47] the mean PFS-16 in individuals with PD 54.34 ± 34.81 was significantly higher ($p < 0.001$) than a control group at 15.03 ±15.53. The PFS-16 remained consistent in this study from H&Y I (51.22 ± 14.73) to H&Y III (53.50 ± 12.00). Indicating that fatigue was a concern for the individuals participating in this study. In a study by Margolius et al[48] the change in PDQ-39 total score and specifically the mobility subscale is expected to deteriorate over time. Similarly; in this current study the mobility subscale declined from H&Y I (23.33 ± 19.69) to H&Y III (41.0 ± 19.48). Finally, the PDQ-39 SI demonstrated a decreased quality of life as the disease progressed from H&Y I (21.93 ± 11.02) to H&Y III (34.04 ± 10.42).

As noted in Table 4.2, the mFSST presents a significant correlation ($p < 0.01$) to the fall risk assessments (FSST and TUG). Likewise, the mFSST significantly correlates ($p \leq 0.05$) to all spatial-temporal parameters of gait. However; the mFSST does not significantly correlate ($p > 0.05$) with any of the QOL measures (FOGQ, PFS-16, PDQ-39, or ABC) used in this study. Posing the possibility that the mFSST only captures a singular aspect of fall risk and does not fully explain changes in quality of life for individuals with PD. This suggests other factors such as cognitive decline and FOF may play a more important role in determining fall risk that dynamic balance testing using the mFSST. While the QOL measures do not significantly correlate with the mFSST, assessing the participation level of the ICF is an important component of the fall risk evaluation process. As noted in Table 4.3, Regression Model 1, which includes all of the significant variables, explains 55% of the fall risk prediction for individuals diagnosed with PD, which is slightly lower than Model 2 (67%), with the addition of the QOL measures. Presenting the need to further explore fall risk assessments for individuals with PD.

Limitations

Participants in this study (*n* = 27) were community dwelling individuals from a local PD support group. Those who volunteered to participate in this study; may not fully depict a comprehensive representation of individuals with PD at varying levels of activity and participation. As those with an increased fall risk may not voluntarily participate in a study assessing fall risk due to fear of falling. Furthermore, this small sample size may not be sufficient enough to show the optimal results of these regression models.

Additionally, the current study only assessed the mFSST, FSST, TUG, spatial-temporal parameters, and QOL assessments while participants were on-medication. Thus, a limitation is this study includes testing only while on-medication, while participants may be at a higher fall risk when off-medication.

Finally, a limitation in this study may be questionnaire fatigue as the questionnaires required around 30 minutes to complete. Hence, participants may not correctly answer the questionnaires to their best ability due to fatigue. Future studies should assess the changes of the mFSST for individuals with PD when off-medication.

CONCLUSION

The mFSST is a fall risk assessment tool that measures dynamic standing balance with minimal space and time required to complete. The mFSST significantly correlates ($p < 0.01$) with other balance assessments (FSST and TUG). In individuals with PD, it also correlates ($p < 0.05$) with the spatial-temporal parameters of gait. However; the mFSST does not correlate with QOL measures in individuals with PD. The mFSST is a feasible fall risk assessment tool that can help predict fall risk when utilized with additional fall risk assessments. To capture changes in all domains of the ICF as PD progresses, the addition of QOL measures (FOGQ, PFS-16, PDQ-39, ABC) provide clinicians with a comprehensive fall risk assessment.

CHAPTER V

EFFECTS OF NON-MOTORIZED TREADMILL TRAINING FOR ONE SESSION ON GAIT AND FALL RISK IN PARKINSON'S DISEASE

INTRODUCTION

Parkinson's disease is a complex disorder characterized by non-motor and motor impairments. As one of the most prevalent diseases involving the central nervous system, PD is estimated to be affecting more than one million people in the United States.[1-4] Within the motor-impairments, mobility deficits resulting from gait abnormalities and postural instability are some of the challenging characteristics that are associated with PD.

Physical therapists often assess and implement evidence-based treatment strategies to improve mobility and promote independence with the goal to improve quality of life in those with PD. However; physical therapists continue to struggle with the most effective way to improve gait abnormalities commonly seen in individuals with PD. As a result, those with Parkinson's disease are at risk for rapid decline in function without intervention.

Treadmill training is the most frequently used exercise modality in those with PD, as it is comparable to daily ambulation.[5] Specifically, motorized treadmill training is often utilized to improve spatial-temporal parameters of gait during physical therapy. Readily available, motorized treadmills are often used clinically and can be used upon discharge from physical therapy. Herman et al[6] found that improvements in gait impairments following treadmill training, may be due to stimulating neuroplasticity, thus improving motor function in individuals with PD. With little research including treadmill training protocols for individuals diagnosed with PD, clinicians often use their own discretion while developing a plan of care. In 2012, Earhart et al[7] discussed the benefits of treadmill training at the same speed as self-selected speed overground. In 2016, a study by Bryant et al[8] found the cardiovascular response to treadmill exercise did not diminish as the disease progressed (Hoehn & Yahr 2, 2.5, or 3). They concluded that treadmill training is a safe therapeutic modality for individuals diagnosed with PD.[8]

Recently, NMT training has become a point of interest among clinicians attempting to increase intensity while treadmill training. During NMT training the participant must generate power to move themselves vertically, and dynamically control the belt speed.[9] NMT training has been found to result in a more natural and efficient gait pattern and improved quality of life in active adults.[9,10] Morgan et al[9] found a significant increase in RPE with an increase of 25% during NMT training as opposed to MT training in adults aged 18-35 years old. Additionally, Morgan et al[9] found when testing at matched speeds between NMT and MT training there was a 67% greater HR in the NMT at submaximal levels. In a study by Hachett et al[11] there was a significant difference in stride length (p = 0.033) and step length (p = 0.039) following NMT training compared to MT in college-aged adults. The specificity and repetition of treadmill training along with the intensity that is associated with NMT, may improve gait parameters thru application of principles of neuroplasticity.[13] Treadmill training using NMT has yet to be studied within the PD population.

Physical therapists should consider parameters such as training intensity, heart rate, and perceived exertion prior to initiating a treadmill training program in individuals with PD. Prior studies have found that training at higher intensity may result in greater improvements in symptom reduction and cognitive function when compared to training at lower intensities.[14,15] Schenkman et al[16] compared high-intensity treadmill training (80-85% maximum HR) to moderate-intensity (60-65% maximum HR) in individuals with PD. Following the high-intensity training there was an increase in VO_2max of 1.9 mL/min/kg (8%) compared to the usual care group which experienced a decline of 1.3 mL/min/kg (5%).[16] With only two serious adverse events out of the 128 participants, the prescription of high-intensity treadmill training is tolerable for individuals with PD. Hence, by boosting the intensity by training at speeds above self-selected speed or increasing cardiovascular demands the benefits of symptom reduction may carryover to improved mobility.

Treadmill training at a level that provides enough intensity to make neuroprotective changes without harming the patient is always a challenge for physical therapists. Currently, limited research is available regarding the feasibility of NMT training and its effect on the spatial-temporal parameters of gait in individuals with PD. The purpose of this study is to compare the immediate effects of two gait training interventions, MT and NMT training by measuring the spatial-temporal parameters of gait and fall risk assessments in individuals with PD.

METHODS

Participants

Nineteen community-dwelling people with Parkinson's disease were recruited from local Parkinson's disease support group through advertisement in a support group email list. The sample required to demonstrate adequate power was calculated using G*Power and determined to be 16 participants for the repeated measures ANOVA for within-between interaction. Inclusion criteria included: age 55-85 years old, diagnosed with Parkinson's disease, H&Y I-III, and able to walk 10 meters with or without assistive device. To detect cognitive impairments, the participants were screened using the MoCA all participants had to score $\geq$ 26/30 on this measure.[17,18] Individuals were excluded if they had a diagnosis of other neurological conditions (stroke, multiple sclerosis) or had uncontrolled conditions such as diabetes, rheumatoid arthritis, congestive heart failure that would make moderate to vigorous aerobic exercise contra-indicated. Participants were asked to take their medication one to two hours prior to testing, to ensure they were tested while on-medication. All participants signed informed consents that had been approved by the Institutional Review Boards at Texas Woman's University in Houston, Texas and the University of St. Augustine for Health Sciences in St. Augustine, Florida. Participant demographic information is presented in Table 5.1.

Table 5.1 Participant Demographics (*n* =16)

Characteristic	Mean (*SD*)
Gender (male, female)	10, 6
Age (years)	73.3 (4.8)
Hoehn & Yahr	
I	6
II	7
III	3
TUG (secs)	9.35 (2.5)
FSST (secs)	10.92 (4.0)
mFSST (secs)	9.37 (2.2)

Abbreviations:
SD- Standard Deviation
TUG- Time Up and Go test
FSST- Four Square Step Test
mFSST- Modified Four Square Step Test
secs- seconds

Instruments

Zeno Walkway System

The Zeno with PKMAS[5] assesses spatial-temporal parameters of gait.[19] The Zeno is a low profile gait mat consisting of a three-layer surface embedded with 16 levels of pressure sensors which sample at a rate of 60Hz to 120Hz to assess dynamic gait.[19] This 20-foot gait mat enables data collection and has demonstrated good test-retest reliability and validity (ICC = 0.844-0.99.)[20] In 2017, a study determined the Zeno Walkway to have excellent concurrent validity (ICC = 0.854 to 0.976) when compared to the

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GAITRite walkway while testing adults at high fall risk gait spatial-temporal parameters of gait (comfortable and fast speeds).[21]

Four Square Step Test

To complete the FSST, participants performed the test as described by Dite et al.[22] Single point canes were placed flat on the ground and in a "+" position resulting in four separate squares. Participants complete the test by stepping into each square with both feet while facing forward throughout the entire test. The stepping sequence for this test include a specific sequence: forward, right, backward, left, right, forward, left, backward.[22,23] Timing begins when the participant steps forward and makes foot contact within square two and ends when the subject steps backwards and returns to square one with both feet (see Figure 5.1). To successfully complete this test, participants are instructed to complete this entire sequence as quickly and safely as possible, without touching the canes and if possible, face forward throughout the entire sequence. The FSST has been shown to have high interrater, intrarater, and test-retest reliability in individuals with PD.[22-24]

Modified Four Square Step Test

Similar to the FSST, the mFSST requires participants to perform the same sequence; with the modification of replacing canes with 2-inch tape.[24] Timing of the mFSST is the same as the FSST beginning with the first foot in square two and ending when both feet return to square one. The mFSST has been deemed a reliable and valid tool to assess fall risk in individuals post stroke.[24]

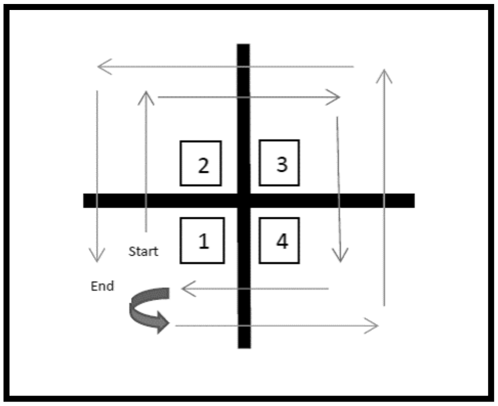

Figure 5.1: FSST and mFSST testing sequence

Timed Up and Go

In 1991, Podsiadlo et al[25] described the TUG as a simple clinical tool to assess lower limb function, mobility and fall risk. TUG is an outcome measure that assesses functional mobility, by measuring the time required for one's ability to stand up from a chair, walk 3 meters, turn around and sit down.[26,27] The TUG demonstrates excellent interrater reliability (ICC = 0.99) and test-retest reliability (ICC = 0.85) in individuals with parkinsonism.[28,29] Foreman et al[30] found the TUG was able to differentiate between fallers and non-fallers ($p < 0.006$) only when off-medication. Determining the mean score for fallers on-medication to be faster at 12.21 seconds (±7.42) and slower while off-medication at 15.5 seconds (±11.03).[30]

Borg Rate of Perceived Exertion

Frequently used in the clinic, the Borg rate of perceived exertion (Borg) was developed to monitor and quantify perceived effort during exercise.[31] The 15-grade scale (6-20) for perceived exertion was developed to denote heart rate ranges from

60-200 beats*min^{-1}.[31] A study by Penko et al[32] found that individuals diagnosed with PD, both heart rate and workload were considered significant predictors of the RPE score ($p < 0.001$). Thus, concluding that the Borg scale is an appropriate tool to monitor intensity when heart rate monitoring is not permissible in individuals with PD.[32] Training at a higher intensity, determined by a higher RPE is a possible approach to promote neuroplastic changes in individuals diagnosed with PD.[33,34]

PROCEDURES

Participants attended two testing sessions for this study at the University of St. Augustine. Upon arrival, participants reviewed the informed consent and completed fall risk assessments (mFSST, TUG) and Zeno gait analysis prior to beginning treadmill training. To complete the mFSST, participants were instructed to “complete the sequence as fast and safe as possible without touching the tape. Both feet must contact each square and if possible, face forward throughout the entire sequence. The clock will begin when I say *Go* and will end when both feet return to square 1. Are you ready?” For the mFSST, participants were permitted to have one practice trial before beginning testing. During that time, assessors provided feedback as needed to ensure correct test performance. Once testing began, participants performed both tests two times and the score was averaged. Two PT students provided SBA while the participant wore a gait belt for safety during the assessment. Participants took rest breaks as needed to prevent any fatigue. During the TUG assessment, participants were instructed to begin seated in a chair, when the PI said “go” the participant was to stand up walk three meters turn around and return to the chair as quickly and safely as possible. One PT student provided SBA while the participant wore a gait belt for safety during the assessment. To determine treadmill training parameters, participants were instructed to walk across the Zeno at both self-selected (SS) and fastest comfortable (FC) speeds three consecutive times and this data was averaged for recorded gait parameters (pretest). During pretest assessments, SBA was provided by a licensed physical therapist or a physical therapy student.

The primary investigator (PI) determined the training parameters for speed based on the average SS and FC speeds. The PI calculated the SS speed, FC speed, and 110% of SS speed for each participant upon completion of Zeno testing. Once calculated, the treadmill training parameters were provided to a licensed physical therapist from the PI. Treadmill training mode (MT or NMT) was randomized by a computer-generated number to determine which mode was performed first. Participants resting heart rate and blood pressure were taken for baseline measurements prior to initiating treadmill training. To eliminate any biases, the PI was blinded to the treadmill training mode and did not participate in any treadmill training.

To begin treadmill training, participants were instructed how to safely get on/off the treadmills. During treadmill training sessions, the participant's BP, HR (Polar, Polar Electro, Bethpage, NY) and Borg were monitored at 2 minutes, 8 minutes, and 10 minutes. Treadmill speed was documented every 30 seconds throughout the duration of the 10-minute session. The treadmill began with 2 minutes of the participants SS gait speed, then 6 minutes of training within a range of 110% of the SS speed up to FC gait speed, followed by 2 minutes at SS gait speed. This totaled up to 10 minutes of treadmill training for each session. To ensure safety while performing treadmill training, participants wore the NxStep harness, however it did not support the participant (0% body weight support). During treadmill training, physical therapists provided verbal cues for encouragement and tactile cues as needed to achieve pre-determined speed. The frequency of cuing was not limited during treadmill training sessions.

Immediate posttest measurements were taken following the treadmill training session by the PI. The participants were instructed to refrain from discussing the mode of treadmill training to ensure the PI remained blinded. Immediate posttest measurements included fall risk assessments (mFSST and TUG) and Zeno gait analysis at SS and FC speeds. Participants completed all assessments with instructions that were consistent with pretest assessments. Two physical therapy students provided SBA and wore a gait belt for safety during the assessment.

To attain 20-minute follow-up measurements, participants were instructed to rest for 20-minutes prior to final posttest measurements. Follow-up measurements were consistent with pretest and immediate posttest assessments. Upon completion of the first session, participants scheduled a follow-up session 5-7 days later to complete the same protocol with the other treadmill intervention. At the end of the second session, participants completed a survey with the PI rating their treadmill training experience for both sessions.

Data analysis

Descriptive statistics were calculated for all variables. Pearson's correlations (*r*) and a 2 x 3 repeated measure of ANOVA for intervention group x time was used to determine the significance of change in fall risk and gait parameters of each time point (pretest, immediate posttest, and 20-minute follow-up) among two different conditions of NMT and MT training. Effect size (Cohen's *d*) was determined using group means, standard deviation, and sample size of 16 based on participants in this study. For all analyses, participants were assessed while on-medication. Statistical significance was set at $\alpha \leq 0.05$ for all analyses. All statistical analyses were calculated using SPSS 25 software (SPSS, INC, Chicago, IL).

RESULTS

A total of 19 participants began this study, 16 were able to complete this study and used for data analysis. Three participants were unable to successfully complete this study due to unrelated illness, shortness of breath on MT, and chronic hip pain prior to beginning treadmill training. No adverse effects resulted from the treadmill training sessions.   Participants ($N = 16$) were able to return to baseline resting heart rate in less than 5 minutes following a seated rest period.

Self-selected gait speed during motorized and non-motorized treadmill training

Mauchly's test indicated the assumption for sphericity had been violated for the main effects of SS gait speed for both treadmill groups: $\chi^2 = 17.25$, $p < 0.001$; therefore, Greenhouse Geiser corrected tests are reported ($\varepsilon = 0.585$). The interaction between time and treadmill on SS gait speed was not significant: $F(1.17,17.56) = 0.47$, $p = 0.53$ (see Figure 5.2). The main effect of time on SS gait speed was not significant $F(1.39,20.81) = 3.042$, $p = 0.85$. Finally, the main effect of treadmill on SS gait speed was not significant $F(1,15) = 1.604$, $p = 0.23$ (see Figure 5.2).

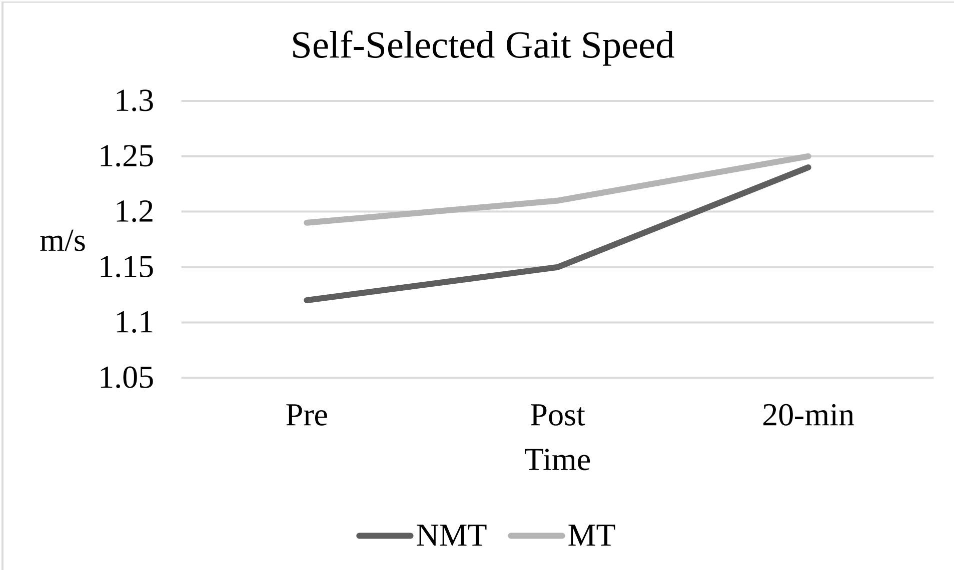

Figure: 5.2. Interaction between time and treadmill for self-selected gait speed
Abbreviations:
Pre- Pretest
Immediate Post- Immediate Posttest
20-min- 20-minute Posttest
m/s- meters per second
NMT- Non-motorized treadmill
MT- Motorized treadmill

To ensure a change in gait speed isn't the result of measurement error, an improvement of 0.18m/s is needed to attain MDC for SS gait speed in individuals with PD.[37] In addition, the minimally clinically important difference (MCID) is the amount of change that a patient or clinician perceives as important. In individuals with PD, it has been determined that a MCID of 0.06 m/s is necessary for patients to perceive an improvement in gait speed.[38] The results did not exceed the MDC for either type of treadmill, but did meet the MCID for the NMT between pretest and 20-minutes post-test as well as immediate posttest and 20-minute posttest. On the MT, the MCID was met between the pretest and the 20-minute post-test. The gait speed means, standard deviations, and effect sizes for both types of treadmills can be found in Tables 5.2 and 5.3.

Table 5.2: Gait speed group means (*SD*) with treadmill training

Time and Treadmill		SS Gait Speed (m/s)	FC Gait Speed (m/s)
Pre	NMT	1.12 (0.3)	1.61 (0.4)
	MT	1.19 (0.2)	1.58 (0.4)
IPost	NMT	1.15 (0.3)	1.59 (0.5)
	MT	1.21 (0.2)	1.63 (0.4)
20-Post	NMT	1.24 (0.2)	1.63 (0.5)
	MT	1.25 (0.2)	1.69 (0.4)

Abbreviations:
SD- Standard Deviation
Pre- Pretest
IPost- Immediate Posttest
20-Post- 20-minute Posttest
m/s- meters per second
NMT- Non-Motorized treadmill
MT- Motorized treadmill
SS- Self-selected
FC- Fastest comfortable

Table 5.3: Effect size (*d*) for gait speed between time assessments of non-motorized and motorized treadmill

	NMT		MT	
	SS	FC	SS	FC
Pre - IPost	0.11	0.04	0.11	0.13
IPost - 20-min	0.38	0.08	0.18	0.14
Pre - 20-min	0.45	0.05	0.29	0.27

Abbreviations:
NMT- Non- Motorized
MT- Motorized
SS- self-selected
FC- fastest comfortable
Pre- Pretest
IPost- Immediate Posttest
20-Min- 20-minute Posttest

Fastest comfortable gait speed during motorized and non-motorized treadmill training

Mauchly's test indicated the assumption for sphericity was met for the main effects of FC gait speed for both treadmill groups $\chi^2 = 1.57$, $p = 0.456$, therefore sphericity assumed tests are reported. The interaction between time and treadmill on FC gait speed was not significant at $F(2,30) = 2.636$, $p = 0.09$ (see Figure 5.3). The main effect of time on FC gait speed was significant $F(2,30) = 3.314$, $p = 0.05$. Pairwise comparisons revealed a significant difference in FC gait speed between pretest and 20-minute posttest ($p = 0.033$) and between immediate post and 20-minute posttest ($p = 0.035$) (see Figure 5.3). Finally, the main effect of treadmill on FC gait speed was not significant $F(1,15) = 0.420$, $p = 0.53$ (see Figure 5.3).

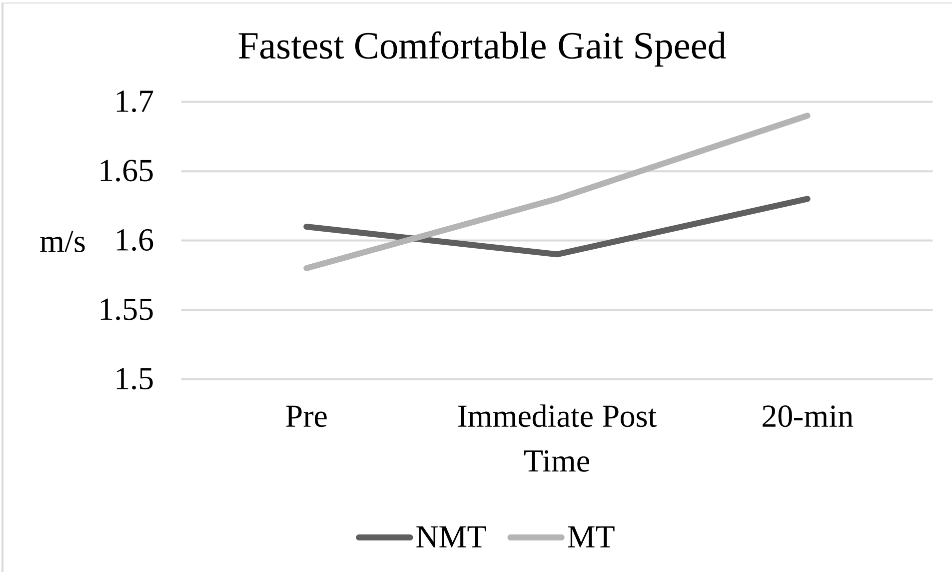

Figure: 5.3. Interaction between time and treadmill for fastest comfortable gait speed
Abbreviations:
Pre- Pretest
Immediate Post- Immediate Posttest
20-min- 20-minute Posttest
m/s- meters per second
NMT- Non-motorized treadmill
MT- Motorized treadmill

The MDC for FC gait speed has been determined to be 0.25m/s for individuals with PD.[37] Again, none of the changes in gait speed exceeded the MDC for FC gait speed. There was a change of .06 m/s (MCID) between the immediate posttest and the 20-minute posttest for the MT only. Group means and effect sizes can be found in Tables 5.2 and 5.3

Modified Four Square Step Test during motorized and non-motorized treadmill training.

Mauchly's test indicated the assumption of sphericity was met for the main effects of mFSST for both treadmill groups: $\chi^2 = 0.14$, $p = 0.934$, therefore sphericity assumed tests are reported. The interaction between time and treadmill on mFSST was not significant $F(2,30) = 0.764$, $p = 0.47$ (see Figure 5.4). The main effects of time on mFSST was significant $F(2,30) = 7.492$, $p \leq 0.001$. Pairwise comparisons revealed a significant difference between pretest and 20-min posttest ($p = 0.016$) and between immediate posttest and 20-minute posttest ($p = 0.012$), however there was no significant difference between pretest and immediate posttest ($p = 1.00$). The main effects of treadmill on mFSST was not significant $F(1,15) = 0.032$, $p = 0.86$. Group means and effect sizes can be found in Tables 5.4 and 5.5. Note, the mean scores for the participants on the mFSST were less than 9.68 seconds. A time greater than 9.68 seconds is considered indicative of fall risks when using the traditional FSST.[23] The MDC for the FSST (traditional test) is 3.25 seconds, neither TM protocol showed a change of this magnitude.[39]

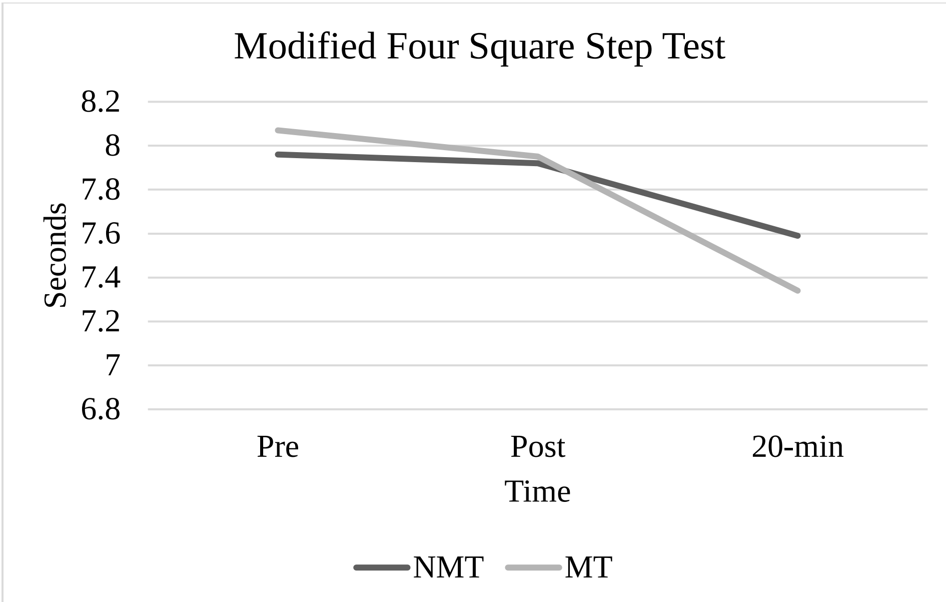

Figure: 5.4. Interaction between treadmill and time for Modified Four Square Step Test
Abbreviations:
Pre- Pretest
Post- Immediate Posttest
20-Min- 20-minute Posttest
NMT- Non-motorized treadmill
MT- Motorized treadmill

Table 5.4: mFSST and TUG group mean (*SD*) by treadmill training

Time	Treadmill	mFSST (sec)	TUG (Sec)
Pre	NMT	7.96 (1.7)	8.52 (2.7)
	MT	8.07 (1.6)	8.05 (1.9)
Post	NMT	7.92 (1.9)	8.65 (3.1)
	MT	7.95 (1.9)	8.02 (1.8)
20-Post	NMT	7.59 (2.0)	8.48 (3.0)
	MT	7.34 (1.4)	8.20 (2.2)

Abbreviations:
NMT- Non- Motorized
MT- Motorized
mFSST- Modified Four Square Step Test
Pre- Pretest
IPost- Immediate Posttest
20-Min- 20-minute Posttest:

Table 5.5: Effect size (*d*) for mFSST and TUG between time assessments of non-motorized and motorized treadmill

Time	mFSST		TUG	
	NMT	MT	NMT	MT
Pre - IPost	0.02	0.07	0.04	0.02
IPost - 20-min	0.17	0.37	0.06	0.09
Pre - 20-min	0.20	0.48	0.01	0.07

Abbreviations:
NMT- Non- Motorized
MT- Motorized
mFSST- Modified Four Square Step Test
TUG- Timed Up and Go
Pre- Pretest
IPost- Immediate Posttest
20-Min- 20-minute Posttest

Timed up and Go during motorized and non-motorized treadmill training.

Mauchly's test indicated the assumption of sphericity was met for the main effects of TUG for both treadmill groups: $\chi^2 = 4.60$, $p = 0.100$, therefore sphericity assumed tests are reported. The interaction between time and treadmill on TUG was not significant $F(2,30) = 0.564$, $p = 0.58$ (see Figure 5.5). The main effects of time on TUG was not significant $F(2,30) = 0.032$, $p = 0.97$. The main effects of treadmill on TUG was not significant $F(1,15) = 2.837$, $p = 0.113$. The MDC is 3.5 seconds for the TUG.[40] The means and effect sizes can be found in Tables 5.4 and 5.5.

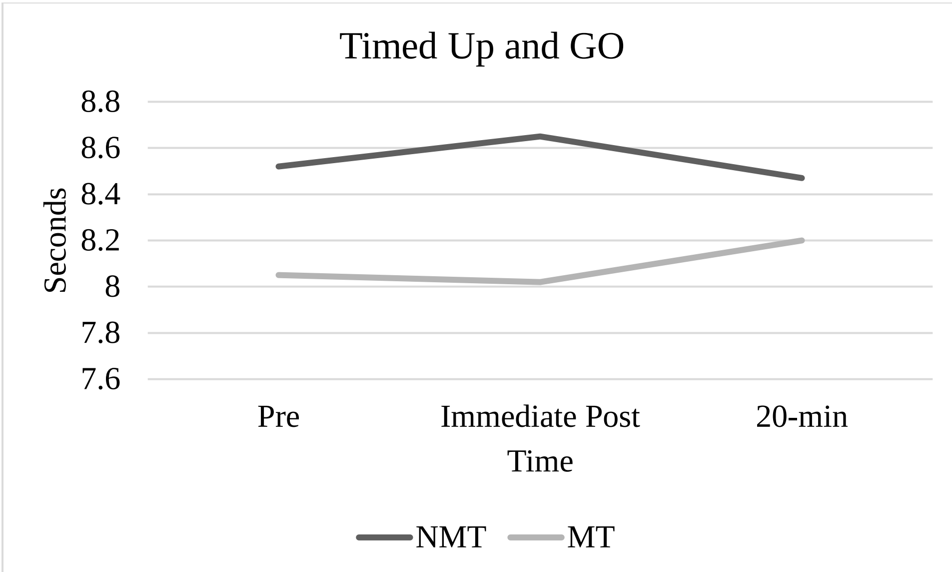

Figure 5.5. Interaction between treadmill and time for Time Up and GO
Abbreviations:
NMT- Non-Motorized Treadmill
MT- Motorized treadmill
Pre- Pretest
Immediate Post- Immediate Posttest
20-min- 20-minute Posttest

Association of gait parameters and fall risk assessments between treadmill training

The association of gait parameters and fall risk assessments between NMT and MT training groups, Pearson's correlations revealed positive high correlations ($r \geq 0.74$) for all assessments (see Table 5.6). There was a strong association in the following measures between testing during the NMT session and the MT session regardless of time.

Table 5.6: Pearson's correlations between non-motorized and motorized treadmill assessments

	Pearson's (*r*)		
	Pre	IPost	20-min
SS (m/s)	0.83	0.81	0.90
FC (m/s)	0.94	0.92	0.91
mFSST (sec)	0.74	0.87	0.84
TUG (sec)	0.91	0.91	0.96

Abbreviations:
SS- self-selected
FC- fastest comfortable
mFSST- modified Four Square Step Test
TUG- Timed Up and Go
m/s- meters/seconds
sec- seconds
Pre- Pretest
IPost- Immediate Posttest
20-Min- 20-minute Posttest

Perceived rate of exertion (Borg scale) during motorized and non-motorized treadmill training.

Mauchly's test indicated the assumption for sphericity was met for the main effects of Borg scale for both treadmill groups: $\chi^2 = 5.997$, $p = 0.05$. To break down the interaction, comparisons were performed comparing treadmill groups and time. A 2 x 3 ANOVA revealed significant interaction $F(2,30) = 3.759$, $p = 0.035$ (see Figure 5.6). Simple effects testing revealed significant differences between Time 1 and Time 2 ($p < 0.001$) and Time 1 and Time 3 ($p = 0.003$) during NMT training. Similarly, there were significant differences between Time 1 and Time 2 ($p = 0.001$) and Time 2 and Time 3 ($p = 0.014$) during MT training. For the simple effects of time, there were significant differences between groups at all time periods: Time 1 ($p = 0.029$), Time 2 ($p = 0.003$), and Time 3 ($p < 0.001$). Group means can be found in Table 5.7.

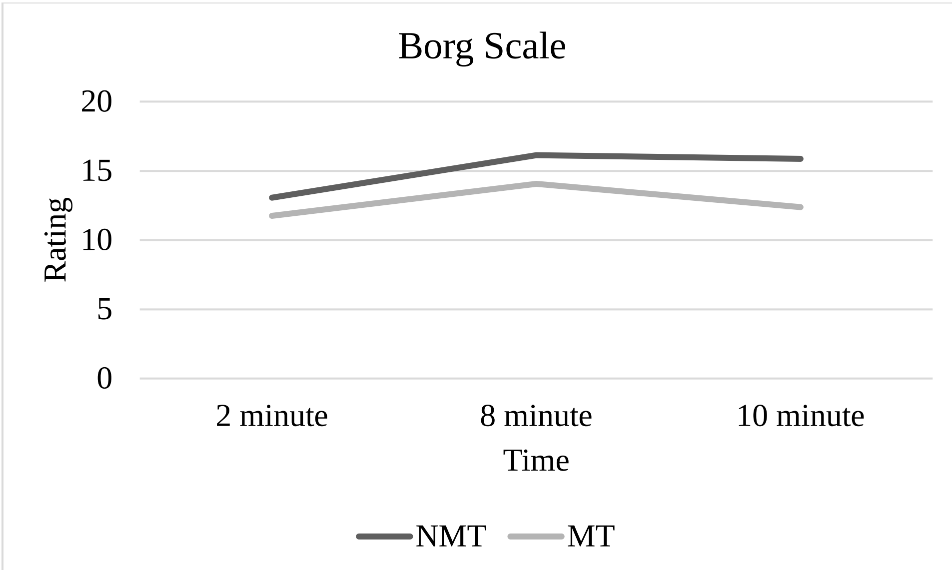

Figure: 5.6. Interaction between treadmill and time for Borg Scale
Abbreviations:
NMT- Non-motorized treadmill
MT- Motorized treadmill

Table 5.7: Borg group mean (*SD*) with treadmill training

Time	Treadmill	Borg Rating
2-minute	NMT	13.06 (2.3)
	MT	11.75 (1.2)
8-minute	NMT	16.13 (2.0)
	MT	14.06 (2.0)
10-minute	NMT	15.87 (2.7)
	MT	12.37 (2.3)

Abbreviations:
NMT- Non-Motorized Treadmill
MT- Motorized treadmill

DISCUSSION

This study assessed the changes in gait parameters and fall risk assessments in individuals with PD using two different types of treadmills. While previous literature has reported the benefits of MT training, this is the first study assessing the immediate effects of NMT training in individuals with PD.

The results of this study aligned with prior studies, finding improvements in SS gait speed following MT training in individuals with PD.[35] This study found similar results with a NMT, however, the improvements from both treadmills were non-significant. In addition, Pearson's correlations revealed strong correlations for all variables during each time interval between protocols. Revealing that the variables were highly related with a linear relationship during all assessment points in this study.

For FC gait speed and mFSST there were significant but small improvements between pretest to 20-minute posttest and from immediate posttest and 20-minute posttest. Revealing that treadmill training (motorized or non-motorized) may have an immediate effect on FC gait speed and fall risk for individuals with PD. Furthermore, these improvements continued for 20-minutes after treadmill training.

The largest effect size was found for SS gait speed, which was a moderate effect size of .45 between pretest and the 20-minute posttest following NMT training. The effect size was smaller (.29) following MT training. For FC gait speed, a small effect size (.05) was found from pretest to 20-minute posttest following NMT, but a comparatively larger effect size of .27 for the same time frame with MT. This may suggest a more beneficial effect of NMT for SS speed, and MT for the FC speed when using treadmill training as a treatment modality.

For the mFSST, there was a significant decrease in the time regardless of group. Interestingly, despite the small changes, the MT showed the strongest effect size (d =.48) between initial testing and follow-up testing with decrease of .73 seconds. There was a smaller effect size found for the NMT during this same time period (.20). The NMT did not seem to influence balance as compared to MT. To further assess fall risk, the TUG following both treadmills showed minimal improvements revealing an effect size less than $d < 0.1$ for all assessment points for both treadmills. This suggests a possible benefit of MT in the balance assessment mFSST, but this was not seen with the TUG.

Reviewing the MDC and MCID reference data, this study did not find improvements that exceeded reported MDC data. However, there were changes that may indicate improvement that may be meaningful to individuals. Specifically, the MCID was met from pretest to 20-minute posttest for SS gait speed following both NMT (0.12 m/s) and MT (0.06m/s). Likewise, the MCID was met for FC gait speed from pretest to 20-minute posttest following MT (0.11 m/s). While NMT training was only able to attain some perceived improvement for SS gait speed. Therefore, this suggests that further research exploring NMT as a treatment modality in individuals with PD is warranted.

The benefits of training at intense levels have been found to reduce symptoms in individuals with PD.[14,15] In alliance with this evidence, this study sought to determine if intensive training with NMT would lead to improvement in gait and balance. One way to assess intensity is by using the Borg scale to measure perceived exertion. The results from this study, seem to indicate that NMT are perceived as more difficult as compared to MT, supported by significant differences between the two types of treadmills at all three assessment points during treadmill training. The highest Borg rating average (16.13) translating to “hard” was reported during NMT training at the eight-minute assessment compared to (14.06) “somewhat hard to hard” during MT training, the NMT Borg rating remained “hard” while the MT was rated as “somewhat hard” by participants. Resulting in participants to continue to express elevated exertional demands following intense training while performing the SS gait speed treadmill training on the NMT. This data must be considered in future research. NMTs do increase the demands, necessary to make neuroprotective changes.

Upon completion of this study, participants answered questions based on their treadmill training experience see Appendix B. Consisting of six questions, participants were asked to answer the questions based on a Likert scale (1 = strongly disagree to 5 = strongly agree; see Figure 5.7). Participants were asked to rate if they “felt safe while performing NMT” the average was 4.25, with 56.3% reporting they strongly agreed. When asked if they felt safe during MT, 75% strongly agreed. When asked if they “enjoyed” NMT or MT treadmill training, a total of 81.3% reported mildly agree and strongly agree form MT. While, response for NMT ranged from strongly disagree to strongly agree with the highest percentage at 25% for “neutral.” Additionally, when asked if “NMT or MT was challenging,” 93.8% agree that NMT is challenging while 50% agree that MT is challenging. Lastly, when asked which treadmill they felt safer performing, 68.8% report feeling safer performing MT compared to NMT.

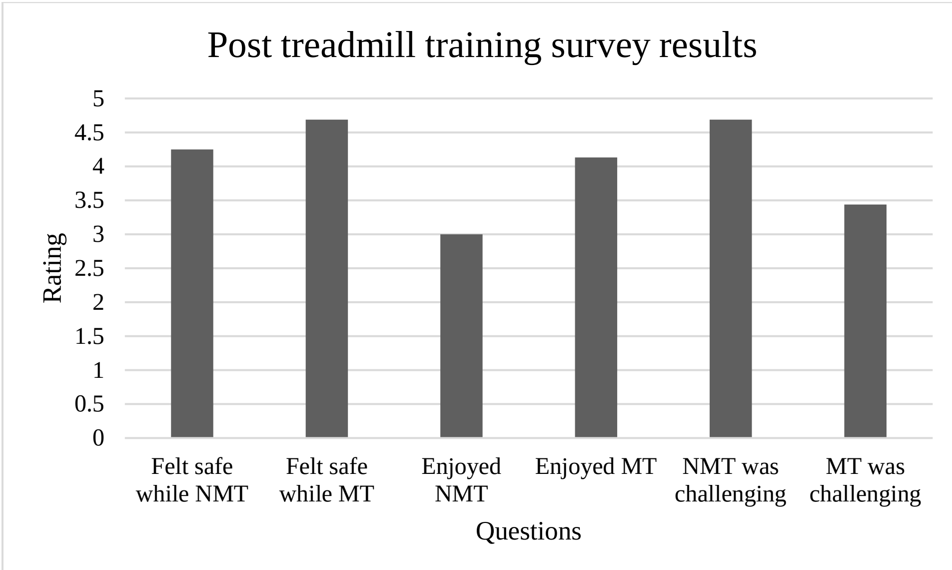

Figure 5.7. Group means for post treadmill training survey
Abbreviations:
NMT- Non-motorized treadmill
MT- Motorized treadmill

When developing a plan of care, physical therapists understand the importance of utilizing interventions to decrease the burden of gait difficulty in Parkinson's disease.[41] This study presents an initial investigation of NMT training for individuals with PD. With both the NMT and MT treadmills resulting in small changes, participants thought NMT was difficult, however it was found to be feasible for individuals with PD. Following 10-minutes of treadmill training, participants were able to attain meaningful changes in gait speed and reach intensity levels that may result in neuroprotective changes. Potentially, decreasing the burdens associated with PD by implementing treadmill training at intense levels to improve mobility. Future studies are necessary to assess the long-term effects of NMT training in individuals with PD.

There are several limitations in this study. One limitation is the duration of this study, participants were only followed for 20 minutes following each intervention. Minimal improvements regardless of device were found following the treadmill training after only one session. Similarly, Phadke et al[42] found minimal improvements in the immediate effects of treadmill training in individuals with stroke. Most treadmill studies use a time frame of at least 4 weeks to show significant improvements.[6,43,44] Concluding that a longer duration of treadmill training may result in significant improvements in mobility and fall risk. Additionally, none of the participants had experience with NMT training prior to participating in this study. Thus, potentially promoting fear and uncertainness while performing NMT training. Meanwhile, all participants reported feeling safer while performing MT treadmill training due to prior exposure to MT training. This could have been improved by allowing one practice NMT training session prior to completing the protocol on the NMT. Thus, providing the participants an opportunity to feel more comfortable with the new equipment prior to testing. Finally, all participants were members of a PD support group. Several participants reported hearing of other participants experience following testing sessions. Discussions between participants regarding treadmill training sessions potentially increased anxiety over testing sessions. Other limitations of this study include small sample size and cuing. Additional participants could have impacted the results in this study. Also, verbal and tactile cues such as “take big steps” or “cuing the gluts” were provided to participants as needed during treadmill training sessions. Hence, the nature of varied cuing promotes a treadmill training experience that was not consistent between participants. Potentially leading to confusion or inconsistency in treadmill training experiences.

The strengths of this study include it being the first known study investigating the feasibility of NMT in this population. In addition, the study confirmed that NMT is perceived as more difficult from an exertion standpoint. NMT was found to be a safe intervention for individuals with PD and data suggests it could be a viable modality to improve gait in this population.

CONCLUSION

As this time, the results of this study are inconclusive as to if treadmill (MT or NMT) training improves mobility and fall risk in individuals with PD. The immediate effects of one session of NMT and MT training did result in perceived meaningful improvements in SS and FC gait speed, however these improvements were not significant. In addition, this study found a significant difference between treadmills when assessing intensity during 10-minute treadmill training sessions. This study also supports the feasibility of intense treadmill training using the NMT or MT for individuals with PD. Future studies of the long-term effects of NMT training in individuals with PD would be needed to determine if significant changes in mobility and fall risk could be attained following NMT training.

CHAPTER VI

THE CLINICAL RELEVANCE OF FALL RISK ASSESSMENT AND THE EFFECTS OF TREADMILL TRAINING ON GAIT PARAMETERS AND FALL RISK IN INDIVIDUALS WITH PARKINSON'S DISEASE

Parkinson's diseases is a progressive disease that is one of the most prevalent diseases involving the CNS, estimated to affect more than one million people in the United States.[1-4] The pathology involves a depletion of DA, within the substantia nigra of the basal ganglia.[1-4] This complex disorder is marked with non-motor and motor impairments, including gait abnormalities and postural instability. As a result of the characteristic postural instability, falls and injuries are common composite symptoms of PD.[5]

Fall risk and fear of falling are common issues noted in individuals with postural instabilities.[6] In 1990, Tinetti et al[7] published an article describing FOF as the lack of self-confidence in performing normal activities without falling. Recently in a study that looked at falls and FOF in individuals with PD, 62% of the participants experienced a fall or frequent falls.[5] Allen et al[8] discussed how FOF is found to be high when compared to actual fall risk in individuals with PD.

In 2016, Roos et al[9] designed the mFSST by simply replacing the canes with 2-inch tape. Once an individual with PD has been determined to be a fall risk, physical therapists strive to develop a plan of care that will implement evidence-based treatment strategies to improve mobility and promote independence with a goal to improve quality of life in those with PD.

When developing a plan of care, physical therapists should consider training intensity when initiating a treadmill training program in individuals with PD. Motorized treadmill training is considered a safe intervention and is often utilized to improve spatial temporal parameters of gait in individuals with PD.[10] Non-motorized treadmill training has become a point of interest among clinicians attempting to increase intensity while treadmill training.[11,12] Prior studies have found that training at higher intensity may result in greater improvements in symptom reduction and cognitive function when compared to training at lower intensities.[13,14]

The purpose of the three studies addressed in this project was to assess a fall risk assessment and to assess the feasibility of NMT training in individuals with PD. Specifically, focusing on the reliability and validity of the mFSST, the relationship of the mFSST with other assessment tools, and the immediate effects of NMT training for individuals with PD. For the first two studies, a total of 28 participants were recruited with 27 completing the studies. For the third study, a total of 19 participants were recruited with 16 completing the study.

The first study was a methodological study, assessing the psychometrics properties of the mFSST. The mFSST was compared to the FSST to determine if this modified assessment tool was as effective as the FSST in determining a fall risk in individuals with PD. The results indicated the mFSST was strongly correlated (r = 0.81) with the FSST. Additionally, the mFSST was also determined to have excellent interrater reliability with a Pearson's correlation $r = 0.999$, $p = 0.001$ and a high level of agreement ($ICC^{(2,2)} = 0.99$). The test-retest reliability was determined to be excellent with a Pearson's correlation of $r = 0.916$, $p = 0.01$ and a high level of agreement ($ICC^{(2,2)} = 0.96$). This study suggests that the mFSST can be used to assess dynamic standing balance in individuals with PD.

The second study assessed the relationship between the mFSST and outcome measures related to fall risk, gait parameters, and quality of life in individuals with PD. The results indicated the strong correlations between mFSST and FSST ($r = 0.81$) and TUG ($r = 0.65$). To determine the predictability of the mFSST, a hierarchical regression was performed revealing a coefficient of determination ($R^2 = 0.58$) and shows moderate strength for predicting fall risk. The regression equation for fall risk = 7.69 + (0.53 TUG) + (-0.73 SS gait speed) + (-2.20 FC gait speed) + (-0.21 FOGQ) + (-0.00 PFS-16) + (0.18 ABC) + (0.03 PDQ-39 SI). This study supports to feasibility of replacing the FSST with the simplified mFSST, however suggests the need to further explore fall risk assessments for individuals with PD.

The third and final study was a randomized one-group pretest-posttest-posttest design. Participants completed 2 sessions of treadmill training, one session of MT and one session of NMT training. While treadmill training, all participants trained beginning at SS speed for the first two-minutes, progressing to an intense six-minutes at 110% of SS up to FC speed, and concluding with the final two- minutes at SS gait speed totaling up to 10-minutes of treadmill training during each session.

In this study, both SS and FC gait speeds improved following MT and NMT training from pretest to 20-minute posttest. The MCID of 0.06 m/s[15] was met following NMT training for both SS and FC gait speed. Meanwhile, the MCID was met solely for FC gait speed following MT training. Higher effect sizes were achieved following NMT for both SS gait speed (d = .45) and FC gait speed (d = .29) when compared to MT. These results align with prior studies, finding improvements in gait speed following MT training in individuals with PD.[16] The results of improved SS and FC gait speed support the feasibility and potential benefits of NMT training for individuals with PD. Furthermore, the implementation of MT training is supported with a greater effect size for mFSST following MT training (d = .48) when compared to NMT training (d = .20). Thus, supporting the use of MT training to improve fall risk in individuals with PD.

The results from this study, seem to indicate that NMT are perceived as more difficult as compared to MT. Supported by significant differences in Borg rating between the two types of treadmills at all three assessment points during treadmill training. Participants rated the highest Borg value at 16.13 (hard) following six-minutes of intense training on NMT compared to 14.06 (somewhat hard) following MT. Explaining a possible relationship between intense treadmill training and perceived exertion. Additionally, when asked if “NMT or MT was challenging,” 93.8% agree that NMT is challenging while 50% agree that MT is challenging. This study concludes that NMT is a feasible approach to drive intensity while treadmill training individuals with PD. Additionally, NMT may result in meaningful changes in gait speeds in individuals with

PD, however future studies over a longer duration are necessary to determine the long-term effects of NMT.

The three studies present findings regarding a modified fall risk assessment tool and a potential treadmill training strategy for individuals with PD. These findings have the potential to make a positive impact on physical therapists' assessment and treatment of individuals with PD. With the mFSST demonstrating high reliability and validity, physical therapists can confidently utilize the mFSST in place of the FSST to assess fall risk in individuals with PD. The mFSST in addition to other outcome measures may provide physical therapists with a more comprehensive fall risk assessment for individuals with PD.

As a result of the treadmill training study, physical therapists can confidently continue MT training to decrease fall risk in individuals with PD. Additionally, physical therapists can feasibly increase intensity demands during treadmill training by using NMT. With minimal adverse effects, NMT training resulted in meaningful immediate improvements in both SS and FC gait speed in individuals with PD. Thus, encouraging physical therapists to continue MT training and implement NMT to increase intensity demands in those who would tolerate the training. While physical therapists strive to find the optimal treatment strategies to improve fall risk and mobility in individuals with PD, NMT and MT training may be feasible strategies to implement for those diagnosed with PD.

There were several limitations for these research studies. With all participants coming from a local PD support group, those who volunteered to participate in this study may not fully depict a comprehensive representation of individuals with PD at varying levels of activity and participation. As those with an increased fall risk and limited mobility may not voluntarily participate in these studies. Furthermore, all testing was completed while participants were on-medication, in which participants may be at a higher fall risk with decreased mobility while off-medication.

Future studies are needed to further explore the relationship between the mFSST and additional fall risk assessment tools for individuals with PD. This will assist physical therapists in providing the most comprehensive fall risk assessment for individuals diagnosed with PD. Additionally, standardized protocols should be developed for treadmill training with individuals diagnosed with PD. Studies assessing treadmill training protocols in conjunction with assessing the long-term effects of NMT training, will provide valuable insight into treatment strategies for individuals diagnosed with PD. The long-term effects will determine if NMT training is an effective strategy to improve mobility and decrease fall risk in individuals diagnosed with PD. These research studies involved individuals diagnosed with PD due to their characteristic postural instability and ability to perform treadmill training. In addition to expanding this study with those diagnosed with PD, future research should include individuals diagnosed with other neurologic diseases.

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APPENDIX A

Treadmill Training Protocol

Treadmill Training Protocol

Participant Number: ____________ Age:_____

Self-selected trial 1:_____ 2:_____ 3:_____ average:____

Fastest comfortable trial 1:_____ 2:_____ 3:_____ average:_____

110% of self-selected gait speed:________

training range:_____________

Begin treadmill training at comfortable speed for 2 minutes

At 2 minutes, increase speed to atleast 110% of self-selected up to fastest comfortable for 6 minutes

At 8 minutes, return to self-selected speed for 2 minutes

Beginning HR:____ BP:______

2 mins: HR:____ BP:_____ Borg:______ Speed:______

8 mins: HR:____ BP:_____ Borg:_______ Speed:______

10 mins: HR:____ BP:_____ Borg:_______ Speed:______

	Speed		Speed		Speed
30 sec		4 min		7 min 30 sec	
1 min		4 min 30 sec		8 in	
1 min 30 sec		5 min		8 min 30 sec	
2 min		5 min 30 sec		9 min	
2 min 30		6 min		9 min 30 sec	
3 min		6 min 30 sec		10 min	
3 min 30 sec		7 min			

APPENDIX B

Treadmill Survey

Treadmill Survey

1) I felt safe while performing Non-Motorized Treadmill training

Strong Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree
1	2	3	4	5

2) I felt safe while performing Motorized Treadmill training

Strong Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree
1	2	3	4	5

3) I enjoyed Non-Motorized Treadmill training session

Strong Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree
1	2	3	4	5

4) I enjoyed Motorized Treadmill training session

Strong Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree
1	2	3	4	5

5) The Non-Motorized Treadmill training was challenging

Strong Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree
1	2	3	4	5

6) The Motorized Treadmill training was challenging

Strong Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree
1	2	3	4	5

7) I felt safer while training on the: (circle one) Motorized Non-Motorized

APPENDIX C

IRB Approval Letters

UNIVERSITY OF ST. AUGUSTINE
FOR HEALTH SCIENCES

June 22, 2018

Anne Boddy, PT, DPT, NCS
1 University Blvd
St Augustine FL 32086

RE: UR-0618-294 *"Investigating the Relationship between Fall Risk and Gait Parameters in Individuals with Parkinson's disease"*

Dear Dr. Boddy,

The Chair of the Institutional Review Board (IRB), responsible for the review of research involving human subjects, has reviewed your original proposal, noted the revisions provided by you upon the reviewers' request and approved the revised project referenced above. Approval for the project will be for one year, starting June 22, 2018.

If a University of St. Augustine For Health Sciences faculty member or student leaves the University prior to completion of a USAHS IRB-approved study, the study may be continued until expiration of that IRB approval. The IRB approval will expire on June 22, 2019.

This approval is granted with the understanding that no changes may be made in the procedures to be followed, nor in the consent form(s) to be used, until after such modifications have been submitted to the IRB for review and approval. Please be sure your consent form includes the IRB contact name and telephone number (Dr. Jeffrey Rot, Chair, University of St. Augustine for Health Sciences Institutional Review Board, 904-770-3534, or jrot@usa.edu). **Researchers must retain a copy of the signed consent form in their files for three years following completion of the project and must provide a copy of the consent form to the subject(s).**

Any unanticipated problems involving risks to human subjects or serious adverse effects must be promptly reported to the IRB.

Prior to the expiration of this approval, you will receive notification of the need for updated information to be used for the project's continuing review.

When project is completed, please notify the IRB in writing. Thank you.

Sincerely,

Jeffrey A. Rot, PT, DHSc, OCS, MTC, FAAOMPT
Chair, IRB

Cc: K. Mitchell

1 University Boulevard - St. Augustine, FL 32086-5783 - (904) 826-0084 - FAX (904) 826-0085 - Website: www.usa.edu

Institutional Review Board
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6700 Fannin, Houston, TX 77030
713-794-2480
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https://www.twu.edu/institutional-review-board-irb/

DATE: June 27, 2018

TO: Ms. Anne Boddy
Physical Therapy - Houston

FROM: Institutional Review Board (IRB) - Houston

Re: Approval for Investigating the Relationship between Fall Risk and Gait Parameters in Individuals with Parkinson's Disease (Protocol #: 20103)

The above referenced study was reviewed at a fully convened meeting of the Houston IRB (operating under FWA00000178). The study was approved on 6/21/2018. This approval is valid for one year and expires on 6/21/2019. The IRB will send an email notification 45 days prior to the expiration date with instructions to extend or close the study. It is your responsibility to request an extension for the study if it is not yet complete, to close the protocol file when the study is complete, and to make certain that the study is not conducted beyond the expiration date.

If applicable, agency approval letters must be submitted to the IRB upon receipt prior to any data collection at that agency. A copy of the approved consent form with the IRB approval stamp is enclosed. Please use the consent form with the most recent approval date stamp when obtaining consent from your participants. A copy of the signed consent forms must be submitted with the request to close the study file at the completion of the study.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Dr. Peggy Gleeson, Physical Therapy - Houston
Dr. Katy Mitchell, Physical Therapy - Houston
Graduate School