# THE INFLUENCE OF AN OVERGROUND LOCOMOTOR TRAINING PROGRAM ON WALKING GAIT PROPULSIVE FORCE IN AMBULATORY PATIENTS WITH PARKINSON'S DISEASE

by

Thomas A. Corfman

A Dissertation
Submitted to the
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of
George Mason University
in Partial Fulfillment of
The Requirements for the Degree
of
Doctor of Philosophy
Rehabilitation Science

Committee:

| | |
|---|---|
| _____ | Rosemary D. Higgins, MD, Chair |
| _____ | Andrew A. Guccione, PT, Ph.D, DPT, FAPTA, Co-Chair |
| _____ | Panagiota Kitsantas, Ph.D, Committee Member |
| _____ | Dan Ding, Ph.D., External Reader |
| _____ | Rosemary D. Higgins, MD, Interim Department Chair |
| _____ | Germaine M. Louis, Ph.D., Dean and Professor, College of Health and Human Services |
| Date: _____ | Spring Semester 2022<br>George Mason University<br>Fairfax, VA |

# The Influence of an Overground Locomotor Training Program on Walking Gait Propulsive Force in Ambulatory Patients with Parkinson's Disease

A Dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at George Mason University

by

Thomas A. Corfman
Master of Science
University of Pittsburgh, 2003
Master of Science
California State University, Sacramento, 1999

Director: Andrew A. Guccione, Professor
George Mason University

Spring Semester 2022
George Mason University
Fairfax, VA

## DEDICATION

This is dedicated to my loving wife Crystal and our two dogs, Sammy and Izzy.

## ACKNOWLEDGEMENTS

I would like to thank the many friends, relatives, and supporters who have made this happen. Drs. Andrew Guccione, Panagiota Kitsantas, and the other members of my committee were of invaluable help. Finally, many thanks go out to Michael Huang for all of his help with MatLab coding and scripting.

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## LIST OF ABBREVIATIONS

Anterior Ground Reaction Force ..... AGRF
Anterior-Posterior ..... A-P
Center of Mass ..... COM
Center of Pressure ..... COP
Ground Reaction Force ..... GRF
Heart Rate ..... HR
Hoehn and Yahr ..... H&Y
Overground Locomotor Training ..... OLT
Parkinson's Disease ..... PD
Posterior Ground Reaction Force ..... PGRF
Postural Instability and Gait Disturbance ..... PIGD
Rate of Rise ..... ROR
Ten Minute Walk Test ..... 10MWT
Vertical Ground Reaction Force ..... VGRF

## ABSTRACT

THE INFLUENCE OF AN OVERGROUND LOCOMOTOR TRAINING PROGRAM ON WALKING GAIT PROPULSIVE FORCE IN AMBULATORY PATIENTS WITH PARKINSON'S DISEASE

Thomas A. Corfman, Ph.D.

George Mason University, 2022

Dissertation Director: Dr. Andrew A. Guccione,

OBJECTIVE: To determine the effect of a 12-week overground locomotor training (OLT) program on the anterior-posterior (A-P) ground reaction force in ambulatory subjects with mild to moderate Parkinson's disease (PD).

DESIGN: This is a pre- and post-test design interventional study.

SETTING: The study was conducted at the university gait analysis laboratory.

METHODS: Participants performed a propulsive force testing procedure before and after the OLT program.

PARTICIPANTS: Eleven adults with mild to moderate PD (Hoehn & Yahr stage 1-3, ambulatory).

INTERVENTIONS: The intervention was a 12-week OLT program.

MAIN OUTCOME MEASURES: Gait parameters: peak anterior ground reaction force (AGRF), rate of rise (ROR) of AGRF, push-off impulse, push-off duration, peak

posterior ground reaction force (PGRF), single stance duration, center of mass (COM) to center of pressure (COP) distance at push-off, and walking speed.

RESULTS: Paired t-tests indicated significant differences in the ROR between pre and post OLT, the push-off impulse pre OLT and post OLT, and the preferred walking speed pre and post OLT. In addition, a Wilcoxon signed-rank test indicated significant differences in the push-off duration between pre and post OLT, and the single stance duration pre and post OLT. No significant differences were observed in peak AGRF and PGRF between pre and post OLT, and in the COM-COP distance between pre and post OLT.

DISCUSSION: Taken together, our results suggest the OLT program was able to improve walking postural and dynamic stability in patients with PD. PD patients were able to spend less time in stance phase, less time in push-off duration, and decrease the rise time of the AGRF (push-off rate increased). This appears to have led to a quicker, more powerful AGRF without changes in peak PGRF, peak AGRF, or push-off posture, and an increase in walking speed in our patients with PD.

# INTRODUCTION

Parkinson's Disease (PD) is a prevalent movement disorder disrupting the lives of individuals in the US, with over 50,000 new cases each year (NIH Fact Sheets - Parkinson's Disease) and a worldwide prevalence of approximately 1% of all individuals over the age of 60 (Tysnes & Storstein, 2017). It is the second most common neurological condition after Alzheimer's (Ascherio & Schwarzschild, 2016), affecting approximately 1 million people in the US and over 10 million worldwide with a substantial and striking sex difference in prevalence impacting more men than women with the condition (Pretzer-Aboff et al., 2016). The cardinal diagnostic signs of the disease are motor dysfunction, specifically tremor, rigidity, and bradykinesia, with more recent recognition of postural instability and gait disturbance (PIGD) as a primary clinical indication of PD (Tysnes & Storstein, 2017). Across the array of motoric disturbances evident over time in individuals with PD, changes in gait characteristics are among the well-described (Iosa et al., 2016).

Walking has been identified as the first activity for which individuals with PD report difficulty (Shulman et al., 2008). Parkinsonian gait is both hypokinetic and bradykinetic (Curtze et al., 2015; Galna et al., 2015). Step size reduction (hypokinesia) and slower cadence (bradykinesia) are both present in PD and gait kinematics, and kinetics (i.e., joint angles, ground reaction forces (GRF) are reduced (Meg E. Morris et

al., 1994; M. Morris et al., 2005). These findings and other evidence suggest that motor output and locomotor pattern coordination are disrupted in PD (Desmurget, Grafton, et al., 2004; Desmurget, Grafton, et al., 2004; Mazzoni et al., 2007).

Three locomotor tasks must be coordinated to have an efficient and stable gait in bipedal locomotion: body weight support, limb advancement, and propulsion (Awad et al., 2020; Sadeghi et al., 1997; David A. Winter, 2009). During the propulsive phase of walking gait, typically measured from midstance to toe-off, the leg muscles are responsible for propelling the body's center of mass forward (Gottschall & Kram, 2003; Tesio & Rota, 2019). The hip abductors and the ankle plantar flexors generate the most significant percentage of the total propulsive force (Sylvester et al., 2021). Several muscles of the leg and trunk provide stability, and the foot provides a stable yet advancing base (Perry & Burnfield, 2010). The anteriorly-directed ground reaction force (AGRF) and its salient metrics (e.g., peak, impulse, duration) have been used to quantitatively measure and characterize the propulsion force during walking using a force platform (Koozekanani et al., 1987; Hsiao et al., 2016; Revi et al., 2020; Wu et al., 2019). However, the rate of rise or push-off rate of the AGRF remains understudied. Previous studies suggest that AGRF is also affected by the distance between the body's center of mass (COM) and the center of pressure (COP) (Miyazaki et al., 2021; Hsiao et al., 2015). Hsiao (2015) states the following:

> Another critical predictor for propulsive force is the position of the COP relative to the body COM. This relative position affects the orientation of the ground reaction force (GRF) vector and, therefore, determines the proportion of the GRF

being distributed anteriorly. (p. 2)

In addition, AGRF peak and AGRF impulse have been shown to scale with walking speed (Lewek, 2011; Peterson et al., 2011; Wu et al., 2019), and are positively related to walking speed (Hsiao et al., 2016).

Almost half of healthy walking's metabolic cost is attributed to producing horizontal propulsion forces (Gottschall & Kram, 2003). The metabolic energy needed by pathological gait is over twice that of healthy gait (Gonzales & Corcoran, 1994; Waters & Mulroy, 1999; Kuo & Donelan, 2010), and physics-based models show that without propulsion, it takes up to four times as much energy to redirect the COM velocity during locomotion (Kuo, 2002; Ruina et al., 2005). Each limb's generation of propulsive forces helps maintain interlimb symmetry, walking speed, and efficiency (Liu et al., 2006). Therefore, functional propulsion is a necessary pre-condition for metabolically economical walking performance.

However, propulsion is compromised in patients with PD. People with PD have greater co-activation of antagonistic muscles and reduced amplitude of the distal lower-extremity musculature, affecting gait performance (Cioni et al., 1997; Dietz et al., 1995; Mitoma et al., 2000; Rodriguez et al., 2013). Kinetic data reveal reduced ankle (push-off) power generation and reduced hip flexion (pull-off) power, and subjects with PD have a reduced third rocker roll-off (forefoot rocker) at the terminal stance of gait (Sofuwa et al., 2005). Studies have also shown that subjects with PD have under-scaling of power generation at push-off, with reduced amplitude of electromyographic activity in the gastrocnemius muscle (Meg E. Morris et al., 1999; Dietz et al., 1995). Ground

reaction force push-off peaks are reduced in patients with PD (Koozekanani et al., 1987; Morris et al., 1999; Peppe et al., 2007), and the anterior ground reaction force (AGRF) is decreased significantly in patients with PD compared to age and gender-matched controls (Sharifmoradi et al., 2016).

In addition, older adults rely more than young adults on hip musculature for power generation, a phenomenon known as a distal-to-proximal redistribution (DeVita & Hortobagyi, 2000). This redistribution may be considered dysregulated, or an additional impairment, increasing metabolic energy costs; the longer muscle fascicles and relatively short tendons spanning the hip are less metabolically favorable than the short fascicles and long, series elastic tendons spanning the ankle (Browne & Franz, 2018; Friederich & Brand, 1990; Zelik et al., 2014). The redistribution may also be considered an adaptation to decreased dynamic stability or plantar flexor strength.

For this study, a performance-based training paradigm was used to develop an over-ground locomotor training (OLT) program to improve walking performance in patients with PD. Performance-based training emphasizes principles of task specificity, practice variation, and progressive overload in an attempt to promote active exploration of real-world movement solutions and physiological adaptation across multiple body systems supporting locomotor function (Gollie & Guccione, 2017). Task-specificity in training applies to both the movements practiced and the environment in which training occurs, however, few gait-training studies in PD have applied both dimensions of this concept concurrently.

Performance-based training also emphasizes that training should be metabolically challenging, as to promote energy systems development, which, in the context of gait rehabilitation, may enable individuals to better meet the bioenergetic demands of sustained walking (Gollie & Guccione, 2017; Guccione et al., 2019). Energy demand is intrinsically tied to movement, thus, enhanced ambulatory ability resulting from training may involve adaptations that enable individuals to more appropriately meet the bioenergetic demands of whole-body activity (Gollie & Guccione, 2017; Guccione et al., 2019). This is a point of particular relevance to individuals with PD given that cardiorespiratory fitness is often diminished in members of this patient population. In addition, the OLT protocol is grounded in dynamical systems theory of motor control and motor learning and incorporates programming principles from the fields of exercise physiology and neurorehabilitation (Davids et al., 2003; Flach et al., 2017; Glazier & Davids, 2009; Glazier, 2017; Gollie & Guccione, 2017; Guccione et al., 2019; Ranganathan & Newell, 2013).

The primary goal of the OLT program is to promote an expansion of a patient's motoric behavioral repertoire for real-world walking. Patients perform a sequence of challenging and repetitive locomotor-specific tasks in an exclusively overground environment without body-weight support or balance assistance. OLT sessions incorporate the practice of the actions involved in each sub-task of walking (e.g., weight shifting, stepping, propulsion) and focus on specific characteristics of locomotor performance (i.e., power, stability, or stepping) in a particular direction of movement (i.e., forward, backward, lateral, rotational). The secondary goal of the OLT program is

to achieve a training stimulus that would promote cardiorespiratory adaptations. Each training session was performed above the subject's 60% age-predicted maximal heart rate (HR). These two training goals were emphasized because recovery of ecologically valid walking capabilities may occur across multiple body systems and these effects may be attained if training concurrently targets motor skill acquisition and physiological adaptation in a task and environmentally specific manner (Fahey et al., 2019; Gollie & Guccione, 2017; Kleim & Jones, 2008; Schmidt & Lee, 2019; Vaz et al., 2017).

The purpose of the present study was to determine the effect of a 12-week over-ground locomotor training (OLT) program on propulsive force generation in ambulatory patients with mild to moderate PD. Specifically, the AGRF and its salient metrics were interrogated, along with walking speed, before and after OLT. Patients with PD may benefit from intervention strategies that target propulsive force production and kinetic gait components. This intervention development and efficacy study is intended to add to the gait rehabilitation strategies currently used for the PD population.

## Specific Aims and Hypotheses

Aim 1: To determine the effect of a 12-week OLT program on the anterior-posterior (A-P) propulsive ground reaction force metrics.

Hypothesis 1a: A 12-week OLT program will modify peak AGRF, as measured by GRF, in subjects with mild to moderate PD.

Hypothesis 1b: A 12-week OLT program will modify the rate of rise (ROR) of the peak AGRF, as measured by GRF, in subjects with mild to moderate PD.

Hypothesis 1c: A 12-week OLT program will modify push-off impulse, as measured by GRF, in subjects with mild to moderate PD.

Hypothesis 1d: A 12-week OLT program will modify push-off duration, as measured by GRF, in subjects with mild to moderate PD.

Aim 2: To determine the effect of a 12-week OLT program on peak PGRF.

Hypothesis 2: A 12-week OLT program will modify peak PGRF, as measured by GRF, in subjects with mild to moderate PD.

Aim 3: To determine the effect of a 12-week OLT program on single stance duration.

Hypothesis 3: A 12-week OLT program will modify single stance duration, as measured by GRF, in subjects with mild to moderate PD.

Aim 4: To determine the effect of a 12-week OLT program on COM-COP distance.

Hypothesis 4: A 12-week OLT program will modify COM-COP distance, as measured by kinematic and GRF data, in subjects with mild to moderate PD.

Aim 5: To determine the effect of a 12-week OLT program on preferred walking speed.

Hypothesis 5: A 12-week OLT program will modify preferred walking speed, as measured by kinematic and GRF data, in subjects with mild to moderate PD.

Aim 6: To conduct a correlation analysis to describe the associations between the gait variable studied in this investigation.

# METHODS

## Study Design

Data were collected prior to COVID (sars-cov-2). Although additional participant data collection was anticipated, George Mason University reduced laboratory research and other nonessential research activities in mid-March 2020, including the elimination of on-campus, in-person human participant research. Therefore, we have chosen to use previously collected data as the basis for this dissertation.

This pre-experimental pilot study used a pre- and post-test design. Testing was performed at two time points: before (pretest) and immediately following the OLT program (post-test). The OLT program was comprised of 24, one-hour training sessions performed twice weekly with at least 48 hours between training sessions. To be included in the analysis, subjects were permitted to miss no more than three consecutive sessions and were required to complete the training protocol within 15 weeks of their initial baseline assessment.

## Ethical Approval

The protocol and procedures were approved by the Institutional Review Board of George Mason University (#1374615-3). The study was registered on clinicaltrials.gov (NCT03864393). Written and verbal explanations of the study protocol and risks related to testing and training procedures were presented to prospective subjects prior to enrollment. Written informed consent was obtained from all participants prior to initiation of testing or training activities.

## Study Sample

Participants were recruited from the greater Washington, DC, metropolitan area using paper and electronic fliers, local support group networking, and online postings. Inclusion criteria consisted of the following: age between 18 and 85 years; diagnosis of mild-to-moderate PD (Hoehn and Yahr (H&Y) score ≤ 3) (Jankovic & Tolosa, 1988); speaks English; and able to ambulate without requiring an assistive device. Exclusion criteria consisted of the following: neurological disease or diagnosis other than PD; uncontrolled cardiovascular, pulmonary, neurological, or metabolic disease which may impact the ability to exercise or in which exercise is contraindicated; medications that may alter heart rate or metabolic data; legal blindness; mini-Mental State Examination score < 24 (Kukull et al., 1994); pregnancy; and concurrent participation in a structured exercise similar to OLT.

Of the 27 individuals screened for this study in response to advertisements, 17 individuals with PD were enrolled in the study. During the pretest functional assessment, one participant displayed uncontrolled hypertension and was thus excluded from further participation. Three participants ceased participation approximately halfway through the 24-session protocol, one citing excessive fatigue following training sessions, one citing a preference to continue a "rock steady boxing" program, and one due to exacerbation of a chronic knee condition. One participant reported mild chest discomfort during the first training session and was referred to a cardiologist for evaluation. This subject resumed the protocol after clearance from their cardiologist. Overall, thirteen individuals completed the 24-session intervention protocol. One subject who completed the protocol

reported an increase in their dopaminergic medication during the training protocol, and was therefore excluded from the final analysis. Another subject was excluded from the final analysis as this subject's posttest data was incomplete. Thus, 11 subjects were included in the final analysis. Participants (7 male, 4 female) were a mean age of 69.7 ± 4.9 years, stood 168.5 ± 7.6 cm, and weighed 68.8 ± 10.9 kg. The Hoehn &Yahr scores for participants ranged from 1-3. Participant characteristics for the final analysis are presented in Tables 1 and 2.

**Table 1: Individual participant characteristics in final analysis.**

| Participant | Age (years) | Gender | Height (cm) | Weight (kg) | Hoehn & Yahr |
|---|---|---|---|---|---|
| 1 | 71 | M | 176.5 | 74.7 | 1 |
| 2 | 71 | M | 176.5 | 79.4 | 1.5 |
| 4 | 76 | F | 174.0 | 61.8 | 1 |
| 5 | 64 | M | 180.5 | 76.3 | 1 |
| 6 | 75 | M | 168.5 | 77.0 | 2 |
| 9 | 70 | F | 156.8 | 46.0 | 2 |
| 10 | 74 | M | 161.5 | 74.8 | 3 |
| 11 | 65 | M | 164.3 | 65.8 | 2 |
| 12 | 65 | F | 160.9 | 55.6 | 2 |
| 14 | 62 | M | 169.0 | 79.4 | 2 |
| 15 | 74 | F | 164.7 | 65.9 | 2 |

**Abbreviations:** M, male; F, female.

**Table 2: Participant characteristics in final analysis (N=11)**

| Participant | Gender n (%) | Age (years) Mean (SD) | Height (cm) Mean (SD) | Weight (kg) Mean (SD) | Hoehn & Yahr |
|---|---|---|---|---|---|
| **Entire sample** | 11 (100) | 69.7 (4.9) | 168.5 (7.6) | 68.8 (10.9) | 1-3 |
| **Male** | 7 (63) | 68.9 (5.1) | 171.0 (7.0) | 75.3 (4.6) | 1-3 |
| **Female** | 4 (37) | 71.3 (4.9) | 164.1 (7.3) | 57.3 (8.7) | 1-2 |

## Enrollment Procedure

The assessment of eligibility and enrollment procedures covered the following steps in the following order. First, participants reported their interest to the study coordinator via a phone call or an email. This was followed by a standardized telephone interview to screen eligibility. Lastly, eligible participants visited the laboratory where a study investigator provided a detailed explanation of the informed consent document. Once participants voluntarily signed the informed consent document, medical history and medication intake lists were reviewed to further screen eligibility. Next, the Mini-Mental State Examination was administered and scored to screen for cognitive function according to the exclusion criteria. Finally, a study investigator administered the H&Y assessment to screen for PD severity according to the inclusion criteria.

## Testing Day Procedure

Participants were asked to refrain from strenuous physical activity for 48 hours prior to testing sessions. All participants were asked to follow their normal dietary and PD medication schedules and were tested during the on-phase at the same time of day during the pretest and post-test. Each participant's height and weight were measured prior

to the start of functional testing. Resting heart rate and blood pressure were recorded with the participant in a seated position prior to any functional tests to screen for excessive hypertension or excessive hypotension. Testing sessions featured two components separated by 20-30 minutes of seated rest. As part of a parent study (ClinicalTrials.gov Identifier: NCT03864393) that will be assessing neuromuscular, kinetic, kinematic, and spatiotemporal adaptations in response to OLT in people with PD, the primary component of testing in the present study was an assessment of walking propulsion kinetics. Testing also assessed an overground 10 Minute Walk Test (10MWT) with continuous cardiopulmonary gas exchange monitoring using a portable metabolic system, the results of which are not the focus of the present study. Randomization of the sequence of the two components of the testing procedure were performed for every other subject enrolled (i.e., 1st, 3rd, 5th, etc.), with the subject in between (i.e., 2nd, 4th, 6th, etc.) performing testing in the opposite order. This was done to ensure an equal balance of testing sequences across the study sample. The testing sequence was kept consistent within each subject from pretest to post-test.

## Propulsion Testing

Participants performed the propulsion testing procedure before and after the OLT program. Participants were asked to walk across a 6-meter platform with four force plates, level with the walking surface, mounted midway. Subjects walked at their self-selected preferred walking speed for 20 trials. For this study, propulsive force was defined by the peak positive AGRF, the ROR of the AGRF, the push-off impulse, and the push-off duration during overground walking. The force plates (Bertec, Columbus, OH)

quantify the GRF in response to the force placed upon it by the subject. The data were collected at a frequency of 1000 Hz.

## Intervention

A performance-based training paradigm was used to develop the OLT program implemented in this study. Specifically, the OLT protocol is grounded in dynamical systems theory of motor control and motor learning and incorporates programming principles from the fields of exercise physiology and neurorehabilitation (Davids et al., 2003; Flach et al., 2017; Glazier & Davids, 2009; Glazier, 2017; Gollie & Guccione, 2017; Guccione et al., 2019; Ranganathan & Newell, 2013). The central goal of the OLT program was to promote an expansion of subjects' motoric behavioral repertoire for real-world walking.

Primary emphasis was placed on providing subjects with a training experience that would theoretically promote motor learning specific to overground walking. More directly, subjects performed a sequence of challenging and repetitive locomotor-specific tasks in an exclusively overground environment without body-weight support or balance assistance. Secondary emphasis was placed on achieving a training stimulus that would theoretically promote cardiorespiratory adaptations. To achieve this goal, OLT trainers modulated the characteristics of rest periods (i.e., interspersed half-squats, mini-multidirectional lunges, or high-knees when needed instead of passive rest) so that the bulk of each training session was performed above 60% age-predicted maximal heart rate (HR). These two overall training objectives were emphasized because a diverse body of literature suggests that recovery of ecologically valid walking capabilities may occur

across multiple body systems and that such effects may be readily attained if training concurrently targets motor skill acquisition and physiological adaptation in a task and environmentally specific manner (Brooks et al., 2004; Gollie & Guccione, 2017; Kleim & Jones, 2008; Schmidt & Lee, 2019; Vaz et al., 2017).

Participants underwent 24, 60-minute bi-weekly OLT sessions over 12-15 weeks. Every session incorporated practice of the actions involved in each sub-task of walking (e.g., weight shifting, stepping, propulsion). However, individual training sessions were "themed", meaning that the focus of the training session was to improve a specific characteristic of locomotor performance (i.e., power, stability, or stepping) in a specific direction of movement (i.e., forward, backward, lateral, rotational). Drills for each day were programmed and coached in a manner that emphasized the theme of the session. For example, a "lateral-power" session incorporated drills that challenged power development through the lower extremities during a variety of lateral walking tasks. In each session, following a brief circuit-style warm-up, sub-tasks of walking were isolated at the beginning of the session and drills progressed in complexity throughout the session using pre-specified time blocks of specific drills (i.e., part-to-whole sequencing). Participants progressed from simple movements relevant to a specific walking action to dynamic walking exercises. Each session culminated with activity rehearsal consisting of dynamic walking at a variety of speeds and tempos and in various directions and patterns. Small hand weights and gait belts were used frequently during various exercises to provide external resistance and to increase the load, intensity, and balance demands of specific drills. Participants wore a heart rate monitor (Polar H10 heart rate sensor, Polar,

USA) throughout training sessions for data recording and to aid OLT trainers in adjusting the intensity of the session to meet the 60% age-predicted maximal heart rate (HR).

## Measures

Gait propulsion parameters were analyzed with Matlab R2021a (The MathWorks, Inc., Natick, MA, USA). Specific outcome measures are depicted in Figure 1.

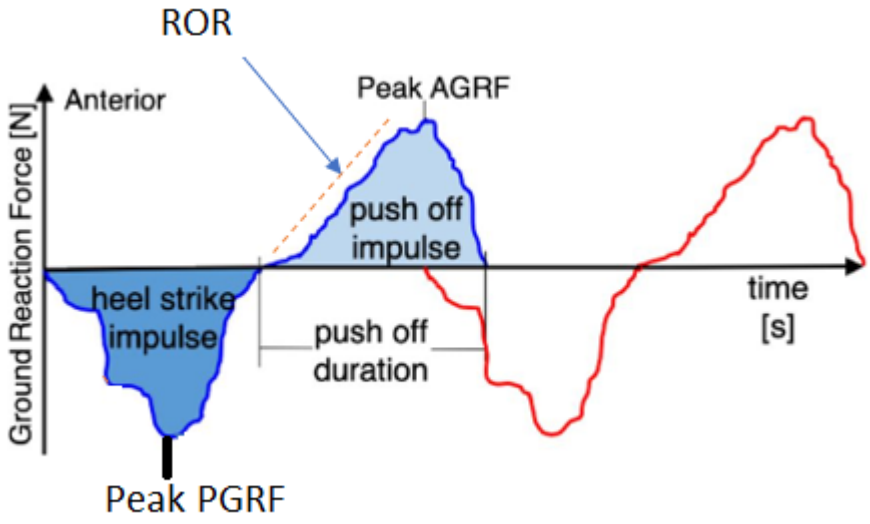



**Figure 1: Definition of Gait Propulsion Parameters** (Farrens et al., 2019).

The peak propulsive force (peak AGRF) was determined as the maxima of the AGRF and assessed by using the findpeaks or maximum function to find the location and the value of the peak.

The rate of rise (ROR) of the AGRF was assessed using the risetime function to determine the rise time of positive-going bilevel waveform transitions.

The push-off impulse was assessed using the trapz function to calculate the area under a set of discrete data by breaking the region into trapezoids. The function then adds the area of each trapezoid to compute the total area.

The push-off duration was assessed as the time duration of the positive AGRF.

Peak braking force (peak PGRF) was determined as the minima of the PGRF and assessed by using the findpeaks or maximum function to find the location and the value of the peak.

Single-stance duration was assessed as the time duration of the negative PGRF and positive AGRF.

The COM-COP distance was assessed by calculating the distance from the COM position to the COP position at the start of propulsion. The sternal marker position was used as a proxy for the COM. COP was determined from the force platform.

The walking speed was assessed by dividing the sternal marker distance traveled by the time of travel.

## Assessor Bias

Even though all subjects received the same intervention and could not be blinded to the intervention, we used a separate team of assessors who did not observe training and a separate team of trainers so that bias from knowing how well a subject performed during testing will not influence a trainer's expectations. Similarly, using a different team of assessors who have no knowledge of performance during training will blunt any influence of assessor bias on test results during the entire study period. Whenever

possible, assessors did not know how a subject performed as the data were stored and downloaded directly from the relevant data collection device.

## Statistical Analysis

All data were screened for missing data, outliers, and normality. Descriptive statistics were calculated for any demographic data and all outcome variables. Means and standard deviations were used to summarize continuous measures, while frequency counts and proportions were used to summarize categorical data. Box plots, line graphs, or histograms were used to plot the data.

The mean and standard deviation were used in measuring pre- and post-test changes in gait propulsion outcomes, including peak AGRF, ROR, push-off impulse, push-off duration, walking speed, single stance duration, and peak PGRF. The paired t-test was used to examine any statistically significant differences in the pre- and post-average values of the gait propulsion outcomes. The Shapiro-Wilk test was used to examine normality. If data were non-normally distributed, the Wilcoxon signed-rank test was utilized instead of the paired t-test. Mean changes in outcomes and their 95% confidence intervals are presented for all outcomes. For normally distributed data, the Cohen's d(within-subjects) effect sizes are presented (Faul et al., 2007). For non-normally distributed data, standardized effect sizes are presented, where Z is the Z-score from a Wilcoxon signed-rank test and n is the total number of observations across pretest and post-test time points for a particular variable (Tomczak & Tomczak, n.d.).

Pearson correlation was used to assess associations between the same pairs of gait propulsion variables. The correlation analysis conducted as part of the present study was

based on previous investigations demonstrating or implying an association between walking speed and gait parameters such as peak AGRF and push-off impulse (Bovi et al., 2011; Fukuchi et al., 2019; Hsiao et al., 2015; Riley et al., 2001; Uematsu et al., 2017). The variables analyzed using the Pearson correlation were pretest average peak AGRF, ROR, push-off impulse, push-off duration, walking speed, single stance duration, and peak PGRF and the posttest peak AGRF, ROR, push-off impulse, push-off duration, walking speed, single stance duration, and peak PGRF.

A Wilcoxon signed-rank test was used to examine differences in the average peak AGRF, ROR, push-off impulse, push-off duration, walking speed, single stance duration, and peak PGRF before and after the OLT program for male and female patients with Parkinson's disease. In addition, a Mann-Whitney U test was used to examine differences in average peak AGRF, ROR, push-off impulse, push-off duration, walking speed, single stance duration, and peak PGRF before and after the OLT program between male and female patients with Parkinson's disease. The Mann-Whitney U-test tests two independent samples, whereas the Wilcoxon signed-rank test tests two dependent samples.

Statistical significance was accepted at $p \leq .05$ for 2-tailed hypotheses. Statistical analyses were performed using IBM SPSS Statistics (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp).

## RESULTS

All hypotheses (1-5) were tested to examine the extent a 12-week OLT program can modify gait propulsion outcomes in subjects with mild to moderate PD. The gait propulsion outcomes studied were: Peak AGRF, ROR of the AGRF, push-off impulse, push-off duration, peak PGRF, single stance duration, and walking speed. The paired t-test or Wilcoxon signed-rank test was used to assess differences in the average values of these measures between pre and post 12-week OLT program. These results are summarized in Table 3. A paired t-test indicated there was not a significant difference in the average peak AGRF pre OLT ($M = 141.43$, $SD = 34.02$) compared to post OLT ($M = 139.01$, $SD = 31.90$), $t(10) = .608$, $p = .557$. A paired t-test indicated there was a significant difference in the average ROR pre OLT ($M = .28$, $SD = .035$) compared to post OLT ($M = .24$, $SD = .054$), $t(10) = 2.92$, $p = .015$. A paired t-test indicated there was a significant difference in the mean push-off impulse pre OLT ($M = 31.36$, $SD = 7.59$) compared to post OLT ($M = 27.29$, $SD = 8.59$), $t(10) = 2.62$, $p = .026$. A Wilcoxon signed-rank test indicated there was a significant difference in the average push-off duration pre OLT ($M = .46$, $SD = .041$) compared to post OLT ($M = .41$, $SD = .084$), $Z = -2.312$, $p = .021$. There was not a significant difference in the average peak PGRF pre OLT ($M = -143.26$, $SD = 26.76$) compared to post OLT ($M = -144.60$, $SD = 35.92$), $t(10) = .197$, $p = .848$. A Wilcoxon signed-rank test indicated there was a significant average difference in the single stance duration pre OLT ($M = .28$, $SD = .035$) compared to post OLT ($M = .24$, $SD = .054$), $Z = -2.845$, $p = .004$. A paired t-test

indicated there was not a significant difference in the COM-COP distance pre OLT (M = 1247.35, SD = 71.1) compared to post OLT (M = 1253.56, SD = 46.7), t (10) = -.486, p = .642. A paired t-test indicated there was a significant average difference in the preferred walking speed pre OLT (M = 1.29, SD = .155) compared to post OLT (M = 1.39, SD = .109), t (10) = -3.34, p = .012.

Large Cohen's effect sizes were found pre to posttest for the average ROR of the AGRF (d = .879), the average push-off impulse (d = .789), the average single stance duration (d = .857), and the average walking speed (d = 1.18). A medium effect size of d = .697 was found for the average push-off duration. Small effect sizes were found for the average peak AGRF, the average peak PGRF, and the average COM-COP distance (d = .183, d = .059, and d= .105), respectively.

**Table 3: Differences in the average gait propulsion outcomes before and after the OLT program in patients with Parkinson's disease.**

| Gait Propulsion Outcomes | Pretest (n=11) Mean (SD) | Posttest (n=11) Mean (SD) | Pre-Post Change Mean (SD) | P-value | Cohen's d |
|---|---|---|---|---|---|
| **Peak AGRF (N)** | 141.43 (34.02) | 139.01 (31.90) | 2.42 (13.20) | .557 | 0.183 |
| **ROR (s)** | .275 (.035) | .241 (.054) | -.034 (.039) | .015 | 0.879 |
| **Push-Off Impulse (N-s)** | 31.36 (7.59) | 27.29 (8.59) | 4.06 (5.15) | .026 | 0.789 |
| **Push-Off Duration (s)*** | .459 (.041) | .409 (.084) | .05 | .021 | 0.697 |
| **Single Stance Duration (s)*** | .981 (.075) | .841 (.176) | .14 | .004 | 0.857 |
| **COM-COP Distance (mm)** | 1247.3 (71.1) | 1253.6 (46.7) | 6.21 (36.1) | .642 | 0.105 |
| **Walking Speed (m/s)** | 1.294 (.176) | 1.388 (.124) | .094 (.083) | .012 | 1.18 |
| **Peak PGRF (N)** | -143.3 (26.76) | -144.6 (35.92) | 1.34 (22.51) | .848 | 0.059 |

**Abbreviations**: N: Newtons; N-s: Newton-seconds; s: seconds; m/s: meters per second. Bold type, shaded values indicate a statistically significant test. Note: * indicates Wilcoxon Signed Rank Test.

The associations between the different measurements of propulsion were examined before the OLT intervention using the Pearson correlation coefficient (Table 4). Before the OLT intervention, the results of the correlation analysis indicate there was a significant strong positive correlation between the peak AGRF and push-off impulse, $r(11) = .936$, $p<.01$, and walking speed, $r(11) = .936$, $p<.01$. A significant, strong negative correlation was found between the peak AGRF and peak PGRF, $r(11) = -.856$, $p<.01$. The results of the correlation analysis also indicate a strong, significant correlation between the ROR and push-off duration, $r(11) = .938$, $p<.01$ and single stance duration, $r(11) = .854$, $p<.01$. In addition, the findings show a moderate, but significant positive correlation between the push-off impulse and walking speed, $r(11) = .723$, $p<.05$. However, a strong negative and statistically significant correlation was found between the push-off impulse and peak PGRF, $r(11) = -.936$, $p<.01$. The results of the correlation analysis also indicate a significant strong positive correlation between the push-off duration and single stance duration, $r(11) = .834$, $p<.01$. The results of the correlation analysis indicate there was a significant moderate negative correlation between the walking speed and peak PGRF, $r(11) = -.732$, $p<.05$.

**Table 4: Correlations among the gait propulsion outcomes prior to the OLT intervention (N=11)**

| PreXPre | **Peak AGRF** | **ROR** | **Push-off Impulse** | **Push-off Duration** | **Walking Speed** | **Single Stance Duration** | **COM-COP Distance** | **Peak PGRF** |
|---|---|---|---|---|---|---|---|---|
| **Peak AGRF** | 1 | | | | | | | |
| **ROR** | -.034 (.92) | 1 | | | | | | |
| **Push-off Impulse** | **.936 (<.01)** | .262 (.44) | 1 | | | | | |
| **Push-off Duration** | .137 (.688) | **.938 (<.01)** | .444 (.171) | 1 | | | | |
| **Walking Speed** | **.910 (<.01)** | -.383 (.349) | **.723 (<.05)** | -.216 (.608) | 1 | | | |
| **Single stance Duration** | .009 (.978) | **.854 (<.01)** | .315 (.346) | **.834 (<.01)** | -.253 (.564) | 1 | | |
| **COM-COP Distance** | .031 (.942) | .345 (.40) | .258 (.537) | .412 (.311) | .061 (.886) | .517 (.189) | 1 | |
| **Peak PGRF** | **-.856 (<.01)** | -.244 (.47) | **-.936 (<.01)** | -.442 (.173) | **-.732 (<.05)** | -.208 (.54) | -.334 (.419) | 1 |

Note: Values are Pearson Correlation (p-value). Bold type, shaded values indicate a statistically significant correlation.

The associations between the different measurements of propulsion were examined after the OLT intervention using the Pearson correlation coefficient (Table 5). After the OLT intervention, the results of the correlation analysis indicate there was a significant strong correlation between the peak AGRF and push-off impulse, $r(11) = .763$, $p<.01$, and walking speed, $r(11) = .858$, $p<.01$. A significant, strong negative correlation was found between the peak AGRF and peak PGRF, $r(11) = -.963$, $p<.01$. The results of the correlation analysis also indicate there was a significant, strong positive correlation between the ROR and the push-off impulse, $r(11) = .786$, $p<.01$, push-off duration, $r(11) = .935$, $p<.01$, COM-COP distance, $r(11) = .860$, $p<.01$, and single stance duration, $r(11) = .870$, $p<.01$. In addition, the findings show a significant, strong positive correlation between the push-off impulse and the push-off duration, $r(11) = .792$, $p<.01$, a significant, strong positive correlation between the push-off impulse and the walking speed, $r(11) = .756$, $p<.05$, a significant, strong positive correlation between the push-off impulse and COM-COP distance, $r(11) = .723$, $p<.05$, and a moderate, but significant correlation between the push-off impulse and single stance duration, $r(11) = .670$, $p<.05$. However, a strong negative and statistically significant correlation was found between the push-off impulse and peak PGRF, $r(11) = -.838$, $p<.01$. The results of the correlation analysis indicate there was a significant, strong positive correlation between the push-off duration and the single stance duration, $r(11) = .945$, $p<.01$, and the COM-COP distance, $r(11) = .717$, $p<.05$. A significant, strong positive correlation was also found between the COM-COP distance and the single stance duration, $r(11) = .802$,

p<.05. A significant, strong negative correlation was also found between the walking speed and the peak PGRF, r (11) = -.810, p<.05.

**Table 5: Correlations among the gait propulsion outcomes after the OLT intervention (N=11)**

| PostXPost | **Peak AGRF** | **ROR** | **Push-off Impulse** | **Push-off Duration** | **Walking Speed** | **Single Stance Duration** | **COM-COP Distance** | **Peak PGRF** |
|---|---|---|---|---|---|---|---|---|
| **Peak AGRF** | 1 | | | | | | | |
| **ROR** | .296 (.377) | 1 | | | | | | |
| **Push-off Impulse** | **.736 (<.01)** | **.786 (<.01)** | 1 | | | | | |
| **Push-off Duration** | .249 (.461) | **.935 (<.01)** | **.792 (<.01)** | 1 | | | | |
| **Walking Speed** | **.858 (<.01)** | .275 (.509) | **.756 (<.05)** | .389 (0.341) | 1 | | | |
| **Single Stance Duration** | .071 (.835) | **0.87 (<.01)** | **0.67 (<.05)** | **0.945 (<.01)** | 0.307 (.459) | 1 | | |
| **COM-COP Distance** | .081 (.848) | **.86 (<.01)** | **.723 (<.05)** | **.717 (<.05)** | -.141 (0.738) | **.802 (<.05)** | 1 | |
| **Peak PGRF** | **-.963 (<.01)** | -.461 (.15) | **-.838 (<.01)** | -.406 (.215) | **-.810 (<.05)** | -.204 (.548) | -.214 (.611) | 1 |

Note: Values are Pearson Correlation (p-value). Bold type, shaded values indicate a statistically significant correlation.

Differences in the average gait propulsion outcomes before and after OLT for male and female patients with PD are shown in Table 6. A Wilcoxon signed-rank test indicated there was a significant difference in the average push-off impulse of male subjects pre OLT (M = 34.77, SD = 6.42) compared to post OLT (M = 30.07, SD = 7.32), Z = -2.197, p = .028. A Wilcoxon signed-rank test indicated there was a significant difference in the average single stance duration of male subjects pre OLT (M = 0.99, SD = .082) compared to post OLT (M = 0.84, SD = .208), Z = -2.197, p = .028.

**Table 6: Differences in the average gait propulsion outcomes before and after OLT for male and female patients with Parkinson's disease**

| **Participant** | **Peak AGRF (N)** Mean (SD) | **ROR (s)** Mean (SD) | **Push-off Impulse (N-s)** Mean (SD) | **Push-off Duration (s)** Mean (SD) | **Walking Speed (m/s)** Mean (SD) | **Single Stance Duration (s)** Mean (SD) | **Peak PGRF (N)** Mean (SD) |
|---|---|---|---|---|---|---|---|
| **Male Pretest (n=7)** | 155.91 (32.8) | .278 (.041) | **34.77* (6.42)** | .467 (.046) | 1.30 (.181) | **.998* (.082)** | -153.06 (27.22) |
| **Male Posttest (n=7)** | 153.15 (23.2 | 0.254 (.060) | **30.07* (7.32)** | .413 (.093) | 1.38 (.125) | **.841* (.208)** | -160.27 (20.51) |
| **P-value** | .499 | .310 | **.028** | .128 | .075 | **.028** | .499 |
| **Female Pretest (n=4)** | 116.10 (19.0) | .261 (.018) | 25.38 (5.90) | .477 (.034) | 1.26 (.007) | .950 (.057) | -126.12 (16.99) |
| **Female Posttest (n=4)** | 114.27 (32.2) | .218 (.037) | 22.43 (9.44) | .401 (.077) | 1.41 (.065) | .840 (.129) | -117.18 (43.42) |
| **P-value** | .715 | .068 | .465 | .068 | .180 | .068 | .465 |

Abbreviations: N: Newtons; N-s: Newton-seconds; s: seconds; m/s: meters per second.

Mann-Whitney U analyses revealed a significant difference between males and females for peak AGRF pre-OLT intervention ($Z = -2.079$, $p = .042$) at a significance level of 0.05, 2-tailed. The Mann-Whitney U analyses revealed no significant difference between males and females for the other gait propulsion measurements.

## DISCUSSION

This study investigated the effects of a 24-session performance-based OLT program on the anteriorly directed propulsive force (AGRF metrics) during walking gait of ambulatory patients with PD. The hypothesis that OLT will modify peak AGRF was not supported in this study. Our results showed no change in the average peak AGRF, indicating OLT did not affect the magnitude of the anteriorly directed propulsive force. However, our results did reveal a statistically significant increase in average preferred walking speed in patients with PD after OLT. This finding supports our hypothesis that OLT will modify preferred walking speed. However, the combined finding that preferred walking speed increased without a concomitant rise in peak AGRF is seemingly not consistent with prior investigations. Push-off forces, specifically peak AGRF and the second peak of the vertical ground reaction force (VGRF) (Figures 2 and 3), typically scale with walking speed (Hsiao et al., 2016; Deffeyes & Peters, 2021; Lewek, 2011; Peterson et al., 2011; Wu et al., 2019).

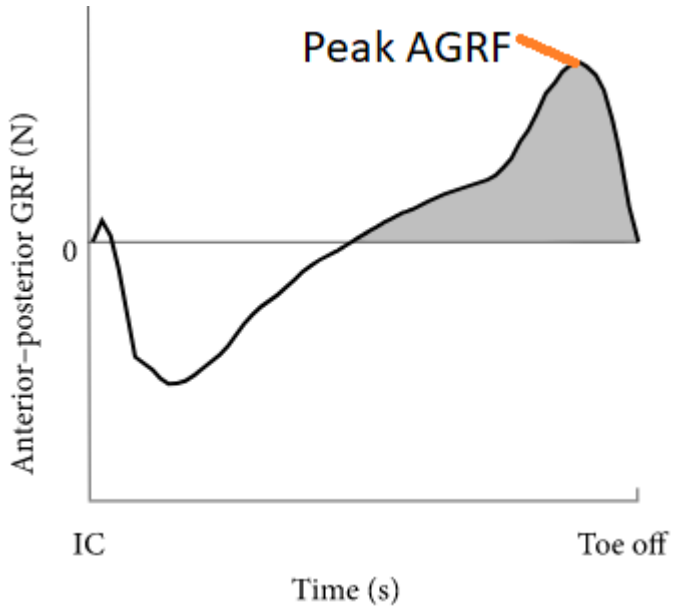



**Figure 2: Generic A-P GRF graphic showing peak AGRF, initial contact (IC), and toe-off.**

An increase in walking speed is typically associated with an increase in peak AGRF, and a decrease in walking speed is typically associated with a decrease in peak AGRF in healthy adults (Andriacchi et al., 1977; Nilsson & Thorstensson, 1989; Wu et al., 2019). To the best of our knowledge, this typical relationship has not been firmly established in PD. Our results, an increase in walking speed without an increase in peak AGRF, suggest that peak AGRF may not be as influential a contributing/causative factor in modulating preferred walking speed in patients with PD as might be inferred from other studies, especially when AGRF is used as the single measure of change after intervention.

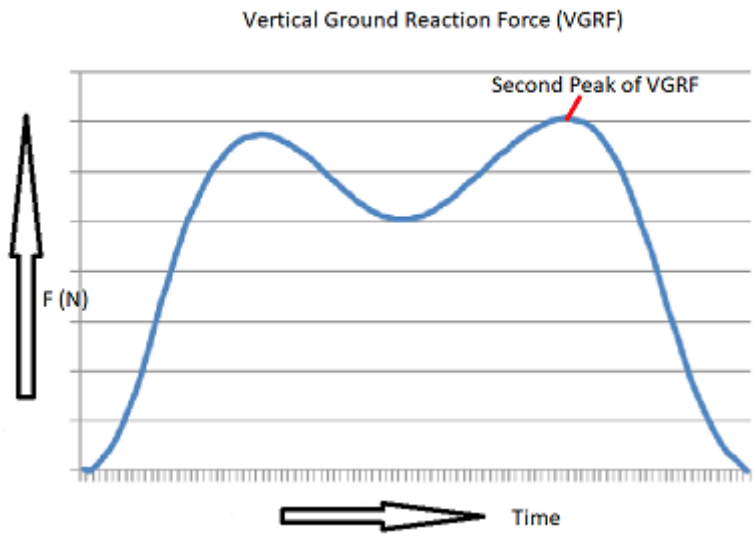



**Figure 3: Generic VGRF graphic showing the second peak of the VGRF.**

Figure 4 shows the changes in the AGRF profile before and after the OLT program and demonstrates the overall results found for the AGRF metrics studied in this investigation.

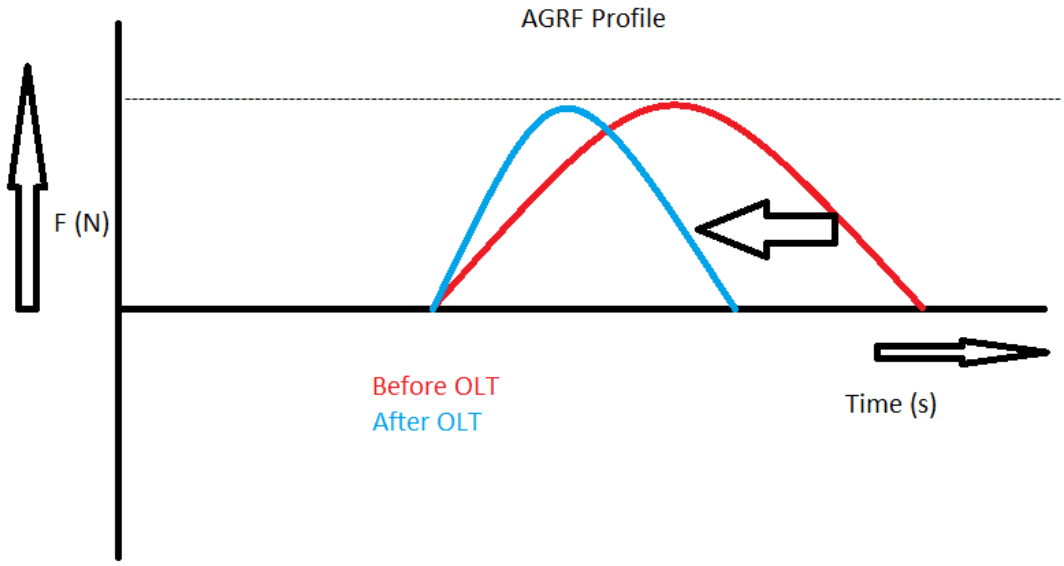



**Figure 4: Generic graphic depiction of the AGRF profile change seen in this study.**

The data from this investigation and the AGRF profile change seen in Figure 4 supported the hypotheses that OLT will modify the ROR of the AGRF, push-off impulse, and push-off duration. Each of these AGRF metrics was significantly decreased following OLT. When comparing the pre-OLT curve (red) and the post-OLT curve (blue), the post-OLT curve (blue) shows a steeper, quicker rise to the peak AGRF; less area under the curve denoting/conveying a smaller impulse; and a shorter duration. This essentially caused a shift to the left and a more compact AGRF profile following OLT.

Patients with PD show reductions in maximal muscle strength (Inkster et al., 2003; Pääsuke et al., 2004) and rate of force development (RFD) (Hammond et al., 2017; Rose et al., 2013). PD also affects the capacity to produce maximal and rapid force (Pelicioni et al., 2021). Our results suggest a diminution in some of the motor control impairments usually associated with PD. During the propulsive phase of walking gait the

leg muscles are responsible for propelling the body's center of mass upward and forward (Gottschall & Kram, 2003; Tesio & Rota, 2019). The decreased ROR of the AGRF suggests that our PD patients were able to increase the rate of muscular force development during the propulsive phase which afforded an alternative strategy to increase walking speed. Muscle power and muscle strength are related but distinct attributes. Power is defined as the ability to perform muscular work per unit time.

$$P = \frac{W}{\Delta\ time}$$

**Equation 1: Power**

Muscle strength is defined as the ability to exert force and muscle power is defined as the ability to exert force quickly.

$$Muscle\ Power = Force\ \times Velocity$$

**Equation 2: Muscle Power**

Or more specifically:

$$Muscle\ Power = dynamic\ muscle\ force\ \times\ muscle\ contraction\ velocity$$

**Equation 3: Muscle Power Specific**

The compact AGRF profile seen after OLT suggests a more powerful AGRF because our PD patients reached the same peak AGRF in a shorter amount of time (i.e., they performed the same amount of work in less time).

The hypothesis that OLT will modify single stance duration was also supported in this investigation. Our results show an average single stance duration of 0.98 s before OLT and a significant decrease in average single stance duration after OLT (0.84 s). The stance phase of gait is measured from initial foot contact to toe-off of the same foot (Figure 2). The average duration of the stance phase is approximately 0.59 to 0.67 s in "normal men" (Murray et al., 1964). At initial contact, the body weight is transferred from one limb to the other and weight acceptance and stability are important tasks during initial contact and single-leg support, and propulsion requires limb and trunk stability as the body progresses beyond the supporting foot (Perry & Burnfield, 2010). A prolonged stance time has been seen in patients with PD and is attributed to the increased time and effort needed for postural stabilization (Farashi, 2021; Muñoz Ospina et al., 2019). In addition, there is a correlation between gait speed and balance in patients with PD (Combs et al., 2014). The decrease in single stance duration observed in this study reflects an improvement in balance and postural stabilization during the stance phase.

The hypothesis that OLT will modify the COM-COP distance was not supported by the results of this investigation. Our results show no significant change in the COM-COP distance after OLT. The distance between the body's COM and the trailing limb's COP is thought to play a role in AGRF production (Figure 6). The COM-COP distance can also be an indicator of stride length. The greater this distance at the start of the propulsive phase of gait, the further the foot is behind the COM. This orientation or push-off posture of the trailing limb allows for more of the propulsive AGRF to be

directed in the anterior direction (Hsiao et al., 2015; Miyazaki et al., 2021). The average COM-COP distance increased by just 6.2 mm following OLT in the present study.

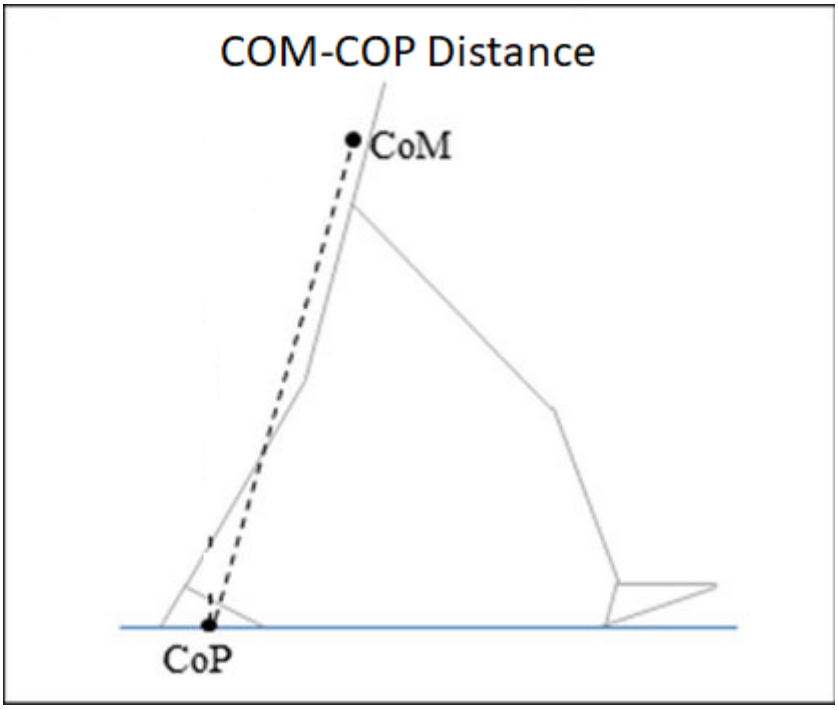



**Figure 5: Generic graphic showing COM-COP distance.**

Walking speed has implications for community living and participation, can predict future disability, hospitalization, and mortality, and has been recommended as a vital sign (Gait and walking speed as a predictor of health, n.d.; Middleton et al., 2015; Robinett & Vondran, 1988). Walking speed is a test of an individual's functional mobility and is, therefore, often a rehabilitation target for people with gait disturbances. The hypothesis that OLT will modify preferred walking speed was supported by the

results of this investigation. After the OLT program, our results reveal a statistically significant increase in preferred walking speed in patients with PD. The increase of 0.094 m/s is within the established minimal clinically important difference in gait speed among persons with PD between 0.05 and 0.22 m/s (Hass et al., 2014). A prior study investigating the effects of overground walking sessions in subjects with mild to moderate PD showed an increase of 0.06 m/s in preferred walking speed with no change in stride length but an increased cadence after overground training (Bello et al., 2013). Their result is notable because gait in PD is thought to be affected by a reduced amplitude of the stride length while the cadence remains unaffected (M. E. Morris et al., 1996).

The correlation analysis conducted as part of the present study was based on previous investigations demonstrating or implying an association between walking speed and gait parameters such as peak AGRF and push-off impulse (Bovi et al., 2011; Fukuchi et al., 2019; Hsiao et al., 2015; Riley et al., 2001; Uematsu et al., 2017). This appears to hold for patients with PD. Our results show a strong positive correlation between walking speed and peak AGRF and push-off impulse. Our results also show a strong negative correlation between walking speed and peak PGRF. In addition, peak PGRF shows a strong negative correlation with peak AGRF and push-off impulse. These results suggest that what occurs during the braking phase determines the outcome of the ensuing propulsive phase. Although the ROR of the AGRF was not correlated with walking speed, it was found to be strongly correlated with push-off impulse, push-off duration, and single stance duration and, therefore, the ROR of the AGRF may play an important role in gait propulsion.

## Summary

Taken together, our results suggest the OLT program was able to improve walking postural and dynamic stability in patients with PD. PD patients were able to spend less time in stance phase, less time in push-off duration, and decrease the rise time of the AGRF (push-off rate increased). This appears to have led to a quicker, more powerful AGRF without changes in peak AGRF, peak PGRF, or push-off posture, and an increase in walking speed in our patients with PD.

**Table 7: Summary of Hypotheses**

| Hypothesis Number | Hypothesis | Supported by Results |
|---|---|---|
| 1a | A 12-week OLT program will modify peak AGRF | No |
| 1b | A 12-week OLT program will modify the rate of rise (ROR) of the peak AGRF | Yes |
| 1c | A 12-week OLT program will modify push-off impulse | Yes |
| 1d | A 12-week OLT program will modify push-off duration | Yes |
| 2 | A 12-week OLT program will modify peak PGRF | No |
| 3 | A 12-week OLT program will modify single stance duration | Yes |
| 4 | A 12-week OLT program will modify COM-COP distance | No |
| 5 | A 12-week OLT program will modify preferred walking speed | Yes |

## LIMITATIONS

There are some limitations in this study that should be acknowledged. The main limitation was that only 11 subjects were included in this study and this study should be replicated in a larger sample. A small sample size reduces the generalizability of our results, and the lack of a healthy age-matched control group makes it difficult to determine if the changes in outcome measures observed were the result of natural changes over time rather than the result of the OLT intervention. In addition, the small sample size does not allow for analyses that would explore the multivariable type of relationships relative to an outcome or dependent variable. This study should be replicated with a larger sample and assess potential confounding relationships that cannot be addressed with this sample size. Our sample of PD subjects consisted mainly of patients at the H&Y stage I and II and was a high-functioning group. Therefore, the results of this investigation should be considered for PD patients in the early stages of the disease. This study investigated the kinetics of the propulsive phase of walking, as evidenced by the AGRF, therefore, spatiotemporal parameters such as stride length, cadence, and double limb support were not measured in this study. In addition, this study was not intended to explore: Changes in EMG activity in the muscles used to produce walking propulsive force, joint angles, joint moments, or muscle property changes at the tissue/cellular level. The present study was not an exploration of the exact mechanism by which OLT affects propulsive force. In terms of the stages of research, the present study is at the intervention efficacy stage.

# CONCLUSION

The findings from this pilot study provide preliminary data supporting the potential for improved propulsive force during walking following the OLT program. The results indicate that the walking dynamic stability of PD patients improved and that the ROR of the AGRF may be an important, yet understudied, determinant of propulsive force generation. The existing literature regarding the relative efficacy of different gait-related interventions in people with PD is sparse, and offers no clear indication regarding the optimal methods to improve overground walking propulsion in PD. Sensory cueing, both auditory and visual, has been used to study overground gait in patients with PD (Ford et al., 2010; Suteerawattananon et al., 2004). Kinematic, haptic, and EEG neurofeedback are also being explored as potential gait rehabilitation strategies in PD (Azarpaikan et al., 2014; Byl et al., 2015; Gonçalves et al., 2021; Iłżecka, 2021). In addition, treadmill only (Bello et al., 2013; Frenkel-Toledo et al., 2005; Herman et al., 2007; Pohl et al., 2003), treadmill with body weight support (Ganessan et al., 2015; I. Miyai et al., 2000; Miyai et al., 2002), and treadmill with additional body weight training paradigms have been investigated in PD (Filippin et al., 2017; Toole et al., 2005; Trigueiro et al., 2015). However, other key training parameters such as environmental specificity and practice variation have been less rigorously studied in PD. The results of our study are notable because they indicate the initial success of a program derived from training concepts frequently used in healthy and other neurologically impaired populations (Davids et al., 2003; Flach et al., 2017; Glazier & Davids, 2009; Glazier,

2017; Gollie & Guccione, 2017; Guccione et al., 2019; Ranganathan & Newell, 2013). Our low-tech and exclusively overground OLT protocol relies on established training principles such as task-specificity, practice variation, and progressive overload, rather than on specialized equipment or activities not closely related to walking, and therefore may provide a foundation and basis for further studies grounded in a similar approach. The OLT program should be further studied for its impact on balance and dynamic stability and its effect on walking safety, the prevention of falls, and independent community living and participation. Additional research is needed to determine the biomechanical, muscular, and neurological mechanisms of the observed AGRF power and ROR of the AGRF (rate of force development) gains and mobility improvements in gait speed.

## APPENDIX A: SIGNED PROPOSAL

# DEPARTMENT OF REHABILITATION SCIENCE DISSERTATION COMMITTEE AND PROPOSAL APPROVAL FORM

**STUDENT: THOMAS CORFMAN**

*PROPOSAL TITLE:*

THE INFLUENCE OF AN OVERGROUND LOCOMOTOR TRAINING PROGRAM ON WALKING GAIT PROPULSIVE FORCE IN AMBULATORY PATIENTS WITH PARKINSON'S DISEASE

Proposed Committee:

Rosemary D. Higgins, MD, Chair

Andrew A. Guccione, PT, Ph.D, DPT, FAPTA, Co-Chair

Panagiota Kitsantas, Ph.D, Committee Member

Dan Ding, Ph.D., External Reader

Rosemary D. Higgins, MD, Interim Department Chair

Date: ___April 23, 2021_____

Spring Semester 2021
George Mason University
Fairfax, VA

**The influence of an over-ground locomotor training program on walking gait propulsive force in ambulatory patients with Parkinson's disease**

**Tom Corfman**

March 23, 2021


## ABSTRACT

**OBJECTIVE:** To determine the effect of a 12-week OLT program on the anterior ground reaction force (AGRF) in ambulatory subjects with mild to moderate PD.

**DESIGN:** Pre-test post-test interventional study.

**SETTING:** University gait analysis laboratory.

**METHODS**: Participants performed propulsive force testing procedure before and after the OLT program.

**PARTICIPANTS:** Twelve adults with mild to moderate Parkinson's disease (Hoehn & Yahr stage 1-3, ambulatory).

**INTERVENTIONS:** 12-week OLT program.

**MAIN OUTCOME MEASURES:** Kinetic gait parameters: peak AGRF, rate of rise (ROR) of AGRF, push-off impulse, push-off duration.

**Specific Aims**

Parkinson's disease (PD) is a debilitating, neurodegenerative disease that manifests as disrupted motor behavior (bradykinesia, tremor, postural instability, rigidity), which dramatically impacts mobility, function, and life quality. PD is a highly common movement disorder disrupting the lives of individuals in the US with over 50,000 new cases each year and a worldwide prevalence of approximately 1% of all individuals over the age of 60. In fact, it is the second most common neurological condition after Alzheimer's affecting approximately 1 million people in the US and over 10 million worldwide with a substantial and striking sex difference in prevalence impacting more men than women with the condition. Neuromuscular control and execution of gait is altered in PD, as persons with PD exhibit increased co-activation of antagonistic muscles and reductions in amplitude of the distal lower-extremity musculature. Kinetic data reveal reduced ankle (push-off) power generation and reduced hip flexion (pull-off) power persist in PD gait. Studies have also shown that subjects with PD have a reduced roll-off at the terminal stance of gait and under scaling of power generation at push-off, with reduced amplitude of electromyographic activity in the gastrocnemius muscle. The generation of propulsive forces by each limb helps maintain interlimb symmetry, walking speed, and efficiency. Although several studies have identified a decrease in walking propulsive force ($F_P$) in subjects with PD, interventional studies to restore, maintain, or slow the decline in $F_P$ production are lacking. Subjects with PD may benefit from intervention strategies that target the $F_P$ production and kinetic gait components.

**Research Question: To what extent can over-ground locomotor training (OLT) influence walking gait propulsive force in ambulatory patients with Parkinson's disease?**

Purpose: To determine the effect of a 12-week OLT program on the anterior ground reaction force (AGRF) in subjects with mild to moderate PD.

Aim 1: To determine the effect of a 12-week OLT program on peak AGRF.

Hypothesis 1: A 12-week OLT program will increase peak AGRF, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how peak AGRF is modified by the OLT program.

Aim 2: To determine the effect of a 12-week OLT program on rate of rise (ROR) of the peak AGRF.

Hypothesis 2: A 12-week OLT program will increase the rate of rise (ROR) of the peak AGRF, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how the rate of force development is modified by the OLT program.

Aim 3: To determine the effect of a 12-week OLT program on push-off impulse.

Hypothesis 3: A 12-week OLT program will increase push-off impulse, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how push-off impulse is modified by the OLT program.

Aim 4: To determine the effect of a 12-week OLT program on push-off duration.

Hypothesis 4: A 12-week OLT program will increase push-off duration, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how push-off duration is modified by the OLT program.

The proposed research will broadly impact the rehabilitation science field by characterizing the magnitude of change and mutability in $F_P$ that can be produced with OLT in subjects with mild to moderate PD. The results of this research may have implications for rehabilitation and physical therapy in the treatment of PD and other neurodegenerative diseases.

**Background and Significance**

Parkinson's Disease (PD) is a highly common movement disorder disrupting the lives of individuals in the US with over 50,000 new cases each year (1) and a world-wide prevalence of approximately 1% of all individuals over the age of 60 (2). In fact, it is the second most common neurological condition after Alzheimer's (3) affecting approximately 1 million people in the US and over 10 million worldwide with a substantial and striking sex difference in prevalence impacting more men than women with the condition (4). The cardinal diagnostic signs of the condition are motor dysfunction, specifically tremor, rigidity, and bradykinesia, with a more recent recognition of postural instability as a primary clinical indication of PD (2). Across the array of motoric disturbances evident over time in individuals with PD, changes in gait characteristics are among the well-described (5).

Movement underlies all physical activity, and the inability to move, and especially to walk, lies at the epicenter of the experience of illness for individuals with PD. In fact, walking has been identified as the first activity for which individuals with PD report difficulty (6). People with PD often present with slowness of gait and this persists as the disease progress (7). Parkinsonian gait is both hypokinetic and bradykinetic (8, 9). Step size reduction (hypokinesia) and slower cadence (bradykinesia) are both present in PD and gait kinematics and kinetics (GRF, joint angles, etc.) are reduced (10, 11). These findings suggest that both motor output and locomotor pattern coordination are disrupted in PD (12, 13, 14, 27).

Although force deficits are widely accepted as an effect of PD, specific mechanisms for decreased neuromuscular force production have not been identified. Aging adults typically demonstrate loss of muscle mass (15) and reduced voluntary neuromuscular force capability (16). However, several studies have shown a severe decline in maximal neuromuscular force in PD compared with healthy, age-matched individuals (7). In non-PD older adults, time to achieve peak force in the quadriceps femoris typically takes less than 1 s, while persons with PD and moderate bradykinesia can take 3–4 s to achieve peak force (17, 18). Several studies report reduced rate of force development (RFD) and strength (maximal force) in persons with PD following withdrawal from dopaminergic therapy (17, 18). This suggests that the weakness and reduction in RFD is a direct result of the disease (dopaminergic denervation of the striatum), and at least partly central in nature. Consequently, persons with PD experience age-related muscle changes at a greater magnitude than their age matched peers (7). The compromised ability to rapidly produce force (reduced RFD) can be observed in aging adults (19). Similarly, muscle power greatly affects walking velocity (20). This indicates that the rate (velocity) at which force can be produced is as important, if not more important, than the maximum force of muscle contraction.

Neuromuscular control and execution of gait is altered in PD, as persons with PD exhibit increased co-activation of antagonistic muscles and reductions in amplitude of the distal lower-extremity musculature. Kinetic data reveal reduced ankle (push-off) power generation and reduced hip flexion (pull-off) power persist in PD gait (21). Studies have also shown that subjects with PD have a reduced roll-off at the terminal stance of gait and under scaling of power generation at push-off, with reduced amplitude of electromyographic activity in the gastrocnemius muscle (22, 23). In addition, older adults rely more than young adults on hip musculature for power generation, a phenomenon known as a distal-to-proximal redistribution (24). This redistribution may explain, at least in part, the greater metabolic energy costs of older adults and could thereby be considered dysregulated; the longer muscle fascicles and relatively short tendons spanning the hip are less metabolically favorable than the short fascicles and long, series elastic tendons spanning the ankle (25, 26). The purpose of this study is to determine how a 12-week over-ground locomotor training (OLT) program modifies walking gait propulsive force in ambulatory patients with Parkinson's disease.

**Specific Aims**

Aim 1: To determine the effect of a 12-week OLT program on peak AGRF.

Hypothesis 1: A 12-week OLT program will increase peak AGRF, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how peak AGRF is modified by the OLT program.

Aim 2: To determine the effect of a 12-week OLT program on rate of rise (ROR) of the peak AGRF.

Hypothesis 2: A 12-week OLT program will increase the rate of rise (ROR) of the peak AGRF, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how the rate of force development is modified by the OLT program.

Aim 3: To determine the effect of a 12-week OLT program on push-off impulse.

Hypothesis 3: A 12-week OLT program will increase push-off impulse, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how push-off impulse is modified by the OLT program.

Aim 4: To determine the effect of a 12-week OLT program on push-off duration.

Hypothesis 4: A 12-week OLT program will increase push-off duration, as measured by GRF, in subjects with mild to moderate PD. The goal of this aim is to determine how push-off duration is modified by the OLT program.

## Methods

*Study Design*

Data were collected prior to COVID (sars-cov-2). Although additional participant data collection was anticipated, George Mason University reduced laboratory research and other nonessential research activities in mid-March 2020, including the elimination of on-campus, in-person human participant research. Therefore, we have chosen to use the previously collected data as the basis for this dissertation proposal.

This pre-experimental pilot study used a pre- and post-test design. Testing was performed at two time-points: before (pretest) and immediately following the OLT program (post-test). The OLT program was comprised of 24, one-hour training sessions performed twice weekly with at least 48 hours between training session. To be included in the analysis, subjects were permitted to miss no more than three consecutive sessions and were required to complete the training protocol within 15 weeks of their initial baseline assessment.

*Ethical Approval*

The protocol and procedures were approved by the Institutional Review Board of George Mason University (#1374615-3). The study was registered on clinicaltrials.gov (NCT03864393). Written and verbal explanations of the study protocol and risks related to testing and training procedures were presented to prospective subjects prior to enrollment. Written informed consent was obtained from all participants prior to initiation of testing or training activities.

*Study Sample*

Participants were recruited from the greater Washington, DC, metropolitan area using paper and electronic fliers, local support group networking, and online postings. Inclusion criteria consisted of the following: age between 18 and 85 years; diagnosis of mild-to-

moderate PD (Hoehn and Yahr (H&Y) score ≤3); speaks English; and able to ambulate without requiring an assistive device. Exclusion criteria consisted of the following: neurological disease or diagnosis other than PD; uncontrolled cardiovascular, pulmonary, neurological, or metabolic disease which may impact the ability to exercise or in which exercise is contraindicated; medications that may alter heart rate or metabolic data; legal blindness; mini-Mental State Examination score <24; pregnancy; and concurrent participation in structured exercise similar to OLT.

The inclusion and exclusion criteria for enrollment into the study were as follows.

Inclusion Criteria

- Participants must be between the ages of 18 and 85.
- Diagnosis of mild to moderate Parkinson's Disease (H&Y 1-3).
- Able to understand basic commands and communicate needs in English.
- Able to ambulate without the use of assistive or orthotic device in an indoor community environment for at least 150'.
- Desire and ability to complete the protocol.

Exclusion Criteria

- Participants must not have any neurological disease diagnosed other than PD.
- Participants must not have any cardiovascular, pulmonary, neurological, metabolic, or other condition whose severity or treatment limits the ability to engage in sustained exercise, or for which exercise is contraindicated.
- Participants must not be taking any medications, such as beta-blockers, calcium channel blocking agents, or antiretrovirals, or medications that may alter heart rate or gas-exchange metabolic data.
- Participants must not have a mini-Mental State Examination score of <24.
- Pregnancy
- Current participation in other clinical trials.

*Enrollment Procedure*

The assessment of eligibility and enrollment procedures covered the following steps in the following order. First, participants reported their interest to the study coordinator via a phone call or an email. This was followed by a standardized telephone interview to

screen eligibility. Lastly, eligible participants visited the laboratory where a study investigator provided a detailed explanation of the informed consent document. Once participants voluntarily signed the informed consent document, medical history and medication intake lists were reviewed to further screen eligibility. Next, the mini-Mental State Examination was administered and scored to screen for cognitive function according to the exclusion criteria. Finally, a study investigator administered the H&Y assessment to screen for PD severity according to the inclusion criteria.

*Testing Day Procedure*

Participants were asked to refrain from strenuous physical activity for 48 hours prior to testing sessions. All participants were asked to follow their normal dietary and PD medication schedules and were tested during the on-phase at the same time of day during the pretest and post-test. Each participant's height and weight were measured prior to the start of functional testing. Resting heart rate and blood pressure were recorded with the participant in a seated position prior to any functional tests to screen for excessive hypertension or excessive hypotension. Testing sessions featured two components separated by 20-30 minutes of seated rest. The primary component of testing was an assessment of walking propulsion kinetics. Testing also assessed an overground 10 Minute Walk Test (10MWT) with continuous cardiopulmonary gas exchange monitoring using a portable metabolic system, the results of which are not the focus of the present study.

*Propulsion Testing*: Participants performed the testing procedure before and after the OLT program. Participants were asked to walk across a 6-meter platform with four forceplates, level with the walking surface, mounted midway. Subjects walked at their self-selected preferred walking speed for 20 trials. For this study, propulsive force will be defined by the peak positive AGRF, the ROR of the AGRF, the push-off impulse, and the push-off duration during over ground walking. The force plates (Bertec, Columbus, OH) quantify the GRF in response to the force placed upon it by the subject. The data will be collected with a frequency of 1500 Hz.

Randomization of the sequence of the two components of testing procedure were performed for every other subject enrolled (i.e., 1$^{st}$, 3$^{rd}$, 5$^{th}$, etc.), with the subject in between (i.e., 2$^{nd}$, 4$^{th}$, 6$^{th}$, etc.) performing testing in the opposite order. This was done to ensure an equal balance of testing sequences across the study sample. The testing sequence was kept consistent within each subject from pretest to post-test

**Intervention**

A performance-based training paradigm was used to develop the OLT program implemented in this study. Specifically, the OLT protocol is grounded in dynamical systems theory of motor control and motor learning and incorporates programming

principles from the fields of exercise physiology and neurorehabilitation. The central goal of the OLT program was to promote an expansion of subjects' motoric behavioral repertoire for real-world walking.

Primary emphasis was placed on providing subjects with a training experience that would theoretically promote motor learning specific to overground walking. More directly, subjects performed a sequence of challenging and repetitive locomotor-specific tasks in an exclusively overground environment without body-weight support or balance assistance. Secondary emphasis was placed on achieving a training stimulus that would theoretically promote cardiorespiratory adaptations. To achieve this goal, OLT trainers modulated the characteristics of rest periods (i.e., interspersed half-squats, mini-multidirectional lunges, or high-knees when needed instead of passive rest) so that the bulk of each training session was performed above 60% age-predicted maximal heart rate (HR). These two overall training objectives were emphasized because a diverse body of literature suggests that recovery of ecologically valid walking capabilities may occur across multiple body systems and that such effects may be readily attained if training concurrently targets motor skill acquisition and physiological adaptation in a task and environmentally specific manner (27-31).

Participants underwent 24, 60-minute bi-weekly OLT sessions over the course of 12-15 weeks. Every session incorporated practice of the actions involved in each sub-task of walking (e.g., weight shifting, stepping, propulsion). However, individual training sessions were "themed", meaning that the focus of the training session was to improve a specific characteristic of locomotor performance (i.e., power, stability, or stepping) in a specific direction of movement (i.e., forward, backward, lateral, rotational). Drills for each day were programmed and coached in a manner that emphasized the theme of the session. For example, a "lateral-power" session incorporated drills that challenged power development through the lower extremities during a variety of lateral walking tasks. In each session, following a brief circuit style warm up, sub-tasks of walking were isolated at the beginning of the session and drills progressed, in complexity throughout the session using pre-specified time blocks of specific drills (i.e., part-to-whole sequencing). Participants progressed from simple movements relevant to a specific walking action to dynamic walking exercises. Each session culminated with activity rehearsal consisting of dynamic walking at a variety of speeds and tempos and in various directions and patterns. Small hand weights and gait belts were used frequently during various exercises to provide external resistance and to increase the load, intensity, and balance demands of specific drills. Participants wore a heart rate monitor (Polar H10 heart rate sensor, Polar, USA) throughout training sessions for data recording and to aid OLT trainers in adjusting the intensity of the session to meet the 60% HR minimum.

**Data Processing**

All data processing will be done using MatLab (MathWorks, Natick, MA). Specific outcome measures are depicted in Figure 1 (left side).

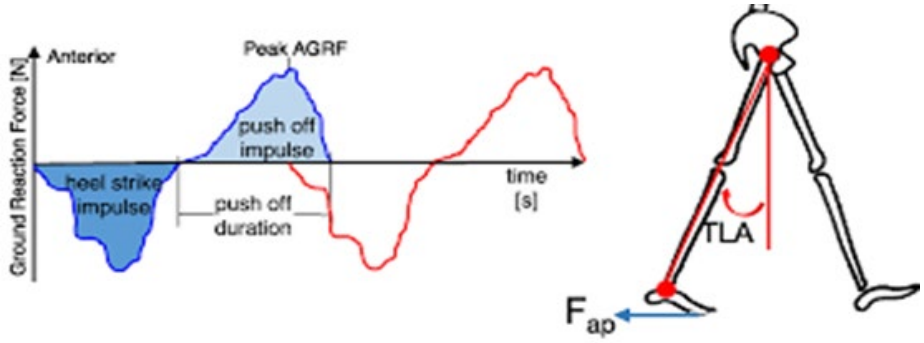
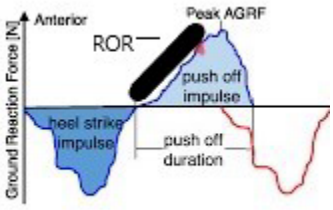



Figure 1




Peak propulsive force will be determined as the maxima (one point) of the AGRF and assessed by averaging the three highest values from a left foot strike and by averaging the three highest values from a right foot strike. This will be done using the findpeaks or maximum function to find the locations and the value of the peaks.

The ROR of the AGRF will be assessed using the same foot strikes noted above. This will be done using the risetime function to determine the rise time of positive-going bilevel waveform transitions.

The push-off impulse will be assessed using the same foot strikes noted above. This will be done using the trapz function to calculate the area under a set of discrete data by breaking the region into trapezoids. The function then adds the area of each trapezoid to compute the total area.

The push-off duration will be assessed using the same foot strikes noted above and is simply the time duration of the positive AGRF.

**Assessor Bias**

Even though all subjects received the same intervention and cannot be blinded to the intervention, we used a separate team of assessors who did not observe training and a separate team of trainers so that bias from knowing how well a subject performed during testing will not influence a trainer's expectations. Similarly, using a different team of

assessors who have no knowledge of performance during training will blunt any influence of assessor bias on test results during the entire study period. Whenever possible, assessors did not know how a subject performed as the data was stored and downloaded directly from the relevant data collection device.

**Ethical Considerations**

Successful completion of this research will help to show the efficacy of OLT in patients with PD and fill a gap in knowledge concerning the effects of OLT on propulsive force in patients with PD. The results of this research may have implications for rehabilitation and physical therapy in the treatment of PD and other neurodegenerative diseases.

There are no direct benefits for participation in this study other than receiving information regarding the subject's current level of functional mobility well beyond what they may receive from medical care or physician visit. They will also receive information regarding the quality and efficiency of their movement patterns and muscle strength which may impact their abilities to perform activities of daily living. The tests included in this study pose no greater risk than typical walking or standing in the participant's home or community. There is the potential risk of a loss of balance or fall, as well as the potential for muscle soreness or strain. The probability of harm is not likely as measures will be implemented to prevent a fall or injury. The severity of harm, should it occur, would be low. To minimize risk for participants a member of the research team will stand within one meter to provide support/assistance should a loss of balance occur.

**Statistical Analysis**

All data will be screened for missing data, outliers, and normality. Descriptive statistics will be calculated for any demographic data and all outcome variables. Means and standard deviations will be used to summarize continuous data, while frequency counts and proportions will be used to summarize categorical data. Box plots, line graphs or histograms may be used to plot the data.

To examine the hypotheses associated with Aims 1-4, a dependent sample t-test will be conducted to examine if mean differences exist between pre- and post-measures of peak AGRF, ROR of the peak AGRF, push-off impulse and push off duration. Dependent sample t-test for paired means is an appropriate statistical analysis if each of the two samples can be matched on a particular characteristic or to examine the effects of a given measurement over time. The assumptions of normality and homogeneity of variance will be assessed. The dependent samples test of correlated mean differences assumes a normal distribution. The paired samples t-test also assumes homogeneity of variances on the difference between both samples. The t-test will be two-tailed with the probability of rejecting the null hypothesis when it is true set at $p < 0.05$.

The Wilcoxon signed rank test will be conducted if the assumptions of the dependent sample t-test (such as normality) are violated in assessing Aims 1-4. The Wilcoxon test is the non-parametric equivalent to the paired or dependent sample t-test and the appropriate analysis to compare differences derived from the same population when the dependent variable is ordinal or continuous. It is used to assess differences from matched pair designs or repeated measures. In this study, a Wilcoxon Signed Rank test will be conducted to determine if differences exist between peak AGRF, ROR of the peak AGRF, push-off impulse and push off duration pre- and post- a 12-week OLT program.

The Pearson correlation coefficient or the Spearman correlation may be used to assess correlations between the continuous dependent variables. One-way repeated measures MANOVA will be used to assess any statistically significant differences in peak AGRF, ROR of the peak AGRF, push-off impulse and push off duration over the two time periods of pre and post of the 12-week OLT program. The assumptions of normality, absence of multivariate outliers, and sphericity will be assessed. The normality assumption requires that the residuals of the repeated measures MANOVA follow a normal distribution (bell-shaped curve). Normality will be assessed graphically using a Q-Q scatterplot (32-34). Statistical Package for the Social Sciences version 27.0.1.0 software will be used for the data analysis (SPSS; Chicago, IL, USA).

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# APPENDIX B: LITERATURE REVIEW

## *Parkinson's Disease*

Parkinson's Disease (PD) is a prevalent movement disorder disrupting the lives of individuals in the US, with over 50,000 new cases each year (NIH Fact Sheets - Parkinson's Disease) and a worldwide prevalence of approximately 1% of all individuals over the age of 60 (Tysnes & Storstein, 2017). It is the second most common neurological condition after Alzheimer's (Ascherio & Schwarzschild, 2016), affecting approximately 1 million people in the US and over 10 million worldwide with a substantial and striking sex difference in prevalence impacting more men than women with the condition (Pretzer-Aboff et al., 2016). The cardinal diagnostic signs of the disease are motor dysfunction, specifically tremor, rigidity, and bradykinesia, with more recent recognition of postural instability and gait disturbance (PIGD) as a primary clinical indication of PD (Tysnes & Storstein, 2017). Across the array of motoric disturbances evident over time in individuals with PD, changes in gait characteristics are among the well-described (Iosa et al., 2016).

## *Parkinson's Disease Etiology and Treatment*

Although the etiology of PD is still unclear, most cases are hypothesized to be due to a combination of genetic and environmental factors. Currently known genetic causes of PD account for approximately 10% of cases (Kalia & Lang, 2015; *Parkinson disease*, 2021). Parkinson's disease (PD) is a progressive neurodegenerative disorder caused by a

depletion of dopamine-producing cells within the substantia nigra that leads to a variety of both motor and non-motor features. Motor symptoms include bradykinesia, resting tremor, rigidity, and postural instability (Magrinelli et al., 2016). Non-motor symptoms include fatigue, depression, olfactory loss, apathy, cognitive impairment, sleep disturbance, pain, and autonomic dysfunction (Chaudhuri & Schapira, 2009). Pharmacologic treatment with levodopa and dopamine agonists usually provides good control of motor signs of PD for 4-6 years. After this, disability often progresses despite best medical management, and many patients develop long-term motor complications, including fluctuations ("wearing-off") and dyskinesias (*Parkinson disease*, 2021). Deep brain stimulation (DBS) is a treatment alternative that reduces several parkinsonian motor symptoms, such as PIGD, tremor, rigidity, and hypokinesia (Rodriguez-Oroz et al., 2005; Stefani et al., 2007). There is evidence that long-term motor improvement from DBS is sustained overall. However, axial signs (i.e., dysarthria, gait disorders, and postural instability) progressively decline over time and contribute to a waning of the initial benefit of this procedure (Castrioto et al., 2011). In recent years, exercise prescription has become a core component of PD management (Ahlskog, 2018; Armstrong & Okun, 2020). In patients with PD, exercise therapy may improve gait, balance, flexibility, aerobic capacity, initiation of movement, and functional independence through a variety of physiotherapy interventions (Parkinson disease, 2021). Generally, studies have shown that exercise improves function, but the observed benefits are small in magnitude and do not last after the exercise is stopped (Suchowersky et al., 2006).

*Walking-based Interventions in Parkinson's Disease*

The existing literature regarding the relative efficacy of different gait-related interventions in people with PD is sparse and offers no clear indication regarding the optimal methods to improve overground walking propulsion in PD. Sensory cueing, both auditory and visual, has been used to study overground gait in patients with PD (Ford et al., 2010; Suteerawattananon et al., 2004). Kinematic, haptic, and EEG neurofeedback are also being explored as potential gait rehabilitation strategies in PD (Azarpaikan et al., 2014; Byl et al., 2015; Gonçalves et al., 2021; Iłżecka, 2021). In addition, treadmill only (Bello et al., 2013; Frenkel-Toledo et al., 2005; Herman et al., 2007; Pohl et al., 2003), treadmill with body weight support (Ganessan et al., 2015; I. Miyai et al., 2000; Miyai et al., 2002), and treadmill with additional bodyweight training paradigms have been investigated in PD (Filippin et al., 2017; Toole et al., 2005; Trigueiro et al., 2015).

Rhythmic auditory stimulation (RAS) is thought to enable more automatic movement by motor synchronization with RAS or muscle entrainment to auditory stimuli in patients with PD (Jeffrey M. Hausdorff et al., 2007; Nombela et al., 2013). Suteerawattananon et al., 2004, examined both auditory and visual cueing in patients with PD and found that both cueing strategies improved gait speed, cadence, and stride length but did so in different ways. The auditory stimulus improved cadence while the visual stimulus improved stride length and simultaneous delivery was no better than each cueing stimulus alone. Rhythmic auditory cueing improves the temporal parameters of gait, and the spatial parameters of gait are enhanced by accessing visual cues (Muthukrishnan et al., 2019).

Treadmill training may act as an external cue, enhancing rhythmicity and decreasing gait variability in patients with PD. Treadmill training with body weight support (BWSTT) has been shown superior to physical therapy in the improvement of activities of daily living (ADLs), motor performance, and ambulation in patients with PD (I. Miyai et al., 2000). In addition, BWSTT has a lasting effect four months post-training (Miyai et al., 2002). Toole et al., (2005) assessed the effects of treadmill walking with 5% of body weight load in patients with PD, observing gains in motor function, walking speed, and stance time. Filippin et al., (2017) compared treadmill walking with 10% of body weight load to conventional physical therapy, observing an increase in magnitude of the second peak and push-off rate of the VGRF, an increase in magnitude of the positive peak of the AGRF, and an increase in stride length after treadmill intervention with the extra body weight.

*Parkinson's Disease and Gait Propulsion*

Of the aforementioned walking studies in patients with PD, only one (Filippin et al., 2017) examined gait propulsion. However, in order to have an efficient and stable gait in bipedal locomotion three locomotor tasks must be coordinated: body weight support, limb advancement, and propulsion (Awad et al., 2020; Sadeghi et al., 1997; David A. Winter, 2009). During the propulsive phase, or push-off, of walking gait, typically measured from midstance to toe-off, the leg muscles are responsible for propelling the body's center of mass forward (Gottschall & Kram, 2003; Tesio & Rota, 2019). The hip abductors and the ankle plantar flexors generate the most significant percentage of the

total propulsive force (Sylvester et al., 2021). Several muscles of the leg and trunk provide stability, and the foot provides a stable yet advancing base (Perry & Burnfield, 2010). The anteriorly-directed ground reaction force (AGRF) and its salient metrics (e.g., peak, impulse, duration) have been used to quantitatively measure and characterize the propulsion force during walking using a force platform (Koozekanani et al., 1987; Hsiao et al., 2016; Revi et al., 2020; Wu et al., 2019). However, the rate of rise or push-off rate of the AGRF remains understudied. Previous studies suggest that AGRF is also affected by the distance between the body's center of mass (COM) and the center of pressure (COP) (Miyazaki et al., 2021; Hsiao et al., 2015). Hsiao (2015) states the following:

> Another critical predictor for propulsive force is the position of the COP relative to the body COM. This relative position affects the orientation of the ground reaction force (GRF) vector and, therefore, determines the proportion of the GRF being distributed anteriorly. (p. 2)

In addition, AGRF peak and AGRF impulse have been shown to scale with walking speed (Lewek, 2011; Peterson et al., 2011; Wu et al., 2019), and are positively related to, walking speed (Hsiao et al., 2016).

Almost half of healthy walking's metabolic cost is attributed to producing horizontal propulsion forces (Gottschall & Kram, 2003). The metabolic energy needed by pathological gait is over twice that of healthy gait (Gonzales & Corcoran, 1994; Waters & Mulroy, 1999; Kuo & Donelan, 2010), and physics-based models show that without propulsion, it takes up to four times as much energy to redirect the COM velocity during locomotion (Kuo, 2002; Ruina et al., 2005). Each limb's generation of propulsive forces

helps maintain interlimb symmetry, walking speed, and efficiency (Liu et al., 2006). Therefore, functional propulsion is a necessary pre-condition for metabolically economical walking performance.

However, propulsion is compromised in patients with PD. People with PD have greater co-activation of antagonistic muscles and reduced amplitude of the distal lower-extremity musculature, affecting gait performance (Cioni et al., 1997; Dietz et al., 1995; Mitoma et al., 2000; Rodriguez et al., 2013). Kinetic data reveal reduced ankle (push-off) power generation and reduced hip flexion (pull-off) power, and subjects with PD have a reduced third rocker roll-off (forefoot rocker) at the terminal stance of gait (Sofuwa et al., 2005). Studies have also shown that subjects with PD have under-scaling of power generation at push-off, with reduced amplitude of electromyographic activity in the gastrocnemius muscle (Meg E. Morris et al., 1999; Dietz et al., 1995). Ground reaction force push-off peaks are reduced in patients with PD (Koozekanani et al., 1987; Morris et al., 1999; Peppe et al., 2007), and the anterior ground reaction force (AGRF) is decreased significantly in patients with PD compared to age and gender-matched controls (Sharifmoradi et al., 2016).

In addition, older adults rely more than young adults on hip musculature for power generation, a phenomenon known as a distal-to-proximal redistribution (DeVita & Hortobagyi, 2000). This redistribution may be considered dysregulated, or an additional impairment, increasing metabolic energy costs; the longer muscle fascicles and relatively short tendons spanning the hip are less metabolically favorable than the short fascicles and long, series elastic tendons spanning the ankle (Browne & Franz, 2018; Friederich &

Brand, 1990; Zelik et al., 2014). The redistribution may also be considered an adaptation to decreased dynamic stability or plantar flexor strength.

*Muscle Weakness and Progressive Resistance Training*

People with PD do show muscle weakness, a decrease in the amount of force generated during voluntary contraction (Corcos, et al., 1996; Falvo, et al., 2008; Roberts, et al., 2015). In addition, power production and muscle endurance are reduced in PD (Schilling, et al., 2009; Skinner, et al., 2015; Stevens-Lapsley, 2012). Such weakness has been suggested to compromise ADLs in patients with PD (Corcos, et al., 2003). Reductions in self-confidence in one's ability to perform ADLs, i.e., walking, may restrict physical activity to avoid falls and injury, which may lead to muscular deficits and atrophy (Adkin et al., 2003; Bloem et al., 2001; Mak & Pang, 2008).

In addition to PD, patients are also confronted with the challenge of normal aging. Miljkovic et al, 2015, summarized the changes in aging skeletal muscle fibers.

1) Muscle fibers: Decrease in number and in size.
2) Fiber type transformation: Fast to slow fiber type (fiber type grouping).
3) Myofilaments: Reduced maximal force; reduction in myosin content.
4) Excitation-contraction coupling: Disrupted or uncoupled; deficits in Ca2+ release
5) Mitochondria: Reduced number; loss of enzyme content (complex I – IV).
6) Adipose infiltration.

A variety of abnormal muscle activation patterns during ballistic and isometric movements have been reported in PD. Pfann, et al., 2001, found a number of

irregularities in EMG activity. Patients with PD displayed reduced agonist burst amplitude and instead showed extra cycles of agonist bursting during the initial phase of movement. Jordan, et al., 1992 also observed this phenomenon and found that PD patients were unable to generate an adequately scaled EMG burst to complete the movement. Rather, they employ a series of small amplitude bursts to complete the movement. The series of bursts, rather than a single burst, may help to explain why PD patients need nearly two times as much time to achieve peak force as the elderly and young subjects in Stelmach et al., 1989: PD, 657 ms; elderly, 388 ms; young, 376 ms.

According to the size principle, motor units are recruited in a fixed order that proceeds from slower motor units (Type I) to faster motor units (Type II). This appears to hold in PD, however, motor units are altered in PD. There is evidence of inconsistent discharge rates, discharge variability, and activation of more motor units at low frequencies of contraction (Glendinning, 1994). In addition, Kelly et al., 2018, notes an accumulation of larger motor units (i.e., myofiber grouping and size) which may result in over-recruitment of the muscle during submaximal contractions, which in turn may cause energy loss and loss of economy/efficiency.

Jang & Remmen (2011) summarized the age-related alterations of the neuromuscular junction. With advancing age, pre-terminal portions of motor axons exhibit regions of abnormal thinning, distension, and sprouting whereas post-synaptic endplates decrease in size, reduce in number, length, and density of post-synaptic folds. Recent studies provide evidence that age-associated increase in oxidative stress plays a crucial role in neuromuscular junction degeneration and progression of sarcopenia

(citation needed). Kelly et al., 2018 suggest that age-related motor unit remodeling, manifested by Type I myofiber grouping is associated with disruptions in neuromuscular junction stability.

The use of progressive resistance training (PRT) to improve gait and balance in people with PD is an emerging area of interest. Several studies have reported beneficial effects on motor function, muscle strength, and endurance following PRT (Brienesse & Emerson, 2013; Daniel M. Corcos et al., 2013; Lima et al., 2013). Although it is unclear as to what mechanisms underpin the improvements in motor symptoms following PRT, several studies suggest that PRT may help to improve muscle strength and mass (Dibble et al., 2006; Dibble et al., 2009; Hirsch et al., 2003) and normalize neuroplasticity that may otherwise be impaired in people with PD (Teo et al., 2014). Despite the evidence supporting the use of PRT to improve clinical measures of motor function, little is known about the effects of PRT on gait and balance measures in people with PD (Tillman et al., 2015). Although PRT consistently improves muscle strength in older adults and in patients with PD it fails to directly translate to improvements in propulsion power generation and walking speed (Beijersbergen et al., 2013).

*Performance-Based Framework*

Performance-based training frameworks emanate from dynamical system theory (Gollie & Guccione, 2017). Dynamic systems theory of motor control proposes that a given movement is a function of interacting component of numerous complex systems (Guccione et al., 2019). Specifically, an individuals' movement at any given point in time

is expressed as a solution in response to the interactions between constraints imposed by the task pursued by the organism, constraints imposed from within the organism, and constraints imposed by the environment (Davids et al., 2003; Glazier & Davids, 2009; Holt et al., 2010; Sparrow & Newell, 1998). Thus, interventions to optimize movement should facilitate an individual's response to the dynamic interplay of constraints that are unique to a specific task and its environmental context. Applying these principles to the context of gait rehabilitation, performance-based frameworks emphasize principles of task specificity, practice variation, and progressive overload in an attempt to promote active exploration of real-world movement solutions and adaptation across multiple body systems responsible for the recovery of locomotor function (Gollie & Guccione, 2017). This approach attempts to account for both physiological adaptation as well as motor learning, as together they may synergistically promote experience-dependent plasticity. Additionally, emphasis on exclusively overground practice flows logically from performance-based concepts and may facilitate exploration of critical constraint interactions in an ecologically valid practice environment. These concepts have not been fully applied in the context of gait rehabilitation for individuals with PD and the effects of performance-based interventions are unknown in people with PD.

*Over-ground locomotor training*

Over-ground locomotor training (OLT) is a performance-based training program with high repetition and resisted movement drills performed at an intensity that is aerobically challenging. OLT incorporates the three primary training principles for

eliciting adaptation and experience-dependent plasticity: task specificity, progressive overload, and practice variability (Kleim & Jones, 2008). To promote locomotor improvements, training procedures include movement drills based on the gait cycle with an emphasis on multi-directional changes in ambulation beyond just forward progression. OLT is intended to affect the propulsive force (AGRF) in ambulatory PD patients by coxing goal-directed behavior and exploring new movement solutions (Ranganathan & Newell, 2013). In a dynamical systems approach, OLT essentially exposes subjects to a variety or combination of organism-task-environment (O-T-E) using ecologically valid drills. OLT confronts O-T-E constraints simultaneously and provides variability in booth perception (information) and action (movement) which leads to increased physical performance (Davids, 2012; Vaz, 2017).

## APPENDIX C: EVIDENCE SUMMARY TABLE

| *Author and Year* | *Stated Study Rationale and Aim* | *Study Design* | *Sample Characteristics: N, Age, and Condition* | *Intervention Details or Procedure* | *Key Outcome Measures* | *Key Findings* |
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| (Adamczyk & Kuo, 2009) | Rationale<br><br>Examine how COM velocities vary as a function of gait parameters such as speed, step length, and step frequency<br><br>Aim<br><br>-Analyze the relationships between velocity magnitudes and directions, the impulses provided by the two legs, and the mechanical work performed on the COM during the transition between steps. These were then compared against the predictions of simple models assuming rigid legs. | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=10<br><br>-Age: Unkown<br><br>-Healthy male and female subjects<br><br>G2<br><br>-Predictive models | -Examined COM velocity and work data from normal human subjects walking at 24 combinations of speed (0.75 to 2.0 m $s^{-1}$) and step length | -COM velocity and work<br><br>-GRF<br><br>-Push-off positive work<br><br>-Collision negative work<br><br>-Walking speed<br><br>-Step length | -Greater walking speeds lead to greater COM velocity magnitude, and greater step lengths lead to greater redirection angle. These variables in turn predict work performed on the COM – a major contributor to metabolic energy expenditure – as a function of walking speed and step length. |
| (Awad et al., 2020) | Aim<br><br>Review article: biomechanical and functional consequences of post-stroke propulsion deficits, review | | | | | - Clinical and technological advances in the areas of propulsion diagnostics and treatment will enable future rigorous |

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| | advances in our understanding of the nature of post-stroke propulsion impairment, and discuss emerging diagnostic and treatment approaches that have the potential to facilitate new rehabilitation paradigms targeting propulsion restoration. | | | | | testing of key neurorehabilitation hypotheses related to propulsion-restorative versus compensatory recovery paradigms, and ultimately the development of clinical practice guidelines capable of recommending diagnostic and treatment approaches based on the best available evidence. |
| (Browne & Franz, 2018) | <u>Rationale</u><br><br>Compared to young adults, older adults walk with smaller propulsive forces and redistribution to more proximal leg muscles for power generation during push-off<br><br><u>Aim</u><br><br>Identify the joint-level modifications used by young and older adults to modulate propulsive forces when walking at their preferred speed. | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | <u>G1</u><br><br>-N=9<br><br>-Age: 25.1<br><br>-healthy young adults<br><br><u>G2</u><br><br>-N=16<br><br>-Age: 75.3<br><br>-older adults | Subjects walked at their PWS for 90 s each while matching their instantaneous $F_P$ to targets representing ±10% and ±20% different from preferred, presented in fully-randomized order. | -Peak Fp<br><br>-Peak Ankle Plantarflexion<br><br>-Peak Hip Extension<br><br>-Trailing Limb Extension<br><br>-Stride Length<br><br>-Redistribution Ratio | - Propulsive force biofeedback that elicits larger than preferred propulsive forces also increases trailing limb extension and attenuates mechanical power demands at the hip in older adults most exhibiting a distal-to-proximal redistribution. |

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| (Cofré et al., 2011) | Rationale<br><br>Ankle joint power generation is reduced in healthy older adults during gait. What fundamental compensatory actions are made at the knee and hip joints by older adults to compensate for this loss of power.<br><br>Aim<br><br>Investigate the effect of aging on lower limb joint power and work during gait. | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=8<br><br>-Age: 66.8<br><br>-Older adults<br><br>G2<br><br>-N=12<br><br>-Age: 26.6<br><br>-Younger adults | The gait patterns of old and young adults were recorded for a range of matched speeds (1.0 m/s, 1.3 m/s, 1.6 m/s) while walking over force plates. | -Hip power<br><br>-Knee power<br><br>-Ankle power | Older adults rely on hip flexors to propel the leg into swing when ankle plantar-flexor function is reduced. This may partly explain how gait changes emerge with aging. |
| (DeVita & Hortobagyi, 2000) | Rationale<br><br>At self-selected walking speeds, the elderly compared with young adults generate decreased joint torques and powers in the lower extremity. These differences may be actual gait-limiting factors and neuromuscular adaptations with age or simply a consciously selected motor pattern to produce a slower gait.<br><br>Aim<br><br>Compare joint torques and powers of young and elderly adults walking at the same speed | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=12<br><br>-Age: 69<br><br>-Older adults<br><br>G2<br><br>-N=14<br><br>-Age: 21<br><br>-Younger adults | Walked at 1.48 m/s over a force platform while being videotaped. | -Hip torque and power<br><br>-Knee torque and power<br><br>-Ankle torque and power | Age caused a redistribution of joint torques and powers, with the elderly using their hip extensors more and their knee extensors and ankle plantar flexors less than young adults when walking at the same speed. |
| (Dietz et al., 1995) | Rationale | -Cross-sectional investigation | G1 | Subjects walked on a split-belt | -Mean spatio- | In the patients' leg muscle EMG activity was less modulated and |

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| | Major clinical signs of Parkinson's disease are poor control of stance and gait associated with altered posture, difficulties in gait initiation, maintenance of balance, reduced stride length, and rigid, poorly modulated motor performance.<br><br>What are the pathophysiological correlates underlying these clinical symptoms?<br><br><u>Aim</u><br><br>The aim was to evaluate (1) the leg muscle activation patterns underlying a broad range of locomotion speeds and their limitations in patients with Parkinson's disease; (2) a possibly impaired coordination between lower limbs (interlimb coordination) which might contribute to the movement disorder in Parkinson's disease. | -No intervention<br><br>-Comparative research | -N=14<br><br>-Age: 61.0<br><br>-PD<br><br><u>G2</u><br><br>-N=10<br><br>-Age: 60.6<br><br>-Age-matched healthy controls | treadmill with speeds of 0.25, 0.5, 0.75 and 1.0 m/set in various combinations for both legs. | temporal parameters<br><br>-Mean EMG (TA, GAS)<br><br>-Joint movements<br><br>-Force signals (GRF) | gastrocnemius EMG amplitude was small during normal and split-belt walking. The amount of co-activation of antagonistic leg muscles during the support phase of the stride cycle was greater in the patients compared to the healthy subjects during normal and split-belt walking. |
| (Gottschall & Kram, 2003) | <u>Rationale</u><br><br>Providing an external horizontal aiding force, the reduction in energy consumption would reflect the metabolic cost of generating horizontal propulsive forces during normal walking.<br><br><u>Aim</u><br><br>Alter the horizontal forces generated during walking and measure the corresponding changes in metabolic rate. | -Repeated-measures, seven-level design (ANOVA) | <u>G1</u><br><br>-N=10<br><br>-Age: 27.3<br><br>-Healthy, male and female. | The subjects walked with no applied horizontal force (0% AHF) at both the beginning and the end of the experiment. Subjects then | -VO2<br><br>-VCO2<br><br>-EMG<br><br>-GRF | Overall, the 47% reduction in metabolic rate, when an external horizontal aiding force is applied, reflects the cost of generating horizontal propulsive forces during normal walking. The 60% reduction in MG activity reflects its important role in generating forward propulsion, whereas the insignificant reduction in Sol activity indicates that |

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| | | | | matched a metronome set to that frequency for the remaining trials. | | it performs functions other than propulsion. |
| (Hammond et al., 2017) | Rationale<br><br>Bradykinesia and reduced neuromuscular force exist in Parkinson's disease.<br><br>Aim<br><br>To evaluate quadriceps femoris rate of force development and quantify potential central and peripheral activation deficits in individuals with Parkinson's disease. | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=7<br><br>-Age: 65.4<br><br>- Hoehn & Yahr≤2<br><br>G2<br><br>-N=6<br><br>-Age: 60.6<br><br>- Age-matched controls | Quadriceps femoris voluntary and stimulated maximal force and rate of force development were evaluated using the interpolated twitch technique. | -maximal force<br><br>-rate of force development | Persons with mild-to-moderate Parkinson's disease display disparities in rate of force development, even without deficits in maximal force. The inability to produce force at a rate comparable to controls is likely a downstream effect of central dysfunction of the motor pathway in Parkinson's disease. |
| (Hsiao et al., 2015) | Rationale<br><br>Although propulsive force has been shown to be related to ankle moment and trailing limb angle, the relative contribution of each factor to propulsive force has never been determined.<br><br>Aim<br><br>To quantify the relative contribution of ankle moment and trailing limb | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=20<br><br>-Age: 27.8<br><br>- Healthy individuals | Gait analysis was performed on an instrumented split-belt treadmill. Kinematic data was recorded | -GRF<br><br>-Ankle moment<br><br>-TLA | Applying a biomechanical-based model, the present results showed that while ankle moment and TLA both contribute linearly to AGRF, the increase in TLA contributes almost twice as much as the ankle moment to the increase in propulsive force during |

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| | angle to propulsive force for able-bodied individuals walking at different speeds. | | | with a 62-marker set and eight camera passive motion capture system. | | speed modulation for able-bodied individuals. |
| (Koozekanani et al., 1987) | Rationale<br>To compensate for dysfunction, corrective signals and abnormal body movements are generated and reflected in the distribution of the GRFs.<br>Aim<br>Evaluate the effects of parkinsonism on the GRFs of an individual's gait. | -Pilot study<br>-Cross-sectional investigation<br>-No intervention | G1<br>-N=2<br>-Age: Both 51<br>- Hoehn & Yahr 1 and 3 | Subjects were asked to walk in front of the cameras and over the force plate. | -Gait analysis<br>-GRFs<br>-Kinematic data | Push-off peak significantly reduced in magnitude |
| (Lewek, 2011) | Rationale<br>BWS alters load receptor feedback and may alter the biomechanical role of the ankle plantarflexors, influencing gait.<br>Aim<br>To characterize the biomechanical adaptations that occur as a result of a change in limb load (controlled indirectly through BWS) and gait speed during treadmill locomotion. | -Cross-sectional investigation<br>-No intervention | G1<br>-N=15<br>7 males<br>-Age: 27.0<br>- Unimpaired | Gait analysis with surface electromyography while walking on an instrumented dual-belt treadmill at seven different speeds (ranging from 0.4 | -Spatio-temporal measures<br>-A-P ground reaction forces<br>-ankle kinetics<br>-muscle activity | Muscle activity remained unaltered by changing BWS across all gait speeds. The use of BWS could provide the advantage of faster walking speeds with the same push-off forces as required of a slower speed. While the use of BWS at slower speeds does not appear to detrimentally affect gait, it may be important to reduce BWS as participants progress with training, to encourage maximal push-off forces. |

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| | | | | to 1.6m/s) and three BWS conditions (ranging from 0% to 40% BWS). | | The reduction in plantarflexor kinetics at higher speeds suggests that the use of BWS in higher functioning individuals may impair the ability to relearn walking. |
| (Miyazaki et al., 2021) | Rationale<br><br>Propulsion force and knee flexion angle are widely used as key parameters to assess gait quality in gait training and gait rehabilitation in older adults<br><br>Aim<br><br>To clarify the relationships between leg extension angle, propulsion force, and knee flexion angle during gait in community-dwelling older adults. | -Cross-sectional investigation<br><br>-No intervention | G1<br><br>-N=588<br><br>363 female<br><br>-Age: 74.6<br><br>- Older adults | Participants walked at a comfortable velocity along a 14 m straight walkway twice. Bilateral hip and knee joint angles were measured during gait using five inertial measurement units | -Gait speed<br><br>-Leg extension angle<br><br>-Knee-flexion angle at mid-swing<br><br>-Hip extension angle at late stance<br><br>-Increase in velocity at late stance | Leg extension angle at late stance was correlated with knee flexion angle at mid-swing and the increase in velocity at the late stance. |
| (Peterson et al., 2011) | Rationale<br><br>The ability to accelerate and decelerate is important for daily activities and likely more demanding than maintaining a steady-state speed. Walking speed is regulated by | -Cross-sectional investigation<br><br>-No intervention | G1<br><br>-N=10<br><br>5 female<br><br>-Age: 28.7<br><br>- Healthy | Each subject completed a 30 s walking trial at their self-selected speed, | -Kinematic data<br><br>-GRF data | Braking and propulsive impulses were positively related to walking speed during acceleration and deceleration on a treadmill. The braking impulse had a greater positive relationship with walking speed than the |

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| | anterior-posterior ground reaction force (AP GRF) impulses.<br><br>Aim<br><br>To identify the relationships between walking speed and AP impulses, step length, and step frequency in healthy subjects accelerating and decelerating at different rates across a speed range of 0.4 to 1.8 m/s. | | | followed by 30 s walking trials at steady-state speeds of 0.4, 0.8, 1.2, 1.6 and 1.8 m/s in random order. | | propulsive impulse, suggesting that subjects modulate the braking impulse more than the propulsive impulse to change speed. |
| (Sharifmoradi et al., 2016) | Rationale<br><br>Aim<br><br>To assess the ground reaction force characteristics of patients with Parkinson's disease (PD) and to compare with healthy age group | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=14<br><br>-Age: 64.0<br><br>- Hoehn & Yahr 2 and 3<br><br>G2<br><br>-N=16<br><br>-Age: 61.4<br><br>- Age-gender matched controls | Subjects were asked to walk at a comfortable pace across force platforms | -Spatio-temporal gait parameters<br><br>-Peak VGRF<br><br>-Peak AGRF | Patients with PD showed a significant decrease in progression force and the second peak of vertical force. These subjects have to decrease their walking speed and increase their double limb support percentage to improve dynamic stability and decrease the magnitude of destabilizing forces. The mean values of propulsive component of anteroposterior force and the second peak of vertical ground reaction force decreased significantly due to performance of ankle joints plantar flexor which decreased in this group of subjects. |

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| (Skinner et al., 2014) | Rationale<br><br>Little is known about the magnitude and distribution of relative muscular effort of persons with PD during ADL.<br><br>Aim<br><br>To determine the relative magnitude of lower extremity moment production that persons with PD use to perform common ADL. | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=15<br><br>-Age: 65 ± 8 yr<br><br>- mild-to-moderate PD<br><br>-Hoehn and Yahr score, 2.6<br><br>G2<br><br>-N=14<br><br>-Age: 65 ± 7 yr<br><br>- Age-gender matched controls (healthy) | During the gait trials, the participants walked across the entire length of the walkway at a comfortable self-selected pace. | -Peak Moments<br><br>--Hip<br><br>--Knee<br><br>--Ankle | Relative effort during GI (271% vs 189%, $P < 0.05$) and gait (270% vs 161%, $P < 0.05$) was significantly greater at the ankle in persons with PD.<br><br>PD caused a redistribution of joint torques, such that PD participants used their hip extensors more and ankle plantarflexors less. |
| (Sofuwa et al., 2005) | Rationale<br><br>Whereas most studies document the spatiotemporal changes of gait at baseline (no intervention level), few have focused on describing the kinematic and the kinetic parameters, especially in the on-phase of the medication cycle.<br><br>Aim<br><br>To compare statistically the spatiotemporal, kinematic, and kinetic parameters of PD gait in the on-phase of the medication cycle with the control values. The study also | -Cross-sectional investigation<br><br>-No intervention<br><br>-Comparative research | G1<br><br>-N=15<br><br>-Age: 63.14<br><br>- mild-to-moderate PD<br><br>-Hoehn and Yahr score, 2 and 3<br><br>G2<br><br>-N=9 | Subjects were instructed to walk at their usual self-selected comfortable speed. | -Kinematic data<br><br>-Kinetic data<br><br>--Jt. Moment<br><br>--Jt. Power<br><br>Force plate (but no GRF reported) | The data confirm that ankle plantarflexors are mostly affected in PD gait. Hip flexors appear to be implicated in the abnormal gait pattern in PD. Walking velocity did not largely affect the results, which suggests that it is not the cause of the kinetic gait deviations found. Lack of correlation between stride length, gait velocity, and ankle and hip power generation suggest that central |

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|---|---|---|---|---|---|---|
| | investigated whether gait speed contributed to some of the observed differences, because patients are expected to walk with reduced gait speed compared with controls | | -Age: 64.41<br>- Age-gender matched controls (healthy) | | | factors, as well as peripheral factors, are involved in the diminished gait parameters in PD. Patients may benefit from novel interventions that influence these factors and correct the gait abnormalities not only at spatiotemporal and kinematic levels but also at kinetic levels |
| (Wu et al., 2019) | Rationale<br>Human walking speeds can be influenced by multiple factors, from energetic considerations to the time to reach a destination. Neurological deficits or lower-limb injuries can lead to slower walking speeds, and the recovery of able-bodied gait speed and behavior from impaired gait is considered an important rehabilitation goal. Because gait studies are typically performed at faster speeds, little normative data exists for very slow speeds (less than 0.6 m/s).<br>Aim<br>To investigate normative gait kinematics and kinetics at extremely slow walking speeds of 0.1 m/s to 0.6 m/s. Hypothesize that speed-related changes at slow speeds will be consistent with those reported at faster speeds. | -Cross-sectional investigation<br>-No intervention<br>-Comparative research | G1<br>-N=10<br>-Age: 23-31<br>- healthy | To determine the mechanics of walking at very slow speeds, healthy, adult subjects to walk on an instrumented treadmill at four different slow walking speeds and one self-selected speed. | -GRFs<br>-Kinematics<br>-EMG | As speed decreased, subjects spent more time in stance but took shorter steps. Step length (and step time) vary strongly with speed, but changes in step width or step variability were either minor or insignificant. Ground reaction force, COM power, and summed joint power magnitudes all decreased with speed, along with magnitudes of joint angles, torques, and powers. COM and summed joint work rates decreased linearly with speed, and COM work during collision and push-off decreased in magnitude in proportion to $\mathbf{v}^{2.8}$ |

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| (Ford et al., 2010) | Rationale<br><br>Aim<br><br>To investigate the progressively increasing external auditory cues during mobility training with persons with Parkinson's disease (PD). | -Cross-sectional investigation<br><br>-Experimental<br><br>-Intervention | G1<br><br>-N=12<br><br>-Age: 23-31<br><br>- Hoehn and Yahr score, 1-3 | Gait training to external auditory cues was based on a participant 's comfortabl e walking pace. Participant s trained for 30min/ses sion, 3 sessions/w k, for 8 weeks. | Walking velocity<br><br>stride length<br><br>cadence | The results of this study show that walking velocity, stride length, and cadence can significantly increase with progressive increases in external auditory cue in persons with mild to moderate PD. |
| (Filippin et al., 2017) | Rationale<br><br>Gait training with additional body load may benefit people with Parkinson's disease who present a reduced gastrocnemius contraction during the gait push-off phase. Studies on the effects of walking training with additional body load in Parkinson's disease are lacking.<br><br>Aim<br><br>To assess the effects of treadmill walking training with additional body | -Cross-sectional investigation<br><br>-Experimental<br><br>-Intervention<br><br>An A1–B–A2 single-case study design | G1<br><br>-N=9<br><br>-Age: 65.88<br><br>- Hoehn and Yahr score, 2-3 | The training consisted of walking on a treadmill wearing a weighted scuba-diving belt which increased the normal body mass by 10%. | -GRFs<br><br>spatiotemp oral<br><br>kinematic variables | A significant increase in propulsive forces, stride length, speed, and maximum hip extension during stance were observed after the training program. No changes in joint range of motion of ankle, knee, and hip were observed. |

load on the gait of people with moderate Parkinson's disease

## APPENDIX D: POSS PROGRAM

**FORWARDS / BACKWARDS WARM UP**

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|---|
| **EXERCISE: 20S ON; 10S REST; (CIRCUIT X 2)** |
| **MARCHING IN PLACE WITH ARM SWINGS** |
| **SQUATS (DEPTH AS TOLERATED) (SLOW DOWN – UP SAFELY)** |
| **SINGLE LEG SWING (STAND CLOSE TO WALL. GOAL IS TO MINIMIZE USE OF HAND ON WALL FOR BALANCE)** |
| **BACK EXTENSIONS (REACH FOR CEILING)** |
| **MARCHING IN PLACE WITH SNOW ANGEL ARMS** |
| **EXERCISE: 20S ON; 10S REST; (CIRCUIT X 2)** |
| **WALKING HIGH KNEE MARCHES** |
| **WALKING BACKWARDS WITH SINGLE ARM ROTATION REACH** |
| **WALKING WITH STRAIGHT LEG FORWARD KICKS (FORWARD FRANKENSTEIN'S)** |
| **WALKING WITH BUTT KICKS** |
| **WALKING SPLIT STEP WITH CONTRALATERAL OVERHEAD REACH** |
| **EXERCISE: 20S ON; 10S REST (CIRCUIT X 2)** |

| |
|---|
| **CALF STRETCH ON WALL** |
| **LATERAL LUNGE ADDUCTOR STRETCH** |

**LATERAL / ROTATION WARM UP**

| |
|---|
| **EXERCISE: 20S ON; 10S REST; (CIRCUIT X 2)** |
| **TRUNK ROTATIONS** |
| **MANUAL RESISTED ISOMETRIC TRUNK ROTATION (APPLY SMOOTH FORCE)** |
| **MARCH CIRCLES - 90° TURNS – (EMPHASIZE HIP ROTATION BOTH LEGS)** |
| **CLOCK LUNGES (DEPTH AS TOLERATED)** |
| **EXERCISE: 20S ON; 10S REST; (CIRCUIT X 2)** |
| **WALKING MARCH WITH 45° TURNS ON EVERY 3$^{RD}$ STEP – (EMPHASIZE HIP ROTATION ON OPEN STEP)** |
| **GRAPEVINES** |
| **WALKING SPLIT STEP WITH TRUNK ROTATION – (ROTATE TOWARDS LEAD LEG)** |
| **LATERAL FRANKENSTEIN'S - AVOID TRUNK TILTING – (1 LEG DOWN, OTHER LEG BACK)** |
| **WALKING WITH ROTATIONAL SWORD PULL EVERY 3$^{RD}$ STEP** |
| **EXERCISE: 20S ON; 10S REST (CIRCUIT X 2)** |
| **CALF STRETCH ON WALL** |
| **LATERAL LUNGE ADDUCTOR STRETCH** |

| |
|---|
| **Integration: 40 sec per drill (1,1,1) (2,2,2) (3,3,3) (4,4,4) (5,5,5) (6,6,6) (7,7,7)** |
| 1. Wall drill – hands on wall – push through floor – knees up |
| 2. Staggered weight shift – 20 seconds each side (emphasize stacked finished position on front leg) |
| 3. Forward walking (pause in middle of each step) (emphasize stacked position on balance leg) |
| 4. Squat steps – non-alternating |
| 5. Squat steps – alternating (switch sides every 3 repetitions) |
| 6. Skater strides |
| 7. Skater strides (3 normal – 3 short and quick – 3 normal – etc) |
| |
| **Rehearsal: 40 sec per drill (8,8,8) (9,9,9) (10,10,10)** |
| 8. Forward walking (4 big steps – full stop – 4 normal steps – full stop) - repeat |
| 9. Forward walking |
| 10. Forward walking – pre-planned starts and stops – (use cones) |

GMU Rehabilitation Science POSSabilities - Phase 1 session 1 (forwards, gait initiation, power) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop ( ) ( )

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|---|
| **Integration: 40 sec per drill (1,1,1) (2,2,2) (3,3,3) (4,4,4) (5,5,5) (6,6,6) (7,7,7)** |
| 1. Even – open step 45° - return to even |
| 2. Staggered – forward step with open 45° – return to staggered |
| 3. Forward walking with alternating open 45° stepping (every 3th step) |
| 4. Forward walking with alternating open 45° stepping (every 3rd step) (light band resistance) |
| 5. Forward walk to cone – stop – 360° march circle (emphasize hip rotation both legs) – finish length (utilize turning in both directions) |
| 6. Y-drill - forward progression throughout |
| 7. Fast forward walk full length – stop – 180° march circle (emphasize hip rotation both legs) – (utilize turning in both directions) |
| |
| **Rehearsal: 40 sec per drill (8,8,8) (9,9,9) (10,10,10)** |
| 8. Figure 8 drill – forward walk whole time |
| 9. Box drill (with cones) – forward walking – (emphasize open stepping around corners) |
| 10. Continuous forward walking laps with pre-planned speed changes (use cones) |

GMU Rehabilitation Science POSSabilities - Phase 1 session 2 (rotational, steady state, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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|---|
| **Integration: 40 sec per drill (1,1,1) (2,2,2) (3,3,3) (4,4,4) (5,5,5) (6,6,6) (7,7,7)** |
| 1. Even – backwards step with high knee pause – staggered – return to even (20 sec each side) |
| 2. Staggered – backwards step with high knee pause – staggered – return to staggered (20 sec each side) |
| 3. Backwards stepping to even stance (non-alternating) |
| 4. Backwards stepping to even stance (alternating) |
| 5. 3 steps forward – 3 steps backward (with pause on one leg in between) |
| 6. 3 steps forwards – 3 steps backward (with high knee pause on one leg in between) |
| 7. Big backwards steps (5 steps – rest - repeat) (full steps) |
| |
| **Rehearsal: 40 sec per drill (8,8,8) (9,9,9) (10,10,10)** |
| 8. backwards steps (full steps) (5 big, 5 normal – repeat) (no rest during step length transition) |
| 9. Backwards walking – forwards walking (shuttle drill with 4 cones) |
| 10. V-drill (forwards and backwards walking) |

GMU Rehabilitation Science POSSabilities – Phase 1 session 3 (backwards, gait initiation, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

| |
|---|
| **Integration: 40 sec per drill (1,1,1) (2,2,2) (3,4,5) (3,4,5) (4,3,5) (6,7) (6,7) (6,7)** |
| 1. Side to side skaters (load and spring) (try for one leg on ground at a time) |
| 2. Even – lateral step – return to even (push-off on return) (talk about force generation through posterior chain/leg and how forefoot is the final point of energy transfer) |
| 3. Even – lateral step – return to even (push-off hard and high knee pause on return) |
| 4. Side stepping with push off (emphasize proper stability with drive leg prior to power development through the floor) (use slight pause at beginning of each rep to coach loading) |
| 5. Side stepping with push off (band resistance) (emphasize proper stability with drive leg prior to power development through the floor) |
| 6. Fast side stepping (emphasize relaxed body, fast/dynamic steps) |
| 7. 4 steps forward walk – 2 dynamic lateral steps (emphasize proper stability with drive leg prior to power development through the floor) |
| |
| **Rehearsal: 40 sec per drill (8,8,8) (9,9,9) (10,10,10)** |
| **8.** Box drill (use cones) (face same direction throughout) (push off with drive leg) |
| 9. 4 backwards steps – 2 side steps (repeat other direction) (continuous) |
| 10. Forward walking with preplanned speed changes (use 2 cones) (very fast – very slow – very fast) |

POSSabilities - Phase 1 session 4 (lateral, steady state, power)
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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|---|
| **Integration: 40 sec per drill (1) (2,3,4) (1) (2,3,4) (1) (2,3,4) (5,5,5) (6,6,6) (7,7,7)** |
| 1. Staggered – high knee/dorsiflexion – staggered – return to staggered (20 sec each side) |
| 2. Ankling (1 set slow) (1 set fast) (1 set medium) |
| 3. Calving (non-alternating) (1 set slow) (1 set fast) (1 set medium) |
| 4. Calving (alternating) (1 set slow) (1 set fast) (1 set medium) |
| 5. Calving with pre-planned speed changes (alternating) |
| 6. 3 meters fast forward walk – 3 meters slow calving – 3 meters fast forward walk (use cones) (alternating) |
| 7. Calving (as big as possible) (alternating) (1 set slow) (1 set fast) (1 set medium) |
| |
| **Rehearsal: 40 sec per drill (8,9,10) (8,9,10) (8,9,10)** |
| 8. Forward walking fly ins (long hallway) (coach them through tall posture and relaxed body) |
| 9. Forward walking with sporadic band resistance (long hallway) (tall posture and relaxed body) |
| 10. Forward walk with pre-planned speed changes (use cones) (medium, fast, slow, fast, medium) (long hallway) (tall posture and relaxed body) |

GMU Rehabilitation Science POSSabilities – Phase 1 session 5 (forward, steady state, stepping) Date:

Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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|---|
| **Integration: 40 sec per drill** (1,1) (2,2) (3,4) (4,3) (2,4,3) (5,5,5) (6,6,6) (7,7,7) |
| 1. Even – lift foot – pause - open step 45° - finish tall and stacked – return to even |
| 2. Even – high knee with pause – open step 90° – finish tall and paused - return to even |
| 3. Even – right open big step 45 – even – left open big step 45 – even (forward progression) (dynamic stepping encouraged) |
| 4. Even – right open big step 45 – even – left open big step 45 – even (forward progression) (heavy band resistance) (emphasize power through floor and balance throughout) |
| 5. Even – high knee with pause – slow open step 45° – walk 5 meters (repeat other direction) (slow walk, medium walk, fast walk) |
| 6. Even – high knee with pause – slow open step 90° – fast walk 5 meters (repeat other direction) (slow walk, medium walk, fast walk) |
| 7. Forward walk full length – stop – 180° march circle (emphasize hip rotation both legs) – forward walk return (80% max pace) |
| |
| **Rehearsal (8) (9) (10)** |
| 8. Figure 8 drill (80 % max pace) (3 mins) |
| 9. Zig-zag cone course (forward walking with 45° turns) (80% max pace) (3 mins) |
| 10. Laps around training perimeter. (3 mins) (switch directions at 90 sec) (90% max pace) |

GMU Rehabilitation Science POSSabilities – Phase1 session 6 (rotational, gait initiation, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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|---|
| **Integration: 40 sec per drill** (1,1) (2,2) (1,2) (3,4,3) (3,4,3) (5,4,5) (5,4,5) (6,4,6) (6,4,6) |
| 1. ((Staggered – to even x2) (staggered – staggered x2)) (hand weights) |
| 2. Backwards walking (one leg fast, one leg slow) |
| 3. Backwards walking (medium pace) |
| 4. Dynamic/powerful backwards steps (band resisted) (coach them to sit hips back and keep chest on top of feet) |
| 5. 3 long backwards steps – 3 normal backwards steps – repeat (emphasize good posture and relaxed body) |
| 6. 3 fast backwards steps – 3 slow backwards steps – repeat (emphasize good posture and relaxed body) |
| |
| **Rehearsal** (1,2) (1,2) (3) |
| 1. Forward walking with band resistance from behind (70% pace. Tell them to drive through resistance with each step) (90 sec) |
| 2. V-drill (facing same direction throughout) (70% pace) (90 sec) |
| 3. Forward walking (85% pace – 4 mins) |

GMU RHBS POSS - Phase 1 session 7 (backwards, steady state, power) Date: Subject ID:

BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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| **Integration** 123. 123. 456. 456. 78. 78. 1234. 56. 78. 9 |
| 1. Side to side skaters (load and spring) (try for one leg on ground at a time) (hold weights) |
| 2. Side to side stepping (step right. Step left) (emphasize balanced weight acceptance on landing leg) |
| 3. Side to side stepping (step right. Step left) (emphasize push off) |
| 4. Side to side stepping (load majority of weight into drive leg and wait) (when trainer claps, push-off and take a dynamic step to the side) (reset, repeat other direction) |
| 5. Lateral stepping triplets (3 dynamic steps left. 3 dynamic steps right) (push-off emphasis) (heavy band lateral walking GAIT INITIATION DRIVING) |
| 6. Lateral stepping (lift feet up above ankle height) (light band resistance around waist) (choo-choo train) |
| 7. Lateral stepping (high knee with lead leg) |
| 8. Lateral stepping (high knee with trail leg) |
| **Rehearsal (9,9) (10)** |
| **9.** Tetris cone drill (high knees on lateral section) (complete as fast as possible) (80% max pace) 2 min |
| 10. 4 mins continuous forward walking (85% max pace) |

GMU Rehabilitation Science POSSabilities – Phase 1 session 8 (lateral, gait initiation, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

40 sec per drill (1,2,3,4) (1,2,3,4) (5,6,7) (5,6,7) (1,2,3,4) (5,6,7) (8,8,8) (9,9,9) (10)

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|---|
| 1. Even – lift with pause – forward step – forward stack – return to even (slow, emphasize control) |
| 2. Staggered weight shift (unplanned speed changes – trainer communicates) |
| 3. Forward walking (1 foot very fast, 1 foot very slow) (switch sides every pass) |
| 4. Forward walking (1 foot very fast, 1 foot very slow) (trainer randomly pushes side of hip and shoulder to supply perturbation) (switch sides every pass) |
| 5. 5 forward steps – stop in stance – 5 forward steps - stop in stance – repeat (1 set slow – emphasize control) (1 set fast – emphasize speed) (1 set medium) |
| 6. Fast forward walking – random change to fast forward ankling (trainer dictates change) (band resistance around waist) |
| 7. Band resisted fast forward walking (emphasize powerful dynamic steps) (variable band resistance from trainer) (use hallway) |
| 8. Forward walk full length with resistance on one side (1 set slow, 1 set faster, 1 set medium) |
| 9. Forward walking trainer walks behind and applies random lateral perturbations to shoulders and hips (jostling) (1 set slow long steps, 1 set faster normal steps, 1 set ) |
| 10. Forward walking (4 mins) |

GMU RHBS POSS - Phase 2 session 9 (forwards, gait initiation, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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| **Integration: 40 sec each drill** (1,2,3,4) (1,2,3,4) (5,6,5) (5,6,5) (7,6,7) (7,6,7) (8,9,8) (8,9,8) |
| 1. 45 open stance weight shifts (stay tall, rotate hips, medium stance length) (hand weights) |
| 2. 45 open stance weight shifts (load into back leg, push off and drive up tall to forward leg) (hand weights) |
| 3. Even – forward open 45 step – return to even (hand weights) |
| 4. Staggered – forward step with open 45° – return to staggered (hand weights) |
| 5. Forward walking with open 45 turn (every 3rd step) (eccentric lunge on 3rd step) (hand weights) |
| 6. Forward walking with open 45 turn (every 3rd step) (band resistance) (coach drive turn) |
| 7. Forward walking with open 45° turn (every 3rd step) (fast pace and long/dynamic steps) |
| 8. Figure 8 drill – forward walk whole time (band resistance from behind) |
| 9. Fast walk to cone – stop – slow march circles – finish walk fast (85% max pace walk) |
| |
| **Rehearsal** (1,2) (1,2) |
| 1. Forward walking zig zag course (2 mins 80% max pace) |
| 2. Forward walk around training perimeter 2 mins (85% max pace) (switch directions at 1 min) |

GMU RHBS POSS - Phase 2 session 10 (rotational, steady state, power) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

| |
|---|
| 40 sec per drill (1,2,3,4) (1,2,3,4) (5,6) (5,6) (7,8) (7,8) (1,2,3,4) (5,6,7,8) (9,10) (9,10) |
| 1. Forward Staggered – high knee hold – forward staggered – (hand weights at side) |
| 2. Forward Staggered – high knee – backwards step – backwards staggered - return to forward staggered (hand weights at side) |
| 3. Backwards walking (high knee on one leg) |
| 4. Backwards walking with high knee |
| 5. Backwards walking with high knee (light band resistance) |
| 6. Backwards walking with long steps (groups of 3) (trainer randomly dictates start of each group) (pause in stance position) |
| 7. backwards walking medium pace – trainer randomly claps – 5 fast forwards steps (emphasize clean transition with definitive first step) |
| 8. Fast backwards walk – stop – 10 high knees in place – fast backwards walk (divide room in half) (80% max pace) |
| 9. V drill (forward and backwards walking) (stay on outside of cones) (80 % max pace) (2 mins continuous) |
| 10. 2 mins continuous forward walking (80% max pace) |

GMU Rehabilitation Science POSSabilities - Phase 2 session 11 (backwards, gait initiation, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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| Integration 40 sec per drill 123. 123. 4567. 4567. 123. 4567. 888. |
| 1. Lateral weight shift (feet slightly wider than hip width) (emphasize complete acceptance of weight on one leg with good posture) |
| 2. Even – lateral step – return to even (push-off on return) (pause and hold with high knee on return) |
| 3. Side to side skaters (load and spring) (try for one leg on ground at a time) (60 seconds) |
| 4. Lateral ankling – (short and fast) – switch at cone – (long and slow) |
| 5. Lateral ankling – (medium pace) – (light band resistance) – choo choo train |
| 6. Lateral calving – trainer stands close behind and applies random lateral perturbations to hips |
| 7. Lateral walking (very fast - very slow - very fast) – 2 cones to dictate speed change |
| 8. Dynamic/fast lateral step x2 to forward walk 4 fast steps (facing one direction) |
| |
| **Rehearsal (9,9,9) (10,10,10) (11)** |
| 9. Tennis ball partner catch lateral shuffle (2 cones) (3 meters) (toss directly to them) 40 sec total |
| 10. Box drill with small obstacle step over (use half of figure 8) (switch at 20 seconds to ensure equal work on both sides) (4 sec total) |
| 11. Forward walking (90% speed 4 mins) |

GMU RHBS POSS - Phase 2 Session 12 (lateral, steady state, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,1) (2,2) (3,3) (4,5,6) (4,5,6) (7,8,9) (7,8,9) (1,2,3) (4,5,6) (7,8,9) (10,11) (10,11) (10,11)

| |
|---|
| 1. Staggered weight shift (tall posture, rock back and forth) (40 sec) |
| 2. Staggered weight shift (tall posture, long stance, load into back leg and drive to stacked finished position) (40 sec) |
| 3. Staggered – load into back leg and push off to high knee with pause – forward staggered stacked finish – return to staggered (40 sec) |
| 4. Forward walking (1 leg high knee march – other leg normal) (band resistance from behind) (up tempo pace, drive through resistance) (40 sec) |
| 5. Walking knee drive march (partner resisted) (drive into ground with each step) (40 sec) |
| 6. Walking fly ins (40 sec) |
| 7. Forward high knee march (alternating) (band resistance from behind) (40 sec) |
| 8. Partner resisted forward walk (40 sec) |
| 9. Walking (continuous – longest strides possible) (40 sec) |
| 10. Band resisted forward walking (heavy) (40 sec) |
| 11. Forward walking (80% pace) (90 sec) |

GMU Rehabilitation Science POSSabilities - Phase 2 Session 13 (forward, steady state, power) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

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|---|
| **Integration: 40 sec each drill** (1,1) (2,2) (3,3) (4,4) (5,6) (5,6) (1,2,3,4,5,6) (7,9,8) (9,8) (9,8) (10) |
| 1. Even – open step 45 – stack and finish tall – return to even |
| 2. Even – open step 45 – stack and finish tall - return to even (resistance band around hips) (movement away from resistance) |
| 3. Even – open step 45 – stack and finish tall - return to even (longer step) (load slightly into back leg and drive to forward tall finish position) |
| 4. Even – quick high knee with pause – open step 45 – stack and finish tall – return to even |
| 5. Even – right open step 45 – even – left open step 45 – even (resistance band around hips providing posterior resistance) (forward progression) (work on powerful dynamic steps) |
| 6. Even – right open step 45 – even – left open step 45 – even (cue them to translate the power practiced in drill 5 into speed) |
| 7. Zig zag obstacle course facilitating 45 degree turns (6 cones total) (coach powerful open step around turns) (use slight pause on drive leg to initially coach the movement) (allow them to flow through the drill after they acclimate to the turns) |
| 8. Zig zag obstacle course facilitating 45 degree turns (6 cones total) (coach powerful open step around turns) (reinforce powerful open step turns from drill 6 – but place focus on posture, relaxation, and SPEED) |
| 9. Zig zag obstacle course facilitating 45 degree turns (6 cones total) (band resistance from behind) (emphasize powerful dynamic steps) |
| 10. X-drill - Fast forward walk to vertex – stop – mini high knee march in place – trainer points to either top cone – participant walks to that cone – repeat (3 mins) |
| |
| **Rehearsal** (1) |
| 1. Forward walk 4 mins (90% max pace) (use training space perimeter marked with 4 cones) (switch directions after 2 mins) (emphasize crisp turns around corners) (motivate them to maintain 90% max pace) |

GMU Rehabilitation Science POSSabilities - Phase 2 session 14 (rotational, gait initiation, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

**40 sec per drill: (1,1) (2,2) (3,3) (4,5) (4,5) (6,7,8) (6,7,8) (1,2,3,4) (5,6,7,8)**

| |
|---|
| 1. Forward Staggered – high knee hold – forward staggered (hand weights at side) |
| 2. Forward Staggered – high knee – backwards step – backwards staggered - return to forward staggered (hand weights at side) |
| 3. Fwd/bkwd rocker drill w/ push off (gradually longer/ more push off) |
| 4. Backwards walking (1 leg fast) (1 leg slow) |
| 5. Bkwd walking (1 leg high knee) (1 leg reg step) |
| 6. Bkwd walking w/ band resistance (long strides) |
| 7. Bkwd walking (longest strides possible) |
| 8. Fwd walking figure 8 (as fast as possible) |
| **Rehearsal (123) (123) (123)** |
| 1. Continuous forwards walking (band resistance) (trainer randomly varies the resistance) (90 sec) |
| 2. Continuous backwards walking (band resistance) (trainer randomly varies the resistance) (90 sec) |
| 3. Forward walking (90 sec) (90% max pace) |

GMU RHBS POSS – Phase 2 session 15 (backwards, steady state, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

| |
|---|
| **Integration: 40 sec per drill** 123. 123. 456. 456. 7. 67. 123. 456. 7. |
| 1. Side to side rocking (load and spring) (try for one leg on ground at a time) |
| 2. Side lunge right – push off towards even – side lunge left – push off towards even (use med ball or hand weight) (slow eccentric phase) |
| 3. Side to side stepping (step right. Step left) (emphasize push-off) |
| 4. Side to side stepping (load majority of weight into leg and wait) (when trainer claps, push-off and take a dynamic step to the side) (reset, repeat other direction) |
| 5. Heavy band resisted lateral walking (emphasize push off) |
| 6. Lateral stepping triplets (3 dynamic steps left. 3 dynamic steps right) (push-off emphasis) |
| 7. Lateral stepping (lift feet up above ankle height) (light band resistance around waist) (choo-choo train) |
| 8. Forward walk with 2 random dynamic lateral steps (emphasize push off) (trainer randomly dictates direction and timing of lateral steps (1 min continuous) (85% max pace) |
| **Rehearsal.** 12. 12. 12. |
| 1. Tennis ball partner catch lateral shuffle (use 2 cones to set boundaries) (3 meters) (throw directly to them) (90 sec) |
| 2. Forward walking (90% max pace) (2 min) |

GMU Rehabilitation Science POSSabilities – Phase 2 Session 16 (lateral, gait initiation, power) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

Order: (1,2) (1,2,3) (2,3) (5,4a) (5,4b) (5,4c) (1,2,3) (6,7a) (6,7b) (6,7c) (8,9,10) (8,9,10) (8,9,10)

| | | |
|---|---|---|
| 1 | Forward staggered weight shift – regular stance<br>(hand weights held at sides) | -Forward stack finish |
| 2 | Forward staggered weight shift – long stance<br>(hand weights held at sides) | -Load into back leg<br>-Push-off to forward stack finish |
| 3 | Even stance – high knee – forward step – return to even<br>(hand weights held at side) | -Land softly and smoothly on forward stepping foot<br>-Forward stack finish |
| 4 | Forward walking - non-alternating calving | -4a) slow speed<br>-4b) fast speed<br>-4c) medium speed |
| 5 | Forward walking – non-alternating calving<br>(70 % max speed) | -Band resistance from behind<br>-Emphasize driving through resistance with control |
| 6 | Forward walking (85% max speed) | -Band resistance from behind<br>-Random variations in the magnitude of resistance<br>-Participant must react to varying resistance and adjust gait to maintain 85% speed |
| 7 | 5 forward steps – stop in staggered stance – 5 forward steps - stop in staggered stance – repeat | -7a) slow speed – emphasize control<br>-7b) fast speed – emphasize dynamic steps<br>-7c) medium speed – emphasize confidence |
| 8 | Forward high knee march (70 % max pace)<br><br>(30 sec) | -Give motivation to drive knees high |
| 9 | Forward walking (70% max pace)<br><br>(40 sec) | -Longest possible strides<br>-Emphasize push off |
| 10 | Forward walking (90 % max pace)<br><br>(90 sec) | -Give motivation to maintain speed |

GMU RHBS POSS - Phase 3 Session 17 (forward, gait initiation, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

40 sec each drill: (1,2) (1,2) (3,4) (3,4) (5,6) (5,6) (1,2,3,4,5,6) (7,8,9) (7,8,9) (7,8,9)

| |
|---|
| 1. Even – high knee with pause - open step 45 – stack and finish tall - return to even (hand weights) |
| 2. Staggered – forward high knee with pause - open step 45 – stack and finish tall – return to staggered (hand weights) |
| 3. Forward walk with open step every 3rd step (pause and hold on every 2nd step) |
| 4. Forward walk with open step every 3rd step (mini eccentric lunge on every 2nd step) (hand weights) |
| 5. Zig zag obstacle course facilitating 45 degree turns (variable band resistance) (6 cones total) |
| 6. Zig zag obstacle course facilitating 45 degree turns (fast speed) (6 cones total) |
| 7. Figure 8 drill – up tempo speed trainer applies random perturbations to shoulder and hip |
| 8. Figure 8 drill – fast speed – variable band resistance from behind |
| 9. Continuous laps around training perimeter. 2 mins (change direction after 1 min) (fast) |

GMU Rehabilitation Science POSSabilities - Phase 3 Session 18 (rotational, steady state, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,2,3) (1,2,3) (4,5,6,7) (4,5,6,7) (1,2,3) (4,5,6,7) (8,9,10) (8,9,10) (8,9,10)

| |
|---|
| 1. staggered weight shift (band resistance from in front) (40 sec) |
| 2. forward stack – high knee – forward stack (40 sec) |
| 3. Fwd / bkwd rocker drill (gradually longer) (40 sec) |
| 4. Backwards walking (non-alternating) (normal step – big step) (band resistance) (40 sec) |
| 5. Backwards walking (non-alternating) (normal step – big step) (40sec) |
| 6. Backwards walking with heavy band resistance (emphasize powerful steps) (40 sec) |
| 7. Backwards walking (40 sec) |
| 8. Forward walk – stop – 5 backwards steps (emphasize clean transition) (trainer dictated transition) – 90% max pace – 1 min |
| 9. forward backward drill – 1 min (max pace) |
| 10. Forward walking - 90% max pace – 90 sec |

GMU RHBS POSS - Phase 3 Session 19 (backwards, gait initiation, power) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,2,3,4) (1,2,3,4) (1,2,3,4) (5,6) (5,6) (5,6) (7,8) (7,8) (7,8)

| |
|---|
| 1. Wide stance – push off – high knee – return to wide stance (40 sec) |
| 2. Side to side skaters with high knee (40 sec) |
| 3. Lateral stepping (high knee with trail leg) (one set slow) (one set fast) (one set medium) (40 sec) |
| 4. Lateral stepping (high knee with lead leg) (one set slow) (one set fast) (one set medium) (40 sec) |
| 5. Lateral stepping (trainer randomly dictates step height) (light band resistance around waist) (choo-choo train) (40 sec) |
| 6. 4 steps forward – 3 high knee lateral steps (right) – 4 steps forward – 3 high knee lateral steps (left) – repeat (40 sec) |
| 7. Tennis ball partner catch lateral shuffle (2 cones) (6 meters) (toss directly to them) (1 min) |
| 8. Forward walking (90 seconds) (as fast as safely can) |

GMU Rehabilitation Science POSSabilities - Phase 3 Session 20 (lateral, steady state, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,1) (2,2) (3,4) (3,4) (5,6,7) (5,6,7) (1,2,3,4,5,6,7) (8,9) (8,9) (8,9)

| |
|---|
| 1. Even – forward step – stack tall – return to even (hand weights) (40 sec) |
| 2. Staggered – forward step through to staggered – pause in mid-swing – stack a finish tall – return to staggered (hand weights) (40 sec) |
| 3. Forward walking – alternating pause at midstance (40 sec) |
| 4. Forward walking (1 leg fast – 1 leg slow) (40 sec) |
| 5. Forward walking – alternating pause (trainer applies random lateral perturbations to hips and shoulders) (40 sec) |
| 6. Forward walking (trainer randomly dictates speed changes – very fast or very slow) (40 sec) |
| 7. Band resisted forward walking (variable band resistance) (40 sec) |
| 8. Figure 8 drill (90 sec) (70% max pace) |
| 9. Forward walking (90 sec) (80% max pace) |

GMU Rehabilitation Science POSSabilities - Phase 3 Session 21 (forward, steady state, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,1) (2,2) (3,3) (1,2,3) (4,5,6) (5,6) (5,6) (7,8,9) (7,8,9) (7,8,9) (10)

| |
|---|
| 1. Open 45 weight shift (rock back and forth) (hand weights) (40 sec) |
| 2. Open 45 weight shift (band resistance from behind only on forward portion of movement) (40 sec) |
| 3. Even – open 45 step - return to even (hand weights) (long step w/ push off) (40 sec) |
| 4. Zig zag obstacle course (encourage proper open step turn with good push off) (40 sec) |
| 5. Zig zag obstacle course (band resistance) (drive through resistance) (40 sec) |
| 6. Zig zag obstacle course (fast speed) (40 sec) |
| 7. Figure 8 (band resistance) (emphasize powerful open step at corners) (40 sec) |
| 8. Figure 8 (band resistance) (drive through resistance) (40 sec) |
| 9. Figure 8 (fast speed) (40 sec) |
| 10. Perimeter walk (fast pace) (4 mins) (switch directions every minute) |

GMU Rehabilitation Science POSSabilities - Phase 3 Session 22 (rotational, gait initiation, power) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,1) (2,2) (3,3) (1,2,3) (4,5,6) (4,5,6) (4,5,6) (7,8) (7,8) (7,8) (9,10) (9,10) (9,10)

| |
|---|
| 1. Forward stacked – high knee hold – forward stacked (hand weights at side) (40 sec) |
| 2. Forward stacked – high knee – backwards step – backwards staggered – return to forward stack (hand weights at side) (40 sec) |
| 3. Backwards ankling (band resistance from in front) (unplanned speed change) (first set without the band to acclimate) (40 sec) |
| 4. Backwards ankling / calving / marching (unplanned transition in step height) (1 set slow pace) (1 set fast pace) (1 set medium pace) (minimum 3 – 4 steps in pattern before change) (40 sec) |
| 5. Backwards long steps / normal steps (unplanned transition – trainer dictates) (40 sec) |
| 6. Backwards long steps (band resistance) (emphasize push off) (40 sec) |
| 7. 5 big backwards steps – stop – 5 fast high knees in place – repeat (40 sec) |
| 8. Backwards fly in (do NOT use hallway) (40 sec) |
| 9. Backwards V drill facing same direction throughout (fast speed) (time competition) |
| 10. Forward walk (90 sec 80% max pace) |

GMU RHBS POSS Phase 3 Session 23 (backwards, steady state, stepping) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

(1,2,3) (1,2,3) (1,2,3) (4,5) (4,5) (4,5) (6,6,6) (7,7,7) (8,8,8) (9)

| |
|---|
| 1. Side to side skaters (load and spring) (try for one leg on ground at a time) (40 sec) |
| 2. Even – lateral step – return to even (high knee with pause on return) (40 sec) |
| 3. Even – lateral lunge weight shift – return to even with high knee pause – 5 steps forward (initiate forward walk from single leg balance) (40 sec) |
| 4. Diagonal skater steps (long steps) (pause on each leg) (40 sec) |
| 5. Diagonal skater steps (medium steps) (no pause) (40 sec) |
| 6. Band resisted lateral stepping (groups of 3) (randomly different magnitude of resistance for each group) (40 sec) |
| 7. Tennis ball partner catch lateral shuffle (emphasize speed) (2 cones) (6 meters) (toss directly to them) (40 sec) |
| 8. Fast forward walk with unplanned 3 quick lateral steps (trainer dictates direction and timing of steps) (aim for 2 sets per pass) (40 sec) |
| 9. Forward walking (80% max speed 4 mins) |

GMU RHBS POSS - Phase 3 Session 24 (lateral, gait initiation, stability) Date:
Subject ID: Total time: BP pre/post: ( ) ( ) HR pre/post: ( ) ( ) HR monitor start/stop: ( ) ( )

## APPENDIX E: STUDY DOCUMENTS

**Link to ClinicalTrials.gov**

To view the study registration on ClinicalTrials.gov, please see the link below:

https://clinicaltrials.gov/ct2/show/NCT03864393

# Medical History Form

George Mason University
Department of Rehabilitation Science
Evaluation of a Power, Agility, and Coordination Program for Individuals with Parkinson's Disease
**HEALTH HISTORY FORM**

Participant Name:_____ ID #:_____

Date of Birth:_____ *PD Only*: Diagnosis Date:_____

---

Emergency Contact:_____Relationship:_____Phone #:_____

---

**What is your dominant:** *a) Arm*: ☐Right ☐Left *b) Leg*: ☐Right ☐Left

*For PD Only*: Which limb is more affected by the disease? ☐Right ☐Left Other:_____

---

**SOCIAL/CULTURAL**

**Race** (Please check all that apply)

- ☐American Indian or Alaska Native
- ☐Asian
- ☐Black or African American
- ☐Hispanic or Latino
- ☐Native Hawaiian or Other Pacific Islander
- ☐White

**Language** (Please check all that apply)

- ☐English understood
- ☐Interpreter needed
- ☐Language you speed most often:_____

**Education** *(Circle highest grade level completed)*

Grades: 1 2 3 4 5 6 7 8 9 10 11 12

Some College / Technical School

College Graduate

Graduate School

**Cultural/Religious**: Any customs or religious beliefs or wishes that might affect participation? _____

_____

_____

**Living Environment**

With whom do you live: _____

Does your home have: *(Circle all that apply)*

Stairs, no railing
Stairs, railing
Ramps
Elevator
Uneven terrain
Assistive devices in bathroom,etc

Do you use: *(Circle all that apply)*

Cane
Walker or rollator
Other:_____
Hearing aids
Glasses

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George Mason University
Department of Rehabilitation Science
Evaluation of a Power, Agility, and Coordination Program for Individuals with Parkinson's Disease
**HEALTH HISTORY FORM**

Participant Name:_____ ID #:_____

Date of Birth:_____ *PD Only*: Diagnosis Date:_____

---

Emergency Contact:_____Relationship:_____Phone #:_____

---

**What is your dominant:** *a) Arm*: ☐ Right ☐ Left *b) Leg*: ☐ Right ☐ Left

*For PD Only*: Which limb is more affected by the disease? ☐ Right ☐ Left Other:_____

---

**SOCIAL/CULTURAL**

**Race** (Please check all that apply)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

**Language** (Please check all that apply)

- ☐ English understood
- ☐ Interpreter needed
- ☐ Language you speed most often:_____

**Education** *(Circle highest grade level completed)*

Grades: 1 2 3 4 5 6 7 8 9 10 11 12

Some College / Technical School

College Graduate

Graduate School

**Cultural/Religious:** Any customs or religious beliefs or wishes that might affect participation? _____

_____

_____

**Living Environment**

With whom do you live: _____

**Does your home have:** *(Circle all that apply)*

Stairs, no railing Elevator

Stairs, railing Uneven terrain

Ramps Assistive devices in bathroom,etc

**Do you use:** *(Circle all that apply)*

Cane Hearing aids

Walker or rollator Glasses

Other:_____

---

George Mason University
Department of Rehabilitation Science
Evaluation of a Power, Agility, and Coordination Program for Individuals with Parkinson's Disease
HEALTH HISTORY FORM

## GENERAL HEALTH / HEALTH HABITS

**Health Rating** Please rate your health: Excellent Good Fair Poor

**Tobacco use**

☐ No

☐ Yes: Cigarettes: # or packs/day_____

Cigars/Pipes: # per day_____

☐ Past Year quit:_____

**Alcohol use**

How many days per week?_____

How many drinks on an average?_____

**Exercise**

Do you exercise beyond normal daily activities and chores?

☐ Yes Describe the exercise: _____

How many days/week: _____ How many minutes:_____

☐ No

## MEDICAL HISTORY (Please check all medical diagnoses and conditions that apply)

☐ Anemia
☐ Arthritis
☐ Bleeding Disorders
☐ Cancer: _____
☐ Chemical Dependency
☐ Communicable Disease
☐ HIV+ ☐ VRE ☐ MRSA
☐ E Coli ☐ Scabies
☐ Depression
☐ Diabetes
☐ Dizziness
☐ Emphysema
☐ Gout
☐ Heart Disease
☐ High Blood Pressure
☐ Irregular or Rapid Heart Beat
☐ Joint Replacement
☐ Kidney Problems
☐ Osteoporosis
☐ Pacemaker
☐ Parkinson's Disease
☐ Current Pregnancy
☐ Stroke
☐ Thyroid Problem

☐ *Other medical condition not listed above:*_____

## CURRENT SYMPTOMS (Please check all symptoms you currently have)

☐ Productive cough
☐ Fever/Chill
☐ Coughing up blood
☐ Night sweats
☐ Nausea/Vomiting
☐ Chest pain
☐ Trouble breathing
☐ Joint pain
☐ Joint stiffness
☐ Rashes or skin changes
☐ Visual changes
☐ Hearing changes
☐ Constipation
☐ Bloody Stools
☐ Pain with urination
☐ Incontinent bladder
☐ Incontinent bowel
☐ Other:_____

George Mason University
Department of Rehabilitation Science
Evaluation of a Power, Agility, and Coordination Program for Individuals with Parkinson's Disease
**HEALTH HISTORY FORM**

---

**FALLS** (Please check)

Are you concerned about falling? ☐ Yes ☐ No  Have you fallen in the last year? ☐ Yes ☐ No  If yes, Date:

Have you fallen more than 2 times? ☐ Yes ☐ No  Has any resulted in injury? ☐ Yes ☐ No

---

**SURGERIES/HOSPITAL PROCEDURES** (Please list the procedure and date)

_____
_____
_____
_____

---

**ALLERGIES / DRUG INTERACTIONS**

_____
_____

---

**CURRENT MEDICATIONS**

| Medication Name | Dose | Frequency | Reason | Time Since Start |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

# Data Collection Sheet

Date:_____ Time of Day: _____ Time of medication:_____ POSS_____ 1

POSSabilities Assessment Pre/Post COSMED turbine:

Assessment Team

| BP | HR | Height(in) | Weight(lbs) |
|---|---|---|---|
| | | | |

| | |
|---|---|
| Mini-mental Exam | |
| Hoehn & Yahr Scale | |
| HHQ | |

**10 Minute Walk**

*(COSMed, APDM):*

POSS###_Pre/Post_10min

sit: 3 min. stand 4 min. walk 10 min. stand recovery 10 min.

| PFS | |
|---|---|
| Before | After |
| | |

| | | | | |
|---|---|---|---|---|
| BP (sit) – 1:00 | BP stand – 3:30 | BP stand – 5:30 | | |
| BP stand – 7:30 | BP stand – 9:30 | BP at 1:00 recovery | BP at 4:00 recovery | BP at 9:00 recovery |

Breaks Taken:

Total distance:

Time delay:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 |
| 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 |

"check mark" in box = lap completed... T1, T2, T2.5, T3, T4, T5, T6, T7, T7.5, T8, T9, T10 in box = tape measurement during lap

**Informed consent**

GEORGE MASON UNIVERSITY

**Department of Rehabilitation Science**

4400 University Drive, MS 2G7, Fairfax, Virginia 22030
Phone: 703-993--1950; Fax: 703-993-6073

# INFORMED CONSENT

## *Effect of Multimodal Exercise Training on Walking Economy in Individuals with Parkinson's Disease*

### RESEARCH PROCEDURES

This research study is being conducted to understand the influence of a multimodal overground locomotor training program (OLT) on walking economy and secondary effects with regard to performance fatigability and propulsion during ambulation in individuals with Parkinson's Disease (PD). If you agree to participate, you will be asked to participate in 24 training sessions following an initial evaluation of your health history and functional abilities, including your cardiorespiratory fitness, and motor function including gait. Training sessions will occur twice per week for 12 weeks. Each session will last approximately one hour. You will also be asked to repeat your initial assessment as a final evaluation following the completion of the training sessions.

*Examination Procedures*

You may be asked to complete the following as part of the pre and post training evaluations:

- Health history questionnaire
- Psychological assessments: used to obtain measurements such as your intellectual function, cognition, memory, judgement, and mood
- Parkinson's disease scales: standardized measures of the course, progression, and severity of PD
- Body composition assessments: measures such as your height and weight
- Fitness assessments: tests and measures of your body's response to physical activity while walking overground, on a treadmill, or cycling on a bike; this often requires wearing a facemask that will collect the air you breathe in and out
- Muscle strength tests: measures of your muscle strength and power which include asking you to push against various types of resistance while wearing sensors over the muscles being used
- Gait and Balance assessments: tests and measures of your walking characteristics and abilities and of your ability to balance during static and dynamic activities; this may include wearing sensors when walking on a platform or treadmill
- Agility, Coordination, and Motor Control Assessments: tests and measures of your ability to plan and execute coordinated movements

The evaluation and assessment will last approximately 90 minutes, one session prior to training and one after training (3 hours of testing total). The testing session will begin with a Health History Questionnaire, Parkinson's Disease scales, psychological state assessment, and assessment of body composition. The order of the remaining assessments will be determined by every other participant drawing a slip of paper with either a 1 or 2 written upon it. When drawing a number from the envelope the chance of drawing either number is 50%.

*Training Procedures*

The training will involve various forms of exercise designed to address your cardiorespiratory fitness, muscle strength and power, and motor function (including balance and gait). Each training session will last approximately 60 minutes, twice a week for 12 weeks. A heart rate monitor and step watch will be used to monitor intensity and volume during each training session. The heart rate monitor consists of a strap around your chest and wrist watch and the step watch is worn around the ankle.

*Videography and photography*

Testing and training sessions may be videotaped. During testing, the motion capture system used to analyze gait includes a video component. Video and photographs may be included in the dissemination of results such as research presentations at conferences and in teaching presentations. You have the right to decline videotaping at any session or at any given point while videotaping. Videos will be used for training and teaching purposes. To the extent possible, you will be videotaped in ways that will diminish facial recognition. Video material (photos and videos) will remain on a secure computer and will be deleted after 5 years after the study is completed. You also may request at any time that your videotapes be completely erased immediately either while participating in the study or after your participation has ended.

*Re-testing Procedures*

At the conclusion of 24 sessions or 12 weeks, you will be retested in the same ways you were tested at the start of the program.

*Time Commitments*

Participants will need to be available for approximately 1.5 hours of testing prior to and following training for approximately 3 total hours of testing and a total of 24 training sessions (two 60-minute sessions per week for 12 weeks). The total time commitment will be approximately 27 hours.

## RISKS

The foreseeable risks or discomforts are similar to the risks that you take when exercising or engaging in moderate physical activity on your own, with or without supervision, at home or in a gym or other facility. The level of exercise or physical activity is in your control, and you will not be asked to engage in any activity that you believe is beyond your ability or tolerance.

You may have some minor discomfort during testing procedures that are similar to any temporary discomfort that you may experience in a routine medical examination or annual physical examination.

You may experience some discomfort from any of the testing or training including muscle fatigue, muscle or joint soreness, and lightheadedness during or in the hours following testing or training. Straining a muscle or spraining a ligament is a very small possibility during testing or training.

You may experience a fall, slip, or trip during testing or training. Every effort will be made to minimize these risks. You will have a research assistant nearby at all times to avoid a fall, slip, or trip.

The risks of exercise testing and supervised training are generally low, although sometimes medical complications do occur. During exercise and moderate physical activity, certain changes in heart rate and rhythm, blood pressure, and respiratory rate are expected, but abnormal or unanticipated changes are small possibilities. Every effort will be made to minimize these risks.

Although rare in occurrence the most serious risks of exercise testing and training include sudden death, heart attack, dizziness, chest pain or tingling in the arm, jaw, or back, shortness of breath, and/or extreme fatigue. Please let the researcher know if you experience any of these symptoms during testing or training activities.

In case of injury during testing or training procedures, the George Mason University research team may provide basic first aid. If appropriate, the staff will call the emergency response team at 911. Neither George Mason University nor the investigators have funds available for payment of medical treatment for injuries that you may sustain while participating in this research. Should you need medical care, you or your insurance carrier will be responsible for payment of the expenses required for medical treatment.

## BENEFITS

There are no direct benefits to you as a participant other than to further the research of interventions designed for people with PD.

## CONFIDENTIALITY

The data in this study will be confidential, including in publications and reports resulting from the research. All participants will be assigned an identification number after agreeing to participate, and all de-identified data will be stored using this identification number. The signed informed consent and the identification number linking data to individuals will be stored by the lead researcher in a locked cabinet in a locked office along with any other forms or papers that have protected personal or health information. Only members of the research team will have access to this information. The de-identified data could be used for future research without additional consent from participants. Monitors, auditors, the Institutional Review Board, and regulatory authorities may have access to the data for verification of clinical trial procedures without violating the confidentiality of the participants to the extent permitted by law.

## PARTICIPATION

Your participation is voluntary, and you may withdraw from the study at any time and for any reason. If you decide not to participate or if you withdraw from the study, there is no penalty or loss of benefits to which you are otherwise entitled. There are no costs to you or any other party except transportation to and from testing or training sessions and parking in compliance with University regulations. You will receive information on how PD has affected your abilities from the testing we will do, and you may or may not improve in these abilities after training.

Your participation in testing or training may be stopped at any time by a member of the research team without your consent for reasons that include a belief by the research team that continued testing or training may affect your health or safety; you are unable to follow or adhere to testing or training instructions; or other administrative reasons that require your withdrawal.

## CONTACT

This research being conducted is led by Dr. Andrew Guccione, Department of Rehabilitation Science, at George Mason University. He may be reached at 703-993-4650 for questions or to report a research-related problem. You may contact the George Mason University Institutional Review Board Office at 703-993-4121 if you have questions or comments regarding your rights as a participant in the research.

This research has been reviewed according to George Mason University procedures governing your participation in this research, IRBnet #: **1374615-1**.

## CONSENT

I have read this form, all my questions have been answered by the research staff, and I agree to participate in this study.
Please indicate below your preference for videography/photography. This will not affect your participation in the study.

☐ I grant permission to videotape my image and likeness as part of this research study.

☐ I DO NOT grant permission to videotape my image and likeness as part of this research study.

_____ _____

**Name** **Date of Signature**

_____

**Signature**

# Standardized Mini-Mental State Examination

| Name of patient: | | DOB: | / / | Name of examiner: | | Date of test: | / / |
|---|---|---|---|---|---|---|---|

## Standardised Mini-Mental State Examination (SMMSE)

***Please see accompanying guidelines for administration and scoring instructions***

**Say:** *I am going to ask you some questions and give you some problems to solve. Please try to answer as best you can.*

**1.** Allow ten seconds for each reply. **Say:**

a) *What year is this?* (accept exact answer only) /1
b) *What season is this?* (during the last week of the old season or first week of a new season, accept either) /1
c) *What month is this?* (on the first day of a new month or the last day of the previous month, accept either) /1
d) *What is today's date?* (accept previous or next date) /1
e) *What day of the week is this?* (accept exact answer only) /1

**2.** Allow ten seconds for each reply. **Say:**

a) *What country are we in?* (accept exact answer only) /1
b) *What state are we in?* (accept exact answer only) /1
c) *What city/town are we in?* (accept exact answer only) /1
d) <At home> *What is the street address of this house?* (accept street name and house number or equivalent in rural areas) /1
<In facility> *What is the name of this building?* (accept exact name of institution only) /1
e) <At home> *What room are we in?* (accept exact answer only) /1
<In facility> *What floor of the building are we on?* (accept exact answer only) /1

**3.** **Say:** *I am going to name three objects. When I am finished, I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes* (say slowly at approximately one-second intervals).

**Ball Car Man**

For repeated use: Bell, jar, fan; bill, tar, can; bull, bar, pan

**Say:** *Please repeat the three items for me* (score one point for each correct reply on the first attempt) /3

Allow 20 seconds for reply; if the person did not repeat all three, repeat until they are learned or up to a maximum of five times (but only score first attempt)

**4.** **Say:** *Spell the word WORLD* (you may help the person to spell the word correctly). **Say:** *Now spell it backwards please* (allow 30 seconds; if the person cannot spell world even with assistance, score zero). Refer to accompanying guide for scoring instructions (score on reverse of this sheet) /5

**5.** **Say:** *Now what were the three objects I asked you to remember?* /3

(score one point for each correct answer regardless of order; allow ten seconds)

**6.** Show wristwatch. **Ask:** *What is this called?* /1

(score one point for correct response; accept 'wristwatch' or 'watch'; do not accept 'clock' or 'time', etc.; allow ten seconds)

1

7. **Show pencil. Ask:** *What is this called?* /1

   (score one point for correct response; accept 'pencil' only; score zero for pen; allow ten seconds for reply)

8. **Say:** *I would like you to repeat a phrase after me: No ifs, ands, or buts* /1

   (allow ten seconds for response. Score one point for a correct repetition. Must be exact, e.g. no ifs or buts, score zero)

9. **Say:** *Read the words on this page and then do what it says* /1

   Then, **hand** the person the sheet with CLOSE YOUR EYES (score on reverse of this sheet) on it. If the subject just reads and does not close eyes, you may repeat: *Read the words on this page and then do what it says*, a maximum of three times. See point number three in Directions for Administration section of accompanying guidelines. Allow ten seconds; score one point only if the person closes their eyes. The person does not have to read aloud.

10. **Hand** the person a pencil and paper. **Say:** *Write any complete sentence on that piece of paper* (allow 30 seconds. Score one point. The sentence must make sense. Ignore spelling errors). /1

11. **Place** design (see page 3), pencil, eraser and paper in front of the person. **Say:** *Copy this design please*. Allow multiple tries. /1

    Wait until the person is finished and hands it back. Score one point for a correctly copied diagram. The person must have drawn a four-sided figure between two five-sided figures. Maximum time: one minute.

12. **Ask** the person if he is right or left handed. **Take** a piece of paper, hold it up in front of the person and **say** the following: *Take this paper in your right/left hand* (whichever is non-dominant), *fold the paper in half once with both hands and put the paper down on the floor.*

Takes paper in correct hand_____ /1

Folds it in half_____ /1

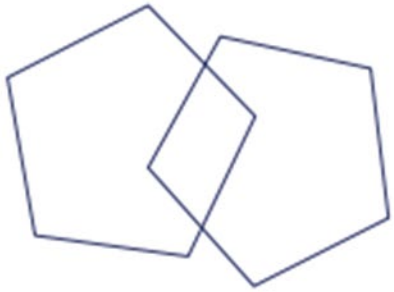
Puts it on the floor_____ /1

**TOTAL TEST SCORE: /30**

ADJUSTED SCORE: /



Molloy DW, Alemayehu E, Roberts R. Reliability of a standardized Mini-Mental State Examination compared with the traditional Mini-Mental state Examination. *American Journal of Psychiatry*, Vol. 14, 1991a, pp.102-105.



Time:

| D | L | R | O | W |
|---|---|---|---|---|
| | | | | |

=

# CLOSE YOUR EYES

3

# Approved IRB Application for Parent Study

GEORGE MASON UNIVERSITY

**Institutional Review Board**

**Application Form**

**Instructions:**

1. CITI certification (www.citiprogram.org) must be completed for all team members at the time of application submission.
2. Complete all sections and required addenda. Submit one complete package via IRBNet.
3. Projects with funding/proposed funding must include a copy of the grant application or proposal.
4. Research may not begin until you have received notification of IRB approval.
5. Handwritten and incomplete forms cannot be accepted.

**1. Study Title**: **Effect of Multimodal Exercise Training on Walking Economy in Individuals With Parkinson's Disease**

**2. Study Investigators**

A. Principal Investigator (*must be faculty/staff and meet PI Eligibility, University Policy 4012*)

Name: **Andrew Guccione** Department: **Rehabilitation Science**

Phone: **703-993-4650** E-mail: **aguccion@gmu.edu**

B. Co-Investigator/Student Researcher

Name: **Clint Wutzke** Department: **Rehabilitation Science**

Phone: **703-993-1903** E-mail: **cwutzke@gmu.edu**

C. Are there additional team members? No ☐ Yes ☒ *If yes, complete Addendum J to list additional team members*

D. Do any investigators or team members have *conflicts of interest* related to the research?

No ☒ Yes ☐ If yes, explain

**3. Study Type:** ☒ Faculty/Staff Research ☒ Doctoral Dissertation ☐ Masters Thesis ☐ Student Project (**Specify** ☐ Grad or ☐ Undergrad) ☐ Other (Specify)

**4. Complete Description of the Study Procedures**

A. Describe the aims and specific purpose of the study:

**Sustained ambulation is a challenge for individuals with Parkinson's disease (PD) as walking economy is frequently compromised. There are also various disease-related skeletal muscle alterations that may contribute to performance fatigability during ambulation. Concomitantly, individuals with PD experience substantial difficulty maintaining sustained forward progression at push-off during the gait cycle due to diminished force production. Exercise is commonly prescribed for these individuals, though traditional exercise approaches to PD have often applied a "one impairment-one modality" paradigm that addresses each impairment seperatly. Interventions to optimize movement should facilitate an individual's response to the challenge of responding to a complex interplay of constraints that are also specific to a task and its environmental context. Thus, there are multiple concurrent targets for exercise interventions that may not fit easily within a "one impairement-one modality" model. A multimodal intervention is designed to address an array of constraining impairments concurrently. However, the evidence-base for multimodal exercise approaches is still developing and far from conclusive. The purpose of this study is to demonstrate that multimodal overground locomotion training (OLT) can promote walking economy during sustained overground ambulation in individuals with PD, and produce concurrent secondary effects that decrease preformance fatigability and increase propulsion. The aims of this study are to 1)**

1

**Evaluate walking economy during sustained overground walking after 12 weeks of multimodal OLT, 2) Evaluate secondary effects of OLT.**

B. Provide a COMPLETE description of the study procedures in the sequence they will occur including the amount of time each procedure will *take (attach all surveys, questionnaires, standardized assessment tools, interview questions, focus group questions/prompts or other instruments of data collection)*:

**Protocol Overview: Subjects will be recruited from the greater Washington D.C. metro area and Northern Virginia areas by word of mouth, healthcare provider referral, support groups, social media posting, and by posted fliers. The study design and participation will be explained to those who are potentially interested in participating in the study. Individuals interested in participating as subjects will complete initial verbal screening to determine eligbility for inclusion. Those subjects who volunteer to participate will then be consented and enrolled for participation if exclusion and inclusion criteria are met.**

**Visit 1: (~ 90 minutes) Subjects meeting inclusion and exclusion criteria will be consented and enrolled in the study. They will then be asked to fill out a medical history form. Height and weight measurements will then be taken. The Hoehn and Yahr and Mini-metnal State Exams (described below) will then be administered by an investigator. Subjects will then be randomized as to the order of testing procedure. Randomization will be performed using blocks of two, whereby the first subjects will draw a number (1 or 2) out of an envelope with 1 indicating the 10-minute walk will be performed first and 2 indicating gait lab propulsion testing will be performed first. The next subject enrolled in the study will do the opposite. This testing pattern will continue with the third subject drawing randomly and the fourth subject doing the opposite and so on. These tests will be separated by a sufficient rest period or as long as it takes to set up for the next testing procedure, with a minimum rest period of 10 minutes but less than 20 minutes for consistency between subjects. Those subjects performing the the 10-minute walk test first will be fitted with a portable metabolic unit consisting of a face mask and torso apparatus similar to a backpack. Wearable sensors will be secured with velcro to both arms, trunk, and legs. The walk will take place in a long corridor within the Peterson Health Sciences Building. Prior to starting the test, subjects will stand in a resting position for at least 3 minutes to gain resting metabolic data. They will then be asked to walk as far as they can in 10 minutes. Following the 10-minute walking period, subjects will again stand in a resting position to obtain recovery data. Subjects will then be provided a 10-20 minute resting period during the transition to the second test. For the second test, subjects will be fitted with reflective markers at pre-specified anatomical landmarks used in a standardized gait marker set, for example medial and lateral knee and ankle joints. Electromyography (EMG) sensors will be placed on lower limb muscles. Subjects will then be asked to walk at both their preferred and fast walking speed over a 6 meter platform with embedded force plates. Subjects will be asked to perform as many trials as necessary to collect sufficient force plate data which is anticipated to be between 20-30 passes. Following this test, subjects will be given the opportunity for a rest period if required before ending the testing day. For those subjects who start with the gait propulsion test, the testing order will include the same procedures yet in the reversed order.**

Visits 2-25: (~1 hour each) For these visits, subjects will perform an overground multimodal locomotor training protocol. Subjects will train individually with 1-2 trained instructors. Each training session will consist of an initial warm-up period, the main training intervention, and a cool-down period. Subjects will wear a Polar chest strap and a StepWatch (research grade pedometer) during each session to enable instructors to modify training within the session to maintain a target intensity zone. The training protocol covers 12 weeks with two sessions per week for a total of 24 sessions.

Visit 26: (~90 minutes): Subjects will repeat the same testing procedures as they did in visit 1 in the same order as they did, determined by the initial randomization process.

Study Procedures:

10-Minute Walk Test: The purpose of this test is to provide a method of perturbation for measuring both performance and perceived fatigability. Subjects will wear a fitted face mask and a torso unit as part of a portable metabolic unit. Wearable sensors will be secured on the torso, upper and lower limbs to measure gait characteristics. Subjects will rest in a standing position for at least 3 minutes prior to beginning this test to collect baseline data. Subjects will then walk over a level corridor as far as they can over a 10-minute interval or until they have to stop walking. Distance covered will be recorded at at 2.5-minute intervals throughout the test and at the end of the time walked if not the full 10 minutes. Velocity will be computed from the distances covered at the time intervals (meters/sec). The 10-minute walk test will be performed during the pre-intervention testing visit and post-intervention testing visit. At least one member of the research team will conduct the test and give limited cueing throughout the test to ensure proper testing procedure but not excessive motivational encouragement. Following the 10-minute walk period (or total time if ended early) subjects will rest in the standing position to obtain recovery data for at least 6 minutes.

Gait Propulsion Testing: Subjects will be outfitted with reflective markers comprised of a standardized full-body marker set for motion capture analysis. EMG sensors will be placed on muscle bellies of lower limb muscles. To establish the maximum voluntary contraction, subjects will be asked to contract muscles against resistance. Subjects will be asked to stand for system calibration for less than one minute and may be asked to move various limbs through a range of motion to ensure accuracy of the system prior to starting the test. Subjects will then be asked to walk across a 6-meter platform with embedded force plates enclosed by safety rails at their preferred and fast walking speed. Subjects will perform approximately 20-30 passes to ensure sufficient data collection by the force plates as appropriate contact with the force plate must be made for valid measurement. Once sufficient data has been collected, markers and sensors will be removed and the subject will be offered a seated rest period if needed.

Multimodal Exercise Intervention: The intent of the multimodal training intervention is to encompass cardiovascular adaptations and locomotor improvements. Cardiovascular adaptations, as evidenced by improved in AT-VO2, have been demonstrated to improve performance fatigability in other clinical populations. To promote cardiovascular adaptation, training sessions will be adjusted in real-time to achieve a pre-determined target HR zone for each subject. HR will be monitored coninuously during each training session. The target HR

intensity during training sessions will be 60% of the subjects predicted maximal HR. The target HR zone will be 60% of predicated maximal HR +/- 5%. The subjects predicted maximal HR will be calculated using the formula: 220-age. To promote locomotor improvements, training procedures will include drills based on gait initiation and termination, agility, muscular power, and steady state actions. Drills will be conducted with an emphasis on direction change beyond usual forward progression. As subjects become familiar with the various drills, instructors will gradually increase the complexity, speed, and volume.

Propulsion Measures: For this study, propulsion will be defined by anterior peak positive ground reaction force (GRF) during overground walking. The force plates measure the GRF in response to the force placed upon it by the subject. In conjuction with motion capture analysis, the propulsive phase of gait can be determined and within that phase the anterior peak vector will be calculated. Peak propulsive force will be determined as the maxima (one point) of the anterior GRF.

Performance Fatigability Test Scoring: Performance fatigability is the rate or extent to which tissue, organ, system or total body function (fatigue) declines in response to a given task. After a 10-minute period of quiet rest in the sitting position, subjects will complete the 10-minute walk test. Distance covered will be recorded at the 2.5-minute interval of the test and for the total test. Velocities for the entire test (total distance walked / total minutes of test) and the first 2.5 minutes of the test (distance covered in the first 2.5 minutes / 2.5 minutes) will be calculated. The fractional change in velocity will then be computed as the quotient of total test velocity / 2.5 minute velocity. For example if the total test velocity and the 2.5-minute velocity were both 82 meters/minute, the total test velocity would be 100% of the velocity at 2.5 minutes. However, if the total test velocity were 80 meters/min and the velocity at 2.5 minutes were 82 meters/minute, then the total test velocity would be only .98 of the 2.5-minute velocity. To calculate the performance fatigability score, the fractional change in velocity will be divided by the distance covered. Thus any 2 subjects could have similar change in velocity scores (for example 0.5) but different total distances (100 versus 200 meters). In this case the performance fatigability score for the first subject would be 0.5/100 = 0.005 versus .5/200 = 0.0025. Scores are multiplied by 1000 to facilitate reporting. A small score indicates lower fatigability. Thus, even though the fractional change in velocity was similar for the 2 hypothetical subjects above, fatigability was less in the second subject as demonstrated by a lower performance fatigability score.

Perceived Fatigability Test Scoring: Perceived fatigability is the rate or magnitude of change in feelings of tiredness or weariness (symptoms of fatigue or perceived fatigue) in response to a given task. After the initial 10-minute sitting rest period, subjects will rate their perception of fatigue or vigor using the left side of the Fatigue and Fatigability Scale. Following the 10-minute walk test, subjects will be asked "compared to when you started, how would you rate your level of tiredness now" using the right side of the scale. The left side is considered a measure of fatigue because a change in fatigue was not assessed. The right side is considered to be a rating of fatigability because it assesses the change in tiredness. The score for the change in tiredness is then normalized to the total distance covered to calculate the perceived fatigability score: perceived fatigability = (change in tiredness / total distance walked) x 100 (multiplied by 100 to facilitate reporting and comparison).

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Cardiopulmonary Gas Exchange Analyes: All gas exchange will be collected using a wearable metabolic unit, the COSMED K5© portable cardiorespiratory testing system. The K5 system uses a galvanic fuel cell and non-dispersive infrared sensor for the analysis of oxygen consumption (VO2) and carbon dioxide expiration (VCO2) in the inhaled and exhaled air and an optoelectronic reader with a high performance turbine flowmeter to measure flow rate. After the unit warms up for approximately 20-30 minutes, flowmeter, gas, scrubber, and delay time calibrations are performed following manufacturer's recommendations. The two-point gas calibration is completed sampling the ambient air and the gas from a certified tank containing 16% O2, 5% CO2, and standard atmospheric Nitrogen. Flowmeter calibration was performed connecting the turbine to a calibrated Hans Rudolph 3-liter syringe and completing six full strokes at a respiratory frequency of 20-25 breaths/min. Delay time calibration was performed with the flowmeter and the sampling line connected to the face mask and by executing six breaths at a given rhythym while breathing in the facemask. The unit uses OMNIA software and has both wireless and bluetooth capabilities. Subjects interface the system by wearing a form-fitting facemask and chest unit. The unit is calibrated prior to each test.

Motion capture system: Our dedicated gait lab includes infrared cameras that capture movements of reflective markers worn by subjects within the volume. Reflective markers will be placed about the subject according to a predetermined full body gait marker model. VICON Nexus software, installed on a PC, is used to collect, identify, and reconstruct the movement data.

EMG sensors for measurement of muscle activity: Noraxon EMG Wireless TeleMyo allows the wireless collection of up to 16 channels of EMG, as well as other analog signals, in real time for up to 300 feet away. The 16 channel DDTS is equipped with EMG preamplifiers, operating in the standalone analog out mode to synchronize with the VICON Nexus software. EMG sensors, DTS EMG probe with EMG lead are attached to Noraxon Dual EMG Electrodes that are secured to the subject's skin over the muscle belly of interest. The sensor and electrode are covered with tape to minimize movement artifacts.

Force plates for GRF measurement: 4 Bertc forceplates are embedded in the center of the 6 meter walkway. The forceplates measure x, y and z axes of the force and moment components, with the output signal fed into an amplifier. This signal output is displayed and recorded into the VICON Nexus software suite.

Wearable sensors for measurement of gait characteristics: APDM wearable sensors contain accelerometers, gyroscopes, and magnetometers. Measurements are collected on the x, y, and z axes at a sample rate of 128 Hz. These sensors are attached to the preselected locations on the subject's body. This data is either wirelessly streamed via an access point and/or logged and stored in the sensor. Participants will also wear a step counter during each training sessions to record the total number of steps taken

Questionnaire:

Medical History Form: Subjects will fill out the medical history form on visit 1.

**Testing/Forms:**

**Hoehn and Yahr: The Hoehn and Yahr scale (HY) is a widely used clinical rating scale, which defines broad categories of motor function in Parkinson's disease. This test will be adminstered by the researchers on visit 1.**

**Standardised Mini-mental State Exam: This test will be administered by researchers on visit 1 and is a 12-point questionnaire that addresses cognitive function.**

C. Describe the target population (age, sex, ethnic background, health status, etc.): **The target population includes men and women over the .age of 18 diagnosed with mild to moderate, Hoehn & Yahr (H&Y) stage 1-3, Parkinson's Disease.**

1. Summarize the inclusion/exclusion criteria for participation in the study:
**- Inclusion Criteria: age > 18; diagnosis of mild to moderate Idiopathic Parkinson's Disease (H&Y 1-3); able to speak English; able to ambulate with no assistive device**
**- Exclusion: neurological disease diagnosis other than PD; uncontrolled cardiovascular, pulmonary, neurological, or metabolic disease which may impact the ability to exercise or in which exercise is contraindicated; any medications, such as beta-blockers, that may alter HR or metabolic data; cognitive or psychiatric impairment precluding informed consent or ability to following unstructions; mini-Mental State Examination score <24; pregnancy; inability to ambulate without assistive device**

2. Are there any enrollment restrictions based on gender, pregnancy, race or ethnic origins? ☒Yes ☐No If yes, please describe the process and reasons for restriction(s): **Those who are pregnant will be excluded from participation in the study as pregnancy may alter the exercise response and adaption and is possibly unsafe to pregnant females.**

3. Do any researchers listed on the application have a relationship to any of the participants that could unduly influence them to participate (including a teacher/student relationship)? ☐Yes ☒No If yes, please describe the relationship and how any possibility of undue influence will be managed:

4. Estimated number of subjects (may use a range): **20-30 individuals with mild to moderate PD**

5. Estimated amount of total participation time per subject: **Total hours = 27. Approximately 3 hours total for testing (pre and post intervention). Approximately 24 hours for training intervention (2x week/12 weeks)**

D. Where will the study occur (*list all study sites and collaborators*)? **RHBS Functional Performance Laboratory; Peterson Hall. George Mason University Fairfax Campus**

E. Describe other approvals that have been/will be sought prior to study initiation (facility authorizations, biosafety review, IRB approval from collaborating institutions, approval from public school system IRBs, etc.): **This study will be registered and approved on Clinicaltrials.gov**

F. Is this study a clinical trial that requires registration on ClinicalTrials.gov? ☒Yes ☐No If yes, please provide the NCT number assigned to the study: to be forwarded when approved

**5. Recruitment and Consent**

A. Describe the processes used for selecting subjects and the methods of recruitment including when, how, and by whom the subjects will be recruited (***attach all recruitment materials including flyers, emails, SONA posting, scripts, etc. and please include the IRBNet number of***

*the project and the PI's name on all recruitment documents*)? **Patients will be recruited using fliers, word of mouth, support groups, social media, physicians and physical therapist referral. Approval will be sought from social media administrators, support groups, physician and physical therapist offices, and other advertising locations prior to advertising.**

B. Describe the consent process including how and where the consent will take place, who will conduct the consent process, information that will be discussed with and distributed to subjects, and how participants will indicate consent even if a waiver of signature is being requested below (*attach all consent documents*): **Potential subjects will have the rationale for the study, study procedures, rights as a human subject, and their ability to terminate participation in the study explained to them. Subjects will have the opportunity to read over the consent form and ask any questions prior to signing. The consent process will take place in a private room in the Functional Performance Laboratory by one of the investigators on the study.**

C. Is a waiver of signature on the Informed Consent being requested? ☐ Yes ☒ No

If yes, complete the following:

1. This waiver is being sought because (*check one*):
   - ☐ The only record linking the subject and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality.
   - ☐ The research presents no more than minimal risk of harm to subjects AND involves no procedure for which written consent is normally required outside of the research context.
2. Explain why the waiver of signature is being requested:

**6. Privacy & Confidentiality**

A. How will the researchers protect the *privacy* of the participants and the *confidentiality* of the data obtained? **Information contained in the database spreadsheet will be identifiable only by a unique identification code. The identification key and data will be accessible only by the Principal and Co-Investigators.**

B. What individually identifiable information will be collected as part of the study data and who will have access to that information? **Identifiable data will include the subject's name, signature, birthday, and medical history. This data willl be listed with the subject's unique identification number on the identification key. This information will be kept in a locked cabinet accessible only to the PI and Co-I, and student investigators.**

C. When will identifiable information/the identification key be destroyed (if applicable)? *Please note that when feasible, the IRB recommends that personal identifiers be destroyed as soon as possible, though research data must be stored for 5 years.* **Signed consent forms and data will be destroyed 5 years after the end of the study. The identification key will be also be destroyed 5 years after the end of the study, though may be destroyed earlier if data collection and analysis are completed sooner.**

D. Where will the data be stored (*Copies of records must be stored on Mason property—for example, in the PI's office*)? **The signed consent form and identification key will be stored in a locked file in the PI's office. Deidentified and non-identifiable data will be kept in a file on a password-protected computer in the Functional Performance Laboratory. Copies of deidentified and non-identifiable data may also be stored on investigators' (PI and Co-Investigators) personal password-protected computers for analysis.**

E. How long will the data be stored (*data must be retained for at least 5 years after the study ends*)? **Deidentified will be stored indefinitely, but for at least 5 years, after the end of the study.**

F. What, if any, are the final plans for disposition/destruction of the data? **The identification key, signed consent forms, or any other identifiable data will be shredded or deleted five years after completion of the study.**

G. Will results of the research be shared with the participants? ☒ Yes ☐ No If yes, describe how this will be accomplished: **Individual results overall will be shared with participants upon request of the participant following completion of data collection and analysis.**

H. Will individually identifiable information be shared with anyone outside of the research team (*If yes, please explain and be sure to include this information in the consent form*)?
☐ Yes ☒ No If yes, please explain:

I. Does the research involve possible disclosure by participants of intent to harm themselves or others or possible disclosure of child abuse or neglect? (*If yes, please explain and be sure to include this information in the consent form*)?
☐ Yes ☒ No If yes, please explain:

**7. Risks**

A. Summarize the nature & amount of risk if any (*include side effects, stress, discomfort, physical risks, psychological and social risks*): **Risks to the participants in this study are minimal.**
**-The participant may experience some discomfort from any of the testing or training including muscle fatigue and/or muscle or joint soreness following testing or training. Straining a muscle or spraining a ligament is a very small possibility during testing or training.**
**-The risks of the protocol exercise testing and supervised training are low as the testing and training intensity are designed and anticipated to be of moderate intensity or below. As with all exercise intervention, there is minimal risk including risk of falling, dizziness, sudden death, heart attack, chest pain or tingling in the arm, jaw, or back, shortness of breath, and/or extreme fatigue. In case of injury during testing or training procedures, the George Mason University research team may provide basic first aid. If appropriate, the team will call the emergency response team at 911. All of the research team have been trained and certified in CPR/AED administration.**

B. Estimate the probability if any (e.g. not likely, likely, etc.) that a given harm may/will occur and its severity: **It is unlikely that a given harm may occur. The testingand training risks are relatively low and all testing is supervised and monitored directly.**

C. What procedure(s) will be utilized to prevent/minimize any potential risks? **Personnel trained in CPR and AED will be present at each testing and exercise testing. Subjects will be monitored at all times during testing and training visually and using heart rate monitors to ensure compliance with target intensity zones. Furthermore, personnel will alter to the balance deficiencies of this population and attendant at all times to the subject to prevent falls if a loss of balance occurs.**

**8. Benefits**

A. Describe any probable benefits (if any) of the research for the subject(s) (*Do not address compensation in this section*): **There are no known direct benefits of this research.**

B. Describe the benefits to society and general knowledge the study is likely to yield: **The health and social costs of living with chronic illness such as PD to society is quite large, particularly with respect to the myriad secondary conditions that may ensue as a result of chronic decreased mobility. This intervention, if effective, may offer an affordable way for individuals with PD to maintain their health and fitness and accrue the same health-related benefits of physical activity as others.**

**9. Financial Information**

A. Is there any internal or external funding or proposed funding for this project? ☐ Yes ☒ No
If yes, funding agency [redacted] and OSP # (if external funding) [redacted] ***(attach grant application)***

B. Are there financial costs to the subjects? ☐ Yes ☒ No If yes, please explain: [redacted]

C. Will subjects be paid or otherwise compensated for research participation? ☐ Yes ☒ No
If yes, please respond to the following questions:

1. Describe the nature of any compensation to subjects (cash, gifts, research credits, etc.): [redacted]
2. Provide a dollar amount/research credit amount, if applicable: [redacted]
3. When and how is the compensation provided to the subject? [redacted]
4. Describe partial compensation if the subject does not complete the study: [redacted]
5. If research credit, what is the non-research alternative to research participation? [redacted]

**10. Special Topics**

A. Will the study involve minors? ☐ Yes ☒ No
*If yes, complete addendum A*

*B.* Will the study involve prisoners? ☐ Yes ☒ No
*If yes, complete addendum B*

C. Will the study specifically target pregnant women, fetuses, or neonates? ☐ Yes ☒ No
*If yes, complete addendum C*

*D.* Will the study involve FDA regulated drugs (other than the use of approved drugs in the course of medical practice)? ☐ Yes ☒ No
*If yes, complete addendum D*

E. Will the study involve evaluation of the safety or effectiveness of FDA regulated devices? ☐ Yes ☒ No
*If yes, complete addendum E*

F. Will false or misleading information be presented to subjects (deception)? ☐ Yes ☒ No
*If yes, complete addendum F*

G. Will participants be audio or videotaped? ☒ Yes ☐ No
*If yes, complete addendum G*

H. Will the research involve other potentially vulnerable participants (e.g. disabled or addicted individuals, populations engaging in illegal behavior)? ☐ Yes ☒ No
*If yes, complete addendum H*

I. Will the research be conducted outside of the United States? ☐ Yes ☒ No
*If yes, complete addendum I*

**11. Investigator Certification**

**I certify that the information provided in this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request and receive approval from the IRB for changes prior to implementing these changes. I will comply with all IRB policies and procedures in the conduct of this research. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol. I understand that I am ultimately responsible for the entire conduct of this research.**

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## BIOGRAPHY

Tom Corfman is a biomedical engineer and physiologist. Tom has been a Rehabilitation Program Specialist at the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) for 17 years. In that time, he has managed the Advanced Rehabilitation Research and Training (ARRT) program, the Small Business Innovation Research (SBIR) program, and is currently the program manager of the Rehabilitation Engineering Research Centers. Prior to NIDILRR, Tom was a Research Associate at the Human Engineering Research Laboratories (HERL), and a Project Co-Investigator for the Rehabilitation Engineering and Research Center on Technology to Improve Wheeled Mobility at the University of Pittsburgh. Tom's research included kinematic, kinetic, electromyography, force sensing array, and forceplate analyses. He also participated in a research effort to clinically recognize child abuse by examining X-rays for femur fracture angle, fracture type, and impact energy. Tom's training includes rehabilitation science and technology, rehabilitation engineering, rehabilitation biomechanics, and prosthetics and orthotics. Tom has participated in the development of wheelchair standards including biomechanical, stability, static strength, and fatigue strength analyses to improve the quality of wheelchairs available to consumers. He also investigated wheelchair and wheelchair occupant reaction to crash situations to reduce the incidence of injuries. Tom taught biomechanics and kinesiology at the California State University, Sacramento, CA and

was an Anesthesia Technologist in the operating rooms of the UC Davis Medical Center, Sacramento CA.