Barre Exercise in Parkinson’s
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I. SPECIFIC AIMS

The primary objectives of this study are to: 1) evaluate the feasibility and acceptability of a barre exercise intervention and 2) gather preliminary data regarding the effect of a barre exercise intervention on balance, strength, functional mobility and quality of life in individuals with mild to moderate Parkinson disease (PD). Individuals with PD (N=15) will be recruited to participate in a pilot barre exercise class led by a certified barre instructor. The intervention will include 24, 45-50 minute group classes (twice weekly for 12 weeks, excluding holidays). Pre- and post-intervention data collection will include assessments of balance, lower extremity strength, and functional mobility.

Specific Aim 1: Assess the feasibility and acceptability of a pilot barre exercise intervention for individuals with mild to moderate PD.

Hypothesis 1a: Participants will participate in the intervention, defined as 75% of participants attending and engaging in 75% of the exercise sessions.
Hypothesis 1b: Participants will complete the intervention study, defined as 75% of total recruited participants remaining enrolled for the total duration of the study.
Hypothesis 1c Participants will rate the intervention as acceptable and satisfactory, as measured by a post-intervention survey.

Specific Aim 2: Determine preliminary effects of a pilot barre exercise intervention on balance, strength, functional mobility and quality of life in individuals with mild to moderate PD.

Hypothesis 2a: Barre will improve functional balance, defined as an improved score on the Mini-BESTest.
Hypothesis 2b: Barre will improve functional lower extremity strength, defined as decreased time taken to complete the Five Times Sit to Stand assessment. Additional functional strength assessments explored include a timed stair ascent and descent task and the Timed Up and Go test.
Hypothesis 2c: Barre will improve functional mobility, defined as an improvement in average gait speed measured in the Ten Meter Walk Test. Additional gait assessments explored include fast as possible and backwards walking in the Ten Meter Walk Test and distance covered in the Two Minute Walk Test.
Exploratory Hypothesis 2d: Barre will improve quality of life, as measured by the Parkinson's Disease Questionnaire (PDQ-39).

II. BACKGROUND AND SIGNIFICANCE

Parkinson disease (PD) is the second most common neurodegenerative disease after Alzheimer disease; and is becoming more common, with over 12 million people expected to have PD in 2040.[1] PD is a hypokinetic disease characterized by motor symptoms including bradykinesia (slowness), rigidity, postural instability, and gait and balance problems.[2] The average onset age for PD is around 60 years.[3] While pharmaceutical methods such as levodopa, the primary medication for PD, have been shown to be effective, some symptoms are unresponsive to medication. Long-term use of levodopa can also lead to gradual efficacy loss and unwanted side effects.[4] Due to the progressive nature and long disease duration of PD, other treatments are needed.

Along with medication, exercise has been shown to improve both motor symptoms and quality of life, with numerous studies demonstrating gait, balance, strength, and flexibility gains in people with PD who participate in exercise programs.[5–7] While traditional exercise programs are effective, they are not always enjoyable or motivating and often suffer from high attrition.[8] Common barriers to exercise for people with PD include fear of falling, environmental factors such as one's social environment and support from a teacher or coach, lack of time, and low outcome expectations. [8,9]

Barre is an exercise modality that combines elements of classical ballet with strength training. Barre involves high repetitions of low impact, isometric movements, requires little to no equipment, and is highly modifiable for different fitness levels.[10] Barre is traditionally performed in a class setting, which promotes increased social interaction and builds community. Furthermore, interventions with dance elements exhibit high adherence rates (often > 80%).[11,12] The exercises in a barre class are also performed holding on to a fixed barre or on the floor, which may address people with PD's fear of falling.

Barre incorporates elements of classical ballet, a codified dance technique that focuses on fluid movement through set positions.[13] While participating in a traditional ballet class may not be of interest or suitable to everyone, there are benefits from performing ballet-based movements including better posture, increased mobility, and improved flexibility.[10] Ballet dancers exhibit better overall postural stability compared to non-dancers.[14] This emphasis on upright alignment and lengthening of the upper body is particularly relevant for this population, as people with PD often demonstrate impaired posture including a flexed neck and trunk.[2] Furthermore, ballet movements often focus on isolation of the lower extremities while maintaining a stationary upper body. This element may improve trunk stability during movement and help to address the common symptom of postural instability of PD.[2] Currently, there is limited research on the benefits of ballet for people with PD. However, initial evidence suggests that a ballet-based intervention can lead to improvements in balance for this population.[15] Similar preliminary evidence illustrates that ballet can also lead to improvements in balance and ataxia in other neurological populations, namely individuals with chronic stroke and multiple sclerosis.[16,17] Therefore, a ballet-based intervention such as barre may be of

particular interest to individuals with PD, especially to address the symptoms of postural instability.

In addition to potential improvements in postural stability, barre incorporates elements of resistance training, which improves strength and functional capacity in people with PD.[18] Individuals with PD often exhibit muscle weakness, particularly in the hip flexors and ankle plantar flexors, which further contributes to postural instability and gait difficulty.[19] Adequate muscle strength is therefore vital for functional mobility in this population. Progressive resistance training leads to significant improvements in functional strength and mobility measures such as the Six Minute Walk Test (6 MWT), Timed Up and Go Test (TUG), Five Times Sit to Stand (FTSTS), and timed stair ascent and descent.[18,20,21] Additionally, the Five Times Sit to Stand (FTSTS) is useful in determining fall risk[22], which is extremely important, as people with PD are at an increased risk for falls which can lead to injury and further reduced mobility.[23] A recent umbrella review suggests that clinicians should encourage and motivate patients to participate in progressive resistance training as part of their usual care exercise regimens.[24] Furthermore, strength training is also championed by community organizations such as the Parkinson's Foundation, who suggest incorporating this type of training 2-3 non-consecutive days a week for a least 30 minutes a session.[25] Thus, participating in a barre class may be a motivating and enjoyable way to incorporate strength training, which is vital for functional mobility, into an exercise routine.

To our knowledge, there is no prior literature on the effects of a barre exercise intervention for individuals with Parkinson disease. However, the combined benefits of incorporating elements of ballet and strength training into one exercise class may lead to higher benefits overall in comparison to each exercise modality on its own. Therefore, barre could have the potential to improve balance, strength, and more than current exercise programs. Additionally, the increased social interaction and dance elements of a barre exercise class may lead to higher adherence and enjoyment, which could help individuals with PD establish consistent exercise regimens outside of intervention sessions.

This study aims to pilot a barre exercise intervention to assess the feasibility and acceptability of this form of exercise for individuals with Parkinson disease as well as preliminarily evaluate barre's potential effects on motor outcomes, including balance, strength, and functional mobility.

III. METHODS

PARTICIPANT RECRUITMENT

Recruitment of participants will occur through:

- Movement Disorders Clinic in the Department of Neurology at Washington University School of Medicine
- Flyers posted around Washington University campuses
- Posted flyers on Washington University Physical Therapy social media pages

    - To protect participant privacy, all comments will be turned off for social media posts.
    - Social media accounts:
        - Washington University in St. Louis Program in Physical Therapy Facebook Page: https://www.facebook.com/WashUPT
        - Washington University in St. Louis Program in Physical Therapy Instagram Page: https://www.instagram.com/wustl_pt/
- Participants who have completed studies within our lab that state they are interested in future research studies.
- Posted flyers at local Parkinson disease community organizations such as the St. Louis chapter of the American Parkinson Disease Association and Rock Steady Boxing.

Once participants have been identified, they will go through a phone screening to determine eligibility. The information collected during the phone screen will only be used for recruitment purposes and will not be used if the person qualifies for the study and signs the consent. Information collected during the phone screen will not be retained if the participants do not qualify.

PARTICIPANT INCLUSION AND EXCLUSION CRITERIA

For inclusion in the study, participants must be:

- diagnosed by a neurologist with idiopathic Parkinson disease
- at least 18 years of age
- a score on the Hoehn & Yahr (H&Y) scale between I-III to indicate mild to moderate disease severity
- able to provide informed consent
- able to walk for 10 continuous minutes without assistance from another person
- stable medication regimen for at least one month prior to enrollment

Participants with PD will be excluded if they have any of the following:

- any neurological condition other than PD
- history of orthopedic or other medical conditions that limit the ability to safely participate in the intervention or
- language, visual, or hearing barriers to participation
- evidence of dementia (Montreal Cognitive Assessment < 24) to ensure understanding of the intervention class instructions

Participants with PD will remain on their normal PD medications throughout the study. Pre- and post-intervention assessments will be conducted in the ON medication state because this represents everyday life. Pre- and post-intervention assessments will occur at the same time of day.

Participants will be paid, via check, for their participation. Participants can receive up to $100 for completing the entire study. Participants will receive $50 for the pre-

intervention in-lab visit 1 and can receive another $50 for the post-intervention in-lab visit 2.

RISKS AND POTENTIAL BENEFITS

Risks:

- Likely/Common
    - Mild
        - Fatigue – Participants may feel tired or weak during the strength, balance, and walking assessment tasks. Additionally, participants may feel tired or weak while participating in the exercise intervention. Research team members will monitor participants and help them take breaks or discontinue the study if necessary.
        - Muscle Soreness- Participants may experience muscle soreness after repeated sessions of the exercise intervention. Research team members will monitor participants and help them take breaks when necessary.
        - Discomfort in answering questions – Participants may experience some discomfort or uneasiness when completing the questionnaires. Participants have the right to refuse to answer any question for any reason.
- Less Likely/Less Common
    - Mild
        - Stumbling- There is the possibility that participants may stumble during the intervention exercises or assessment tasks. Participants will be fitted with a gait belt that a research team member will use to assist participants in regaining their balance. During all assessment tasks, a member of the research team will be close to the participant to make sure they do not fall to the floor. During the exercise intervention sessions, participants will perform the majority of exercises holding on to the back of a chair or laying down on a yoga mat for support.
- Rare
    - Serious
        - Falling- It is unlikely that a participant will fall during testing or the exercise intervention and will be injured as a result of a fall. Participants will be closely attended by trained members of the research team during testing and the intervention sessions to ensure the safest of conditions. Breaks and exercise modifications will be encouraged, and participants can discontinue testing or the exercise session if they feel unsteady or unsafe.

Benefits:

Participants may benefit from the barre exercise sessions by showing improved functional mobility, balance, and strength.

MATERIALS

Pre-assessment materials via phone

- Phone screen to inform the participant about the study and ask questions to determine eligibility.

Evaluation materials during pre-intervention visit 1 and post-intervention visit 2

- Six Opal inertial sensors (APDM, Inc.) will be worn to output postural sway and gait measures during the balance, gait, and functional strength assessments. These sensors are attached with elastic Velcro bands and are placed on the tops of the feet, wrists, sternum, and lumbar spine.

Barre exercise intervention session materials

- Ballet barre- Participants will be provided with a sturdy ballet barre to use as their barre.
- Chairs- Each participant will be provided with a sturdy chair to use for seated warm-up and cool-down.
- Yoga mats – Each participant will be provided with a yoga mat to support them during floor-based exercises.
- Yoga blocks – Each participant will be provided with a yoga block to support them during floor-based exercises and aid with individual modifications.

PROTOCOL

Pre-Intervention Visit 1

Participants will receive and sign the informed consent document during the first pre-intervention visit. A trained researcher will go through this document with the participant to explain the study objectives, outline the procedure, and ensure participants have ample opportunity to ask questions and clarify understanding.

After consent is obtained, a trained researcher will administer the Montreal Cognitive Assessment (MoCA), the New Freezing of Gait Questionnaire (NFOG-Q), and the MDS-UPDRS-III. In addition, the research team will collect demographic information, medical history, and obtain a current medication list. After this in-person screening, the research team will determine if the participant meets the inclusion criteria.

If the participant meets the inclusion criteria following in-person screening, sensors will be placed on both feet, wrists, the sternum, and lumbar spine to record data during gait, balance, and functional strength assessments. All participants will be also be fitted with a gait belt and closely monitored by members of the research team to prevent falls.

Balance Assessment: Participants will first complete the Mini-BESTest, which is a clinically relevant balance test that is both valid and reliable for individuals with PD.[26] The sensors will record postural sway and gait data during the various sections of this test.

Gait Assessments: After completing the Mini-BESTest, participants will complete gait assessments. The sensors will record spatiotemporal gait variables during each walking task.

> Two Minute Walk Test: This gait assessment will be used to measure walking endurance. Participants are asked to cover as much ground as possible over the course of two minutes. Following this assessment, the Borg Scale Rating of Perceived Exertion will be administered to measure exertion levels during the Two Minute Walk Test.
>
> Ten Meter Walk Test: This gait assessment will be used to assess average gait speed. Participants will be asked to complete this test under three conditions: 1) normal forwards gait speed, 2) fast as possible gait speed, and 3) backwards walking at a normal, safe gait speed. Only the first condition, normal forwards gait speed, will be used as a primary outcome.

Functional Strength Assessments: Following the gait assessments, participants will complete the following functional strength assessments. These assessments will serve as proxy measures for lower extremity strength. The Borg Scale Rating of Perceived Exertion will again be administered following all of the functional strength assessments listed below.

> Five Times Sit to Stand: Participants will be asked to start sitting with their arms folded across their chest and with their back against the chair. Participants are then asked to stand up and sit down five times as quickly as they can.
>
> Stair Ascent and Descent: Participants will be asked to ascend and descend one flight of stairs (building's standard flight of 12 stairs) as quickly and safely as possible under close supervision by a research team member.
>
> Timed Up and Go (TUG): This test is administered as part of the Mini-BESTest. Participants will be asked to stand up from a chair, walk three meters at their normal, comfortable gait speed, and sit back down.

All motor assessments, including the MDS-UPDRS-III, balance, gait, and functional strength assessments will be filmed with participant consent. These video recordings will be stored in a secure online Box folder and will only be accessed by members of the research team to regrade assessments as necessary. Video records will be destroyed after all analyses and publications are complete.

Upon completion of the above motor evaluations, participants will be asked to complete three surveys. These include the Parkinson disease Questionnaire (PDQ-39), used to measure quality of life, the Activities-specific Balance Confidence Scale (ABC), and questions regarding current exercise habits.

Intervention

All participants will be assigned to the pilot barre exercise intervention. The intervention classes will occur in the Movement Disorders Research Center and consist of twice weekly, 45-50 minute group exercise classes for 12 weeks (excluding holidays). In total, participants will receive 24 classes. The barre exercise intervention will be delivered by an International Ballet Barre Fitness Association (IBBFA) certified barre instructor with a bachelor of arts (BA) in dance and extensive dance-teaching experience. Additional research team members will also be present in the classes to monitor safety and help participants when needed. The barre exercise program will combine elements of classical ballet and strength training, focusing on repetition of low impact, isometric movements. The class will begin with a short seated warm-up, move into 30 minutes of barre exercises holding on to the back of a chair as the fixed barre, continue into core exercises performed laying down on a mat, and finish with a cool down. After each class, the participants will rate how difficult the session was using a visual analog scale (VAS). This scale will be used to determine to what level the class should progress at as the weeks go on. Progression may include introduction of more challenging exercises and increased repetitions. Participants will be encouraged to modify the exercises as needed for safety.

Post-Intervention Visit Two

All assessments and procedures will be repeated after completion of the barre exercise program as mentioned in “Pre-Intervention Visit 1”. This includes the MDS-UPDRS-III, the New Freezing of Gait Questionnaire (NFOG-Q), all motor assessments, and the PDQ-39.

Again, all motor assessments, including the MDS-UPDRS-III, balance, gait, and functional strength assessments will be filmed with participant consent. Video records will again be destroyed after all analyses and publications are complete.

An additional survey will be administered, measuring participant experiences with the exercise classes, including satisfaction and acceptability.

OUTCOME MEASURES

A variety of outcome measures will be used for this study.

- Primary Outcomes
    - Feasibility and Acceptability

        - Participation- defined as the number of individuals who attend and participate in at least 75% of the classes
        - Retention- defined as the percentage of participants who complete the intervention, regardless of the number of sessions they attended
        - Client Satisfaction and Acceptability Questionnaire (CSQ)- mean group rating on measure of self-reported satisfaction of a program
- Secondary Outcomes
    - Balance
        - Mini-BESTest– a measure that quantifies overall balance dysfunction
    - Gait
        - Gait Speed in the 10MWT- a measure of how quickly someone walks at their normal, comfortable gait speed across a 10-meter distance; measured in meters/second
    - Functional Strength
        - Five Times Sit to Stand Time – total time it takes for an individual to perform five repetitions of standing up and sitting back down in a chair as quickly as possible

- Additional Outcomes
    - Gait
        - 10MWT fast as possible gait speed- a measure used to assess average maximum gait speed to determine ability to modulate gait
        - 10MWT backwards walking at comfortable pace – a measure used to assess gait speed in a more challenging condition that also assesses dynamic balance and spatial awareness
        - 2MWT distance- total distance a person can cover while walking continuously for two minutes; a measure of walking endurance
    - Functional Strength
        - Stair Ascent and Descent – total time it takes for an individual to ascend and descend a standard flight of 10 stairs as quickly and safely as possible
        - TUG- total time it takes for an individual to stand up from the chair, walk three meters, and sit back down in the chair at normal, comfortable gait speed
    - Quality of Life
        - Parkinson Disease Questionnaire (PDQ-39) – a patient-reported questionnaire that assesses PD-specific health quality of life in the past month
    - New Freezing of Gait Questionnaire (NFOG-Q) – a patient-reported questionnaire that assesses frequency, severity, and duration of freezing of gait episodes
    - Borg Rating Scale of Perceived Exertion – a 15-point scale with written descriptors designed to standardize perceived exertion across tasks and individuals

The following forms and assessments will also be collected during Pre-Intervention Visit 1:

- Montreal Cognitive Assessment (MoCA)- a valid, sensitive screening tool for mild cognitive impairment
- Demographics Form
- Medical History
- Medication List
- Current exercise habits survey
- Activities-specific Balance Confidence Scale (ABC) – a patient-reported questionnaire that assesses balance confidence while performing various activities
- MDS-UPDRS- gold standard measure of global disease severity in PD, including motor and non-motor symptoms as well as activities of daily living

IV. STATISICAL ANALYSES

Aim 1: Assess the feasibility and acceptability of a pilot barre exercise intervention for individuals with mild to moderate PD.

- Feasibility Objectives
    - Participation: 75% of participants will attend 75% of the 24 sessions.
    - Retention: 75% of recruited participants will complete the intervention and remain enrolled for the duration of the study.
- Satisfaction and Acceptability- Demonstrate that this group exercise class is acceptable, defined as a minimum average rating of > 1.5 out of 4 on the Client Satisfaction and Acceptability Questionnaire (CSQ).

Due to the preliminary nature of the study and small expected sample size, only motor trends, defined as average group change in score from pre- to post-intervention will be reported. Additionally, published MCIDs will be used to establish if the average improvement of the group reached clinical significance.

Aim 2: Determine the effects of a pilot barre exercise intervention on balance, strength, functional mobility and quality of life in individuals with mild to moderate PD.

Hypothesis 2a: Barre will improve functional balance, defined as an improved score on the Mini-BESTest.

- MCID- A 4-point increase in total score will denote a clinically-meaningful improvement in functional balance.[27]

Hypothesis 2b: Barre will improve functional lower extremity strength, defined as decreased time taken to complete the Five Times Sit to Stand assessment. Additional functional strength assessments explored include a timed stair ascent and descent task and the Timed Up and Go test.

- MCID- A 2.3 second decrease[28]will denote a clinically-meaningful improvement in Five Times Sit to Stand assessment. There are no valid MCIDs for the timed stair ascent and descent task and the Timed Up and Go test. Therefore, a small effect size will be considered a positive effect for each of these tests.

Hypothesis 2c: Barre will improve functional mobility, defined as an improvement average gait speed measured in the Ten Meter Walk Test. Additional gait assessments explored include fast as possible and backwards walking in the Ten Meter Walk Test and distance covered in the Two Minute Walk Test.

- MCID- A 0.05 m/s increase in gait speed will denote a moderate clinically-meaningful improvement in forward, normal gait speed.[29] There is no valid MCID for the Two Minute Walk Test. Therefore, a small effect size will be considered a positive effect.

Exploratory Hypothesis 2d: Barre will improve quality of life, as measured by the Parkinson's Disease Questionnaire (PDQ-39).

- MCID- A 4.22-point increase on the PDQ-39 will denote clinically-meaningful improvement in quality of life.[30]

V. MONITORING

The data safety and monitoring plan includes recording all reportable events according to the IRB policy. The PI will review all reportable events as they occur.

Study progress and safety will be checked monthly for accuracy, compliance, and completeness by the senior scientist and concerns will be discussed with the PI.

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