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Evaluation of Fall Risk, Functional Mobility and Quality of Life Changes of Community-Dwelling Older Adults with Parkinson's Disease Participating in a Community Exercise Program

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Evaluation of fall risk, functional mobility and quality of life changes of community-dwelling older adults with Parkinson's disease participating in a community exercise program

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A Scholarly Project Submitted to the Graduate Faculty of the

Department of Physical Therapy
School of Medicine and Health Sciences
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in partial fulfillment of the requirements for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota
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This Scholarly Project, submitted by Gabrielle Dahl, Elizabeth Hermanson, Laura Nelson, and Kayla Selinger in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

Title Evaluation of fall risk, functional mobility and quality of life changes of community-dwelling older adults with Parkinson's disease participating in a community exercise program

Department Physical Therapy

Degree Doctor of Physical Therapy

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ABSTRACT

Purpose/Hypothesis: Falls are evident in the older population and are a common and disabling feature of Parkinson Disease (PD). The benefits of activity are well known to decrease balance deficits and increase overall quality of life in the older adult population. In addition highly challenging exercises have been suggested to increase neuroplasticity in individuals with PD. The effect of challenging exercises on clinical outcomes in a structured Physical Therapy setting is documented in literature; however, the effect of a community based program is not well documented. Our pilot study examined the effect of a community exercise program on improving quality of life and decreasing fall risk as well as overall satisfaction with the program.

Methods: Seven participants, 3 females and 4 males, age range 54-78 years old, participated twice weekly in a challenging exercise program incorporating various transitional movements, large movements, rotational movements, and cognitive verbal tasks. Pre-tests were administered followed by a post test at 3 months. Tasks included gait speed forward and backward, timed up and go (TUG), cognitive timed up and go (CTUG), functional reach, 30 second sit-to-stand, and a quality of life questionnaire, the PDQ-39. Comparison of pre- and post- test scores was performed to note any minimally detectable changes in scores.

Results: No significant differences in functional reach, TUG, or gait speed were noted; however, researchers observed improvement in quality of movement during gait. All participants improved in CTUG and 30 second sit-to-stand. Six participants’ quality of life scores improved most notably in speech and walking one half mile. All 7 participants highly recommended continuing the program.
Conclusion: These findings are consistent with recent literature. The challenging exercises in a community based program produced objective improvements. Participants all had positive comments regarding the program such as "I feel better, I'm more alert, and I feel I move around better" and "The most beneficial part of this program is that it exists!!!"
CHAPTER I

BACKGROUND AND PURPOSE

Parkinson's Disease (PD) is one of the most common neurodegenerative diseases, second only to Alzheimer's disease, affecting primarily the elderly population.¹ The prevalence of worldwide PD is expected to reach approximately 9 million by the year 2030,² indicating the need for research regarding causes, treatment and long term disease management. Specific causes of PD remain largely unknown, though there are thought to be both genetic and non-genetic risk factors.¹ Exposure to harmful substances such as pesticides, herbicides, and heavy metals as a causative factor for PD has been the subject of much research, along with dietary considerations such as coffee and alcohol consumption. Increased age and smoking have shown to be the only risk factors with consistent results, while evidence for other postulated risk factors has been inconclusive.¹ Onset and diagnosis is rare before the age of 50 years, with a significant increase seen after age 60.²

Parkinson's disease is characterized by abnormality in the basal ganglia, specifically the degeneration of cells which produce the neurotransmitter dopamine in the substantia nigra.³ This degeneration may be caused by altered cell mechanics, such as proteosomal or lysosomal dysfunction, accumulation of synuclein, or altered mitochondrial activity.² As a result of this degeneration, a depletion of dopamine occurs, causing symptoms.³ Damage to the medial substantia nigra results in a tremor dominant form of PD, while damage to the lateral substantia nigra results in an akinetic or rigid form of PD.³ Treatment of PD symptoms has targeted dopamine deficiency and aimed to replace the neurotransmitter.² Other important interventions for PD include patient education,
pharmacologic and non-pharmacologic interventions, and support as individuals live with the disease.²

The progressive nature of PD manifests in both motor and non-motor features, which can impact function in a variety of ways.⁴ Classic signs and symptoms of PD include resting tremor, bradykinesia, rigidity, and postural instability.⁴ Secondary clinical features include motor symptoms such as shuffling gait, freezing, dystonia, hypomimia, dysarthria, dysphagia, sialorrhoea, micrographia, festination, and glabellar reflexes, as well as non-motor symptoms such as cognitive or neurobehavioral abnormalities, sleep disorders, sensory abnormalities, autonomic dysfunction, depression or fatigue.²⁴ Progression of the disease is variable, but is often more rapid in individuals with late onset PD.⁴ Disease progression has also been shown to vary depending on symptoms displayed. Rapid disease progression and poorer prognosis is associated with individuals who exhibit bradykinesia, postural instability and gait dysfunction compared to those who do not exhibit these symptoms.³⁵ Individuals demonstrating a tremor are often less cognitively impaired than those with akinesia or gait dysfunction.⁵ Overall, impaired motor learning is seen in PD populations as compared to healthy individuals, making rehabilitation for this population very important.⁵

Individuals with PD have been shown to have reduced levels of physical activity compared to healthy peers, as well as decreased levels of strength and functional ability.⁷ This is due to impaired basal ganglia having an inadequate effect on the cortical motor centers, leading to less activation of motor neurons and muscle weakness. This mechanism also contributes to impaired balance, increased risk of falls, and disability.⁸ Research has shown positive effects of exercise on PD to decrease these symptoms. With the exception of tremors, tailored physical activity has shown to improve the affected motor symptoms of PD patients including disturbances such as freezing of gait (FoG), stride variability, and balance impairments.⁹ A systematic review and meta-analysis on the effectiveness of exercise on individuals with PD found exercise to be an effective intervention to improve leg strength, balance, walking, and health
related quality of life. Another study on the effects of exercise on cognition in individuals with PD found exercise was shown to increase frontal lobe based executive function (i.e. spatial working memory and verbal fluency). Exercise has been shown to be a physiological tool that protects at risk or compromised neurons in individuals with PD. It may protect vulnerable dopamine neurons or rescue affected neurons. Exercise may also recruit other undamaged parts of the brain to help improve function in the individual.

Prefrontal cognitive circuits are critically involved in early phases of motor learning, making cognitive engagement an important component of exercise with PD. Cognitive engagement may be facilitated by feedback (e.g. verbal or proprioceptive), cueing, dual tasking, and motivation. There are a variety of different exercise modalities that use these concepts in individuals with PD, including treadmill training, amplitude training, Tai Chi, boxing, and tango dancing.

The ability for an individual to fluctuate walking speed suggests ability to adapt to a variety of environments and task demands. Parkinson’s Disease presents with common characteristics of gait patterns including bradykinesia, tremors, rigidity, postural deformities, postural instability, and freezing. A combination of these characteristics can be observed in individuals with PD and can hinder their community mobility. These characteristics can be demonstrated as shorter step length, longer step time, decreased cadence, and decreased single support duration. By measuring gait parameters such as velocity (distance walked in cm/s), cadence (steps per minute), stride length (heel-to-heel distance of the same lower limb in the gait cycle in cm), single support ratio (single limb support phase duration/gait cycle duration as a %), double support ratio (double limb support duration/gait cycle duration as a %), swing phase ratio (swing phase duration/gait cycle duration as a %) and stance phase ratio (stance phase duration/gait cycle duration as a %), one can determine functional status of an individual, as well as a prediction of survival rate. Research delineates the prediction of survival based on gait speed, age, and gender, with a linear rise in survival rate based upon increasing gait speeds.
There are a variety of methods available to measure gait parameters, including paper-and-pencil tests, electronic foot switches, and video-based analysis; all of which are labor-intensive, time-consuming, and inefficient for collecting valid and reliable data. The GAITRite® instrumentation was used throughout this study to compound specific gait parameters in order to detect change following the exercise program. The GAITRite® system consists of a mat with embedded sensors which are triggered as mechanical pressure is applied. The GAITRite® software calculates elapsed time after sensor activation and does not rely on derived formulas to document temporal events. This walkway system is proven to have strong concurrent validity and is a reliable tool for objectively measuring spatial and temporal parameters of gait. Research has demonstrated good to excellent test-retest reliability for the GAITRite®, indicating this system is an objective gait assessment for evaluation or intervention and is capable of detecting genuine changes in gait.

Sit-to-stands are often used clinically for assessment and intervention for general lower extremity strength, functional endurance, and risk for falls. The 30-second sit-to-stand and the 5-times sit-to-stand tests are both recognized as valid tests. Among community dwelling elderly the 30-second test has been shown to have excellent test-retest reliability of 0.89, interrater reliability of 0.95, and criterion validity of 0.77. The 5-times test has been shown to have interrater reliability of 0.99, and test-retest reliability of 0.64–0.96 in community dwelling older adults with Parkinson’s Disease. The 5-Times test offers greater precision as the times are recorded in seconds, while the 30-second test scores in number of complete repetitions. The 5-times test has also been shown to effectively predict fall risk, assessing level of strength, balance, and bradykinesia as opposed to severity of PD. One benefit of the 30-second test is the absence of a minimum requirement for sit-to-stands, and thus it is useful if participants are unable to complete 5 full repetitions. Another advantage of the 30-second test is that is also assesses endurance, challenging the participant in a manner similar to stair climbing and other daily functions. The 30-second test has also been shown to be able to adequately predict average
and peak power of the lower extremity muscles in community dwelling older adults.\textsuperscript{28}

As balance has a significant impact on daily functioning and safety in adults with PD, functional balance and risk for falls should be assessed. The Functional Reach Test (FRT) correlates to every day reaching tasks, such as reaching across a countertop or into a cupboard.\textsuperscript{29} Functional reach also relates to spinal range of motion, which is critical for completing safe transfers and mobility.\textsuperscript{30} The FRT has been shown to have a specificity of 0.92 when assessing risk and history of falls in patients with PD, and a positive predictive value of 0.90 for predicting risk of future falls.\textsuperscript{31} Another factor greatly attributing to falls and quality of life in individuals with PD is misjudgment of abilities and fear of falling. It has been shown that individuals with PD often underestimate their reaching capabilities, and when performing the FRT are able to reach farther than they expect.\textsuperscript{32} Utilizing the FRT therefore allows the testers to see how fear of reaching may play into willingness to reach and participate in daily tasks at home. Overall, it has been shown that the FRT is one of the best balance assessments for individuals with PD due to the amount of information gained with quick, easy, and inexpensive test administration.\textsuperscript{33}

An estimated 70 to 87 percent of those with Parkinson’s disease experience a fall at some point.\textsuperscript{34} Occurrence of a fall in the previous year is often used as a predictor of future falls, though this fall prediction method is insufficient as it does not recognize progression of the disease or any medical complications.\textsuperscript{34} The Timed Up & Go (TUG) test offers objective data in an effort to identify fall risk. The TUG is a measure of physical performance which requires minimal equipment and time to administer. A subject is measured on the ability to stand up, walk 3 meters, turn, walk back and sit down safely. Assessment of the ability to turn is one important aspect of the TUG, as turning is often affected even in mildly-impaired individuals with PD.\textsuperscript{35} The test is timed and normative data has been established, with the minimal detectable change at 3.5 seconds or 29.8 percent in the PD population.\textsuperscript{36} The TUG has shown to have a high test-retest reliability and inter-rater reliability in PD populations, with a sensitivity of
0.66 and specificity of 0.62. Longer TUG times are associated with increased fall risk and decreased mobility, with a cut-off time of 11.5 seconds. The TUG may be an accurate assessment tool for identification of fall risk in individuals with PD.

A negative correlation has been found between TUG results and verbal executive functioning, with slower TUG performance associated with worse executive functioning. TUG performance and verbal executive functioning are also associated with, and may be predictors of, quality of life as measured by the Parkinson Disease Questionnaire-39 (PDQ-39). Research has also shown that individuals with decreased postural stability and gait performance tend to demonstrate increased times on the TUG, as well as greater cognitive impairment than non-fallers.

Research has shown individuals with PD have an increased incidence of gait deviations such as a reduction in gait speed, reduced stride length, and altered stride pattern while dual tasking compared to age-matched controls. While the TUG is easy to perform and provides sufficiently reliable data, dual-tasking with the TUG has been found to more accurately identify fall risk. The addition of a cognitive task while performing the TUG has been shown to have greater sensitivity (0.76) and specificity (0.73) in regards to fall prediction in community dwelling elderly individuals than the TUG alone. A cognitive TUG (CTUG) cutoff time of 14.7 seconds was discovered as a predictor of falls in this population.

Quality of life refers to an individual’s sense of well-being, purpose of life, autonomy, and ability to assume worthwhile roles and participate in significant relationships. For individuals affected by PD, multiple aspects of life may be involved, including general function, symptoms, demands of a changing body, communication dysfunction, unpredictability, and altered sense of identity. By failing to address psychosocial factors as such in a chronic disease, one may be limiting effectiveness of treatment.

The Parkinson’s Disease Questionnaire-39 (PDQ-39) is a 39-item self-report questionnaire, which assesses eight PD specific health related quality of
life dimensions (mobility, ADL’s, emotional well-being, stigma, social support, cognition, communication, bodily discomfort). This assessment also looks at the impact of PD on specific dimensions of overall functioning and well-being. The 39-items are scored on a 5-point ordinal scoring system: 0 = never, 1 = occasionally, 2 = sometimes, 3 = often, 4 = always. Each dimension total score ranges from 0 (never have difficulty) to 100 (always have difficulty); lower scores reflect better quality of life. The overall score can be summarized in the Parkinson’s Disease Summary Index (PDSI) or PDQ-39 Summary Index (PDQ-39 SI). Increased age and longer disease duration are correlated with poorer PDQ-39 scores, and poorer tremor, rigidity and bradykinesia scores also correlate with poorer PDQ-39 scores. The PDQ-39 has been shown to have good reliability, validity, responsiveness, and reproducibility, and is used in many trials to assess effectiveness of treatment.

Parkinson Wellness Recovery (PWRMoves™) is a community exercise program for individuals with PD that follows similar principles to LSVT BIG® (Lee Silverman Voice Treatment), a protocol developed specifically to address the unique movement impairments involved with PD. One study found the degree of change in Unified Parkinson’s Disease Rating Scale (UPDRS) motor score was considered as clinically relevant in patients participating in BIG®. In contrast, UPDRS motor scores did not improve in patients training in Nordic walking with the same amount of supervised sessions.

PWRMoves™ has identified four moves which represent the building blocks of function: PWR!Up™ (posture), PWR!Rock™ (weight shift), PWR!Twist™ (trunk rotation), and PWR!Step™ (transition). These moves are performed in four different positions: floor (supine/prone), quadruped, sitting, and standing. The goal is for the exercises to be performed with biomechanically optimal posture and movement, yet with full effort and body awareness. PWRMoves™ also incorporates cognitive engagement into the exercise routine to target cognitive symptoms of PD.
The purpose of this study was to evaluate the effectiveness of a community exercise program (PWR!Moves™) on fall reduction and functional improvement in a sample of community dwelling elderly individuals with PD.
CHAPTER II
METHODS

All participants were community-dwelling individuals with a primary PD diagnosis and were ambulatory with or without an assistive device. Seven participants volunteered to undergo testing, three females and four males, with an age range from 54-78 years old. These participants were recruited from a PD support group and the PWR!Moves™ exercise class at the local YMCA [Appendix I: IRB]. All participants gave informed consent prior to beginning the study [Appendix II: Informed Consent]. A gait belt was placed on each participant for safety throughout all assessments. Subjects were tested at three different stations, with the order of testing consistent among subjects and at initial and final testing. Prior to assessment on program participants, testers performed a trial on three community dwelling older adults, as well as on each other, in order to improve intra-rater reliability. The order of stations was as follows: GAITRite®, 30-second and 5-times sit to stand, Functional Reach Test, Timed Up & Go, Cognitive Timed Up & Go [Appendix III: Data Collection Sheet]. Upon completion of these stations, participants were asked to complete a quality of life and satisfaction questionnaire, the Parkinson’s Disease Questionnaire - 39 [Appendix IV: PDQ-39]. An initial assessment was completed on March 3, 2015, shortly after initiation of the exercise program, with the final assessment following on June 2, 2015.

Gait Speed
Tape marked the floor three feet on either side of the mat, allowing for acceleration and deceleration zones and ensuring that the participants reached their steady state speed when walking across the mat. Each subject completed
three walking trials on the GAITRite® system. The first trial was at the participant’s normal walking pace, the second trial was at the participant’s fastest walking pace, and the third trial was backwards walking. Prior to beginning each walking trial, participants received instructions on how to perform the trial and the importance of safety was emphasized. Two spotters provided supervision during each trial for safety.

Data was collected through the GAITRite® computer system for each of the trials. Footfalls that did not fall entirely on the GAITRite® mat were deleted. Information including gait speed, step length, stride length, base of support, step time, stride time, swing time, stance time, single support time, double support time, and degree of toe in/toe out was obtained from the GAITRite®, with gait speed as the main focus.

30-Second Sit-to-Stand Test

The participant was asked to sit in the center of a standard chair without armrests, with feet flat on the floor and arms folded over the chest. The chair was placed 3-6 inches from the wall to allow for safety should a subject experience loss of balance during testing, though far enough away from the wall to prevent compensation using the chair for bracing while standing. After instructions and a practice repetition, the tester said “3-2-1, Go.” The participant then came to a complete stand, followed by a complete sit, as many times as safely possible in 30 seconds. The number of stands completed in 30 seconds was used as the participant's score, with the final stand counting if the participant was over halfway standing when 30 seconds had elapsed. Two spotters were present for safety.

5-Times Sit-to-Stand Test

The set up for this test was identical to that of the 30-second sit-to-stand, with the same two spotters providing supervision. Upon the command “3-2-1 Go,” the participant came to a complete stand, followed by a complete sit for five
repetitions, as fast as they were safely able. The time in seconds that the participant took to complete five full repetitions was recorded.

**Functional Reach Test**

Paper was taped to the gymnasium wall for marking, as well as a yardstick taped parallel to the floor at each participant’s shoulder height. The participant received instructions to stand next to the wall with the right shoulder, without touching it, and raise the extended right arm into 90 degrees of shoulder flexion while maintaining the hand in a closed fist. The tester marked the participant’s starting point on the paper based on the position of the 3rd metacarpal. The participant was instructed to “reach as far forward as you are able to safely, without taking a step and without turning the body.” The tester marked the ending position of the 3rd metacarpal on the paper. This was repeated for three trials, and the average distance of three trials was recorded. Two spotters provided supervision during each trial for safety.

**Timed Up & Go (TUG)**

The Timed Up & Go (TUG) was performed using a standard arm chair with arm rests. The seat back of the chair was placed 3 inches from the wall to allow for safety should a subject experience significant loss of balance during testing, though far enough away from the wall to prevent compensation using the chair for bracing while standing. A tape line was placed on the floor at the front and back of the chair to ensure consistent chair placement over the course of testing. Another piece of tape was placed 3 meters directly in front of the chair. Subjects were instructed, “When you are ready, stand up from the chair, walk around the tape, return to the chair and sit down.” The timer started as the participant initiated standing and was stopped as soon as the patient was fully seated. The course for walking was demonstrated by the administrator prior to the trial run. Each subject was given one untimed practice run, followed by one timed test. Spotters were available to assist as needed, but were instructed not to interfere with the course. Assistive devices were allowed as needed by
participants. Participants were allowed to use their hands to assist with standing, though no specific instructions were provided regarding the use of hands. Time in seconds was recorded on each subject’s data sheet.

**Cognitive Timed Up & Go (CTUG)**

The Cognitive Timed Up & Go (CTUG) was performed immediately following the TUG. The same protocol was used, with the added instruction of counting backwards from 100 by 3's, audibly, while walking the TUG course. The administrator counted number of counting errors, as well as noted any deviations from the TUG path. For participants who had difficulty counting backward by 3’s, the option of listing as many colors as possible was provided. Time in seconds was recorded on each subject’s data sheet.

**PDQ-39**

The PDQ-39 was administered following the completion of the described motor assessments. Each participant was provided with a pen and clipboard containing the 39-subject questionnaire. Assistance was provided as needed for reading, writing, and comprehension of the questions.
CHAPTER III
RESULTS

Seven participants completed initial and final assessments. The following tables represent the data collected from initial and final testing. Interpretation of the data is described below each table.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Initial</th>
<th>Final</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.314</td>
<td>1.114</td>
<td>-0.2</td>
</tr>
<tr>
<td>2</td>
<td>0.929</td>
<td>0.782</td>
<td>-0.147</td>
</tr>
<tr>
<td>3</td>
<td>0.681</td>
<td>0.853</td>
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<tr>
<td>4</td>
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<td>1.273</td>
<td>0.08</td>
</tr>
<tr>
<td>5</td>
<td>1.094</td>
<td>1.242</td>
<td>0.148</td>
</tr>
<tr>
<td>6</td>
<td>1.242</td>
<td>1.159</td>
<td>-0.083</td>
</tr>
<tr>
<td>7</td>
<td>1.147</td>
<td>1.041</td>
<td>-0.106</td>
</tr>
</tbody>
</table>

Three of the seven participants saw an increase in their comfortable gait speed, although the overall average was 0.019 meters/second slower than initial testing. The greatest amount of improvement was 0.172 meters/second faster than initial testing, while the least improvement was 0.147 meters/second slower than initial testing.
Four of the seven participants saw an increase in rapid gait speed, with an average improvement of 0.001 meters/second faster than initial testing. The greatest improvement was 0.391 meters/second faster than initial testing, while the least improvement was 0.267 meters/second slower than initial testing.

<table>
<thead>
<tr>
<th>Participant</th>
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<th>Difference</th>
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</thead>
<tbody>
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<tr>
<td>6</td>
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<tr>
<td>7</td>
<td>1.755</td>
<td>1.507</td>
<td>-0.248</td>
</tr>
</tbody>
</table>
### Table 3: Gait Speed - Backward (m/sec)

<table>
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<tr>
<th>Participant</th>
<th>Initial</th>
<th>Final</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
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<td>0.068</td>
</tr>
<tr>
<td>2</td>
<td>0.423</td>
<td>0.521</td>
<td>0.098</td>
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<tr>
<td>3</td>
<td>0.213</td>
<td>0.597</td>
<td>0.384</td>
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<td>4</td>
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<td>5</td>
<td>0.414</td>
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<td>0.011</td>
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<td>0.977</td>
<td>0.268</td>
</tr>
<tr>
<td>7</td>
<td>0.542</td>
<td>0.694</td>
<td>0.152</td>
</tr>
</tbody>
</table>

Six of the seven participants saw an increase in backward walking speed, with an average improvement of 0.139 meters/second faster than initial testing. The greatest improvement was 0.384 meters/second faster than initial testing, while the least improvement was 0.011 meters/second slower than initial testing.

### Table 4: 30 Second Sit-to-Stand (repetitions)

<table>
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<tr>
<th>Participant</th>
<th>Initial</th>
<th>Final</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
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<td>15</td>
<td>+5</td>
</tr>
<tr>
<td>2</td>
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</tr>
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<td>14</td>
<td>+2</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
<td>13</td>
<td>+1</td>
</tr>
</tbody>
</table>

All participants saw an increase in sit-to-stand repetitions from initial to final testing. The average improvement for the seven participants was 2.7 repetitions, with the smallest improvement being 1 complete repetition and the greatest improvement being 5 complete repetitions.
All participants saw a decrease in the time required to complete 5 sit-to-stands. The average improvement was 3.05 seconds, with the smallest improvement being 1.3 seconds and the greatest improvement being 7.31 seconds faster at final testing compared to initial testing.

Three of the seven participants saw a decrease in time required to complete the TUG, for an average improvement of 0.704 seconds. The greatest amount of improvement was 3.68 seconds faster than initial testing, while the least improvement was 1.55 seconds slower than initial testing.
Table 7: CTUG (seconds)

<table>
<thead>
<tr>
<th>Participant</th>
<th>Initial</th>
<th>Final</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11.13</td>
<td>9.13</td>
<td>-2</td>
</tr>
<tr>
<td>2</td>
<td>18.06</td>
<td>13.78</td>
<td>-4.28</td>
</tr>
<tr>
<td>3</td>
<td>17.5</td>
<td>11.91</td>
<td>-5.59</td>
</tr>
<tr>
<td>4</td>
<td>10.65</td>
<td>9.32</td>
<td>-1.33</td>
</tr>
<tr>
<td>5</td>
<td>15.59</td>
<td>15.34</td>
<td>-0.25</td>
</tr>
<tr>
<td>6</td>
<td>11.28</td>
<td>8.87</td>
<td>-2.41</td>
</tr>
<tr>
<td>7</td>
<td>11.37</td>
<td>9.59</td>
<td>-1.78</td>
</tr>
</tbody>
</table>

All seven participants decreased the time required to complete the CTUG, for an average improvement of 2.52 seconds at final testing. The smallest amount of improvement was 0.25 seconds faster, while the largest difference was 5.59 seconds faster at final testing.

Table 8: Functional Reach Test (inches)

<table>
<thead>
<tr>
<th>Participant</th>
<th>Initial</th>
<th>Final</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3.6</td>
<td>2.657</td>
<td>-0.943</td>
</tr>
<tr>
<td>2</td>
<td>8.59</td>
<td>8.18</td>
<td>-0.41</td>
</tr>
<tr>
<td>3</td>
<td>6.82</td>
<td>9.18</td>
<td>2.36</td>
</tr>
<tr>
<td>4</td>
<td>6.17</td>
<td>7.25</td>
<td>1.08</td>
</tr>
<tr>
<td>5</td>
<td>8.33</td>
<td>10.72</td>
<td>2.39</td>
</tr>
<tr>
<td>7</td>
<td>10.04</td>
<td>7.9</td>
<td>-2.14</td>
</tr>
</tbody>
</table>

Three of the six participants improved in the FRT, with an overall average improvement of 0.39 inches. The greatest improvement was 2.39 inches further than initial testing, while the least improvement seen was 2.14 inches less than initial testing. The results for Participant 6 were excluded for this assessment, as the participant was unable to perform the task properly at final testing due to an injury.
<table>
<thead>
<tr>
<th>Participant</th>
<th>Initial</th>
<th>Final</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>24</td>
<td>19</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>43</td>
<td>-18</td>
</tr>
<tr>
<td>3</td>
<td>29</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>4</td>
<td>45</td>
<td>32</td>
<td>13</td>
</tr>
<tr>
<td>5</td>
<td>32</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>6</td>
<td>36</td>
<td>26</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>36</td>
<td>23</td>
<td>13</td>
</tr>
</tbody>
</table>

Six of the seven participants saw a decrease in PDQ-39 scores, with lower scores reflecting better quality of life. The overall average improvement was 7.7 points. The greatest improvement was 16 points fewer from initial to final testing, while the least improvement was 18 points more from initial to final testing.
CHAPTER IV
DISCUSSION

With the relatively small sample size (n=7) used in this study, it is difficult to draw reliable conclusions from the results. General statements may be made, however, regarding specific tests and overall satisfaction with the program. Noted improvement in scores for all participants was observed in both 30-second and 5-times sit-to-stand, as well as the CTUG. A general improvement in quality of movement was also observed in all participants, though this may not have been reflected in all tests. It should be noted that of the 7 individuals who participated in testing, 6 had completed the LSVT BIG® program prior to attending the PWR!Moves™ community program.

Participant satisfaction was assessed by asking whether each participant felt the PWR!Moves™ program has been beneficial. Responses were positive and included comments such as:

"I move better."
"Keeps my body moving."
"Easier to put on and take off my jacket, however it is still not easy."
"Yes the exercise is beneficial."
"The most beneficial part of this program is that it exists."
"Yes, I feel better. I'm more alert and I feel I move around better."
"I felt I could walk better and do ADL skills better after exercise."

In addition to the positive comments shared by participants, a testament to the overall satisfaction with the program can be seen in attendance over time.
Throughout the three-month testing period, the number of class participants significantly increased, increasing from 5 initial participants to 12 in attendance at times. Of the 7 individuals who participated in initial testing, all returned for final testing, as well as 3 additional participants who wished to be evaluated but did not participate in the study.

Overall, the GAITRite® results were variable with positive, negative, and near null differences. The normal gait speed results demonstrated an average of 0.019 meters/second decrease in speed when comparing initial and final results. Fast walking results averaged a 0.001 meters/second decrease in speed from initial to final trials. Backward walking averaged a 0.139 meters/second increase in speed from initial to final trials. These variable results are deceiving when comparing observation from initial to final trials. Some hypotheses to this variation can be: increased concentration on gait mechanics (arm swing, step length, foot placement, weight shifting, etc.), time of day of data collection (initial testing occurred in the afternoon versus final testing in the morning), differences in medications between trials, or amount of motivation. Another component to consider is the amount of time spent working on gait throughout the PWR!Moves™ program. The program was newly established at the time of data collection, so working on the basic components of the exercises such as posture and weight shifting in the seated and floor positions had a larger emphasis than gait mechanics during this time.

Both the 5-time and 30-second sit-to-stand tests yielded improvements for all participants, with an average 30-second test improvement of 2.7 stands, and an average 5-times test improvement of 3.05 seconds. The participants not only improved in speed, but in the quality of sit-to-stands, with more fluid movements observed at final compared to initial testing. Sit-to-stands were consistently emphasized during classes, and these results demonstrate the principle of specificity of training. In future studies, researchers may eliminate the 5-time test in order to avoid redundancy of activities for participants, as well as redundancy in data findings. The 30-second test would be preferred in order to assess endurance, as well as balance and lower extremity strength.
The FRT results varied greatly from initial to final testing. While a few improvements were seen, there were also small decreases in reaching distance for some participants. The overall average was an increase in reaching by 0.39 inches, which is insignificant to show any progress across the group of participants. This unexpected result may be attributed to a lack of reaching activities done in standing during the PWR!Moves™ classes, as most reaching activities were done in the seated position. It can be noted that following final testing the classes progressed to incorporate more reaching and weight shifting activities in standing. It is also possible that some discrepancy in the FRT results could be attributed to testing error. One participant was excluded from the results of the FRT as the participant sustained an injury to the shoulder following a fall and was unable to properly perform the assessment at final testing.

The TUG yielded varied results from initial to final testing. While a few participants saw a slower time, improved overall quality of gait and turning was observed. Other participants saw a marked decrease in time required for the test. An average decrease of 0.704 seconds was observed, indicating slight improvement overall. The CTUG was more consistent, with all participants showing improvement and an average decrease in time of 2.52 seconds. This is indicative of improved dual tasking and safer ambulation.

A great emphasis was placed on cognitive tasks during class, including "brain games" prior to exercise class and the incorporation of various counting methods while performing exercises (ex: counting forward and backward, listing the months of the year forward and backward, encouraging participants to count out loud while performing exercises), which may explain the notable improvement in CTUG results. It is difficult to conclude whether the "brain games" prior to exercising, or the incorporation of cognitive challenges during exercise had a greater impact, or a combination of the two. Improvements in cognition were also noted while participants completed the PDQ-39 and in conversation with testers. Participants were observed to demonstrate more confidence and ability to carry on a conversation during the final testing compared to initial testing, which may be related to improved cognition or an
increased comfort level having performed the testing previously and become familiar with the testers.

For future studies, it would be beneficial to video the GAITRite® assessments. By obtaining video at initial and final recordings, one could view the quality of gait mechanics and the similarities and differences between initial and final trials. Characteristics of gait that may be viewed through observation though not evident through GAITRite® assessments include, but are not limited to: arm swing, balance, level of concentration, line of vision, posture, ankle and hip strategies, and range of motion. Although the results of this study do not show a significant increase in gait speed, the quality of gait was evident through observation.

Another recommendation for future studies would be increased consistency in training and methods of the instructor. Two main instructors taught the class, each with a different emphasis. One instructor focused heavily on posture, which was thought to be very beneficial for the participants. The other instructor addressed posture, and also emphasized incorporation of cognitive activities into exercises for improved dual task training. Both approaches are important to the success of the class, and continued emphasis on both posture and cognitive tasks would be beneficial in the future.

A number of physical therapy students volunteered their time and assistance for the program, as well as University of North Dakota physical therapy faculty and YMCA volunteers. These individuals attended class weekly and offered feedback and assistance to program participants. One-on-one assistance was given to a small number of participants who required help transitioning to and from the floor. The assistance from students and staff not only provided the benefit of extra hands to safely assist the participants with difficult exercises, but participants were able to better understand the importance of the exercises and how they translate into functional abilities.

Participants of the PWR!Moves™ program not only attended these exercise classes for the benefit of exercise, but also for a feeling of community and social interaction with peers. It was clear through observation that the
participants formed friendships and were able to share their experiences together. One participant noted, "I feel I'm among friends." This social aspect of the program is notable with improvement in quality of life scores in participants.

Through observation and comments of participants, it is evident that the PWR!Moves™ program is a beneficial supplement to the LSVT BIG® program. The two programs share a foundation of exercises specific to the PD population. Compliance of home exercise programs often declines following discharge from physical therapy, making a sedentary lifestyle a concern for people with PD. Research has found that individuals with mild to moderate PD are ambulatory at moderate or higher intensity only 5 percent of the day, placing this population at higher risk for comorbidities such as stroke, diabetes, coronary artery disease, and more. Routine physical activity for individuals with PD helps to provide long-term reductions in disability risk and maintain optimal quality of life. Therefore, a community based program such as PWR!Moves™ is beneficial to individuals living with PD in order to delay the onset of disablement, optimize function, and improve quality of life.
APPENDIX I

IRB
University of North Dakota Human Subjects Review Form  
January 2015 Version

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted – responses must be typed on the form.

Principal Investigator: Beverly Johnson, PT, DSc & Meridee Danks, DPT  
Telephone: 701-777-3871 E-mail Address: bev.johnson@med.und.edu  
Complete Mailing Address: 501 North Columbia Road; Stop 9037; Grand Forks, ND 58201  
School/College: School of Medicine & Health Sciences; UND Department: Physical Therapy

Student Advisor (if applicable): Beverly Johnson, PT, DSc, GCS,CEEAA & Meridee Danks, DPT, NCS  
Telephone: 701-777-3871 E-mail Address: bev.johnson@med.und.edu  
Address or Box #: 9037  
School/College: SMHS; University of North Dakota Department: Physical Therapy

*** All IRB applications must include a Key Personnel Listing. 

Project Title: Evaluation of fall risk, functional mobility and quality of life changes of community-dwelling older adults with Parkinson’s Disease participating in a community exercise program.

Proposed Project Dates: Beginning Date: February 24, 2015 Completion Date: December 2016 (Including data analysis)

Funding agencies supporting this research: NA

Did the contract with the funding entity go through UND Grants and Contracts Administration? ☐ YES or ☒ NO  
Attach a copy of the contract. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☐ YES or ☒ NO

Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

☒ YES or ☐ NO

Will any data be collected at or obtained from another organization outside the University of North Dakota?

☐ YES or ☒ NO

If yes to either of the previous two questions, list all organizations: YMCA, Grand Forks, ND

Revised 1/9/15
Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB? □ YES ☒ NO □ N/A

If yes, does the external site plan to rely on UND’s IRB for approval of this study? □ YES □ NO ☒ N/A

(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

<table>
<thead>
<tr>
<th>Board Name</th>
<th>Date submitted:</th>
<th>Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>□ Approved □ Pending</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ Approved □ Pending</td>
</tr>
</tbody>
</table>

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

Type of Project: Check “Yes” or “No” for each of the following.

□ YES or □ NO New Project

□ YES or ☒ NO Continuation/Renewal

Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.

□ YES or □ NO Compliance Application and submit it with this form.

□ YES or □ NO Does your project include Genetic Research?

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

☐ Children (< 18 years)

☐ Prisoners

☐ Other __________________________

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

This study will involve: Check all that apply.

☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements)

☐ Radiation

☐ New Drugs (IND) IND # _____ Attach Approval

☐ Investigational Device Exemption (IDE) # _____ Attach Approval

☐ Non-approved Use of Drug(s)

☐ None of the above will be involved in this study

☐ Stem Cells

☐ Discarded Tissue

☐ Fetal Tissue

☐ Human Blood or Fluids

☐ Other ______

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

Falls are evident in the older population and are a common and disabling feature of Parkinson Disease (PD). The benefits of activity are well known to decrease balance deficits and increase overall quality of life in the older adult population. In addition highly challenging exercises have been suggested to increase neuroplasticity in individuals with PD. The effect of challenging exercises on clinical outcomes is not well documented. In our pilot study, we will examine the effect of a community exercise program on improving quality of life, decreasing risk of falls and look at overall satisfaction of the program.

Revised 1/9/15 2
II. Protocol Description

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

   Recruitment will be done by the researchers with the assistance of the YMCA staff. Research study will be explained to participants of the community exercise program within two to three weeks of the start of the class. Recruitment will target adults with Parkinson Disease (PD) that sign up for the exercise program and are 45 years of age or older. Recruitment will start 2-3 weeks prior to test date and will end once testing begins.

   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.

   Inclusionary criteria: adults ages 45 and older, diagnosed with PD, independent community dwelling, male and female, independent ambulators, participating in the YMCA exercise program for individuals with PD and ability to follow and understand instructions.

   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

   Exclusionary criteria is medically unstable and uncontrolled health status (cardiopulmonary, infection, inflammatory or terminal illness) and being homebound (unable to independently leave home).

   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

   The study goal will have a minimum of 12 subjects.

   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

2. Description of Methodology.

   a) Describe the procedures used to obtain informed consent.

   Participants of the community exercise program for individuals with PD at the Grand Forks YMCA will be asked if they would like to be a part of this study. Interested participants will be told about the study, provided time to ask questions and if interested asked to sign a consent form, and will be given a copy of the consent form.

   b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

   The research will be conducted at the Grand Forks YMCA gym.

   c) Indicate who will carry out the research procedures.

   Graduate level physical therapy students who have been trained on each assessment and have completed IRB training (Gabrielle Dahl, Kayla Hoff, Laura Nelson, Elizabeth Richards). Principle Investigator's, Beverly Johnson and Meridee Danks, licensed PT's with extensive experience assessing the older adult population including balance/gait assessments.

   d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

   Participants in a community exercise program for individuals with PD will be offered the opportunity to participate in a pilot project consisting of a pre and post assessment of their functional level. Pre Assessment will take place at the onset of the exercise program with a post assessment three months after the start of the program. A quality of life/satisfaction questionnaire, Parkinson's Disease...
Quetionnaire -39 (PDQ 39), and five standardized assessments for strength, balance and endurance that are designed for the older adult population with PD will be administered. Assessment scores will be compared to the national norms for their age group. The total time for testing will be no more than one hour. The assessments include:

1. The Timed Up and Go (TUG) and Cognitive TUG test was developed as a brief screen for mobility and falls risk. The TUG measures, in seconds, the time it takes for an individual to stand up from a standard arm chair, walk a distance of 3 meters, turn, walk back to the chair, and sit down again. The activity is repeated with the participant performing a memory activity. The participant wears his/her regular footwear and uses his/her customary walking aid (none, cane, or walker). No physical assistance is given. A safety belt will be used when performing this assessment. One minute to complete.

2. Gait Speed has been shown to be predictive of falls and overall functional ability for older adults. Gait speed can be calculated either manually or by computerized system (GAITRite). GAITRite is a portable gait analysis system that automates measuring gait parameters via an electronic walkway. Participants will walk both forward and backward. Testing requires minimal setup and test time (~ 10 minutes), and has minimal to no risk requiring no placement of any devices on the patient. All participants will wear a safety belt during this activity to minimize risk. Standard protocol will be used to obtain gait speed for each subject using GAITRite when possible.

3. 30 second sit-to-stand: assessment to measure a person’s endurance, balance and general strength in the lower extremities. Poor lower extremity endurance can lead to decreased mobility in the community and a decrease in activities of daily living. The participant is instructed to go from a sit-to-stand position repeated as many times as the individual is able within a 30 second timeframe. The assessment generally takes under three minutes to complete.

4. Functional Reach Test is a brief screen to predict fall risk. Participants are asked to reach out with their arm and lean forward. This requires strategies at the hip and ankle. Distance reached is measured and compared to industry standards. No physical assistance is given. A safety belt is used when performing this assessment. Less than One minute to complete.

5. The Parkinson's Disease Questionnaire-39 (PDQ 39) contains 39 questions related to health and daily activities. It is a 39-item self-reported questionnaire which assesses Parkinson's disease-specific health related quality of life and well being including the level of concern about falling during social or physical activities inside and outside the home whether or not the person actually does the activity. The level of occurrence is measured on a five point scale ranging from never to always. About 10 minutes to complete.

e) Describe audio/visual procedures and proper disposal of tapes.
   NA

f) Describe the qualifications of the individuals conducting all procedures used in the study. Graduate level physical therapy students who have been trained on each assessments and have completed IRB training. Principal Investigator's (PI's) are Beverly Johnson and Meridee Danks. Both PI's are licensed PT's and have had extensive experience with the older adult population and balance/gait assessment. Dr. Danks is Board Certified in Neurology and Dr Johnson is Board Certified in Geriatrics and completed a Doctor of Science in Geriatrics.
g) Describe compensation procedures (payment or class credit for the subjects, etc.).

NA

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

   a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
      Balance, strength and gait assessments are similar to daily activity. There is a chance of loss of balance. To minimize risk of injury a safety belt and spotter's will be used. Subjects will be instructed that they may quit the activity at any time if they do not feel safe during the activity.
   b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
      Data will be linked initially but after analysis of data the link will be destroyed. Each participant will be designated a number or a letter so confidentiality is maintained. The link will be kept initially in order to properly place each participants results into grouping to compare results. Link will be destroyed after this process.
   c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
      NA
   d) If the PI will be the lead-investigator for a multi-center study, or if the PI’s organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
      NA

4. Subject Protection.
   a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
      Will decrease risk of falls through use of a safety belt and spotters. Assessments will be stopped if any adverse conditions arise.
   b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.
      Participants will be designated a number or letter to eliminate the use of identifying information. Any data/information reported will be only in aggregate form.
   c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
      Each participant will be provided with a copy of the consent form prior to assessment being performed.
   d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.
      Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
          2) who will have access to the data
          3) how the data will be destroyed
          4) the storage location of consent forms and personal data (separate from research data)
          5) how the consent forms will be destroyed

      1. Research data will be stored in a locked file cabinet in the UND PT Department separate from consent forms.

Revise 19/15
2. Only investigators and our dedicated statistician, will have access to the information.
3. The data will be retained a minimum of three years following completion of the study. After the retention period data will be shredded.
4. The consent forms and personal data will be stored in a separate locked file cabinet in the UND PT Department.
5. Consent forms will be retained a minimum of three years following completion of the study. After the retention period consent forms will be shredded.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). Adverse reactions are unlikely. If any problems occur the participant will be referred to a medical facility.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved. Any medical treatment that are required would be the responsibility of the participant.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

We will provide an educational brochure on fall prevention, and balance assessment scores to the participants at no cost to increase awareness and education. Our research may contribute to literature as to the benefits of activity in preventing falls and increase quality of life in older adult population with PD.

IV. Consent Form
 Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating ‘see attached consent form’ is not sufficient. The items listed below must be addressed on this form.):

1) The person who will conduct the consent interview  
2) The person who will provide consent or permission  
3) Any waiting period between informing the prospective participant and obtaining consent  
4) Steps taken to minimize the possibility of coercion or undue influence  
5) The language to be used by those obtaining consent  
6) The language understood by the prospective participant or the legally authorized representative  
7) The information to be communicated to the prospective participant or the legally authorized representative

1. The researchers 
2. The participant 
3. Time for questions to be asked and then the participant will have the opportunity to consent.  
4. N/A  
5. English  
6. English  
7. Purpose of the study, tests being conducted, how to perform tests, and how risk will be minimized

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. Please note: All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8th grade reading level, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:
- [ ] Signed Student Consent to Release of Educational Record Form (students and medical residents only);
- [x] Investigator Letter of Assurance of Compliance; (all researchers)
Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
Key Personnel Listing
Surveys, interview questions, etc. (if applicable);
Printed web screens (if survey is over the Internet); and
Advertisements (flyer, social media postings, email/letters, etc.).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date:

(Student Advisor) Date:

**All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.**

Requirements for submitting proposals:
Additional information can be found on the IRB website at: http://und.edu/research/resources/human-subjects/index.cfm

Original, signed proposals and all attachments, along with the necessary number of copies (see below), should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Twamley Hall.

Required Number of Copies:
- Expedited Review: Submit the signed original and 1 copy of the entire proposal.
- Full Board Review: Submit the signed original and 22 copies of the entire proposal by the deadline listed on the IRB website: http://und.edu/research/resources/human-subjects/meeting-schedule.cfm
- Clinical Medical Subcommittee and Full Board Review: Submit the signed original and 24 copies of the entire proposal by the deadline listed on the IRB website: http://und.edu/research/resources/human-subjects/meeting-schedule.cfm

Prior to receiving IRB approval, researchers must complete the required IRB human subjects’ education. Please go to: http://und.edu/research/resources/human-subjects/human-subject-education.cfm

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company’s protocol must be provided.
INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

I ________________________________
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University’s policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)

2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.

3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Investigator Signature ____________________________ Date ____________________________
STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UND Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your IRB application.

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board's access to those portions of my educational record which involve research that I wish to conduct under the Board's auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The title of the study to which this release pertains is ____________________________

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

ID # ____________________________  Printed Name ____________________________

Date ____________________________ Signature of Student Researcher

1Consent required by 20 U.S.C. 1232g.
APPENDIX II

INFORMED CONSENT FORM
INFORMED CONSENT

TITLE: Evaluation of fall risk, functional mobility and quality of life changes of community-dwelling older adults with Parkinson’s Disease participating in a community exercise program.

PROJECT DIRECTOR: Beverly Johnson, PT, DSc, GCS, and Meridee Danks, DPT, NCS

PHONE #: 701-777-3871
DEPARTMENT: UND – Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in this research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part and meet study criteria (older than 45, diagnosed with Parkinson Disease (PD), community dwelling, ability to walk independently with or without an assistive device and are participating in the YMCA exercise program for individuals with Parkinson Disease). Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

PURPOSE OF THIS STUDY AND YOUR PARTICIPATION

You are invited to be in a research study evaluating program satisfaction, fall risk and quality of functional mobility of community-dwelling adults with Parkinson’s disease participating in the community exercise program offered at the YMCA. Falls are common in the older population and often contribute to decreased health status and increase in medical costs. Activity can improve balance and increase overall quality of life. In our study, we will examine the effect of a community exercise program designed for individuals with PD. Your participation in the study will consist of two sessions, an evaluation session at the beginning of the exercise program and a follow-up assessment after 3 months of participation in the program. The first assessment will be no longer than one hour and the follow-up session no longer than 30 minutes. Our goal is for at least twelve people to take part in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

In random order you will complete five tests:

1. The Timed Up and Go (TUG) test & Cognitive Timed Up and Go test were developed as a brief screen for mobility and falls risk. The TUG measures, in seconds, the time it takes for an individual to stand up from a standard arm chair, walk a distance of 3 meters, turn, walk back to the chair, and sit down again. The activity is repeated with the participant performing a memory activity. The participant wears his/her regular footwear and uses
his/her customary walking aid (none, cane, or walker). No physical assistance is given. A safety belt will be used when performing this assessment. Less than Five minutes to complete.

2. Walking speed has been shown to be predictive of falls and overall functional ability. Speed will be calculated either manually having the participant walk up to 20 feet or by using GAITRite, a computerized system. The GAITRite is an electronic walkway that participants will walk over up to 3 times and calculates the speed of motion and your foot placement. Participants will walk both forward and backward. Testing requires about 10 minutes for setup and testing and has minimal to no risk. A safety belt will be used when performing this assessment.

3. 30 second sit-to-stand is an assessment to measure a person’s endurance and general strength in the lower extremities. Poor lower extremity endurance can lead to decreased mobility in the community and a decrease in activities of daily living. The participant is instructed to go from a sit-to-stand position repeated as many times as the individual is able within a 30 second timeframe. The assessment generally takes under three minutes to complete.

4. Functional Reach Test is a brief screen to predict fall risk. Individuals will be asked to reach out with their arm and lean forward as far as they are able. No physical assistance is given. A safety belt will be used when performing this assessment. Less than One minute to complete.

5. The Parkinson’s Disease Questionnaire contains 39 questions related to health and daily activities. This tool was developed by researchers to assess a person’s symptoms related to PD, function, wellbeing and quality of life.

WHAT ARE THE RISKS OF THE STUDY?

There may be some risk from being in this study such as loss of balance. This will be reduced by providing close supervision with safety belts and a spotter during assessment activities. You may choose to stop any activity they do not feel comfortable with. Rest periods will be provided between tests as needed.

WHAT ARE THE BENEFITS OF THE STUDY?

A brochure will be provided to educate and provide awareness to participants on fall prevention. You will also receive the score from your assessment at no cost. We hope our research will contribute to literature concerning the role of this exercise program in preventing falls and improving mobility for individuals with PD.

CONFIDENTIALITY

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Investigators and our statistician
will have access to the information. Your study record may be reviewed by government agencies, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of destroying any links between you and your information. Any information used for this study will not include identifying factors.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota. You will not have any direct costs for being in this research study. Indirect costs include transportation and your time.

CONTACTS AND QUESTIONS?

The researchers conducting this study are Beverly Johnson and Meridee Danks. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Beverly Johnson at 701-777-3871 or Meridee Danks at 701-777-3861 or the Physical Therapy Department at 701-777-2831.

If you have questions regarding your rights as a research participant subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at 701-777-4279. Please call this number if you cannot reach research staff, or if you wish to talk with someone else.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject’s Name __________________________________________

Signature of Subject ___________________________ Date ____________

I have discussed the above points with the subject or, when appropriate, with the subject’s legally authorized representative.

Signature of Subject ___________________________ Date ____________

Approval Date: FEB 2 5 2015              
Expiration Date: FEB 2 4 2016 
University of North Dakota IRB
APPENDIX III

DATA COLLECTION SHEET
PD Program Data Sheet - Spring 2015

1. Approximate date diagnosed with Parkinson's Disease Date

2. Number of falls in the past year

3. Number of prescription medications

4. Have you participated in Physical Therapy in the "BIG" Program Yes__ NO_

4. PDQ 39 Total Score ______

5. 30 Second Sit to Stand Test Number of Stands ____

<table>
<thead>
<tr>
<th>Age</th>
<th>60-64</th>
<th>65-69</th>
<th>70-74</th>
<th>75-79</th>
<th>80-84</th>
<th>85-89</th>
<th>90-94</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>16</td>
<td>15</td>
<td>14</td>
<td>14</td>
<td>12</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Women</td>
<td>15</td>
<td>14</td>
<td>13</td>
<td>12</td>
<td>11</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>

6. Gait Speed Gait Speed Comfortable Walking in meters/second ______

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Mean Comfortable Walking Speed (Bohannon 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-59</td>
<td>Male</td>
<td>1.1 m/sec</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>1.1 m/sec</td>
</tr>
<tr>
<td>60-69</td>
<td>Male</td>
<td>1.0 m/sec</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>1.0 m/sec</td>
</tr>
<tr>
<td>70-79</td>
<td>Male</td>
<td>1.0 m/sec</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>0.9 m/sec</td>
</tr>
<tr>
<td>80-89</td>
<td>Male</td>
<td>0.8 m/sec</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>0.8 m/sec</td>
</tr>
</tbody>
</table>

Gait Speed Walking Rapidly yet Safe in meters/second ______

Gait Speed Backward Comfortable Walking meters/second ______
7. Timed Up and Go Test (TUG)

Time required to complete test ______

≥ 12 seconds to complete the TUG are at a high risk for falling

8. Cognitive TUG

Time required to complete test ______

9. Functional Reach

Trial #1

Trial #2

Trial #3

Average of 3 Reaches

Negative test ≥ 10 inches

< 6 inches limited functional mobility and 4X more likely to have 2 falls in 6 months
APPENDIX IV

PARKINSON’S DISEASE QUESTIONNAIRE - 39
**PDQ-39 QUESTIONNAIRE**

**Please complete the following**

*Due to having Parkinson’s disease, how often during the last month have you...?*

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always or cannot do at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Had difficulty doing the leisure activities which you would like to do?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Had difficulty looking after your home, e.g. DIY, housework, cooking?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Had difficulty carrying bags of shopping?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Had problems walking half a mile?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Had problems walking 100 yards?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Had problems getting around the house as easily as you would like?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Had difficulty getting around in public?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Needed someone else to accompany you when you went out?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Felt frightened or worried about falling over in public?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Been confined to the house more than you would like?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Had difficulty washing yourself?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Had difficulty dressing yourself?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Had problems doing up your shoe laces?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please check that you have ticked one box for each question before going on to the next page*
Due to having Parkinson's disease, how often during the last month have you....

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always or cannot do at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Had problems writing clearly?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Had difficulty cutting up your food?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Had difficulty holding a drink without spilling it?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Felt depressed?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Felt isolated and lonely?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Felt weepy or tearful?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Felt angry or bitter?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Felt anxious?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Felt worried about your future?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Felt you had to conceal your Parkinson's from people?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Avoided situations which involve eating or drinking in public?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Felt embarrassed in public due to having Parkinson's disease?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Felt worried by other people's reaction to you?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Had problems with your close personal relationships?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Lacked support in the ways you need from your spouse or partner?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>If you do not have a spouse or partner tick here</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>Lacked support in the ways you need from your family or close friends?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please check that you have ticked one box for each question before going on to the next page.
Due to having Parkinson’s disease, how often during the last month have you...

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Occasionally</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexpectedly fallen asleep during the day?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Had problems with your concentration, e.g. when reading or watching TV?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Felt your memory was bad?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Had distressing dreams or hallucinations?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Had difficulty with your speech?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Felt unable to communicate with people properly?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Felt ignored by people?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Had painful muscle cramps or spasms?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Had aches and pains in your joints or body?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Felt unpleasantly hot or cold?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Please check that you have ticked one box for each question before going on to the next page.

Thank you for completing the PDQ 39 questionnaire.
REFERENCES


