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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: Part II

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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: Part II

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Department of Physical Therapy School of Medicine and Health Sciences University of North Dakota

Partial fulfillment of the requirements for the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota May, 2017 This Scholarly Project, submitted by Lauren Trudel, Brittany Bleichner, and Courtney McDonald in partial fulfillment of the requirements of 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: Part II						
Department	Physical Therapy						
Degree	Doctor of Physical Therapy						
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#### ABSTRACT

Purpose/Hypothesis: As a person ages, the risk of a fall increases. Parkinson Disease (PD) is most commonly seen in the elderly population, which presents with symptoms such as bradykinesia, decreased balance, tremors, postural instability, and muscle weakness. These symptoms are associated with an increase in falls; therefore, a person with PD is more susceptible to falls than the average elderly individual. Exercise has been shown to combat those symptoms affecting people with PD. This study is an extension of a previous study, which examined the effect of a community based exercise program, for people with PD, on quality of life and decreasing fall risk.

Methods: Eight subjects, six females and two males, ranging from 55-77 years old, participated biweekly in a community exercise program that incorporated challenging exercises focused on transitional, big, and rotational movements while also including cognitive and verbal demands. Pre-testing was completed followed by a posttest administered three months later and again twelve months later. Outcome measures tested included gait speed, 30 second sit-to-stand, timed up and go (TUG), cognitive timed up and go (CTUG), and the quality of life questionnaire, the PDQ-8. Pre and posttest scores were compared to evaluate if statistically significant change was present or if trends were detected.

Results: No significant positive difference was found in TUG, CTUG, 30 second sit to stand, gait speed, or the PDQ-8 in the majority of the individuals with PD participating in the group exercise program. Although the results were not consistent with the previous year's data or current research on the effects of exercise on PD symptoms, all the participating individuals agreed the group exercise program should be continued and expanded.

Conclusions: The findings are not consistent with current literature, but the positive findings in this study were the psychological and psychosocial aspects of being active with a group of people who have a similar outlook on life.

#### **CHAPTER 1**

#### **BACKGROUND AND PURPOSE**

Parkinson's Disease (PD) is a progressive, neurodegenerative condition that affects 7 million people worldwide, as of 2015.<sup>1</sup> The prevalence of this disease is 1-2/1000 but is typically associated with the elderly population; the incidence of PD increases above the age of 50.<sup>2</sup> PD affects a large portion of the population and the cause is ultimately unknown<sup>3</sup>, indicating a need for research regarding causes, treatment, and long term management of the disease.

Risk factors in the genetic and toxic domains are being discovered but the cause of Parkinson's disease is still unknown.<sup>2</sup> Research has been completed on exposure to harmful substances such as pesticides, herbicides, and heavy metals, as well as dietary considerations such as coffee and alcohol consumption as causation factors for PD.<sup>3</sup>

Parkinson's Disease is the degeneration of cells, which produce the neurotransmitter dopamine, this is found in the substantia nigra of the basal ganglia. This loss and depletion of dopaminergic neurons manifests both motor and nonmotor symptoms and may be the cause of any of the symptoms discussed below. Damage to the medial substantia nigra results in a form of PD in which tremors are dominant, while damage to the lateral substantia nigra results in an akinetic or rigid form of PD. Motor symptoms that may be present include, bradykinesia, resting tremor, postural instability, muscle weakness or

atrophy, balance deficits, gait impairments, decreased cardiorespiratory fitness, and rigidity.<sup>5</sup> The nonmotor symptoms associated with PD may include abnormal sensory complaints, fatigue, sleep disturbances, hallucinations, apathy, cognitive decline, and autonomic dysfunction.<sup>5,6</sup> Depression is considered to be the most common non-motor symptom.<sup>6</sup>

Progression of PD is variable as well as the combination of symptoms.

Late onset PD typically progresses more rapidly.<sup>4</sup> The symptoms of bradykinesia, postural instability, and gait dysfunction often signal rapid progression and a poor prognosis.<sup>4,6</sup> Individuals without tremors typically present with a more severe case of PD compared to individuals with a tremor. Individuals without tremors have a higher risk of cognitive impairments, rapidly decreasing motor function, dementia, and depression.<sup>6</sup>

The impaired basal ganglia decreases its efficiency on the cortical motor centers, which leads to decreased activation of motor neurons, resulting in muscle weakness and impaired balance. These symptoms create an increased risk for falls. Exercise has been shown to improve the motor systems that have been affected by PD, including freezing of gait (FoG), stride length, and balance deficits. The effectiveness of exercise on individuals with PD was analyzed by muscle weakness and impaired balance. These symptoms create an increased risk for falls. Exercise has been shown to improve the motor systems that have been affected by PD, including freezing of gait (FoG), stride length, and balance deficits. The effectiveness of exercise on individuals with PD was analyzed by Goodwin, et al. in 2008. The meta-analysis concluded that exercise affected

lower extremity strength, balance, gait pattern, and quality of life positively. 9,10

Current treatment of Parkinson's Disease focuses on the deficiency of dopamine and implements use of an artificial replacement for the neurotransmitter. 11 Common medications are levodopa, benserazide, carbodopa, and entacapone or a combination of two or more of these medications. 12,13 Neurosurgical treatment has also been shown to decrease symptoms of PD temporarily. High frequency stimulation of various sections of the basal ganglia have been used in certain PD cases.4 Exercise has also been shown to delay or reverse functional decline temporarily which will aid in the individual's safety and functional independence. 9,14 There are many studies currently being completed to conclude which exercise is best for people with PD, including cycling<sup>15</sup>, treadmill training<sup>16</sup>, amplitude training<sup>17</sup>, Tai Chi<sup>18</sup>, boxing<sup>19</sup>, and dancing<sup>20</sup>. Exercise has been shown to be the most effective non-pharmacological aid to target symptoms. Research indicates improvements in gait speed, stride length, cognition, quality of life, and a decrease in motor and balance symptoms.8 Improving these areas of function will have direct effects on safety, risk of falling, and quality of life.

Individuals with PD can experience one or many of the characteristics described above. The functional assessments chosen for this study took into account the possible symptoms while being highly specific and sensitive. Gait was one area measured in the study population; gait parameters can be measured to help predict the functional status of an individual with PD. The gait

parameters include: velocity, cadence, stride length, single and double limb support, and swing and stance phase.<sup>21</sup>

The GAITRite® instrumentation was used throughout the course of this study to assess the different gait characteristics in order to discover change upon the completion of the exercise program. The GAITRite® system consists of a mat with embedded sensors which are triggered as mechanical pressure is applied. The GAITRite® has strong validity<sup>21</sup> and reliability<sup>21</sup> and is a great tool to objectively measure different characteristics of gait. This tool has proven to be a reliable measure to be used as both an evaluation and intervention technique and can be helpful in detecting changes in gait in individuals with PD.<sup>21,22</sup>

Sit-to-stands are another tool to be used as a functional lower extremity strength assessment and can also be used as an intervention strategy in individuals with PD. The 30-second sit-to-stand test was the assessment tool used throughout the course of this study. This test was developed to overcome the floor effect of the five or ten repetition sit-to-stand test in older adults. The 30-second sit-to-stand test shows excellent test-retest reliability (0.89), interrater reliability (0.95), and criterion validity (0.77) among community-dwelling adults with PD.<sup>23</sup> The 30-second sit-to-stand test was scored by the number of sit-to-stands completed. This test is useful as it allows researchers to understand where an individual is at functionally with lower extremity strength.<sup>24</sup> Another advantage of the 30-second sit-to-stand test is that it assesses an individual's endurance and provides a challenge comparable to functional activities such as stair climbing.<sup>25</sup> It is a good test to utilize as it does not require the individual to

complete a minimum number of sit-to-stands, but rather allows them to go at their own pace.<sup>25</sup>

Falls have been proven to be a concern for individuals with PD. Around 70-87 percent of those with PD experience a fall at some point in their lives.<sup>26</sup> An individual's fall history is used as a strong predictor for assessing future fall risk, although it proves to be insufficient when solely evaluated as many different aspects can play a role in falls among individuals with PD.<sup>26</sup> The Timed Up & Go (TUG) is a tool to identify fall risk in individuals with PD. It is an easy test to administer as it does not require much effort, equipment, or time to complete. Each subject is measured on the ability to stand up, walk 3 meters, turn, walk back and sit down safely. The TUG features a turning component which is often difficult for individuals with PD.<sup>27</sup> The TUG has shown to have a high test-retest reliability and interrater reliability, 0.80 and 0.99 respectively.<sup>26</sup> As the TUG times increase, so does the risk of falls. 26 The TUG displays a cut-off time of 11.5 seconds and established normative data states a minimal detectable change of 3.5 seconds.<sup>28</sup> Overall, the TUG is a good predictor of falls among individuals with PD. Slower TUG times have been found to be associated with decreased verbal executive functioning.<sup>29</sup> These two factors are also strong predictors in measuring quality of life as determined by the Parkinson's Disease Questionnaire.

While the TUG provides reliable data, research has shown that incorporating a cognitive component and creating an environment requiring dual-tasking is a better predictor of fall risk in individuals with PD.<sup>30</sup> Thus, the

Cognitive Timed Up & Go (CTUG) is used as a dual-task dynamic measure for identifying fall risk. The addition of a cognitive task to the TUG has shown greater sensitivity (.76) and specificity (.73) for predicting falls.<sup>30</sup> The functional outcome measures described were chosen to evaluate subjects of the study who are involved in the group exercise program for people with PD. The exercise program is based on the Parkinson Wellness Recovery program as well as additional exercise routines.

Parkinson Wellness Recovery (PWR!Moves<sup>TM</sup>) is a community exercise program that focuses on PD-specific exercises of high amplitude and effort to maintain and restore optimal function for it's subjects. The program is based on four foundational exercises that focus on skills known to commonly disrupt mobility and function in individuals with PD. Those four exercises include antigravity extension, weight shifting, axial mobility, and rotational movements. The program allows for various adaptations of each exercise based on the severity of the disease process and can be performed in supine, prone, quadruped, sitting, or standing. The PWR!Moves<sup>TM</sup> program also incorporates a cognitive component into the various exercises to combat the cognitive symptoms in PD.<sup>31</sup>

PWR!Moves<sup>™</sup> is an evolution of the LSVT BIG<sup>®</sup> program and based on similar principles and although there is currently insufficient research to support the success of the PWR!Moves<sup>™</sup> exercise program, there was one study supporting improvement in function for subjects of the BIG<sup>®</sup> program.<sup>31-33</sup> The study found that for those participating in BIG<sup>®</sup>, there was a clinically significant

degree of change in the motor score of the Unified Parkinson's Disease Rating Scale(UPDRS), while the comparison group which only completed training in Nordic walking did not show any improvement in UPDRS motor scores after the same number of treatment sessions.<sup>33</sup>

The purpose of this study was to evaluate the effectiveness of a group exercise program, specifically one using foundational theory in PWR!Moves<sup>™</sup>, on improving overall function in a sample of community dwelling individuals with PD.

#### CHAPTER II

#### **METHODS**

#### Subjects

A total of 8 subjects with a primary diagnosis of PD completed the study: 6 females and 2 males. Community dwelling subjects were recruited for the study from a YMCA led PWR!Moves<sup>TM</sup> exercise class with foundational information of PWR!Moves<sup>TM</sup> and from a local PD support group [Appendix A: IRB]. The age range of the subjects was 55-77 years old and all individuals were ambulatory without an assistive device.

#### **Procedures**

Prior to administering outcome measures, all subjects gave informed consent [Appendix B: Informed Consent]. A gait belt was used consistently with each subject, and an additional person spotting the subject, when necessary, were available during each of the tests completed to ensure safety. Subjects completed outcome measures at three separate stations. To improve tester consistency each tester was responsible for specific test completed. Each tester also completed trials on six community dwelling individuals over the age of 55 as well as three trials on students prior to the start of the study. All subjects completed the PDQ-39 or the PDQ-8 and additional interview questions about the quality of the PWR!Moves<sup>TM</sup> exercise class. Three of the subjects were

chosen for more in-depth interviews to discuss the exercise program as well as the effect Parkinson's has had on their lives. Each subject was evaluated using the following outcome measures.

#### **Outcome Measures**

#### Gait Speed:

The GAITRite® system was used to evaluate each subject's gait speed. 21 Tape was used to mark a line on the floor three feet before the GAITRite® mat as well as three feet after the mat. Subjects started behind the line, walked across the mat, and continued walking until they passed the second tape line to allow for areas of acceleration and deceleration and ensure a steady speed was reached when walking across the mat. 21,22 Each subject completed two trials. The first trial the subjects were instructed to walk across the mat at their normal walking pace. The second trial the subjects were instructed to walk across the mat at their fastest walking pace. One spotter was used to guard each subject during each trial. The spotter stood to the side of the participant to ensure the subject's pace was not influenced. The GAITRite® computer system recorded data for each of the trials. Information computed included gait speed, base of support, step length, stride length, degree of toe in/out, swing phase time, stance phase time, double limb support time, single limb support time, step time, and stride time. The main data point analyzed was gait speed [Appendix C: Data Collection Sheet].

#### 30 Second Sit To Stand:

The 30 second sit to stand was used to evaluate each subject's functional lower extremity strength as it can help detect early decline in functional independence. The CDC standard protocol was used during this study. The chair used was 17 inches in height, with no armrests, and was placed against a wall to prevent moving. Subjects started the test by sitting in the middle of the chair, feet on the floor shoulder width apart, and their arms across their chest. Instructions were given to come to a complete stand followed by a complete seated position in order for the action to count towards the end total. Instructions were given for the subject to complete as many sit to stand actions as possible in the 30-second time period. One examiner recorded the 30-second period while a second examiner was there for safety. This functional test was completed once per subject. Data was recorded on each individual subject's data collection sheet.

#### Timed Up and Go (TUG):

The Timed Get Up & Go (TUG) was performed in order to determine the fall risk among subjects. Standard norms of the TUG include: using a standard arm chair with arm rests, a 3 meter distance length, staying consistent with an assistive device if needed, and instructing the subject to begin and end the test with their back against the back of the chair. Subjects were instructed to sit in a standard arm chair with arm rests. They were instructed to use the armrests, if needed, when going from sit to stand and vice versa. The chair was placed nearly against a wall in order to ensure safety. The standardized distance of 3 meters was

used.<sup>36</sup> Colored tape was used to mark the distance required to walk for the test, placing one piece of tape at the base of the chair and a second piece of tape 3 meters away from the first piece of tape. Subjects were instructed, "When I say 'Go', stand up from the chair, using the arm rests as needed, walk safely at your normal walking speed past the tape, turn around and walk back to the chair and sit down". Instructions were given to assure subject's back was in full contact with the back of the chair before the timer was stopped. The test was demonstrated by the administrator prior to the subjects performing the test. Each subject was given one untimed practice run, followed by one timed test. The administrator walked behind the subject during the trials in order to not influence the subjects pace. A spotter was available to assist the subjects as needed, as well as help the administrator record data. Assistive devices were allowed but were not needed for any of the subjects. Time, in seconds, was recorded on the subject's individual data sheet.

#### Cognitive Timed Up and Go (CTUG):

The Cognitive Timed Up & Go (CTUG) was performed immediately following both TUG trials. The CTUG is an advanced form of the TUG, adding a cognitive component to the TUG. The CTUG is a dual-task test which has been found to better predict the fall risk in community-dwelling adults with PD.<sup>30</sup> The TUG protocol was also used as the standard CTUG protocol with additional instructions given to begin counting backwards from 100 by 3's as soon as the test began.<sup>36</sup> The administrator made note of increased difficulty with counting

during the course of the test, as well as any gait deviations. The option was given to count to 20 by 3's beginning with 0 for one individual who was not able to complete the above protocol. Time in seconds was recorded on the subject's individual data sheet.

#### PDQ-8:

The PDQ-39 was administered following the completion of functional outcome measures. This questionnaire evaluates the quality of life of a person with Parkinson's Disease over the course of the past month. "Quality of life (QoL) is a multidimensional concept that reflects a subjective evaluation of a person's satisfaction with life and concerns, among others, the relationships with family or relatives, a person's own health, the health of another close person, finances, housing, independence, religion, social life, and leisure activities". This test has excellent predictive validity for QoL in people with PD.38 Each subject was provided with a pen and clipboard containing the PDQ-39. We noticed the subjects' difficulty in completing all 39 questions, therefore, the questions included in the PDQ-8 were established as the minimum amount of the questionnaire completed by each subject. The PDQ-8 focuses on one main item from each of the eight scales on the PDQ-39. All questionnaires were scored as a PDQ-8 [Appendix D: PDQ-39]. The PDQ-8 has not been studied to its full extent but the minimal studies that have used the PDQ-8 established excellent validity of r=0.96 which is comparable to the PDQ-39.39 Each subject was given assistance as needed for reading, comprehension, and answering of questions.

#### CHAPTER III

#### **RESULTS**

Eight subjects completed the testing; six were re-checks to be compared with past data and two were initial functional tests.

# **Gait Speed**

Table 1	Gait Speed - normal (m/sec)						
Subject	Initial	Re-check 1	Difference initial to recheck1	Re-check 2	Difference re-check 1 to 2	Difference initial to final	
1	1.31	1.11	0.2	.968	0.142	0.342	
3	.681	NA*	-	.79	_	-0.109	
4	1.19	1.27	-0.08	1.02	0.25	0.17	
5	1.094	1.242	-0.148	NA*	_	-	
7	1.147	1.04	0.104	1.25	-0.21	-0.103	
9	NA*	NA*	-	-	_	-	
10	1.04	_	-		-	_	
11	.95	_	-	-	-	<u>,</u>	

<sup>\*</sup>Subject unavailable for testing

Only five of the eight subjects above have been participating in the study long enough to have re-check data, and of those five, only three were available for both re-check 1 and 2. The greatest amount of improvement from initial testing to

re-check 2 was a 0.103 meters/second increase in normal gait speed, while the greatest decline was 0.342 meters/second slower than initial testing. The greatest amount of improvement from re-check 1 to re-check 2 was 0.21 meters/second increase in normal gait speed, while the greatest decline was 0.25 meters/second slower than re-check 1 testing.

Table 2	Gait Speed - fast (m/sec)						
Subject	Initial	Re-check 1	Difference initial to re-check 1	Re-check 2	Difference re-check 1 to 2	Difference initial to final	
1	1.822	1.565	0.257	1.68	-0.115	0.142	
3	1.072	1.41	-0.338	1.5	-0.09	-0.428	
4	1.42	1.44	-0.02	1.33	0.11	0.09	
5	1.623	1.661	-0.038	NA*	_	-	
7	1.755	1.5	0.155	1.73	-0.23	0.025	
9	1.4	NA*	-		-	-	
10	1.48	•	-	_	•	-	
11	1.24		_	_	-	-	

<sup>\*</sup>Subject unavailable for testing

Only five of the eight subjects above have been participating in the study long enough to have re-check data and of those five, four were available for both re-check 1 and 2. The greatest amount of improvement from initial testing to re-check 2 was a 0.428 meters/second increase in fast gait speed, while the greatest decline was 0.142 meters/second slower than initial testing. The greatest amount of improvement from re-check 1 to re-check 2 was 0.23

meters/second increase in fast gait speed, while the greatest decline was 0.11 meters/second slower than re-check 1 testing.

### 30 Second Sit to Stand:

Table 3	30 Second Sit to Stand						
Subject	Initial	Re-check	Difference initial to re- check 1	Re-check 2	Difference re-check 1 to 2	Difference initial to final	
1	10	15	5	11	-4	1	
3	7	10	3	11	1	4	
4	11	15	4	8	-7	-3	
5	8	10	2	8	-2	0	
7	12	13	1	9	-4	-3	
9	14	15	1	-	-	-	
10	11	-	_	_	_	_	
11	7	-	-	_	H	_	

Table 4	30 Second Sit to	30 Second Sit to Stand Normative Values <sup>35</sup>				
Age	Men	Women				
60-64	<14	<12				
65-69	<12	<11				
70-74	<12	<10				
75-79	<11	<10				

All recurrent subjects had an improvement from their initial and re-check 1 testing scores. However, due to environmental variables and limitations to the study, we

saw a decline in four of the six subjects' numbers from re-check 1 to re-check 2. The variables and limitations are discussed in length below. The greatest decline was 7 while the greatest improvement was 1. Subjects are at an increased risk of falls if their scores are lower than the CDC normative values based on their age and gender.<sup>35</sup>

#### Timed Up and Go

Table 5	TUG (seconds)						
Subject	Initial	Re-check 1	Difference initial to re- check 1	Re-check 2	Difference re-check 1 to 2	Difference initial to final	
1	10.15	6.47	3.68	10.16	-3.69	-0.01	
3	10.85	12.07	-1.22	13.0	-0.93	-2.15	
4	8.81	8.97	-0.16	10.25	-1.28	-1.44	
5	12.34	10.16	2.18	12.72	-2.56	-0.38	
7	7.32	8.87	-1.55	8.22	0.65	-0.9	
9	9.43	9.69	-0.26	-	-	-	
10	10.93	-	-	_	-	-	
11	10.38	_	_	_	-	_	

Two of the eight subjects saw a decrease in the amount of time required to complete the TUG. The greatest amount of improvement when comparing the initial check to re-check 2 was -0.01 seconds. When comparing re-check 1 to the re-check 2 an improvement of 3.69 seconds was noted. The greatest amount of decline was 2.15 when comparing the initial check to re-check 2 and 2.56 when comparing re-check 1 to re-check 2.

# Cognitive Timed Up and Go

Table 6	CTUG (seconds)						
Subject	Initial	Re-check 1	Difference initial to re-check 1	Re-check 2	Difference re-check 1 to 2	Difference from initial to final	
1	11.13	9.13	2	12.78	-3.65	-1.65	
3	17.50	11.91	5.59	14*	-2.09	3.5	
4	10.65	9.32	1.33	12.53	-3.21	-1.88	
5	15.59	15.34	0.25	15.32	0.02	0.27	
7	11.37	9.59	1.78	8.65	0.94	2.72	
9	-	12.47	-	10.94	1.53	-	
10	11.41	-	-			_	
11	12.75	_	_	-	-		

<sup>\*</sup>Counting forward

Three of the eight subjects decreased the time required to complete the CTUG.

The greatest amount of improvement was recorded as 3.50 seconds when comparing the initial check to re-check 2 and 1.53 seconds when comparing the re-check 1 to re-check 2. The greatest amount of decline was recorded as 1.88 seconds when comparing the initial check to re-check 2 and 3.65 seconds when comparing re-check 1 to re-check 2. During the past re-check, when comparing the initial data to re-check 1, all 5 subjects showed a decrease in time required to complete the CTUG.

PDQ-8

Table 7	PDQ-8						
Subject	Initial	Re-check 1	Difference initial to re-check 1	Re-check 2	Difference re-check 1 to 2	Difference from initial to final	
1	18.75	15.625	3.125	34.4	-18.775	-15.65	
3	15.625	9.375	6.249	6.25	3.125	9.375	
4	21.875	18.75	3.125	18.75	0	3.125	
5	21.875	6.25	15.625	6.25	0	15.625	
7	21.875	9.375	12.5	12.5	-3.125	9.375	
9	18.75	25	-6.25	-	_	-	
10	12.5	-	_	_	_	-	
11	21.875		-	H	-	-	

The Parkinson's Disease Questionnaire-39 (PDQ-39) was given to each subject but only the questions from the Parkinson's Disease Questionnaire-8 (PDQ-8) were scored, as the PDQ-39 was a daunting task to complete for many subjects. Prior questionnaires were fully completed and scored PDQ-39; we took the questionnaires from the previous testing dates and rescored them as PD-8 so they are comparable to the current data. We can correlate low numbers with a decreased quality of life and difficulty performing daily tasks. The scores show all subjects under 34.4%; the lowest being 6.25%.

#### CHAPTER IV

#### DISCUSSION/CONCLUSION

It is difficult to make significant conclusions with this study because of the small sample size and the inability to compare various subjects to previous data. There were also discrepancies between the exercise program from re-check 1 to re-check 2, including different instructors and the addition of cycling classes and drumming exercises to the PWR!Moves<sup>TM</sup> exercises.

Gait speed is a functional measure often referred to as the sixth vital sign due to its strong tendencies to predict future physical and cognitive decline.

Overall, the results yielded using the GAITRite® instrumentation for gait speed were variable. The normal gait speed results showed an average of a 0.075 m/s decrease in gait speed from initial testing to re-check 2, while the fast gait speed results showed an average of a 0.171 m/s increase in gait speed from initial testing to re-check 2. While statistically significant improvements were not consistently apparent; subjectively, data collectors noticed improvements in the quality of gait and confidence with which it was performed. One possible explanation for the lack of improvement in gait speed times is that gait was not an emphasized component of the PWR!Moves<sup>TM</sup> exercise classes. Most exercises focused on postural stability and posture in a seated or standing position. In the future, this class may benefit from incorporating detailed instruction on the various aspects of gait mechanics and ways each individual

can improve to make their quality of movement more successful. Other possible hypotheses for the varying results may be individual medication schedules or changes, as these were not taken into account or the time of day testing was completed.

The 30 second sit to stand is a functional assessment of lower extremity strength. The sit to stand motion and lower extremity strength are used for daily activities such as rising and returning to sit from a chair, toilet, or bed, stair climbing and transitioning from a car seat. Six of the subjects had an increase in number of repetitions from initial to re-check 1. This distinguished that the exercise program was successful in improving the sit to stand motion and lower extremity strength in these individuals. There was a decline for five of the six subjects who completed re-check 2; this could have been for a number of reasons including inconsistent exercise instructors, disease progression, environmental factors, and study limitations. Subjects are at an increased risk for falls if their scores are lower than the CDC normative values based on their age and gender. Subjects 1,9, and 10 of this study are not at increased risk of falls because their scores were comparable to the normative values for their age and gender, but the other subjects are at an increased risk for falls.

The TUG yielded variable results from both re-check 1 to the re-check 2 and from the initial check to re-check 2. While two subjects' times improved in both categories, the majority of the subjects saw an increase in the overall time required to complete the test. An average decrease in time from re-check 1 to re-check 2 and from the initial check to re-check 2 of 1.56 seconds and 0.98

seconds, respectively, was recorded, indicating a slight decrease in improvement. This was unexpected as the data from the initial to re-check 1 was significant showing the improvement of completion time after participation in the exercise program. The CTUG was more consistent in the fact that about half of the subjects showed an increase in the time it took to complete the test, while the other half recorded a decrease in time. The average decrease in time from re-check 1 to re-check 2 of 6.46 seconds was recorded and the average increase in time from the initial check to re-check 2 of 2.96 seconds was recorded, indicating both a slight increase and decrease among subjects. This was variable in comparison to the data from initial to re-check 1 as subjects had significant improvements in their completion time with a cognitive component added. The reason for an increase in time for the subjects to complete the TUG and CTUG is ultimately unknown, but may be associated with variable exercise instructors, environmental factors, disease progression, or study limitations.

The Parkinson's Disease Questionnaire-39 (PDQ-39) was given to each subject but only the questions from the Parkinson's Disease Questionnaire-8 (PDQ-8) were scored, as the PDQ-39 was a daunting task to complete for many subjects. Prior year's questionnaires that were fully completed and scored as a PDQ-39 were taken and rescored as PDQ-8, which made them more comparable to the current data. The PDQ-8 was used to look at the psychosocial aspects of having a progressive disease along with the other functional assessments that were performed with the subjects. We chose to include the PDQ-8 because the study subjects expressed their enjoyment of the social

aspect of having a group exercise program but also the difficult aspects of quality of life that came with the progressive disease. The motivation and socialization aspects throughout the course of the group exercise program have shown to be comparable from study to study. Correlation can be made between low numbers, a decreased quality of life, and difficulty performing daily tasks. The scores show all subjects under 34.4%; the lowest being 6.25%. All current scores declined from the previous year's study, which is an unforeseen outcome of this study as the subjects appeared to have improved but the data was not significant. This does not correlate with the multitude of research that has been completed concluding an increase in quality of life with exercise.

While the data did not yield the results we had hypothesized, three of the eight subjects agreed to answer the following questions about the group exercise program and life with PD which led to a conclusion of the exercise group being a positive aspect of the subjects lives. The questions asked of the three subjects are the following;

#### What are the benefits of the PWR!Moves™ program?

The three individuals we interviewed all agreed that it was good for them to get exercise. Another aspect that was mentioned was that the subjects in the group become "like family." They are able to share their experiences and ideas, along with getting information from each other. One individual mentioned that because it is a group interaction setting that it is a good reminder for him to speak louder and facilitate strong vocal projections.

#### 2. Should the YMCA keep this program? Why or why not?

All subjects agreed that the YMCA should continue to offer this program to individuals with PD. They noted that it gets people up and moving. This program educates people on all aspects of PD. Subjects are aware of the minimal support group resources within the community and believe this is an area that could improve.

#### 3. How do you think the cognitive class has benefitted you?

The cognitive class was beneficial for improvement of fine motor skills and "helps with finger motions." The majority of the comments regarding the cognitive class were negative. They did not feel as though they were treated as able-minded adults, stating "it feels as though they treat us like children."

#### 4. What can be changed about the programs to make them better?

They expressed that the exercise program is getting better as it develops over the years but some suggestions would be to increase the frequency of the classes, provide more consistency to the class structure, to incorporate additional stretching components, and offer progressive class levels depending on the individual's ability. Regarding the cognitive class, suggestions were made to include more in-depth, critical thinking and activities. The subjects suggested discussing critical knowledge topics and the use of technology as opposed to crossword puzzles. This would allow incorporating more challenging tasks to stimulate their thought process in order to have an effect cognitive change.

#### 5. What support groups/services have you used in the community?

Each subject responded that they attend the support group put on by Altru Hospital, every first Tuesday of the month. One subject mentioned that she also uses blogs to communicate with other individuals and families dealing with PD. This is not used just for support but also serves as motivation for her.

#### 6. What is the more difficult/challenging task during your day?

One subject noted that getting out of bed in the morning was difficult. Another subject noted that buttoning shirts and jackets was the most challenging part of his day. The third subject responded that the end of her day is "rotten," especially if she has had recent medical changes.

#### 7. How have you changed your home for safety?

One subject said they installed handrails, gotten rid of many (not all) rugs, and created a workout room for her and her husband in her basement. This space is designed specifically for her to perform high-level balance and strength activities with the support of her husband for safety. Another subject installed hand rails in his garage, has floor lights that remain on at all times, and has quit using his stepladder. The final subject renovated his bathroom to include a walk-in shower.

# 8. What suggestions for us as Physical Therapists (PTs) would you recommend?

Responses were noted for PTs to remain open-minded and not assume that PTs understand all that there is to know about PD. Although PTs have an educational background in PD, PTs lack the personal insight into the day-to-day functions and psychosocial aspects of each individual with PD. The subjects mentioned

that each individual presents differently with their PD symptoms and that it is important for PTs to really listen to each individual's complaints. The subjects want PTs to be more receptive to the individuality of both their mental and physical abilities; to understand them as a whole person and not only by their physical abilities and disease process symptoms.

#### 9. What do you want to know about fall prevention?

One subject wants to know the reason behind his falling and if alternative treatment such as chiropractic and acupuncture would have an effect on preventing falls. The others gave advice on how they prevent falls. They suggested having night-lights, especially when using the restroom in the middle of the night, not having dogs to trip over, to install hand railings, and to give adequate time to adjust when coming to standing from sitting.

#### CONCLUSION

After interviewing these subjects it is evident that even though they did not make improvements in the outcome measures, this class is beneficial for their social well being, maintaining their current level of function, and improving their QOL. There is evidence that regular exercise benefits older adults by improving mood, strength, cognitive and executive functioning. There is minimal research on the effects of exercise on the QOL of a person with a degenerative disease, but Tanaka, et al. concluded that there was a significant benefit for this population as well. <sup>36,40</sup>

For future studies, it would be beneficial for the exercise program to be more structured. This program was taught by three different instructors that were not PWR!Moves!™ certified instructors which resulted in inconsistent exercise circuits that were not necessarily PWR!Moves!™ exercises, but were still strength and balance based. Other limitations to the study included not taking in to account the time of day the exercise and functional testing were performed, the time of day the subjects took their medication, and the small sample size available. The decline in data could also be do to the fact that PD is a progressive disease that exercise and medication cannot stop. Although there is research concluding effectiveness of medications and exercise, these will not stop the progression of PD and we may be seeing this in the research data. The data was not what we had anticipated upon follow up of the group exercise

program. We ask ourselves if the insignificant results are due to the progressive nature of the disease or the exercise program limitations. Also, if it not been for the exercise program, would the results have been skewed in an even more negative way?

Although there is no statistical significance in the data compared to previous functional measurements, the subjects expressed the importance of the group exercise program for other psychological and psychosocial reasons. The motivation and socialization aspects throughout the course of the exercise program have shown to be comparable from study to study.

# APPENDIX A 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: 701-777-3	B-mail Address: bev.johnson@med.und.edu			
Complete Mailing Addr	ess: 501 North Columbia Road; Stop 9037; Grand Forks, ND 58201			
School/College: School	of Medicine & Health Sciences; UND Department: Physical Therapy			
Student Advisor (if ap	olicable): Beverly Johnson, PT, DSc, GCS, CEEAA & Meridee Danks, DPT, NCS			
Telephone: <u>701-777-3</u>	E-mail Address: bev.johnson@med.und.edu			
Address or Box #: 9037				
School/College: SMHS	University of North Dakota Department: Physical Therapy			
	ons must include a Key Personnel Listing.			
	n of fall risk, functional mobility and quality of life changes of community-dwelling older adults with			
Parkinson's Diesase pari	icipating in a community exercise program.			
Proposed Project Date				
Runding agencies cunn	(Including data analysis) orting this research: NA			
randing agencies supp	NA			
	he funding entity go through UND Grants and Contracts Administration? YES or NO tract. Do not include any budgetary information. The IRB will not be able to review the study without ith the funding agency,			
☐ YES or ⊠ NO	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?			
If yes to either of the previous two questions, list all organizations:  YMCA, Grand Forks, ND				

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. \_\_\_\_\_\_ Date submitted: \_\_\_\_\_ Status: \_\_\_ Approved \_\_\_ Pending Date submitted: \_\_\_\_\_ Status: \_\_\_ Approved \_\_ Pending (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. X YES or NO New Project YES or NO Dissertation/Thesis/Independent Study YES or NO Continuation/Renewal YES or NO Student Research Project Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, ☐ YES or ⊠ NO along with a signed copy of this form with the changes bolded or highlighted. Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form. ☐ YES or ☒ NO ☐ 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) **UND Students** Prisoners Pregnant Women/Fetuses Cognitively impaired persons or persons unable to consent 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) Stem Cells Radiation Discarded Tissue New Drugs (IND) IND # \_\_\_\_ Attach Approval Fetal Tissue Investigational Device Exemption (IDE) # Attach Approval Human Blood or Fluids Other \_\_\_\_ Non-approved Use of Drug(s) None of the above will be involved in this study

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

#### L 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.

#### 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 critera 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. Pilot Study

#### 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 consisiting 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

Ouetionnaire -39 (PDO 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 of 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-tostand 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 asssistance is given. A saftey belt is used when performing this assessmetn. Less than One minute to complete.
- 5. The Parkinson's Disease Questionnaire-39 (PDQ 39) contains 39 questions related to health and daily activites. It is a 39-item self-reported questionnaire which assesses Parkinson's disease-specific health related qulaity 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 occurance 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 poplation 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.

#### 3. Risk Identification.

- 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 guit 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 multicenter 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 will be designated a number or letter to eliminate the use of identifying information. Any data/information repoted 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.

- 2. Only investigaors 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 consnet 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 occurs the participant will be referred to a medical facility.
- Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs
  - 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

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 quesitons 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	attac	hmen	ts:
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	Signed Student Consent to Release of Educational Record Form (students and medical residents only);	
X	Investigator Letter of Assurance of Compliance; (all researchers)	

<ul> <li>         \( \sum_{\text{consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Key Personnel Listing}} \)         \( \sum_{\text{consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Key Personnel Listing}} \)         \( \sum_{\text{consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{\text{Consent form, or Waiver or Waiver or Alteration of Informed Consent Requirements} \) (Form IC 702-B)         \( \sum_{Consent form, or Waiver or Waiver</li></ul>				
By signing below, you are verifying that the in information is accurate and that the project w	formation provided in the Human Subjects Review Form and attached ill be completed as indicated.			
(Principal Investigator)	Date:			
(Student Advisor)	Date:			
	ust list a faculty member as a student advisor on the first page of the nust have that person sign the application.**			

Requirements for submitting proposals:

Additional information can be found on the IRB website at: http://umd.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

#### Required Number of Copies:

- Expedited Review: Submit the signed original and 1 copy of the entire proposal.
- Pull 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			
-(Nam	ne of Investigator)		
Review applica engage Human Commi	w Board, I will fully comply and assume really be federal regulations and University policed in research. Specific regulations include a Subjects 45 CFR 46. I will also assure co	eval of the University of North Dakota Institution sponsibility for the enforcement of compliance cies for the protection of the rights of human so the Federal Common Rule for Protection of the compliance to the ethical principles set forth in the set of Biomedical and Behavioral Research documents	with all abjects e Rights of ne National
I under followi	• 1	research involving human subjects and agree to	o the
	review PRIOR to initiating the changes. ( where necessary to eliminate apparent imm	roved protocol for this project, I will submit A proposal may be changed without prior IRB mediate hazards to the subjects or others. Howe hours of any change, and IRB review is required IRB.)	ever, the
	If any problems involving human subjects the IRB Coordinator.	occur, I will immediately notify the Chair of the	ne IRB, or
3.	I will cooperate with the UND IRB by sub a timely manner.	omitting Research Project Review and Progress	Reports in
	rstand the failure to do so may result in the le reporting to federal agencies.	suspension or termination of proposed research	ı and
Investi	igator 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<sup>1</sup>

and Privacy Act of 1974, I hereby consent to the ose portions of my educational record which er the Board's auspices. I understand that the
ased on a question from a participant or under
ch this release pertains is
y educational record will not be released except on a lwill not permit any other party to have access to also understand that this policy will be explained to ation and that this release will be kept with the study
Printed Name
Signature of Student Researcher

<sup>&</sup>lt;sup>1</sup>Consent required by 20 U.S.C. 1232g.

# APPENDIX B 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

Approval Date:	DEC	17	2015	
Expiration Date:	DEC	13	2016	
University of North Dakota IRB				

D-4-	
Date _	
Subject Initials	

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 videos your movement. 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.

Approval Date:	DEC	1.7	2015	
Expiration Date:	BEC	15	2016	
University of North Dakota IRB				

Date	
Subject Initials	

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 Nam	1e	
Signature of S	ubject	Date
I have discuss authorized rep		subject or, when appropriate, with the subject's legal
Signature of S	ubject	Date
proval Date:	DFC 1.7 2015	
	DEC 19 2018	Date Subject Initials

# APPENDIX C DATA COLLECTION SHEET

Subject #	
Age	

# PD Program Data Sheet-Spring 2016

Number of prescription medications  Have you participated in Physical Therapy in the "BIG" Program? Yes Have you participated in the PWR!Moves program? Yes No  PDQ 39  Total Score	N					
Have you participated in the PWR!Moves program? Yes No	N					
PDQ 39 Total Score						
	4. PDQ 39 <b>Total Score</b>					
. 30 Second Sit to Stand Test Number of St	ands					
Age 60-64 65-69 70-74 75-79 80-84 85-89	90-94					
Men 16 15 14 14 12 11	10					
Women 15 14 13 12 11 10	8					
Gait Speed Gait Speed Comfortable Walking in meters/sed	ond _					
	Gender Mean Comfortable Walking Speed (Bohannon 2008)					
Age Gender Mean Comfortable Walking Speed (Bohannon 2	2008)					
Age Gender Mean Comfortable Walking Speed (Bohannon 2 50-59 Male 1.1 m/sec	2008)					
	2008)					
50-59 Male 1.1 m/sec	2008)					
50-59         Male         1.1 m/sec           Female         1.1 m/sec	2008)					
50-59       Male       1.1 m/sec         Female       1.1 m/sec         60-69       Male       1.0 m/sec	2008)					
50-59         Male         1.1 m/sec           Female         1.1 m/sec           60-69         Male         1.0 m/sec           Female         1.0 m/sec	2008)					
50-59         Male         1.1 m/sec           Female         1.1 m/sec           60-69         Male         1.0 m/sec           Female         1.0 m/sec           70-79         Male         1.0 m/sec	2008)					

	Subject # Age
7. Timed Up and Go Test (TUG)  ≥ 12 seconds to complete	Time required to complete test te the TUG are at a high risk for falling
8. Cognitive TUG	Time required to complete test

Test	Initial	Re-check 1	Re-check 2
# Falls			
# Prescriptions			
BIG/PWR! program			
PDQ 39			
30 sec sit-to-stand			
Gait Speed			
TUG			
Cognitive TUG			

# APPENDIX D PARKINSON'S DISEASE QUESTIONNAIRE-39 (PDQ-8 HIGHLIGHTED)



# PDQ-39 QUESTIONNAIRE

## Please complete the following

#### Please tick one box for each question

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

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

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

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

#### Please tick one box for each question Due to having Parkinson's disease, how often during the last month have you.... Never Occasionally Sometimes Often **Always** 30 Unexpectedly fallen asleep during the day? 31 Had problems with your concentration, e.g. when reading or watching TV? 32 Felt your memory was bad? 33 Had distressing dreams or hallucinations? 34 Had difficulty with your speech? 35 Felt unable to communicate with people properly? 36 Felt ignored by people? 37 Had painful muscle cramps or spasms? 38 Had aches and pains in your joints or body? 39 Felt unpleasantly hot or cold?

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

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