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## Impact of a Community-Based Rock Steady Boxing Program for People with Parkinson's Disease: A Pilot Study

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IMPACT OF A COMMUNITY-BASED ROCK STEADY BOXING PROGRAM FOR  
PEOPLE WITH PARKINSON'S DISEASE: A PILOT STUDY.

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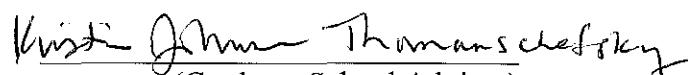
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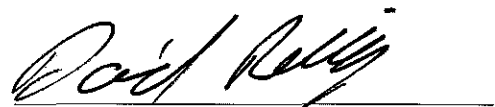
In partial fulfillment of the requirements for the degree of

**Doctor of Physical Therapy**

**Grand Forks, North Dakota  
May 2018**

This Scholarly Project, submitted by Katerina Hoime, Rachel Klein, Jamie Maciejewski and Molly Nienhuis in partial fulfillment of the requirement 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 hereby approved.

  
(Graduate School Advisor)

  
(Chairperson, Physical Therapy)

## PERMISSION

Title            Impact of a community-based rock steady boxing program for people with Parkinson's Disease: A Pilot Study

Department    Physical Therapy

Degree         Doctor of Physical Therapy

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## ABSTRACT

**Purpose/Hypothesis :** High-intensity physical exercise has been shown to be beneficial in managing motor and nonmotor symptoms of Parkinson's Disease (PD). Exercise may also have global effects on factors that influence brain health and cognition. Programs that incorporate goal-based motor skill learning have shown promise in being more effective than aerobic exercise alone. People with PD have a need for ongoing, continuous, community-based exercise programs that are engaging and accessible. The purpose of this study was to examine the effect of a community-based exercise program, Rock Steady Boxing, on improving quality of life and physical mobility skills in people with PD.

**Methods :** Ten participants, five females and five males, mean age 69.6 years old ( $\pm 12$  SD), clinically diagnosed with PD with a mean disease duration of 12.1 years ( $\pm 10$  years) were recruited. Physical Therapist and Physical Therapy students collaborated with a local YMCA® to offer a Rock Steady boxing program (non-contact) to promote mobility, high intensity exercise, cognitive engagement, and transitional movements. Pre- and post-assessment at three months included gait speed, Parkinson's Disease Questionnaire-39 (PDQ-39) for quality of life change, Mini BESTest to measure balance/mobility, Five Times Sit to Stand to measure strength, Four Square Step Test for agility, and the Six Minute Walk Test to measure endurance.

Results : Five of the 10 participants reported an improvement in overall PDQ-39 scores. Of the 10 participants, 30% showed minimally clinically important change in cognition (MCID -1.8) and mobility (MCID -3.2), and 20% reported improvement in bodily discomfort (MCID -2.1). Post-test results of other measures were not statistically significant. Eight of the 10 participants attended the class, with a mean attendance of 6.7 visits (range 0-11), and indicated a plan to continue the exercise class. Statements from participants included: “more confidence with walking and moving”, “more alert”, and “enjoy the social aspect.” Three of the 10 also reported a reduction in falls, and one reported an increase in falls during the three-month timeframe.

Conclusions : The outcomes of this pilot study show promise in improving quality of life and mobility in older adults with PD. Despite the progressive nature of PD, 30-50% of the participants in this study reported meaningful change in quality of life subscales while attending a three-month exercise program. More research is warranted to determine long-term benefits.

Clinical Relevance : Community-based exercise programs tailored to people with PD appear beneficial in improving functional mobility and quality of life. Programs that incorporate a combination of high intensity exercise, skill-based training, cognitive engagement and social interaction are recommended. People with PD will benefit from consistent attendance at classes that are designed to be both physically and financially accessible, to minimize barriers and encourage long-term exercise participation.

KEYWORDS: Parkinson's, community, exercise.

## CHAPTER I

### BACKGROUND AND PURPOSE

Parkinson's Disease (PD) is a progressive neurodegenerative disorder that affects the motor components of the central nervous system (CNS). There are several traits that characterize the disease that include tremor, rigidity, bradykinesia, gait disturbance, postural instability, frequent falls, and difficulty with basic activities of daily living (ADL). The physical motor symptoms that come with PD stem from the grey matter in the basal ganglia, or the substantia nigra. The neurons of the substantia nigra begin to lose their nucleus, resulting in a decreased ability to produce dopamine. Dopamine is the neurotransmitter that provides the signal for the basal ganglia to create normal movement patterns. The lack of dopamine results in the physical characteristics listed above.<sup>1</sup> Other non-motor symptoms can include constipation, depression, genitourinary problems, pain, and sleep disorders.<sup>2</sup> Combining the motor and non-motor systems of PD results in a reduced quality of life (QOL).<sup>2,3</sup>

Unfortunately, the epidemiology of PD is not well understood, but there are consistent risk factors linked to it. There are autosomal links, specifically PARK 1 to PARK 11 that provide insight into the molecular pathogenesis of the disease. Exposure to toxic chemicals and having more formal years of education are risk factors that increase the likelihood of developing PD. A history of smoking would lead a person to a lower risk of developing PD.<sup>1,4</sup> PD is a progressive disease that cannot be cured. However, it

will be discussed how exercise benefits in reducing the progression of the disease. The onset of PD typically begins after 40 years of age, but 10% of cases will develop some symptoms before then. It is estimated that 40 million people worldwide will be diagnosed with PD by 2020.<sup>1</sup> This alarming number should give rise to concern for what can be done to cease progression or reverse the life changing effects of PD.

This current study was performed to determine the impact of a community-based exercise program called Rock Steady Boxing on PD. In this study, we examined the effects of Rock Steady Boxing at a local YMCA® on improving QOL, improving physical mobility skills, and decreasing risk of falls in people with PD. One major purpose of this study was to see if the interventions included in the program would reduce the participants' risk of falling, increase their mobility, and give them more freedom to participate in the community. The methods sections provides a more detailed overview of the program.

IRB approval for this study was received from the University of North Dakota (Appendix A).

### Falls and PD

Individuals with PD are at a higher risk of falling and experiencing complications of falls. Research is mixed on how to best create a plan of care for individuals with PD in order to reduce risk of falls and thereby increase QOL.

The incidence of falls and fall-related activity avoidance has been studied for the PD population. In a study with 109 participants, 68.3% reported at least one fall in the past year and 50.5% reported greater than two falls in the last year.<sup>5</sup> Another study with 141 participants and a six-month time frame noted that 45% of participants had at least

one fall and/or near fall. On average, participants reported an average of five falls in the six-month recording period, with a range of two to twelve falls.<sup>6</sup> Fifty-nine percent of the participant population studied by Gray et al<sup>7</sup> experienced falls in the three-month study.

Prior research on falls in those with PD indicates that fallers had more advance disease than non-fallers.<sup>7, 8, 9</sup> There are several PD symptoms that have been linked to an increase fall risk including freezing, orthostatic hypotension, and involuntary movements.<sup>7, 10</sup> Those experiencing urinary incontinence have shown a six-times increased probability of falling.<sup>8</sup> Additional causes of falls have been linked to posture, co-existing neurological disorders, heart arrhythmias, and toppling falls.<sup>10</sup> Turning, walking, and rising are all ADLs that create difficulty for individuals with PD that increase fall risk.<sup>7</sup>

Individuals with PD classified as “fallers” showed significant differences in measures of balance and gait including standing in tandem, mean duration of standing in tandem, and Timed Up and Go (TUG). Fallers were noted to have decreased tandem stance duration time. TUG times were significantly shorter in non-fallers.<sup>8</sup>

Individuals with PD have been noted to engage in activity avoidance due to fear of falling. Activities that are most avoided by individuals with PD, regardless of fall status, are going out when its slippery, reaching for something overhead, and walking one kilometer. Those that have experienced falls within the past six months are most likely to avoid crowds, going out when its slippery, and traveling by public transportation.<sup>11</sup>

For those with near falls in the last six months, the number one avoided activity was going out when it was slippery, followed by going to a place with crowds and walking a kilometer as the third most avoided activity. For those with a fear of falling

who had not experienced a fall or near fall yet, the order of fear was going out when slippery, reaching for something overhead, and walking one kilometer.<sup>11</sup>

Research has indicated higher amounts of activity avoidance with those who have experienced recurrent falls vs. those who have had a single fall. Those who have experienced near falls were more likely to avoid certain activities, although not to the extent of those that had experienced falls. Those with a fear of falling, but no history of falling were noted to be more likely to exhibit activity avoidance behaviors, although not as strong as those that have had near falls, a single fall, or recurrent falls.<sup>11</sup>

The Hoehn and Yahr (H&Y) Scale is a scale that was developed in 1967 and is used to assess the stage of PD which an individual is currently. The original scale included stages I through V but has been modified to include one-and-a-half; and two-and-a-half to have more progressions of the disease.<sup>12, 13</sup> This will be referenced in the next few paragraphs.

A correlation was found between the H&Y staging and activity avoidance, with higher activity avoidance with higher H&Y staging. There was statistical significance between each stage except I and II; and I and III. It is important to note that activity avoidance often begins when individuals are in stage I. Early intervention is important so that people with PD can avoid social isolation. The findings of the study indicate that health care professionals should not only ask about recent falls, but about near falls and fear of falling.<sup>11</sup>

One study noted three significant independent predictors for future falls. In order of most to least likely to predict future falls: fear of falling, history of near falls, and retropulsion.<sup>6</sup> A history of falls is a predictor of future falls, but a history of near falls is

not.<sup>5</sup> Lindholm et al<sup>6</sup> urged the importance of asking about near falls early on in the disease process as falls and near falls were noted in their study with people who had mild PD. Addressing this area early on can help decrease activity avoidance and sedentary behavior. The longer an individual has had PD, the higher the H&Y staging and cognitive and depressive scores. Additionally, these individuals were more likely to be classified as “fallers”.<sup>5</sup>

The ability to safely engage in dual-task activities, such as walking and talking, is negatively impacted by PD. The relationship between step length, step velocity, and time spent in double limb support was examined between those with PD and healthy controls. All individuals were under dual-task conditions. There were no differences noted for stride length or gait velocity. A significant difference between groups was noted for time spent in double limb support. The healthy control group spent more time in double limb support as cognitive demand increased, indicating that they were able to engage compensatory strategies to avoid falling, whereas those with PD did not readily engage those strategies. There was a loss of automaticity in individuals with PD.<sup>14</sup>

One author performed a large investigation of dual-task performance for individuals with PD compared with a similar aged group for control. Results indicated gait characteristics that reflected postural stability show a disproportionate effect suggesting a dual-task coordination deficit in people with PD. Those that had dual tasks under conscious control showed the lowest threshold and greatest interference with gait patterns.<sup>15</sup>

Sparrow et al<sup>16</sup> completed a study using exercise to improve balance and reduce falls for those with PD. Assessments utilized were the Mini BESTest and the Falls

Efficacy Scale-International (FES-I). The exercise class focused on the following six components: strengthening, range of motion, anticipatory balance activities, reactive balance activities, altering sensory input, and gait training.

The control group and intervention group showed no differences in data at baseline. Post-test results indicated that the intervention group had a decrease in their FES-1 score of 3.2 (95% confidence interval), however there was no significant carry over effect noted. The treatment effect on the Mini BESTest was one-and-a-half with borderline significant carryover. The estimated decrease in falls from the intervention was 37% per month with poor carryover post-treatment.<sup>16</sup>

#### Aerobic Exercise and PD

Research has shown that physical activity has many health benefits to the body including improving mood, blood flow, QOL, functional mobility, and preventing or slowing down the progression of health conditions such as heart disease and diabetes in adults.<sup>17</sup> According to Petzinger et al,<sup>17</sup> aerobic activity is defined as “vigorous and sustained physical activity that leads to increased cardiopulmonary function resulting in improved oxygen consumption and blood flow to the brain”. The benefits of exercise carries over to individuals with PD by improving their balance, leg strength, working memory, QOL, number of falls, walking speed, and step length.<sup>1</sup> Different exercise modalities produce different benefits. For example, Tai Chi has been shown to improve weight shifting; treadmill training has been shown to improve gait speed and step length; and boxing improves multidirectional movements that help with overall balance.<sup>17</sup>

Petzinger et al<sup>17</sup> found exercises that incorporated goal based training into aerobic activity can help to improve neuroplasticity and automaticity versus aerobic exercise

alone. Neuroplasticity the way the brain encodes and processes experiences and new behaviors. It is the idea that the brain is continually making connections. Exercise can help the brain maintain old connections, form new connections, and attempt to restore connections that were once thought to be lost.

Research indicates that participants who pedaled on stationary bike at a rate 30% greater than what they preferred showed benefits in aerobic fitness and coordination.<sup>18</sup> The forced exercise intensity on a stationary bike improved motor function and CNS function for those with PD. Studies compared exercise intervention to a control group of no exercise and saw benefits such as improvements on postural instability; improvements in movement amplitude in the upper and lower limbs; and improvements in gait speed and TUG score of the individuals in the exercise group when being compared to the control group.<sup>19, 20, 21</sup> King et al<sup>22</sup> focused on giving a progression of exercises that are dual-tasks to help improve neuroplasticity in the brain that they consider constraint-focused agility exercise. Their goals were to provide exercises that aim to focus on delaying disability and work to improve/maintain mobility in people with PD using exercise ideas such as kayaking, boxing, lunges, Pilates, and Tai Chi.

A study was conducted using a 10-month community-based group exercise class for individuals with PD. The study focused on forward walking and backward walking treadmill training; and hip and spinal stability on exercise mats. There was noted improvements in ambulation endurance however, there was no change in number of falls of the participants.<sup>23</sup>

Research indicates that those who engaged in moderate intensity exercise for two-and-a-half hours or more per week saw improvements in their health-related QOL (HRQOL) and mobility. Individuals who partake in moderate intensity exercise can see benefits such as decrease in the severity of symptoms and a delay in the progression of PD. Although the disease is classified as neurodegenerative and has no cure at this time, maintenance of both motor and non-motor symptoms can be improved through exercise. Thus, there will be an improved QOL, which is the current goal of treatment.<sup>24</sup>

### Boxing and PD

Boxing is a relatively non-traditional form of exercise that has been found to be beneficial in countering many Parkinsonian motor symptoms such as axial rigidity, bradykinesia, and freezing. A non-contact boxing workout for individuals with PD includes movement in multiple planes; can be customized to meet the intensity and skill level requirements of the participant; and allows dual tasking by counting and naming punches or maintaining a particular punching pattern.<sup>22</sup> These boxing components are what leads to the improvement in the multidirectional movements and overall balance.<sup>17</sup> Due to the relatively new nature of boxing as an intervention for PD, research is somewhat limited, but the studies that have been performed show promising results worthy of further investigation. Boxing has also shown potential to be a catalyst for functional recovery in individuals with other neurological conditions, such as stroke. Individuals who had experienced a stroke and performed seated boxing exercises as part of their rehabilitation program showed increases in upper limb function, balance, walking ability, and QOL.<sup>25</sup>

Individuals with PD participating in a boxing program have shown both short-term and long-term improvements in gait, balance, ADLs, QOL, and functional mobility.<sup>26,27</sup> Gait has been noted as an area of improvement in two different studies. In a randomized controlled trial, the boxing group showed a statistically significant increase in median distance walked during the Six Minute Walk Test (6MWT) and statistically significant improvement in gait velocity from pre- to post-test, as compared to control groups.<sup>28</sup> It was also noted that individuals with mild PD showed improvements earlier than those with moderate to severe PD, especially in gait.<sup>26</sup>

Forced intense exercise is an integral component in boxing training for individuals with PD because high-intensity exercise that is personalized may favorably influence both motor and non-motor symptoms in patients with mild to moderate PD.<sup>29</sup> Exercising at a higher intensity than preferred has shown increased aerobic benefits and coordination, resulting in improved motor and CNS function.<sup>18</sup> The participants in the study by Alberts et al<sup>18</sup> used the principle of forced intense exercise while cycling. Boxing utilizes the forced intense exercise in a more dynamic and functional realm due to the added components of stepping, weight shifting, and balance. The level of difficulty should be increased when the individual is able to perform the task, and participants must be encouraged to push themselves beyond their self-selected exercise level in order to achieve the previously mentioned benefits.

Rock Steady Boxing was founded in 2006 by Scott C. Newman, an individual living with PD. This non-contact boxing program finds its basis in research highlighting the neuroprotective effect of forced intense exercise (emphasizing gross muscle movements, balance, core strength, and rhythm). Rock Steady Boxing has grown

exponentially since its origin, and now consists of more than 280 programs in 44 states and 12 international locations.<sup>30</sup>

## CHAPTER II

### METHODS

Participants were recruited from a local PD support group, a Parkinson's Wellness Recovery Exercise class at the local YMCA®, and the surrounding communities by word of mouth. All participants gave informed consent before beginning the study (Appendix B). For safety, each participant wore a gait belt during all assessments. Participants met the following inclusion criteria: community-dwelling adult with a diagnosis of PD and capable of independent ambulation with or without an assistive device.

Fourteen participants volunteered for functional testing, and were initially tested. Ten participants (five males and five females) were retested. The reason participants were unable to be retested ranged from illness (two participants), knee pain (one participant), and status post-deep brain stimulation (one participant). The participants' mean age was 69.6 years old ( $\pm 12$  SD). The participants had all been clinically diagnosed with PD with a mean disease duration of 12.1 years ( $\pm 10$  years SD).

The participants had the opportunity to attend the Rock Steady Boxing class once per week over a span of 11 weeks. The classes lasted for 90 minutes, and included the following general components: cognitive-exercises, warm ups, stretching, shadow boxing, strength, agility, endurance circuits, boxing with heavy bags, speed bags, speed mitts, and cool-downs. The participants were encouraged to give full effort and push themselves throughout the entire class. The class was led by two instructors who had

earned Rock Steady Boxing certifications in Indianapolis, Indiana. A local boxing coach, who has instructed professional boxers, donated his time to coach participants on boxing technique and form during the classes. Physical therapy students from the local university, current or retired physical therapists, and community volunteers also donated their time to the class.

The ability to dual-task is altered as PD progress. In attempt to combat the cognitive components of the disease and maintain the ability to dual-task, each class incorporated a dual-task station where the participants performed a physical activity that required active cognition during physical activity. For example, the participant would be doing flashcards with a volunteer while performing step-ups using a handrail.

The set-up of the pre- and post-testing of participants was as follows. The participants were given the opportunity to complete the Parkinson's Disease Questionnaire-39 (PDQ-39) as a measure of QOL. If the participants had questions, a researcher was available to provide assistance with completion of the questionnaire. Next, the participants were assessed at four stations. The first station consisted of the Mini BESTest Balance Assessment. The second station included the TUG test, the five time sit to stand test (5xSTS), and the TUG-cognitive (TUG-C). The third station consisted of use of the GAITRite® to perform gait analysis of walking at a comfortable pace, fast pace, and backwards walking. The fourth and final station contained the Four-Square Step Test (FSST) and 6MWT, including measurement of subjects' vital signs (blood pressure, pulse rate, oxygen saturation) before and after as per 6MWT as per protocol. The order of the stations was altered to accommodate participants who were experiencing fatigue. The participants answered questions about their medications and

fall history (Appendix C). The initial assessment was completed on January 26 and February 2, 2017. Participants began the Rock Steady Boxing program on February 14, 2017, and the follow-up assessment was performed on April 20, 2017.

### PDQ-39

The PDQ-39 was selected to measure the overall QOL of participants (Appendix D). The PDQ-39 is comprised of the following eight scales: mobility, ADL, emotional well-being, stigma, social support, cognition, communication, and bodily discomfort. The PDQ-39 uses a 5-point ordinal scoring system where 0 = never, 1 = occasionally, 2 = sometimes, 3 = often, and 4 = always. The total score of the PDQ-39 ranges from 0 (never have difficulty) to 100 (always have difficulty), with lower scores reflecting better QOL.

The PDQ-39 shows sensitivity to change in people with PD when compared with other QOL instruments, yielding a decline at 6, 12, and 18 months of  $F(3,61)=9.0$ ,  $P<0.0001$ .<sup>31</sup> The separate scales of the PDQ-39 have test-retest reliability ranging from 0.68-0.94, internal reliability ranging from 0.69-0.94, and construct validity in relation to other measures.<sup>32</sup> The Minimal Detectible Change (MDC) for the individual scales of the PDQ-39 ranges from 12.24 to 24.48.<sup>33</sup> The Minimal Clinical Important Difference (MCID) for each of the scales for patients reporting their health as “about the same,” or “a little worse” is as follows: mobility (-1.5, -3.2), ADL (-0.7, -4.4), emotional well-being (0.3, -4.2), stigma (0.8, -5.6), social support (-1.2, -11.4), cognition (0.4, -1.8), communication (-0.8, -4.2), bodily discomfort (1.3, -2.1).<sup>34</sup> The PDQ-39 can be performed in a timely manner and is an appropriate health-related QOL instrument

because it has been tested thoroughly, contains adequate clinimetric characteristics, has been used in a large number of studies, and is available in many languages.<sup>35</sup>

### Mini BESTest

The Mini BESTest was utilized to measure several aspects of life that PD affects including anticipatory postural control, reactive postural control, sensory orientation, and dynamic gait. The reliability, validity, and detectable change of this test has been previously established in the following studies. Leddy et al<sup>36</sup> and Schlenstedt et al<sup>37</sup> noted interrater and test-retest reliability to have high reliability of intraclass correlation coefficient ICCs of  $\geq 0.91$  and  $\geq 0.88$  respectively to  $\geq 0.95$ . Schlenstedt et al<sup>37</sup> also concluded that the Mini BESTest has minimal ceiling effects when compared to the Berg Balance Scale. Lofgren et al<sup>38</sup> determined the Mini BESTest results were worse for patients with PD compared to a control group and among people with moderate motor severity compared to those with mild severity.

The equipment used included a gait belt, chair without arm rests, stopwatch, two-inch foam surface, 10-degree incline ramp, and two three-inch yoga blocks stacked on a six-inch wood block to create a nine-inch obstacle. The process of events was followed in line with the order portrayed in Appendix E. The patient was given a brief overview of what was to happen before beginning the Mini BESTest. The words were not followed precisely as printed. Several participants needed repetition of the instructions, additional explanation, or rephrasing of the wording.

Both the TUG and the TUG-C tests are part of the Mini BESTest. For the purposes of testing the participants in a timely manner, they were pulled out of the Mini BESTest and tested by a separate examiner who demonstrated intra-rater reliability.

## Timed Up and Go Assessment

The TUG was administered to each participant under standardized conditions and instructions, with the same evaluator each time. Instructions were given by the evaluator: "When I say go, I want you to stand up without using your hands and walk across the floor to the line on the ground, turn around and come back and sit back down." The test analyzed the ability to stand up, walk three meters, turn around and sit back down. It was documented when participants used a personal AD for safety. A stop watch was used to measure time and was started when the examiner said "go". Time was stopped when the participant's buttocks touched the seat of the chair upon return.

The TUG has been used to assess fall risk in individuals with PD. Nocera et al<sup>39</sup> determined that the TUG was able to correctly classify over 70% of the "falling" population of their study correctly using the assessment. Additionally, it was noted that the results were more accurate when individuals tested were at lower H&Y stages. Slow performance on the TUG and longer duration of PD symptoms are noted to be independent risk factors for being classified as a faller. The TUG is an objective tool to measure fall risks for patients, with more reliability noted in early stages of the disease.<sup>8</sup>

The TUG was noted to have a high ICC (0.99) when administered by experienced physical therapist in both "on" and "off" times of medication cycles. The ICC for novice administrators was slightly lower, 0.87, during the "off" medication time and 0.99 during the "on" time. Additional notes from the research done by Morris et al,<sup>40</sup> was that as medications wore off, movements became inconsistent. At the peak dose of medication, the movements returned to being consistent. It was also noted that trials two to four were most reliable, as participants generally moved too slow on the first of the five TUGs and

too fast on the last, which demonstrated learning. Results of the test indicated high retest reliability and inter-rater reliability.

#### Timed Up and Go – Cognitive Assessment

The instructions for completing the Timed Up and Go – Cognitive (TUG-C) were “I would like you to start counting backwards from 97 by threes.” (Appendix E) When participants demonstrated the ability to count back and their counting speed was noted, they were instructed, as described above, to complete the TUG-C while continuing to count backwards by threes from where they left off. Time started when the examiner said “Go”, and ended when the examiners buttocks touched the chair up return. If participants were unable to count backwards, they recited the months of the year backwards starting with December.

Vance et al<sup>41</sup> examined dual-tasking and the TUG-C and related it to fall risks with PD. It is known that individuals with PD are more likely to have challenges with their gait when they are dual-tasking. When individuals with PD focus on two different tasks, safety is decreased and fall risk increases, according to past research. Vance et al<sup>41</sup> examined the TUG, TUG-C, and TUG manual while participants were in their “on” stage of medications, as defined by two hours after taking medications. The TUG-C tested with the highest sensitivity and specificity, 76.5 and 73.7, respectively. The other two tests resulted in lower sensitivities and specificities indicating decreased ability to predict falls as independent tests. The likelihood ratio of the TUG-C was done and indicated that the test was 2.9 times more likely to correctly categorize a faller compared to a non-faller.

This study determined cut off times for predicting falls for each test. They are 12 seconds, 14.7 seconds, and 13.2 seconds for the TUG, TUG-C and TUG manual,

respectively. The results indicate individuals with PD have difficulty automatizing gait when they are challenged cognitively.<sup>41</sup>

It was noted that there was an increased fall rate associated with men and a higher H&Y stage in this study. Non-fallers had lower H&Y stage scores.<sup>41</sup>

It can be concluded from this study that the TUG-C may be the most useful test of the TUG, TUG-C, and TUG manual when predicting fall rates. Its applicability is increased when combined with history of falls, disease severity, and freezing of gait.<sup>41</sup>

#### Five Time Sit to Stand Test

The 5xSTS was administered to participants to analyze their ability to initiate movement and functional strength of their lower extremities. Participants were instructed as follows, "Cross your arms over your chest and when I say 'Go!', stand up all the way, as fast as, you can five times in a row." Timing began when the examiner said go and ended when the participants buttocks reached the seat of the chair after completing the fifth stand. If participants were unable to complete the 5xSTS with proper testing form, the test was not scored.

Duncan et al<sup>42</sup> examined inter-rater reliability and test retest reliability of the 5xSTS for individuals with PD. They discovered that there was a high ICC of 0.99 for inter-rater reliability of PD and a one-week retest reliability of 0.76, proving it to be a useful test. Interestingly, the study found no difference in 5xSTS time for disease severity or differences between sexes. This is thought to be explained through compensatory strategies that evolve as the disease process evolves. The average time required to complete the 5xSTS was 20.25 +/- 14.12 seconds. When comparing individuals with PD to healthy elderly, elderly people with balance problems and individuals with chronic

stroke, the PD population moved slower. Balance and bradykinesia were thought to be the limiting factors for the PD group rather than strength. Decreased balance and the associated negative confidence changes that accompany it, often lead to decreased QOL. The study results support the use of the 5xSTS test as a quick and useful tool to assess balance, coordination, and fall risk.

Peterson et al<sup>43</sup> analyzed the reliability MDC for individuals with PD when completing the 5xSTS. The researchers analyzed 5xSTS, 30 second Sit to Stand (STS), and Functional Gait Assessment (FGA). The tests were all conducted during the “on” time of medications for the participants. The results indicated that the 5xSTS had fair to good test-retest reliability with an ICC of 0.74 and a MDC of 10 seconds. This study also examined the 30 second STS test and determined an ICC test-retest reliability of 0.94 and MDC of three times. Additionally, the 30 second STS test was noted to have excellent six- to eight-day re-testability. The study suggested that the 30 second STS test may be a better functional test for individuals with PD than the 5xSTS test. This information should be taken into consideration for future studies.

#### GAITRite® Assessment

The GAITRite® was selected to measure and analyze multiple components of gait, including but not limited to gait velocity, step and stride length, base of support width, and comparisons from the right leg to the left leg. The GAITRite® was selected as the tool for measurement of gait because A.J. Nelson et al<sup>44</sup> determined that “the discriminant function derived from the predictor variables had a Wilks’ lambda coefficient of 0.11, which meant that is accounted for 89% of the variance between Parkinson’s and non-Parkinson’s groups” when measuring gait velocity between the two

groups.<sup>44</sup> Using the GAITRite® for individuals with PD produces measurements with ICC ranging from 0.88-0.91 for gait parameters of step length and walking speed.<sup>45</sup> A MDC in gait speed for individuals with PD is 0.18 m/sec for comfortable gait speed and 0.25 m/sec for fastest gait speed.<sup>46</sup> The GAITRite® system was also used to record video footage of the participants during the trials.

Tape was used to mark the floor three feet before and three feet beyond the GAITRite® mat. This allowed the patients to accelerate to the indicated pace before stepping onto the mat and decelerate after stepping off of the mat. The participants performed two trials walking at a comfortable pace, two trials at their “fastest pace while still feeling safe,” and one trial of backwards walking. Before each trial, the participants were given instructions which included that they should walk from tape line to tape line, and walk at the speed indicated. The participants were given the cue, “Begin walking.” when it was time for their trial to begin. For the backwards walking trial, the participants began at the immediate edge of the mat in order to prevent tripping and identify early festating gait patterns within the first few feet of the trial. Each participant wore a gait belt, and a spotter provided supervision during all trials for safety.

The data was collected and stored on the GAITRite® computer system for each trial. Footfalls that were not completely registered by the GAITRite® were deleted, and the trial was repeated if fewer than four footfalls were detected by the GAITRite® mat. Information collected included gait velocity, step length, stride length, ambulation time, distance, step time, cycle time, swing time, stance time, single support time, double support time, base of support, toe/in out measurements, and video footage of the subjects ambulating on the GAITRite® mat.

## Four Square Step Test

The Four Square Step Test (FSST), while relatively new, was chosen to see how well participants within the study can change direction while maintaining their balance. According to Roos et al,<sup>47</sup> "the FSST evaluates dynamic balance by requiring individuals to step over canes in multiple directions while being timed." Dite et al<sup>48</sup> explains "The FSST has been shown to be reliable and valid in community-dwelling older adults without disability and is fast and easy to administer" it can easily be incorporated into clinical practice and research studies.

The equipment required to complete this test included four canes and a stopwatch. We utilized plastic piping that interlocked and duplicated the design of canes. The grid's square one is located in the bottom left quadrant, with squares two, three, and four following in order going clockwise. First the instructions were given by the examiner. "Try to complete the sequence as fast as possible without touching the canes, but in a safe manner. Both feet must make contact in the square before moving on to the next square. You will start in square one and once you return to square one, the order will reverse going counterclockwise. The time will stop once you return back to square twice." The examiner first demonstrated the sequence with the correct technique, and then the participant was given a practice trial with verbal cues to ensure understanding. The participants completed two timed trials with the number of times they hit the grid recorded. The timed trials did not include any verbal cues from the examiner. Both timed trials were recorded with the fastest time being recorded as the score. A spotter was used to ensure safety of the participants. Not all participants in our study were able to complete this test due to safety and balance concerns, as well as an inability to step backwards or

an inability to complete the test without verbal cues. The same five participants completed the FSST in both pre- and post-testing.

Research by Duncan et al<sup>49</sup> discussed how FSST had excellent reliability in both “on” and “off” medication stages along with inter-rater reliability. Participants who took greater than 9.68 seconds are noted to be at a greater risk for falling. In a study conducted in 2013 by Wagner et al,<sup>50</sup> it was determined that the MDC was 4.6 seconds while Roos et al claimed the MDC was 6.73 seconds.<sup>47</sup> According to Whitney et al,<sup>51</sup> the reliability between two timed trials was .93 and noted a cutoff score of 12 seconds concluded in a sensitivity of 80% and specificity of 92% in identifying subjects with one or more risk factors of falling.

#### 6 Minute Walk Test

The 6MWT is a sub-maximal test to determine the aerobic capacity of an individual. This test was chosen because people with PD often display a shuffling gait pattern and can become fatigued after walking for extended periods of time. Tools used in the test included a stopwatch, a measuring wheel to determine the distance, an automatic blood pressure cuff, and a pulse oximeter. The participants were seated for 10 minutes prior to checking their vital signs which included blood pressure, heart rate and oxygen saturation levels.

Once vital signs were recorded, the participant was given instructions on the 6MWT. The participant was informed, "The object of this test is to walk as far as possible in 6 minutes. You will walk back and forth in this hallway... you are permitted to slow down, to stop and to rest as necessary... you will be walking back and forth around the cones... time will continue for the full six minutes, whether you slow, rest, or

stop”. (Appendix F) The participant was informed that the number of laps they walk would be counted, a verbal cue at each minute starting at one minute will be given, and the walk would be completed in silence so the participant can focus on their walking. A physical therapist walked alongside the participant for safety. If the participant used an AD, this was permitted during the 6MWT, and the AD was documented. The testing area should have been 30 meters or 100 feet of straight unimpeded hallway. However, due to constraints at the testing site the lap distance varied from 50 feet to 100 feet. Exact distance for each subject was measured and recorded.

After the six minutes were up from the test, the remaining distance a patient had walked that was shy of a full lap was measured by a measuring wheel. This value was added to the amount of feet covered based on number of full laps completed during the six minutes.

## CHAPTER III

### RESULTS AND STATISTICAL ANALYSIS

Ten participants completed the initial and final assessments. The PDQ-39 was the assessment tool that reflected the most change in participants. Other measures used either did not show significant change, were inconclusive, or displayed a decline in ability.

Five of the 10 participants reported an improvement in overall PDQ-39 scores. Of the 10 retested individuals, three showed improvements above the MCID of -1.8 in cognition and the MCID of - 3.2 in mobility. Two participants reported improvements in bodily discomfort of MCID -2.1. There were no other scales noted to have significant changes.

Three participants showed a significant MCID decrease in mobility scores, while three individuals showed significant MCID improvement in mobility scores. Three participants showed a significant MCID decline in bodily discomfort, in contrast with the two participants who had significant MCID improvements. One participant declined in the cognition scale and three participants displayed improvements in cognition.

Table 1. PDQ - 39

Subject #	1		2		3		4		6		7		8		10		11		12	
	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT
PDQ - 39	50	73	16	23	43	49	25	17	37	30	30	40	28	19	63	49	43	43	40	35
Mobility	18	25	10	8	18	19	10	5	12	16	6	13	4	3	29	25	21	15	12	10
ADL	9	16	2	6	12	11	6	6	2	3	11	9	1	1	5	3	7	7	8	6
Emotional well-being	0	1	0	1	4	5	1	1	2	0	3	4	10	5	9	7	5	6	2	2
Stigma	8	7	1	2	1	0	2	0	0	0	1	1	7	3	6	3	1	2	4	5
Social Support	2	2	0	0	0	2	0	0	0	0	0	1	2	3	1	0	0	3	0	0
Cognition	4	9	2	2	1	2	3	3	8	6	5	4	1	2	8	5	3	2	3	1
Communication	8	9	1	2	6	6	2	2	8	4	1	5	0	0	2	0	5	5	5	8
Bodily Discomfort	1	4	0	2	1	4	1	0	5	1	3	3	3	2	3	6	1	3	6	3

Minimal clinically important difference improvement

Minimal clinically important difference decline

No Data (ND)

Test = T

Retest = ReT

The additional subcategories of the PDQ-39 that did not have any MCID changes or minimal outliers were ADL, Emotions, Stigma, Social Support and Communication. One participant's score for the ADL subscale met the MCID threshold for decline. The Emotion subscale had one individual who met the subscale for MCID improvement. There was no MCID significant change for Stigma or Communication. One individual met the threshold for a significant decline on the Social Support subscale.

Table 2. Mini BESTest

subject #	1		2		3		4		6		7		8		10		11		12	
	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT
Mini-BESTest	14	14	9	8	7	8	10	10	18	16	15	19	22	25	15	14	18	15	15	13
Anticipatory	4	4	0	2	1	1	3	4	2	2	3	3	5	5	3	3	4	4	4	3
Reactive Postural	1	0	2	0	3	0	1	1	3	5	2	3	4	5	1	2	3	3	1	3
Sensory Orientation	6	5	3	2	1	2	2	1	6	4	5	6	5	6	5	3	5	4	3	3
Dynamic Gait	3	5	4	4	2	5	4	4	7	5	5	7	8	9	6	6	6	4	7	4
TUG (sec)	17.6	16.5	17.6	18.8	9.78	19.0	14.3	15.7	11.7	17.9	13.4	14.6	9.97	9.7	12.4	12.3	10.7	11.3	11.9	11.7
CogTUG (sec)	21.7	24.7	22.9	33.4	19.4	23.0	23.8	33.8	16.7	15.9	14.2	15.2	11.3	9.6	17.7	33.1	34.8	13.6	16.3	13.7

Minimal clinically important difference improvement

Minimal clinically important difference decline

No Data (ND)

Test = T

Retest = ReT

The Mini BESTest scores, unfortunately, did not provide minimally clinical important differences for any of the subjects. Five out of 10 participants improved or maintained the overall score of the Mini BESTest. The most improved section was the reactive posture where 7 out of the 10 participants improved or maintained their scores. The least improved section was sensory orientation where 4 out of 10 participants improved or maintained their scores.

Four of 10 participants improved on the TUG and TUG-C from pre- to post-testing.

Table 3. Five Times Sit to Stand

Subject #	1		2		3		4		6		7		8		10		11		12	
	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT
Time in secs	19.0	75.5	23.3	18.5	12.2	ND	18.7	122.2	11.5	10.8	19.9	14.5	10.0	8.87	11.3	10.8	11.0	15.9	12.4	13.1

Improvement in times

Decline in times

No Data (ND)

Test = T

Retest = ReT

There are no norms for detecting change on the 5xSTS at this time. Five of the 10 subjects were noted to have improvements in time since the original test date.

Table 4. GAITRite®

Subject #	1		2		3		4		6		7		8		10		11		12	
	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT
Comfortable speed	1.16	0.99	0.87	0.89	1.02	0.82	0.81	0.63	0.94	0.91	1.01	0.40	1.03	1.04	0.83	0.65	1.04	0.80	1.02	1.07
Fast speed	1.83	1.75	1.17	1.31	1.50	1.24	1.00	0.99	1.49	1.85	1.64	0.97	1.85	1.72	1.28	1.23	1.30	1.33	1.37	1.59
Backward speed	ND	ND	0.23	0.17	1.00	0.59	0.31	0.46	0.36	0.78	0.41	0.48	0.83	0.96	0.35	0.34	0.74	ND	0.38	0.63

Minimal clinically important difference improvement

Minimal clinically important difference decline

No Data (ND)

Test = T

Retest = ReT

For comfortable gait speed, five of the participants showed a decrease in gait speed that met the MDC threshold. No other participants met the MDC threshold for comfortable gait speed, but three participants showed an increase in the velocity of comfortable gait, and two participants showed a decrease in the velocity of their comfortable gait. For fast gait speed, one participant met the MDC threshold for decrease in gait speed, and one participant met the MDC threshold for increase in fast gait speed. The rest did not meet MDC threshold, but three participants showed an increase in gait speed, and five participants showed a decrease in gait speed. There are no established norms for significant change of backward gait velocity. One participant was unable to complete the backwards gait trial on both the initial and post-test, and one participant completed the initial test, but was unable to complete the post-test trial. Of the remaining eight participants, five showed an increase in their backwards gait speed, and three showed a decrease in backwards gait speed.

Table 5. Four Square Step Test

Subject #	1		2		3		4		6		7		8		10		11		12	
	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT
4 – Square Step Test	ND	ND	ND	ND	9.00	11.8	ND	ND	14.8	9.72	ND	ND	8.52	7.70	15.3	11.5	ND	ND	12.7	13.9

Improvement in times  
Decline in times  
No Data (ND)

Test = T  
Retest = ReT

Of the five participants who completed the FSST, three individuals improved their speed and met the MDC. The other two participants had a decrease in their score. Some of the participants did not complete this test at all due to safety concerns.

Table 6. 6 Minute Walk Test

Subj ect #	1		2		3		4		6		7		8		10		11		12	
	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT	T	ReT
6 minu te walk test	700	518	805	528	900	625	400	636	975	728	850	761	1,216	1,076	780	1,179	1,000	455	970	1,023

Improvement in times

Decline in times

No Data (ND)

Test = T

Retest = ReT

All 10 participants were able to complete the 6MWT. Seven of the individuals showed a decrease in the distance they could walk in six minutes compared to when they were first tested. Three of the 10 individuals met the MCD and had an improvement in scoring with the 6MWT. Several variables that could have played into this declines include the participant having an “off” day or walking in a different setting than for initial testing.

Participants from the Rock Steady Boxing gave comments on the day of post-testing. Some of the comments about the program included:

"My daughter thinks my strength and balance has improved"

"I feel more confident in my balance and walk better"

"It is a good workout"

"I like the social aspect"

"The class is fun, it gets you out of the house and opportunity to meet new people"

"I am very tired the rest of the day after boxing class, it is a good workout. I feel more alert."

"I feel more confident with walking and moving."

"I feel stronger."

Seven of the 10 participants who were re-tested said they would recommend this class to others with PD. The one individual who said they would not recommend the class made a comment about the class saying they were not sure if it was right for them. The Rock Steady Boxing program started locally February 2017 and is expanding to other communities within the region in the upcoming months.

## CHAPTER IV

### DISCUSSION

While PD is a neurodegenerative disease, research has suggested that intense exercise has neuroprotective effects, which may have a positive effect on reducing the progression of PD.<sup>28</sup> The results indicate fewer falls or maintenance of fall level for a portion of participants, and improvement in QOL. This was reflected by improved PDQ-39 scores, suggesting the benefits of exercise. The sample size (n=10) for this pilot study was small making it difficult to draw reliable conclusions from the results.

Current research indicates individuals can see a delay in the progression and a reduction of symptoms by exercising at an appropriate intensity. Rafferty et al<sup>24</sup> also analyzed the benefits of exercise and its effect on a patient's HRQOL. Conclusions made from this article were that the individuals who were consistent in exercising had smaller declines in their HRQOL scores and better mobility than those who did not exercise. Research supported by American Academy of Neurology suggests two-and-a-half hours, or more, per week at a moderate intensity is the level where these benefits can be seen.<sup>24</sup> Participants completed 90-minutes of exercise in the Rock Steady Boxing program once a week. This may have been a factor in the limited improvements noted. Some of the participants, however, were also enrolled in the Parkinson's Wellness Recovery class and therefore engaged in additional exercise classes per week. This could explain some improvement as this was not controlled for. Not all participants reached the

recommended goal of two-and-a-half hours of exercise per week. Additionally, the intensity at which participants were able to exercise was variable and individuals did not always meet or maintain a moderate to vigorous exercise level. A slower progression of symptoms and greater QOL are positive to see since PD is neurodegenerative and any maintenance is seen as an improvement.

Anticipated results of this study were expected to be more positive, like those of previous exercise-based studies in people with PD. However, the study had a short duration of 11 weeks with one class per week. There were additional confounding variables that decreased the physical impact the Rock Steady Boxing course. These will be addressed in the upcoming limitation section.

Class attendance was varied. Eight of the 10 participants who were reassessed attended an average of 6.7 classes (range 0-11) over the 11-week intervention period. During post-testing, participants were asked if their number of falls had increased, decreased, or stayed the same. Three of the participants subjectively noted a decrease in falls in the almost three-month intervention period. Four participants noted no change and one noted an increase in falls. One individual had no prior falls before the class had begun. There was no trend of improvement or decline based on how many times individual attended class. More subjective comments indicated that participants had become more confident over the three-month time frame since pre-testing.

As indicated above, prior research notes that individuals with PD are at a high fall risk. Seven of the 10 participant subjectively noted either an improvement or no change in the amount of falling with the intervention of Rock Steady Boxing. Individuals who

are experiencing less falls are likely to have increased confidence and be more likely to engage in social and community events and have increased QOL.

It is important to recognize that those with PD will start to avoid activities early on and continue to avoid activities through the progression of their disease. Individuals with PD are often aware of the situations that are dangerous for them and avoid them as a safety technique. However, this can lead to social isolation and decreased physical activity.<sup>6, 11</sup> Therefore, an important role of the physical therapist and the health care team is education and safety interventions to promote an active lifestyle starting immediately after diagnosis to promote and maintain a positive QOL.<sup>11</sup>

Community-based exercise programs such as Rock Steady Boxing have several benefits. The Rock Steady Boxing classes promoted high levels of exertion with PD specific exercises designed by a certified Rock Steady Boxing instructor. Cognition of the participants was challenged in each session through "brain-games" and boxing specific activities such as calling out right and left punches to specific targets. The individual had to interpret the verbal cues such as "punch right, punch left, uppercut, jab" and quickly demonstrate the motor component which emphasizes the work on the dual-task practice. The class was designed to promote multidirectional movements to combat the rigidity and postural deficits that are common to PD. Arguably one of the greatest benefits of the class was the social support and education participants received from other participants and the instructors. Several participants also completed the exercise course with their cornerman, a close friend or family member who supports them, which encourages participation in activities. The social aspect of Rock Steady Boxing provides accountability to the class, and at times when a participants' presence in the class is

absent, many people noticed. An additional benefit noticed from the class was that many participants used the time to help share information and research they had found that could be beneficial to others.

Participant perceived weaknesses of this class were minimal. At the end of the study, participants were asked whether they would recommend the class to future participants or would attend the course again. Nine out of 10 participants stated they would, but noted that they were often fatigued after completing the course.

### Limitations

There are several important limitations to note. Pre- and post-testing times were not standardized due to the subjects being tested at different times during the day. It is possible that the different testing times could have varied medication effectiveness. The Mini BESTest was followed with the wording provided. However, many of the participants needed additional explanation and a visual of what to do before they were successful in completing the tasks. This would give them practice and take away from them utilizing their own methods. There were several participants that were not comfortable counting backwards by three's when preparing for the TUG-C test. These individuals stated the months of the year backwards instead. While this made the test possible, it decreased standardization. There were space constraints when completing the 6MWT and participants completed the tests in different settings that included a hallway and gym with varying distances to walk.

Each testing station had different volunteers helping and these individuals varied between pre- and post- testing. Additionally, a couple participants completed the testing stations out of order based on timing constraints, efficiency, and patient fatigue level.

The intake forms and pre-testing forms asked participants the number of medications they were on. The questions did not discern between medication types or purpose of medications, making post-test evaluation of medications difficult.

Several of the participants that were involved in the Rock Steady Boxing course were also involved in a Parkinson's Wellness Recovery class two days a week. Most participants within the class were not recently diagnosed with PD, which demonstrates the lack of variability of onset of diagnosis with participants. This made it difficult to distinguish between the benefits of the Rock Steady Boxing course versus being active in general. A significant issue encountered with collecting post-testing data was that the participants were very fatigued. Several of them had participated in three days of exercise prior to the post-testing and, therefore, were having difficulties with motor planning and fatigue. Also, the majority of the participants had been consistently exercising in community programs for close to two years before participating in this study. If the participants had been new to exercise, greater improvements may have been noted.

Two participants who retested were recovering from illness and showed a decline in their motor skills. One participant had been out of state for most the study duration, limiting the number of classes attended.

## CHAPTER V

### CONCLUSION

The primary outcomes of this pilot study were an improvement in the quality of life and mobility in older adults with PD. Despite the progressive nature of PD, three of the 10 participants noted a decrease in the number of falls they were experiencing and six noted no change in their number of falls over the three month intervention period. Those participating in the program stated they enjoyed the social support offered by the class and noted that they were "more alert and confident when moving around." More research is warranted to determine longterm benefits of Rock Steady Boxing as an intervention for management of PD. Overall, the importance of exercise is evident. All healthcare providers should be familiar with local facilities and options to provide additional resources for their patients.

APPENDIX A  
IRB

January 12, 2017

**Institutional Review Board**

Twamley Hall, Room 106

264 Centennial Dr Stop 7134

Grand Forks, ND 58202-7134

Phone: 701.777.4279

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<b>Principal Investigator:</b>	Kristin Johnson, PT, DPT, GCS, NCS
<b>Project Title:</b>	Impact of A Community-Based Rock Steady Boxing Program for People with Parkinson's Disease: Evaluation of Fall Risk, Functional Mobility and Quality of Life Changes
<b>IRB Project Number:</b>	IRB-201701-164
<b>Project Review Level:</b>	Expedited 4
<b>Date of IRB Approval:</b>	01/10/2017
<b>Expiration Date of This Approval:</b>	01/09/2018
<b>Consent Form Approval Date:</b>	01/10/2017

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your original consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. **You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used.** It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

Prior to implementation, submit any changes to or departures from the protocol or consent form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website:

<http://und.edu/research/resources/human-subjects/>

Sincerely,



Michelle L. Bowles, M.P.A., CIP  
IRB Coordinator

MLB/sb  
Enclosures

Cc: Chair, Physical Therapy

# 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:** Kristin Johnson, PT, DPT, GCS, NCS

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School/College: University of North Dakota

Department: Physical Therapy

**Student Advisor (if applicable):** Kristin Johnson, PT, DPT, GCS, NCS

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E-mail Address: Kristin.L.Johnson@med.und.edu

Address or Box #: 9037

School/College: University of North Dakota

Department: Physical Therapy

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

**Project Title:** Impact of a community-based Rock Steady Boxing program for people with Parkinson's disease:

Evaluation of fall risk, functional mobility and quality of life changes.

**Proposed Project Dates:** Beginning Date: January 9, 2017

Completion Date: December 2018

(Including data analysis)

**Funding agencies supporting this research:** N/A

**Did the grant proposal with the funding entity go through UND Grants & Contracts Admin.?** ☐ YES or ☒ NO

Attach a copy of the grant proposal. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the grant proposal submitted to 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, North Dakota

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.

_____	Date submitted: _____	Status: <input type="checkbox"/> Approved <input type="checkbox"/> Pending
_____	Date submitted: _____	Status: <input type="checkbox"/> Approved <input type="checkbox"/> 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.

- |                                                                        |                                                                                                                                                                                        |                                                                        |                                       |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------|
| <input checked="" type="checkbox"/> YES or <input type="checkbox"/> NO | New Project                                                                                                                                                                            | <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Dissertation/Thesis/Independent Study |
| <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Continuation/Renewal                                                                                                                                                                   | <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Student Research Project              |
| <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | 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. |                                                                        |                                       |
| <input type="checkbox"/> YES or <input checked="" type="checkbox"/> NO | Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.                                      |                                                                        |                                       |
| <input type="checkbox"/> YES or <input checked="" type="checkbox"/> 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
- ☐ Cognitively impaired persons or persons unable to consent
- ☒ Other \_\_\_\_\_

- ☐ UND Students
- ☐ Pregnant Women/Fetuses

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.

- |                                                                                                   |                                                |
|---------------------------------------------------------------------------------------------------|------------------------------------------------|
| <input type="checkbox"/> Deception (Attach Waiver or Alteration of Informed Consent Requirements) | <input type="checkbox"/> Stem Cells            |
| <input type="checkbox"/> Radiation                                                                | <input type="checkbox"/> Discarded Tissue      |
| <input type="checkbox"/> New Drugs (IND) IND # _____ Attach Approval                              | <input type="checkbox"/> Fetal Tissue          |
| <input type="checkbox"/> Investigational Device Exemption (IDE) # _____ Attach Approval           | <input type="checkbox"/> Human Blood or Fluids |
| <input type="checkbox"/> Non-approved Use of Drug(s)                                              | <input type="checkbox"/> Other _____           |
| <input checked="" type="checkbox"/> None of the above will be involved in this study              |                                                |

### **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).

Parkinson's disease (PD) is a progressive neuro-degenerative disease characterized by bradykinesia, rigidity, tremor and postural instability. People with PD often have difficulty with automatic movements, weight shifting, foot clearance, turning, direction changes, anticipatory balance, and balance reactions. Falls are evident in the older population and are a common and disabling feature of PD as well. High-intensity physical exercise has been shown to be beneficial in managing motor and non-motor symptoms of PD. Exercise may also have global effects on factors that influence brain health and cognition. Exercise that incorporates goal-based motor skill learning has shown promise in being more effective than aerobic exercise alone. People with PD have a need for ongoing, continuous, community-based exercise programs that are engaging and accessible. In this study, we will examine the effect of a YMCA community-based exercise program, Rock Steady Boxing, on improving quality of life, improving physical mobility skills, and decreasing risk of falls in people with Parkinson's disease

### **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's Disease (PD) that sign up for the exercise program and are 25 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. Inclusion criteria: adults ages 25 and older, diagnosed with PD, 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: medially unstable and/or 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 the study. Interested participants will be told about the study, provided time to ask questions and if interested, will be asked to sign a consent form. Client 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.  
Principle investigator: Kristin Johnson. Co-investigators: Beverly Johnson and Meridee Danks. All three are licensed Physical Therapists with extensive experience assessing the older adult population including balance/gait assessments. Graduate level PT students (to be determined) trained on each assessment, and have completed IRB training, may assist with the project.
- 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 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 Questionnaire- 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 and within a disease-specific range if available. The total time for testing will be no more than one hour.

The assessments include:

- 1) Mini BESTest: Clinical balance assessment tool that aims to target and identify 4 different balance control systems so that specific rehabilitation approaches can be designed for different balance deficits. It is a 14 item test scored on a 3 level ordinal scale (0-2). Testing requires minimal setup time. Small equipment used: incline board, 4-inch foam pad, 9-inch high shoe box/obstacle
- 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 be asked to walk forward at their self-selected pace, backward at their self-selected pace, and then forward at their fastest safe pace. Testing requires minimal setup and test time (~10 minutes) and has minimal to no risk, and requires 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) Five times sit to stand: A measure of functional lower limb muscle strength, may be useful in quantifying functional change of transitional movements. Reduced lower extremity strength can lead to decreased mobility in the community, decrease activities of daily living and increase risk of falls. The participant

is instructed to go from a sit to stand position five times as fast as the individual can complete it. The assessment generally takes less than one minute to complete.

- 4) Four Square Step Test: a test of dynamic balance that clinically assesses the participant's ability to step over objects forward, sideways, and backwards. A practice trial is allowed, then two timed trials. No physical assistance is given but a cane is allowed if needed (if it is usual device). A safety belt will be used when performing this assessment. Less than five minutes 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.
- 6) Six minute walk test: Assesses distance walked over 6 minutes as a sub-maximal test of aerobic capacity/endurance. A device is allowed if needed, and a safety belt will be used when performing the assessment. Six minutes to complete.

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

The GAITrite has video capability during gait velocity testing. Participants will be videotaped as part of the protocol. Tapes will be stored in a secure file with the GAITrite data. Data and videos will be retained a minimum of three years following completion of the study. After the retention period, the forms will be shredded and videos will be destroyed.

- f) Describe the qualifications of the individuals conducting all procedures used in the study.

Principle Investigator (PI) is Kristin Johnson. Co-investigators are Beverly Johnson and Meridee Danks. All three are licensed PT's and have had extensive experience with the older adult population and balance/gait assessment. Dr. Kristin Johnson specialized in the treatment of people with Parkinson's disease from 2008 to 2016, is ABPTS board-certified in both Neurology and Geriatrics. Dr. Beverly Johnson is board-certified in Geriatrics and has completed a doctor of Science in Geriatrics. Dr. Danks is board-certified in Neurology. Graduate level physical therapy students who have been trained on each assessment and have completed IRB training.

- 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 spotters will be used. Subjects will be instructed that they may stop 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 participant's results into grouping to compare results. The 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 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 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, the 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 the 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 treatments 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 reducing fall risk and increasing quality of life in adults 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 (English, French, German, etc.) to be used by those obtaining consent

6) The language (English, French, German, etc.) 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 person who will conduct the consent interview

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 obtained 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 8<sup>th</sup> grade reading level** and must be written in the second 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);
- ☒ 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 Kristin L. Johnson  
(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<sup>1</sup>**

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

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

APPENDIX B  
INFORMED CONSENT

## INFORMED CONSENT

**TITLE:** Impact of a community-based Rock Steady Boxing program for people with Parkinson's disease: Evaluation of fall risk, functional mobility and quality of life changes.

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

**PHONE #:** 701-777-3673

**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 25, 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 45 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 six tests:

1. The Mini BESTest is a clinical balance test that aims to target and identify 4 different balance control systems. It is a 14 item test. A safety belt will be used when performing this assessment. Less than fifteen 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

Approval Date: JAN 10 2017

Expiration Date: JAN 9 2018

Date \_\_\_\_\_  
Subject Initials \_\_\_\_\_

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 at a comfortable and fast pace, then backward at a comfortable pace. 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. Five times sit-to-stand is an assessment to measure a person's 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 sitting position to a full standing position as fast as possible five times in a row. The assessment generally takes under one minute to complete.
4. Four Square Step test is a multidirectional stepping test used to predict fall risk. Individuals will be asked to step into 4 different squares over a small threshold, moving forward, to the right, backwards and to the left, then reversing direction. A practice trial is allowed, then two timed trials. No physical assistance is given but a cane is allowed if needed (if it is usual device). A safety belt will be used when performing this assessment. Less than five minutes 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, well-being and quality of life.
6. The Six minute walk test is an endurance test in which the participant is asked to walk as far as possible in a six minute time frame. A device is allowed if needed, and a safety belt will be used when performing the assessment. Six minutes to complete.

#### **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: JAN 10 2017

Expiration Date: JAN 9 2018

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 Kristin Johnson, 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 **Kristin Johnson at 701-777-3673, 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: JAN 10 2017

Expiration Date: JAN 9 2018

Date \_\_\_\_\_  
Subject Initials \_\_\_\_\_

APPENDIX C  
DATA COLLECTION SHEETS

Subject # \_\_\_\_\_  
Age \_\_\_\_\_  
Date \_\_\_\_\_

**PD Program Data Sheet- Spring 2017**

\_\_\_ 1. Approximate date diagnosed with Parkinson's Disease      Year \_\_\_\_\_

\_\_\_ 2. Number of falls in the past year \_\_\_\_\_

Typical direction of falls, if applicable (forward/back/sideways) \_\_\_\_\_

\_\_\_ 3. Number of prescription medications \_\_\_\_\_

Time of last medication (PD-related): \_\_\_\_\_

"On" / "Off" / "In-between" during testing \_\_\_\_\_

\_\_\_ 4. How many hours per week do you exercise? \_\_\_\_\_

Type of exercise: \_\_\_\_\_

\_\_\_ 5. PDQ 39      Total Score \_\_\_\_\_

\_\_\_ 6. Five Times Sit to Stand Test      Time required to complete test \_\_\_\_\_  
(*>15 sec. indicates higher risk for falling, in community dwelling adults with PD*)

\_\_\_ 7. Gait Speed (GAITrite/10 Meter Walk Test)

Comfortable Walking in meters/second \_\_\_\_\_

Gait Speed Walking Rapidly yet Safe in meters/second \_\_\_\_\_

Gait Speed Backward Comfortable Walking meters/second \_\_\_\_\_

Device used: \_\_\_\_\_

Subject # \_\_\_\_\_  
 Age \_\_\_\_\_  
 Date \_\_\_\_\_

Age	Gender	Mean Comfortable Walking Speed (Bohannon 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
	Female	0.9 m/sec
80-89	Male	0.8 m/sec
	Female	0.8 m/sec

\_\_\_\_ 8. MiniBESTest Total Score (out of 28 points) \_\_\_\_\_  
 (see attached form)

\_\_\_\_ 9. Four Square Step Test (*>15 sec. indicates higher risk for falling, in community dwelling older adults*)

Trial #1 \_\_\_\_\_ # touches to grid \_\_\_\_\_

Trial #2 \_\_\_\_\_ # touches to grid \_\_\_\_\_

Additional Trials (if appl.) \_\_\_\_\_ # touches to grid \_\_\_\_\_

Best time \_\_\_\_\_

Comments \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

\_\_\_\_ 10. Six Minute Walk Test Total Distance (in feet) \_\_\_\_\_  
 Device used: \_\_\_\_\_

Additional Comments: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

APPENDIX D  
PARKINSON'S DISEASE QUESTIONNAIRE-39

# Parkinson's Disease Quality of Life Questionnaire (PDQ-39)

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

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always or cannot do at all
1. had difficulty doing the leisure activities you would like to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. had difficulty looking after your home, for example, housework, cooking or yardwork?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. had difficulty carrying grocery bags?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. had problems walking half a mile?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. had problems walking 100 yards (approximately 1 block)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. had problems getting around the house as easily as you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. had difficulty getting around in public places?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. needed someone else to accompany you when you went out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please verify that you have **checked 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...

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always or cannot do at all
9. felt frightened or worried about falling in public?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. been confined to the house more than you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. had difficulty showering and bathing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. had difficulty dressing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. had difficulty with buttons or shoelaces?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. had problems writing clearly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. had difficulty cutting up your food?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. had difficulty holding a drink without spilling it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. felt depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. felt isolated and lonely?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please verify that you have **checked 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...

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always
19. felt weepy or tearful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. felt angry or bitter?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. felt anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. felt worried about your future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. felt you had to hide your Parkinson's from people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. avoided situations which involve eating or drinking in public?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. felt embarrassed in public due to having Parkinson's disease?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. felt worried about other people's reaction to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. had problems with your close personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please verify that you have **checked 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...

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always
28. lacked the support you needed from your spouse or partner? <i>If you do not have a spouse or Partner, please check here</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. lacked the support you needed from your family or close friends?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. unexpectedly fallen asleep during the day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. had problems with your concentration, for example when reading or watching TV?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. felt your memory was failing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. had distressing dreams or hallucinations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. had difficulty speaking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. felt unable to communicate effectively?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. felt ignored by people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please verify that you have **checked 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...

Please **check one box** for each question

	Never	Occasionally	Sometimes	Often	Always
<b>37.</b> had painful muscle cramps or spasms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>38.</b> had aches and pains in your joints or body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>39.</b> felt uncomfortably hot or cold?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please verify that you have checked one box for each question.

***Thank you for completing the questionnaire.***

APPENDIX E  
Mini BESTest

## Mini-BESTest: Balance Evaluation Systems Test

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### ANTICIPATORY

SUB SCORE: /6

#### 1. SIT TO STAND

Instruction: "Cross your arms across your chest. Try not to use your hands unless you must. Do not let your legs lean against the back of the chair when you stand. Please stand up now."

(2) Normal: Comes to stand without use of hands and stabilizes independently.

(1) Moderate: Comes to stand WITH use of hands on first attempt.

(0) Severe: Unable to stand up from chair without assistance, OR needs several attempts with use of hands.

#### 2. RISE TO TOES

Instruction: "Place your feet shoulder width apart. Place your hands on your hips. Try to rise as high as you can onto your toes. I will count out loud to 3 seconds. Try to hold this pose for at least 3 seconds. Look straight ahead. Rise now."

(2) Normal: Stable for 3 s with maximum height.

(1) Moderate: Heels up, but not full range (smaller than when holding hands), OR noticeable instability for 3 s.

(0) Severe:  $\leq 3$  s.

#### 3. STAND ON ONE LEG

Instruction: "Look straight ahead. Keep your hands on your hips. Lift your leg off of the ground behind you without touching or resting your raised leg upon your other standing leg. Stay standing on one leg as long as you can. Look straight ahead. Lift now."

Left: Time in Seconds Trial 1: \_\_\_\_\_ Trial 2: \_\_\_\_\_

Right: Time in Seconds Trial 1: \_\_\_\_\_ Trial 2: \_\_\_\_\_

(2) Normal: 20 s.

(2) Normal: 20 s.

(1) Moderate:  $< 20$  s.

(1) Moderate:  $< 20$  s.

(0) Severe: Unable.

(0) Severe: Unable

To score each side separately use the trial with the longest time.

To calculate the sub-score and total score use the side [left or right] with the lowest numerical score [i.e. the worse side].

### REACTIVE POSTURAL CONTROL

SUB SCORE: /6

#### 4. COMPENSATORY STEPPING CORRECTION- FORWARD

Instruction: "Stand with your feet shoulder width apart, arms at your sides. Lean forward against my hands beyond your forward limits. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

(2) Normal: Recovers independently with a single, large step (second realignment step is allowed).

(1) Moderate: More than one step used to recover equilibrium.

(0) Severe: No step, OR would fall if not caught, OR falls spontaneously.

#### 5. COMPENSATORY STEPPING CORRECTION- BACKWARD

Instruction: "Stand with your feet shoulder width apart, arms at your sides. Lean backward against my hands beyond your backward limits. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

(2) Normal: Recovers independently with a single, large step.

(1) Moderate: More than one step used to recover equilibrium.

(0) Severe: No step, OR would fall if not caught, OR falls spontaneously.

#### 6. COMPENSATORY STEPPING CORRECTION- LATERAL

Instruction: "Stand with your feet together, arms down at your sides. Lean into my hand beyond your sideways limit. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

Left

Right

(2) Normal: Recovers independently with 1 step (crossover or lateral OK).

(2) Normal: Recovers independently with 1 step (crossover or lateral OK).

(1) Moderate: Several steps to recover equilibrium.

(1) Moderate: Several steps to recover equilibrium.

(0) Severe: Falls, or cannot step.

(0) Severe: Falls, or cannot step.

Use the side with the lowest score to calculate sub-score and total score.

### SENSORY ORIENTATION

SUB SCORE: /6

#### 7. STANCE (FEET TOGETHER); EYES OPEN, FIRM SURFACE

Instruction: "Place your hands on your hips. Place your feet together until almost touching. Look straight ahead. Be as stable and still as possible, until I say stop."

Time in seconds: \_\_\_\_\_

(2) Normal: 30 s.

(1) Moderate:  $< 30$  s.

(0) Severe: Unable.

### 8. STANCE (FEET TOGETHER); EYES CLOSED, FOAM SURFACE

Instruction: "Step onto the foam. Place your hands on your hips. Place your feet together until almost touching. Be as stable and still as possible, until I say stop. I will start timing when you close your eyes."

Time in seconds: \_\_\_\_\_

- (2) Normal: 30 s.
- (1) Moderate: < 30 s.
- (0) Severe: Unable.

### 9. INCLINE- EYES CLOSED

Instruction: "Step onto the incline ramp. Please stand on the incline ramp with your toes toward the top. Place your feet shoulder width apart and have your arms down at your sides. I will start timing when you close your eyes."

Time in seconds: \_\_\_\_\_

- (2) Normal: Stands independently 30 s and aligns with gravity.
- (1) Moderate: Stands independently <30 s OR aligns with surface.
- (0) Severe: Unable.

### DYNAMIC GAIT

SUB SCORE: \_\_\_\_\_ /10

### 10. CHANGE IN GAIT SPEED

Instruction: "Begin walking at your normal speed, when I tell you 'fast', walk as fast as you can. When I say 'slow', walk very slowly."

- (2) Normal: Significantly changes walking speed without imbalance.
- (1) Moderate: Unable to change walking speed or signs of imbalance.
- (0) Severe: Unable to achieve significant change in walking speed AND signs of imbalance.

### 11. WALK WITH HEAD TURNS – HORIZONTAL

Instruction: "Begin walking at your normal speed, when I say 'right', turn your head and look to the right. When I say 'left' turn your head and look to the left. Try to keep yourself walking in a straight line."

- (2) Normal: performs head turns with no change in gait speed and good balance.
- (1) Moderate: performs head turns with reduction in gait speed.
- (0) Severe: performs head turns with imbalance.

### 12. WALK WITH PIVOT TURNS

Instruction: "Begin walking at your normal speed. When I tell you to 'turn and stop', turn as quickly as you can, face the opposite direction, and stop. After the turn, your feet should be close together."

- (2) Normal: Turns with feet close FAST ( $\leq 3$  steps) with good balance.
- (1) Moderate: Turns with feet close SLOW ( $\geq 4$  steps) with good balance.
- (0) Severe: Cannot turn with feet close at any speed without imbalance.

### 13. STEP OVER OBSTACLES

Instruction: "Begin walking at your normal speed. When you get to the box, step over it, not around it and keep walking."

- (2) Normal: Able to step over box with minimal change of gait speed and with good balance.
- (1) Moderate: Steps over box but touches box OR displays cautious behavior by slowing gait.
- (0) Severe: Unable to step over box OR steps around box.

### 14. TIMED UP & GO WITH DUAL TASK [3 METER WALK]

Instruction TUG: "When I say 'Go', stand up from chair, walk at your normal speed across the tape on the floor, turn around, and come back to sit in the chair."

Instruction TUG with Dual Task: "Count backwards by threes starting at \_\_\_\_\_. When I say 'Go', stand up from chair, walk at your normal speed across the tape on the floor, turn around, and come back to sit in the chair. Continue counting backwards the entire time."

TUG: \_\_\_\_\_ seconds; Dual Task TUG: \_\_\_\_\_ seconds

- (2) Normal: No noticeable change in sitting, standing or walking while backward counting when compared to TUG without Dual Task.
- (1) Moderate: Dual Task affects either counting OR walking ( $>10\%$ ) when compared to the TUG without Dual Task.
- (0) Severe: Stops counting while walking OR stops walking while counting.

When scoring item 14, if subject's gait speed slows more than 10% between the TUG without and with a Dual Task the score could be decreased by a point.

TOTAL SCORE: \_\_\_\_\_ /21

## Mini-BESTest Instructions

**Subject Conditions:** Subject should be tested with flat-heeled shoes OR shoes and socks off.

**Equipment:** Temper® foam (also called T-foam™ 4 inches thick, medium density T41 firmness rating), chair without arm rests or wheels, incline ramp, stopwatch, a box (9" height) and a 3 meter distance measured out and marked on the floor with tape [from chair].

**Scoring:** The test has a maximum score of 28 points from 14 items that are each scored from 0-2.

"0" indicates the lowest level of function and "2" the highest level of function.

If a subject must use an assistive device for an item, score that item one category lower.

If a subject requires physical assistance to perform an item, score "0" for that item.

For **Item 3** (stand on one leg) and **Item 6** (compensatory stepping-lateral) only include the score for one side (the worse score).

For **Item 3** (stand on one leg) select the best time of the 2 trials [from a given side] for the score.

For **Item 14** (timed up & go with dual task) if a person's gait slows greater than 10% between the TUG without and with a dual task then the score should be decreased by a point.

1. SIT TO STAND	Note the initiation of the movement, and the use of the subject's hands on the seat of the chair, the thighs, or the thrusting of the arms forward.
2. RISE TO TOES	Allow the subject two attempts. Score the best attempt. (If you suspect that subject is using less than full height, ask the subject to rise up while holding the examiners' hands.) Make sure the subject looks at a non-moving target 4-12 feet away.
3. STAND ON ONE LEG	Allow the subject two attempts and record the times. Record the number of seconds the subject can hold up to a maximum of 20 seconds. Stop timing when the subject moves hands off of hips or puts a foot down. Make sure the subject looks at a non-moving target 4-12 feet ahead. Repeat on other side.
4. COMPENSATORY STEPPING CORRECTION-FORWARD	Stand in front of the subject with one hand on each shoulder and ask the subject to lean forward (Make sure there is room for them to step forward). Require the subject to lean until the subject's shoulders and hips are in front of toes. After you feel the subject's body weight in your hands, very suddenly release your support. The test must elicit a step. NOTE: Be prepared to catch subject.
5. COMPENSATORY STEPPING CORRECTION - BACKWARD	Stand behind the subject with one hand on each scapula and ask the subject to lean backward (Make sure there is room for the subject to step backward.) Require the subject to lean until their shoulders and hips are in back of their heels. After you feel the subject's body weight in your hands, very suddenly release your support. Test must elicit a step. NOTE: Be prepared to catch subject.
6. COMPENSATORY STEPPING CORRECTION- LATERAL	Stand to the side of the subject, place one hand on the side of the subject's pelvis, and have the subject lean their whole body into your hands. Require the subject to lean until the midline of the pelvis is over the right (or left) foot and then suddenly release your hold. NOTE: Be prepared to catch subject.
7. STANCE (FEET TOGETHER); EYES OPEN, FIRM SURFACE	Record the time the subject was able to stand with feet together up to a maximum of 30 seconds. Make sure subject looks at a non-moving target 4-12 feet away.
8. STANCE (FEET TOGETHER); EYES CLOSED, FOAM SURFACE	Use medium density Temper® foam, 4 inches thick. Assist subject in stepping onto foam. Record the time the subject was able to stand in each condition to a maximum of 30 seconds. Have the subject step off of the foam between trials. Flip the foam over between each trial to ensure the foam has retained its shape.
9. INCLINE EYES CLOSED	Aid the subject onto the ramp. Once the subject closes eyes, begin timing and record time. Note if there is excessive sway.
10. CHANGE IN SPEED	Allow the subject to take 3-5 steps at normal speed, and then say "fast". After 3-5 fast steps, say "slow". Allow 3-5 slow steps before the subject stops walking.
11. WALK WITH HEAD TURNS-HORIZONTAL	Allow the subject to reach normal speed, and give the commands "right, left" every 3-5 steps. Score if you see a problem in either direction. If subject has severe cervical restrictions allow combined head and trunk movements.
12. WALK WITH PIVOT TURNS	Demonstrate a pivot turn. Once the subject is walking at normal speed, say "turn and stop." Count the number of steps from "turn" until the subject is stable. Imbalance may be indicated by wide stance, extra stepping or trunk motion.
13. STEP OVER OBSTACLES	Place the box (9 inches or 23 cm height) 10 feet away from where the subject will begin walking. Two shoeboxes taped together works well to create this apparatus.
14. TIMED UP & GO WITH DUAL TASK	Use the TUG time to determine the effects of dual tasking. The subject should walk a 3 meter distance. TUG: Have the subject sitting with the subject's back against the chair. The subject will be timed from the moment you say "Go" until the subject returns to sitting. Stop timing when the subject's buttocks hit the chair bottom and the subject's back is against the chair. The chair should be firm without arms. TUG With Dual Task: While sitting determine how fast and accurately the subject can count backwards by threes starting from a number between 100-90. Then, ask the subject to count from a different number and after a few numbers say "Go". Time the subject from the moment you say "Go" until the subject returns to the sitting position. Score dual task as affecting counting or walking if speed slows (>10%) from TUG and or new signs of imbalance.

APPENDIX F  
6 MINUTE WALK TEST



## INSTRUCTIONS FOR SIX MINUTE WALK TEST FORM SMW, VERSION 1.0 (QxQ)

### I. GENERAL INSTRUCTIONS

The Six Minute Walk Test Form is filled out by the study clinician conducting the test. Using a paper copy of the form to record the data while the test is in progress is recommended.

The Six Minute Walk, an assessment of lung function is the Flexible Block A procedure. Usually the walk should follow shortly after spirometry since it is performed after bronchodilation (for participants with COPD and/or asthma).

The testing area must be a 30m (100 ft.) segment of straight, unimpeded hallway.

Prepare the area by applying markers for the endpoints and 3m intervals to the baseboard on one side of the hall, with special attention to avoid doorways, etc.

Use the provided 30m metric tape measure. If a pre-existing 100 ft. (30.48m) course with 10ft. markers has been previously laid out, it may be used.

If available, place the traffic cones at the center of the proximal and distal turn points. Place the turn signs at the proximal and distal turn points of the course.

Have ready the following materials: *stopwatch/timer, worksheet for counting laps, oximeter, Borg breathlessness and exertion scales, a chair that can be easily moved along the walking course, emergency equipment (according to local policy): telephone, sphygmomanometer, oxygen source.*

**A "warm-up" period before the test should not be performed.**

**Participants should use their usual walking aids during the test (cane, walker, etc.) and be dressed in comfortable clothing and walking shoes.**

*In general, it is preferable to use room air. If the participant is on long-term oxygen therapy with a resting saturation off oxygen of less than 88%, supplemental oxygen may be used during the test. Future yearly tests should be done at the same amount of supplemental oxygen if possible.*

*The University of Utah will use 1.5L/min by continuous nasal canula for all subjects to simulate sea level inspired pO<sub>2</sub> unless the participant is receiving a high flow rate of long-term oxygen therapy **and** desaturates to less than 88% on 1.5L/min at rest (see above). All other sites should use room air as noted above.*

*See the SPIROMICS MOP 2, Section 2.14 for further details on oxygen use.*

*Prior to the test, the participant should sit in a chair, located near the starting position for at least 10 minutes before assessing pulse and SpO<sub>2</sub> (and Blood Pressure if not taken and recorded within 4 hours prior to test).*

**If systolic BP is > 200mmHg or < 60mmHg, or diastolic blood pressure > 110mmHg discontinue the test.**

**If resting heart rate is > 120 or < 50 beats per minute discontinue the test.**

**If resting SpO2 is < 88% the participant is not eligible to continue the test** (exception noted above for participants on long-term oxygen therapy).

**Reasons for immediately stopping the test include:**

- if SpO2 falls below 80%
- the participant asks to stop the test
- if the participant experiences chest pain
- intolerable dyspnea
- leg cramps
- staggering
- diaphoresis
- pale or ashen appearance

## **II. DETAILED INSTRUCTIONS FOR CHALLENGE**

Explain the use of the modified Borg scale (0-10) for assessing breathlessness.

Explain the use of the Borg rating of perceived exertion scale (6-20) for rating perceived exertion.

Read the following instructions to the participant:

*"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."*

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.

Record completed and partial laps on the lap count worksheet.

Say to the participant:

*"Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog. Start now, or whenever you are ready."*

Standardized Encouragement read in a steady voice:

After the 1<sup>st</sup> minute: *"You are doing well. You have 5 minutes to go."*

When the timer shows 4 minutes remaining: *"Keep up the good work. You have 4 minutes to go."*

When the timer shows 3 minutes remaining: *"You are doing well. You are halfway done."*

When the timer shows 2 minutes remaining: *"Keep up the good work. You have only 2 minutes left."*

When the timer shows 1 minute remaining: *"You are doing well. You only have 1 minute to go."*

With 15 seconds to go: *"In a moment I'm going to tell you to stop. When I do, just stop right where you are and I will come to you."*

At 6 minutes: *"Stop"*

If the participant stops at any time prior, you can say: *"You can lean against the wall if you would like; then continue walking whenever you feel able."*

**Do not use other words of encouragement (or body language) to influence the patient's walking speed.** Accompany the participant along the walking course, but keep just behind them. Do not lead them.

**If available record the distance at which the oxygen saturation drops < 88%.**

### III GENERAL INSTRUCTIONS FOR THE FORM

**Header Information:** The header information consists of key fields which uniquely identify each recorded instance of a form.

**FORM DATE:** Record date this is being completed. Select the date from the pop up calendar or type in the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

**INITIALS:** Record the staff code of the person entering the data on this form. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS data please contact the GIC in order to receive your own individual staff code.

### III. DETAILED INSTRUCTIONS FOR EACH ITEM

Item 1. Medications taken since post-bronchodilator spirometry: Record 'Y' for Yes or 'N' for No. If No, go to Item 2. If Yes, complete 1a-c.

Item1a-c. Record medication name, dose and time taken for up to 3 medications. Record time in hours and minutes. Choose AM or PM.

Item 2. Blood pressure more than 4 hours prior to 6MW: Record 'Y' for Yes or 'N' for No. If No, go to Item 3. If Yes, complete Item2a-b.

Item2a. Record systolic pressure

Item2b. Record diastolic pressure

Item 3. Supplemental Oxygen during test : Record 'Y' for Yes or 'N' for No. If No, go to Item 4. If Yes, complete Item 3a-b.

Item3a. Oxygen Flow rate: Record in Liters per minute.

Item3b. Oxygen type: Record 1 for continuous flow nasal canula or 2 for Pulsed delivery system (conserver).

Item4a. SpO2 at rest prior to 6MW: Record as percentage.

Item4b. Pulse: Record beats per minute.

Item 5. Continuous oximetry recorded: Record 'Y' for Yes, or 'N' for No.

Item 6. Start of 6-minute walk: Record time in hours and minutes. Choose AM or PM.

Item 7. Immediately following 6MW: Record the following:

Item7a. SpO2: Record as percentage.

Item7b. Pulse: Record beats per minute.

Item7c. Breathlessness: Record participant's response from 0-10 on the Modified Borg Scale (0=no breathlessness, nothing at all, 0.5=very, very slight, 1=very slight, 2=slight breathlessness, 3=moderate, 4=somewhat severe, 5=severe breathlessness, 6=is between

*severe breathlessness and very severe breathlessness, 7=very severe breathlessness, 8=between very severe breathlessness and very,very severe breathlessness, 9=very, very severe breathlessness, 10=maximum breathlessness.)*

Item7d. Exertion: Record participant's response from 6-20 on the Borg Scale of Perceived Exertion (6=*none*, 7-8=*very,very light*, 9-10=*very light*, 11-12=*fairly light*, 13-14=*somewhat hard*, 15-16=*hard*, 17-18=*very hard*, 19-20=*very,very hard*).

Item 8a. Type of course used: Select the type of course used. Record 1 for 30 meters x 2 lengths, 2 for 100 feet x 2 lengths, or 3 for other. If Other, specify in the space provided.

Item 8b. Record the number of completed laps

Item 8c. Record the distance walked the final partial lap in meters if 8a is in meters or in feet if 8b is in feet.

Item 9. Stopped before 6 minutes: Record Y for Yes or N for No. If No skip out of form. If Yes answer 9a and 10.

Item9a. Duration: Record in minutes and seconds.

Item 10. Reason for stopping: Record one response 1-5. (1=*desaturation <80%*, 2=*foot, knee, hip or other orthopedic pain*, 3=*muscle fatigue or pain*, 4=*breathlessness*, 5=*adverse event*)

Item105. If response to Item 10=5, select all that apply. (*a=angina, b=lightheadedness, c=intolerable dyspnea, d=leg cramps, e=staggering, f=diaphoresis, g=pale or ashen appearance, h=mental confusion or headache, i=other*). If other is selected, please explain.

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