EFFECTS OF INTERVAL ACTIVE-ASSISTED CYCLING ON BALANCE IN INDIVIDUALS WITH PARKINSON’S DISEASE

A dissertation submitted to the Kent State University College and Graduate School of Education, Health, and Human Services in partial fulfillment of the requirements for the degree of Doctor of Philosophy

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PURPOSE: The purpose of the present investigation was to examine the effect of interval active-assisted cycling on balance in individuals with Parkinson’s disease. We examined the effects of high rate interval active-assisted cycling on upper extremity motor function, Unified Parkinson’s Disease Rating Scale (UPDRS), Berg balance scale and H-reflex of the soleus.

METHODS: Twenty older individuals (50-79 years) with idiopathic Parkinson’s disease were randomly assigned to two groups, a control group and an exercise group. On the first visit all subjects completed baseline assessments of cardiovascular fitness (YMCA Submaximal cycling test), motor function (upper extremity and UPDRS), balance (Berg Balance Scale and Biodex Balance System SD), H-reflex sensitivity and quality of life (PDQ). All the individuals repeated these tests (except the submaximal test) after four weeks. The exercise group than came into the laboratory three times a week for four weeks to complete high rate interval active-assisted cycling. The exercise program consisted of 5 minutes of warm-up, 30 minutes of interval active-assisted cycling and 5 minutes of cool down. Metabolic and perceptual data were collected at baseline and every two minutes during exercise. The control group only visited the lab for assessments.

RESULTS: Data were analyzed using an analysis of variance with repeated measures. Interval active-assisted cycling improved UPDRS scores in the exercise group compared to the control group. It did not significantly
improve balance or upper extremity tremor in the exercise group compared to the control group. CONCLUSIONS: A four week interval active-assisted cycling program does not improve balance or upper extremity tremor but does improve UPDRS scores in individuals with PD.
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CHAPTER I
INTRODUCTION

Parkinson’s disease (PD) is a progressive neurodegenerative disorder that results in tremor, rigidity, bradykinesia and postural instability (Falvo, Schilling, & Earhart, 2008). Individuals with PD usually have deficits in mobility which can lead to loss of independence, injuries and inactivity (Keus, Bloem, Hendriks, Bredero-Cohen, & Munneke, 2007). As PD progresses balance impairment results in an increase in falling and a decrease in quality of life (Matinolli et al., 2009; Bohnen & Cham, 2006). Despite medical and surgical intervention people with PD may demonstrate a deterioration in their mobility. With the progressive nature of PD and the short-term effect of medication on balance it is critical to identify rehabilitative interventions that minimize disease related impairments of PD.

A number of studies have shown that there is improvement in motor function, muscle strength and also changes in neuroplasticity after bouts of exercise, including aerobic, resistance and balance training (Falvo, et al., 2008; Goodwin, Richards, Taylor, Taylor, & Campbell, 2008; Keus, et al., 2007). It is agreed that more beneficial exercise rehabilitation strategies should attempt to correct the underlying neurological deficits (integrating proprioceptive and sensory feedback), ultimately resulting in improvements in overall PD symptoms (Sage & Almeida, 2009). Resistance training studies have concluded that resistance training can show functional improvements in gait and mobility (Dibble et al., 2006; Scandalis, Bosak, Berliner, Helman, & Wells, 2001). Hirsch, Toole, Maitland, & Rider, 2003, also concluded that improvements may also be seen in balance
and muscle strength in individuals with PD. Balance training studies have concluded that balance training can show improvements in balance in individuals with PD (Hirsch, Toole, Maitland, & Rider, 2003; Smania et al., 2010). Aerobic training studies have concluded that aerobic training can show improvements in gait and mobility (Herman, Giladi, Gruendlinger, & Hausdorff, 2007; Miyai et al., 2000; Miyai et al., 2002). Ridgel, Muller, Kim, Fickes, & Mera, 2011, has shown that passive cycling along with active-assisted cycling has shown improvements in motor function in individuals with PD. It is still unclear what mechanisms are responsible for the improvements in PD symptoms, what frequency of the training should be done, what the duration of the training should be and if the effects of the training are long term.

Statement of Problem

It is clear that exercise improves motor symptoms (tremor, rigidity, bradykinesia and postural instability) of PD. However there is still little consensus about the duration or frequency of the exercise that is required. Furthermore, few studies have examined how cycling affects balance in individuals with PD. This study is novel in that we looked at how interval active-assisted cycling will affect balance in individuals with PD.

Purpose of the Study

The purpose of the proposed investigation was multi-faceted and examined the following:

1. The effects of interval active-assisted high-rate cycling on balance in individuals with Parkinson’s disease. This present investigation was designed to hypothesize that interval active-assisted high-rate cycling will promote
greater improvements in balance parameters than in individuals who do not exercise.

2. The effects of interval active-assisted high-rate cycling on upper extremity motor function in individuals with Parkinson’s disease. The present investigation was designed to hypothesize that interval active-assisted high-rate cycling will promote greater upper extremity motor improvements than in individuals who do not exercise.

3. The effects of interval active-assisted high-rate cycling on overall UPDRS score in individuals with Parkinson’s disease. The present investigation was designed to hypothesize that interval active-assisted high-rate cycling will promote greater improvements in UPDRS motor scores than in individuals who do not exercise.

4. The effects of interval active-assisted high-rate cycling on the sensitivity of sensory afferents, as measured via the Hoffman reflex pathway, in individuals with Parkinson’s disease. The present investigation was designed to hypothesize that interval active-assisted high-rate cycling will increase the sensitivity of the sensory afferents which will improve overall balance.

Summary

Many previous studies have concluded that exercise may improve: muscular strength, mobility, balance and gait in individuals with PD. The current investigation examined how a novel form of exercise, interval active-assisted cycling effected balance
and motor function in individuals with PD and provided additional insight into the role of exercise intensity in improving the symptoms of PD.
CHAPTER II
REVIEW OF LITERATURE

Parkinson’s Disease

Parkinson’s disease (PD) is a neurological disorder that is most common among older adults. Based on an incidence rate of 16 to 19 per 100,000 per year, it is estimated that more than 2 million Americans, and 6 million people worldwide, are currently living with PD (Morris, Martin, & Schenkman, 2010). It is a progressive neurodegenerative disorder and is manifested by the loss of dopaminergic neurons in the midbrain (brainstem) and resulting disruption of the basal ganglia circuitry which is important in voluntary movement (Falvo, et al., 2008). This results in tremor, rigidity, progressive bradykinesia (slowness of movement) and postural instability. Patients with PD often confront problems with mobility deficits, including difficulties with transfers, posture, balance and walking (Keus, et al., 2007). This frequently leads to loss of independence, fear of falling, injuries and inactivity.

Balance Deficits in Parkinson’s Disease

Balance impairment in Parkinson’s disease results in an increased risk of falling and a decrease in quality of life (Matinolli, et al., 2009). Between 38% and 68% of people with PD fall each year and those with PD for more than 20 years have experienced at least one fall (Latt, Lord, Morris, & Fung, 2009). A cross sectional study by Ashburn, Stack, Pickering, & Ward, 2011, concluded that difficulties in gait and postural control play an important role in these falls. Furthermore, muscle weakness is often present in individuals with Parkinson’s disease and is associated with reduced postural stability.
Overall these combined central nervous system and peripheral muscle impairments can result in progression towards immobility (Dibble, et al., 2006). Balance impairment becomes more debilitating as Parkinson’s disease progresses (Bohnen & Cham, 2006). Despite medical and surgical intervention people with PD often show deterioration in their mobility. According to Matinolli, Korpelainen, Sotaniemi, Mylyla, & Korpelainen (2011), the main problem is that balance impairment is associated with a poor response to the dopaminergic medication. Matinolli et al. 2009, supports this statement by concluding that although the pathophysiological triggers of PD remains unknown it is believed to be partly of non-dopaminergic origin. According to Smania, Corato, Tinazzi, Stanzani, Fiaschi, Girardi, & Gandolfi, 2010, the mechanisms of postural instability in PD actually may involve dysfunction at the level of several neural subsystems. Abnormalities have been found in the processing of afferent inputs from vestibular, proprioceptive and visual systems (Smania, et al., 2010). With the progressive nature of PD and the short-term effect of medication on balance it is critical to identify rehabilitative interventions that minimize disease related impairments of PD.

**Exercise in Parkinson’s Disease**

There have been a number of studies which have examined the benefits of exercise, including aerobic, resistance and balance training on motor symptoms in PD. Most of these studies report benefits in motor function as well as strength improvements. Furthermore, there is evidence that shows that exercise has neuroplasticity benefits (Smith & Zigmond, 2003). This is possibly due to the release of neurotrophic factors being released and greater cerebral oxygenation (Goodwin, et al., 2008). Hirsch, et al.,
2003, also stated that rehabilitative training can stimulate neural growth, synaptogenesis
and even neurogenesis. There are five key principles of exercise that enhance
neuroplasticity in relation to PD: 1) intense activity, (2) complex activities, (3) increase
dopamine levels, (4) activities that promote relearning and (5) exercise needs to be
introduce at an early stage (Fox, Ramig, Ciucci, Sapir, McFarland, & Farley, 2006).
These activities should be intense and complex to help with the slowing of the
progression of PD. Overall it is agreed exercise rehabilitation strategies should attempt to
correct the underlying neurological deficits (integrating proprioceptive and sensory
feedback), ultimately resulting in improvements in overall symptoms (Sage & Almeida,
2009).

**Resistance Training**

Muscular adaptations contribute to force enhancement. Furthermore, neural
adaptations also contribute to increases in muscular strength (Gabriel, Kamen, & Frost,
2006). The neural mechanisms that are likely responsible are altertations in agonist-
antagonist coactivation, increases in motor unit firing rates and changes in descending
drive to the motoneurons (Gabriel, et al., 2006). Still there are other questions that still
need to be answered such as 1), what spinal circuitry sites change in response to exercise
training and 2) is there a change in receptor sensitivity?

According to Hirsch and colleagues (2003), recent work with animal models of
PD indicated that rehabilitative training can stimulate a number of changes within the
brain and spinal cord (neuroplasticity). These events include neuronal overgrowth,
neurotrophic factor expression, synaptogenesis and neurogenesis. Hirsch, et al., 2003,
examined PD individuals that underwent a 10 week high intensity resistance training program and showed that sensory orientation improved (how well individuals maintain balance under progressively more difficult conditions). Muscle strength also increased and stayed elevated for 4 weeks after training. It can be concluded that balance and strength can be improved in people with PD when doing a high intensity resistance training program.

There have been various studies that have looked at resistance training and how it effects gait and mobility in persons with PD. Dibble, et al., 2006, examined mobility after a 12 week high-force eccentric resistance training program and found that there was an increase in mobility (6 minute walk) at the end of the study. Scandalis, et al. 2001, examined gait after an 8 week resistance training program and concluded that there were significant gains in stride length, walking velocity and postural angles at the end of the study. Both studies show that resistance training can produce functional improvements in gait and mobility and may be a useful part of exercise for individuals with PD. Although it is still unclear whether neural adaptations promote these changes and also what duration and frequency of resistance training exercise is most beneficial.

**Balance Training**

Balance training, such as balancing on foam, the use of elastic bands and retropulsion tests, have been shown to improve balance in individuals with PD (Hirsch, et al., 2003; Toole, Hirsch, Forkink, Lehman, & Maitland, 2000). One study on balance training showed that a 10 week, 3 day/week, 30 minute balance training program improved overall balance in subjects with PD (Hirsch, et al., 2003). Another study on
balance training showed that a 21 session of 50 minutes each session improved balance in subjects with PD (Smania, et al., 2010). In this study there was an overall improvement in their Berg Balance Scale, the postural transfer test and their UPDRS. A significant difference in this study showed that at a one-month follow-up improvement was maintained in all outcome measures. It is still unclear what type of frequency and duration is needed and also if improvements will be maintained for a significant time period after the treatment is over.

**Aerobic Training**

At thirty years of age the human brain shows structural decline in the frontal, parietal and temporal lobes (Raz, 2000). The decline is associated with the deterioration of a wide variety of cognitive functions and central nervous system health. It is important to determine mechanisms to offset or reverse these declines since adults are surviving to advanced age. Cardiovascular exercise has been associated with improved cognitive function in older individuals (S. Colcombe & Kramer, 2003; Kramer et al., 1999) but there is little known about the structural brain changes. In a study individuals 60-79 years of age participated in aerobic training or toning and stretching (S. J. Colcombe et al., 2006). They determined that there were significant increases in brain volume of the individuals that participated in the aerobic training. It is suggested that cardiovascular fitness is associated with the sparing of brain tissue in aging. Therefore, it appears that aerobic fitness can maintain and enhance central nervous system health and cognitive functioning in older individuals.
With aging brain tissues can become damaged but there is increasing evidence that these tissues can self repair. The self repair can be done through a variety of experiences including motor activity (Smith & Zigmond, 2003). Dobrossy & Dunnett, 2003, showed that in mice damage done to the neostriatum can be reduced by prior motor training. Smith & Zigmond, 2003, destroyed dopamine neurons in mice with a chemical called 6-hydroxydopamine. It was found that forced exercise can actually reduced vulnerability of dopamine neurons to 6-hydroxydopamine. This protection is due to an increase in the availability of GDNF. These two studies suggest that exercise will protect against a variety of neurodegenerative conditions.

Although beneficial effects of exercise in individuals with Parkinson’s disease have been documented, there are still questions about the possible mechanisms that are responsible for these effects. The search for mechanisms of these improvements is difficult in humans but by using rodent models, the researchers were able to determine changes in striatal dopamine in the 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP)-lesioned mouse (Petzinger et al., 2007). The MPTP-lesioned mouse has a 60% loss of nigrostriatal neurons and an 80-90% depletion of striatal dopamine. The mice completed exercise and it was found that exercise lead to improvement of motor performance. The exercise leads to compensatory changes in the MPTP-lesioned mouse that resulted in increased synaptic dopamine availability through increased release, reduced uptake, and decrease in decay (Petzinger, et al., 2007). It is still unclear the molecular mechanisms that link exercise and dopaminergic neurotransmission.
The nigrostriatal dopminergic system has been associated with the pathology of PD and the brain levels of monoamine neurotransmitters are influenced by exercise then an examination of chronic aerobic exercise effects on PD is warranted (Bergen et al., 2002). The researchers conducted a study with a 16 week aerobic exercise intervention. Individuals with PD improved in both aerobic capacity and also in movement initiation. The improvement in movement initiation suggests that aerobic exercise may reduce the detrimental effect of neuromuscular slowing within PD, which improves the individual’s ability to initiate and perform movement patterns. In another study the PD individuals did 20 sessions of aerobic training and 20 sessions of Qigong (Chinese Physiotherapy) (Burini et al., 2006). It was found that aerobic training exerts a significant impact on the ability of moderately disabled PD patients to cope with exercise but it did not improve their self sufficiency and quality of life (Burini, et al., 2006).

Various studies have indicated that treadmill training can promote a more stable walking pattern in individuals with PD and can help restore rhythmicity, reduce gait variability and reduce the risk of falling. In one study researchers had individuals with PD walked on the treadmill for 30 minutes, four times a week for 6 weeks (Herman, et al., 2007). The investigators found that individuals with PD improved their UPDRS and increased their gait speed. It can be concluded that there is a potential to minimize impairments in gait and reduce fall risk with a treadmill training program. In another study individuals with PD completed four weeks of a body weight-supported treadmill training program (Miyai, et al., 2000). The investigators found that the treadmill body weight support training produced even greater improvements in activities of daily living,
motor performance and ambulation. Although these studies determine that aerobic training is beneficial in individuals with Parkinson’s disease they do not look at the long term benefits. Another study looked at whether body weight-supported treadmill training is of long term benefit for individuals with PD (Miyai, et al., 2002). The investigators found that the effects of a one month treadmill training program lasted for four months after the training was done. However the mechanisms responsible for the long term functional improvements are still unclear.

**Mechanisms**

**Proprioceptive Reflexes**

The Hoffman reflex (H-reflex) is the electrical analogue of the stretch reflex (Zehr, 2002). When simulation is applied, Ia afferents will be recruited before smaller motor axons (Li & Bak, 1976). By stimulating the H-reflex, adaptive plasticity of the central nervous system can be examined (Wolpaw & Tennissen, 2001). A further issue would be the extent and significance of the short-term H-reflex changes that are seen during different types of movement (Zehr, 2002). It can be stated that by using the H-reflex, changes in the human reflex pathways and the plasticity of the neuromuscular system can be evaluated.

Studies have shown that bouts of loaded leg cycling reduced the amplitude of the H-reflex (Avela, Kyrolainen, Komi, & Rama, 1999; Bulbulian, 2002; Bulbulian & Bowles, 1992; Bulbulian & Darabos, 1986; deVries, Simard, Wiswell, Heckathorne, & Carabetta, 1982; deVries, Wiswell, Bulbulian, & Moritani, 1981). The reduction in the H-reflex is considered the “tranquilizing” effect of exercise that is control by the central
nervous system and generalized beyond a single spinal segmental level. Researchers looked at the H-reflex of the soleus and the flexor carpi radialis during leg cycling (Motl & Dishman, 2003). Their findings showed a decrease in the H-reflex in the soleus but not in the flexor carpi radialis. This study disproves the tranquilizing effect and states that the reduction of the H-reflex does not generalize beyond the spinal segmental level and instead is likely the result of segmental processes associated with the repetitive stretching or activation of the soleus muscle.

The behavior of the soleus H-reflex is considered to be motor task dependent (Larsen & Voigt, 2004). The H-reflex during a motor task is most likely determined by the ongoing presynaptic inhibition of the Ia afferents during the movement and is described by a linear relationship between the H-reflex amplitude and the level of motoneuron activation (Larsen & Voigt, 2004). The speed of movement and the motor recruitment level is altered when motor tasks are changed. A study that looked at how speed and motor recruitment separately influences the soleus H-reflex when the motor task is unchanged (cycling) (Larsen & Voigt, 2004). They concluded that both parameters do influence the gain of the soleus H-reflex. It is still unclear though the functional significance of a change in reflex gain.

One study examined the H-reflex behavior in individuals with PD compared to individuals without PD (Kushnir, Klein, Pollak, & Rabey, 2002). They concluded that the H-reflex threshold was the same or higher than the M response threshold in individuals with PD compared to those without PD and this can be used as a parameter in assessment of rigidity in individuals with PD. A possible explanation for the behavior
changes was an abnormality in reciprocal inhibition that are possible mechanisms of changes of the H-reflex behavior in PD patients.
CHAPTER III

METHODOLOGY

The purpose of the current investigation is to evaluate the effects of interval active-assisted cycling on balance in persons’ with Parkinson’s disease.

Participants

Twenty older individuals (50-79 years) with idiopathic Parkinson’s disease and no contraindications to exercise including cardiovascular disease or stroke were recruited via direct contact with the principal investigator. All volunteers were interviewed over the telephone with the American Heart Association/American College of Sports Medicine pre-screening questionnaire. Participants were excluded from the study if they report cardiovascular, metabolic or respiratory disease. All approved participants were asked to complete a four page health history for a more complete assessment of physical health. Informed consent was obtained from each subject prior to participation and the protocol was approved by the Kent State University IRB.

Pre-Experimental Testing

Participants reported to the Exercise Science Laboratory at which time they were asked to compete a baseline fitness assessment (YMCA Submaximal Cycling Test) to determine fitness level. Motor function of the upper extremity was assessed using the Kinesia Motor Assessment System (Cleveland Medical Devices, Cleveland, OH). Kinesia provided quantitative scores for the degree of tremor, bradykinesia and quality of upper extremity movement. Subjects worked through seven upper extremity motor tasks while wearing the device. Outcome variables included amplitude, speed and frequency.
Balance was assessed using the Biodex Balance System SD. The Biodex Balance System quantifies the ability to maintain postural stability on an unstable surface (static stability) and the ability to move the centre of mass within the limits of stability (dynamic stability) utilizing a circular platform that moves in the anterior-posterior and medial-lateral axes. The device offers several levels of difficulty which determines the rate of deflection of the platform. Each level of difficulty was preceded by a 30-second practice trial and was tested once. A rest period of 2 minutes was given between each level of difficulty. Individuals performed three separate tests: the postural stability test, the M-CTSIB test and the fall risk assessment test. The Berg balance scale test (Berg, Maki, Williams, Holliday, & Wood-Dauphinee, 1992) was also administered. The Berg balance scale measured impairment in balance function by assessing the performance of functional tasks. The 14-item functional tasks were completed where a score ranging from 0-4 will be given. A score of 0 indicated the lowest level of function and a score of 4 indicated the highest level of function. Unified Parkinson’s Disease Rating Scales (UPDRS) was administered to determine the progression of the disease among the participants. This test is used in the clinical setting and has sections which examine upper and lower extremity tremor, bradykinesia and rigidity, walking, posture and balance. Each of the fourteen tests was scored on a scale from 0-4 and the total was summed. A score of 0 indicated normal and a score of 4 indicated high severity of Parkinson’s disease. Finally, a quality of life questionnaire specific to Parkinson’s disease, the PDQ-39 (Peto, Jenkinson, Fitzpatrick, & Greenhall, 1995), will be given to the subjects. The questionnaire will determine the subjects self perceived quality of life relating to their
Parkinson’s disease symptoms. All tests (excluding submaximal test) were repeated at the end of the study.

**Preliminary Data**

A case study done previously on an individual with PD has provided the structure on the experimental procedures listed below (with a few increases in rpm during the session as the only changes). I have opted to use this case study because it was proven that variability in high-rate active-assisted cycling showed improvements in UPDRS scores by 27 percent. The data also demonstrated that according to the PDQ-39 (a self-reported questionnaire about quality of life) there was an improvement in mobility experienced by the individual.

**Experimental Procedures**

The experimental protocol was four weeks in length with one day for pre-testing and one day for post-testing. The twenty individuals with idiopathic Parkinson’s disease were randomly placed into one of two groups. Group 1 was the control group. They did not perform any type of exercise during the study. Group 2 was the cycling group. Participants were asked to exercise in the lab three times a week for the four weeks. Table 1 provides the exercise paradigm. Each cycling session began with 5 minutes of warm up. Participants then completed 30 minutes of interval active-assisted high-rate cycling followed by 5 minutes of cool down. The high rate cycling was done on a motorized semi-recumbent cycle (Motomed Viva 2).
Table 1. Exercise Paradigm

<table>
<thead>
<tr>
<th>Phase</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gear</td>
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<td>20</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>20</td>
<td>20</td>
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<tr>
<td>Time (mins)</td>
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<td>2:30</td>
<td>5:00</td>
<td>4:00</td>
<td>6:00</td>
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<td>90</td>
<td>65</td>
<td>90</td>
<td>60</td>
<td>45</td>
</tr>
<tr>
<td>Passive/Active</td>
<td>Passive</td>
<td>Passive</td>
<td>Active</td>
<td>Active</td>
<td>Active</td>
<td>Active</td>
<td>Active</td>
<td>Active</td>
<td>Passive</td>
<td>Passive</td>
</tr>
</tbody>
</table>

Metabolic and Perceptual Measurements

Heart rate was measured via a Polar heart rate monitor (Accurex Plus, Polar Electro, Inc., Woodbury, NY) and heart rate values were recorded every 2 minutes. Participants heart rate was maintained within the range of 40-70% of their estimated VO$_2$max as calculated by the baseline fitness test. Ratings of Perceived Exertion (RPE) recordings were obtained every 2 minutes via Borg’s RPE 6-20 scale (Borg, 1970). Subjects RPE was varied between 6 and 15 due to the work that was being performed.

H-Reflex

Measurement of the H-reflex involves electrical stimulation of a mixed peripheral nerve which contains both motor and sensory axons. The Hoffman-reflex (H-reflex) of the soleus was measured via electromyogram recordings (EMG) on the soleus muscle of the most affected leg. The subject was sitting down with their most effected leg straight out (on another chair) and their foot was plantar flexed. The tibial nerve (S1 and S2) was electrically stimulated placing a surface plate electrodes in the popliteal fossa. EMG electrodes were placed one half of the distance between the mid-popliteal crease and the medial malleolus or just distal to the belly of the MG; medial to the Achilles tendon. The
position of the electrodes were recorded and mapped so that post-intervention measurements are the same. A single 1 ms was delivered every 8 s to the tibial nerve. The stimulation intensity started out as 0 mV and was gradually increased until the H-wave appears. With a maximal H-wave there was a small M-wave and the amplitude of the M-wave was monitored to maintain constancy of nerve stimulation. This procedure, to obtain the maximal H-wave and M-wave was completed within 15 stimulations. Ten consecutive recordings were then recorded and averaged using an arithmetic mean to form a single maximal H-wave and maximal M-wave. The maximal waves were used then to compute the H/M ratio.

**Statistical Analysis**

All data were analyzed via SPSS 17.0 software. Data were assessed using a two group x two time repeated measures analysis of variance (ANOVA). In the event that the ANOVA revealed a significant main effect or interaction, further exploration via paired samples t-tests with Bonferroni adjustments was performed.
CHAPTER IV

RESULTS

The purpose of this current investigation was multifaceted and primarily examined the effect of interval active-assisted high rate cycling on balance in individuals with Parkinson’s disease. In addition, the procedures outlined in Chapter III were selected to determine the effects of interval active-assisted high rate cycling on upper extremity tremor, UPDRS, Berg balance test and H-reflex of the soleus.

Participant Characteristics

Participant characteristics are outlined in Table 2. A total of twenty individuals with Parkinson’s disease were evaluated. All participants were diagnosed with idiopathic Parkinson’s disease and were not involved in any other exercise program that could alter their physiological responses to the interval active-assisted high rate cycling paradigm. An analysis via paired sample t-test with Bonferroni adjustments showed no significant differences of participant characteristics in the exercise group compared to participants in the control group (age, \( p = 0.060 \); Hoehn and Yahr, \( p = 0.642 \); Levadopa dosage, \( p = 0.684 \); estimated \( VO_{2\text{max}} \), \( p = 0.553 \); and resting heart rate (RHR), \( p = 0.867 \)).
Table 2. Participant Characteristics

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Gender</th>
<th>Hoehn and Yahr</th>
<th>Levadopa (mg)</th>
<th>VO_{2max} (ml·kg^{-1}·min^{-1})</th>
<th>RHR (bpm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ex</td>
<td>Con</td>
<td>Ex</td>
<td>Con</td>
<td>Ex</td>
<td>Con</td>
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<td>F</td>
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<td>64</td>
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<td>M</td>
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<td>75</td>
<td>M</td>
<td>M</td>
<td>2</td>
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<td>74</td>
<td>55</td>
<td>M</td>
<td>F</td>
<td>1</td>
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<tr>
<td>71</td>
<td>73</td>
<td>M</td>
<td>M</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Motor Function

Unified Parkinson’s Disease Rating Scale

In order to assess overall motor function, UPDRS Motor III scores pre (week 0) and post (week 4) for the exercise and control groups were compared (Figure 1). Decreases in the motor score represent improvement in motor function. A repeated measures analysis of variance (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. There was a significant group (exercise, control) x time (week 0, week 4) interaction (p=0.04). Further post-hoc analysis via paired sample t-test with Bonferroni adjustments showed that individuals in the exercise group improved (p<0.001) while the control group did not (p=0.654). There was a 23.8% improvement in the overall motor score for the exercise group compared to a 5% improvement in the control group.
In order to examine which motor functions showed the greatest changes after the intervention, each individual component of the UPDRS scores was examined (Table 3, Appendix B). The individual components include upper body motor function, lower body motor function, tremor, bradykinesia, posture and gait. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups at week 0 and after week 4 for each individual component. The ANOVA revealed a group x time interaction for lower body (p=0.002), upper body (p=0.050), posture (p=0.009), tremor (p=0.006) and bradykinesia (p=0.017). Further analysis via paired...
sample t-test with Bonferroni adjustments showed that individuals in the exercise group improved in the lower body (p< 0.001) compared to controls (p=0.528), the upper body (p< 0.001) compared to controls (p=0.950), in posture (p<0.001) compare to controls (p=0.452), in tremor (p<0.001) compared to controls (p=0.367) and in bradykinesia (p<0.001) compared to controls (p=0.904).

**Table 3. Individual components of overall UPDRS scores**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exercise Group Pre (Mean ± SD)</th>
<th>Exercise Group Post (Mean ± SD)</th>
<th>Control Group Pre (Mean ± SD)</th>
<th>Control Group Post (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Body</td>
<td>16.7 (± 5.62)</td>
<td>12.6 (± 5.04)*</td>
<td>10.5 (± 4.35)</td>
<td>11.3 (± 7.26)</td>
</tr>
<tr>
<td>Upper Body</td>
<td>14.2 (± 3.08)</td>
<td>9.6 (± 2.72)*</td>
<td>10.8 (± 4.10)</td>
<td>10.9 (± 7.13)</td>
</tr>
<tr>
<td>Tremor</td>
<td>9.2 (± 4.05)</td>
<td>5.6 (± 4.40)*</td>
<td>5.2 (± 4.59)</td>
<td>6.4 (± 6.50)</td>
</tr>
<tr>
<td>Bradykinesia</td>
<td>13.7 (± 3.02)</td>
<td>9.7 (± 3.68)*</td>
<td>10.6 (± 2.91)</td>
<td>10.4 (± 6.74)</td>
</tr>
<tr>
<td>Posture</td>
<td>8.6 (± 3.44)</td>
<td>6.5 (± 4.06)*</td>
<td>4.8 (± 2.62)</td>
<td>5.4 (± 4.45)</td>
</tr>
<tr>
<td>Gait</td>
<td>2.4 (± .84)</td>
<td>2.1 (± .88)</td>
<td>1.2 (± .79)</td>
<td>1.3 (± 1.06)</td>
</tr>
</tbody>
</table>

**Kinesia**

Individuals completed seven different upper extremity motor tasks. These tasks were divided up into three different scores: resting tremor, posture tremor and kinetic tremor.

Resting tremor scores pre and post for the exercise and control groups are depicted in Figure 2. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.992) and no main effect for time (p=0.831).
Posture tremor scores pre and post for the exercise and control groups are depicted in Figure 3. A decrease in tremor score suggests motor improvement. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed a group x time interaction (p=0.041) with the exercise group decreasing posture tremor by 28% and the control increasing posture tremor by 33%.

*Figure 2.* Resting tremor scores (M±SEM) of exercise and control groups.
Figure 3. Posture tremor scores (M±SEM) of exercise and control groups.

Kinetic tremor scores pre and post for the exercise and control groups are depicted in Figure 4. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.203) and no main effect for time (p=0.179).
Figure 4. Kinetic tremor scores (M±SEM) of exercise and control groups.

Overall tremor scores for the exercise group and control group are depicted in Figure 5. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.198).
Average tremor scores pre and post for the exercise group and control group are depicted in Figure 6. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.191).
**Figure 6.** Average tremor scores of exercise and control groups.

**Balance**

**Biodex Balance System SD**

Individuals completed three separate trials of the postural stability test on the Biodex Balance System SD. The mean score of those trials were used. The overall postural stability scores pre and post for the exercise and control groups are depicted in Figure 7. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared
to week 4. The ANOVA revealed a group x time interaction (p=0.030). Further analysis via paired sample t-test with Bonferroni adjustments showed that individuals in the exercise group did not improve (p=0.590) while the control group did improve (p=0.019).

![Postural stability scores (M ± SEM) of exercise and control groups.](image)

*Figure 7. Postural stability scores (M ± SEM) of exercise and control groups.*

The individual components of the overall postural stability scores are listed in Table 4. The individual components include anterior/posterior stability and medial/lateral stability. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups at week 0 and after week 4 for each individual component. The ANOVA revealed no group x time interaction for
anterior/posterior stability (p=0.06) and no group x time interaction for medial lateral stability (p=0.077).

**Table 4. Individual components of overall postural stability scores**

<table>
<thead>
<tr>
<th></th>
<th>Exercise Group Pre (Mean ± SD)</th>
<th>Exercise Group Post (Mean ± SD)</th>
<th>Control Group Pre (Mean ± SD)</th>
<th>Control Group Post (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anterior/Posterior</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stability</td>
<td>1.01 (±.96)</td>
<td>.93 (±.91)</td>
<td>1.29 (±1.67)</td>
<td>.73 (±.88)</td>
</tr>
<tr>
<td><strong>Medial/Lateral</strong></td>
<td>.69 (±.34)</td>
<td>.61 (±.47)</td>
<td>.88 (±.68)</td>
<td>.55 (±.62)</td>
</tr>
</tbody>
</table>

Individuals completed four separate tests of the modified clinical test of sensory integration and balance (CTSIB1, 2, 3 and 4) on the Biodex Balance System SD. The tests were scored individually. The CTSIB1 (eyes open on a firm surface) test scores pre and post for the exercise and control groups are depicted in Figure 8. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.706) and no main effect for time (p=0.837).
Figure 8. CTSIB1 scores (M±SEM) of exercise and control groups.

CTSIB2 (eyes closed on a firm surface) test scores pre and post for the exercise and control groups are depicted in Figure 9. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.110) and no main effect for time (p=0.997). However, the exercise groups’ score decreased by 9% while the control groups’ score increased by 12%.
CTSIB3 (eyes opened on a foam surface) test scores pre and post for the exercise and control groups are depicted in Figure 10. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.665) and no main effect for time (p=0.987).
CTSIB3 scores (M±SEM) of exercise and control groups.

CTSIB4 (eyes closed on a foam surface) test scores pre and post for the exercise and control groups are depicted in Figure 11. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.288) and no main effect for time (p=0.130). However, the exercise groups’ score decreased by 18% compared to the control groups’ score only decreasing by 5%.
Figure 11. CTSIB4 scores (M±SEM) of exercise and control groups.

Individuals completed three separate trials of the fall risk test on the Biodex Balance System SD. The mean score of those trials were used. The overall fall risk scores pre and post for the exercise and control groups are depicted in Figure 12. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.144) and no main effect for time (p=0.173).
Figure 12. Fall risk scores (M±SEM) of exercise and control groups.

Berg Balance Scale

Berg balance scale scores pre and post for the exercise and control groups are depicted in Figure 13. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.102) and no main effect for time (p=0.958). However, the exercise groups’ score increased by 4.6% and the control groups’ score decreased by 4.4%.
Figure 13. Berg Balance scores (M±SEM) of exercise and control groups.

**Parkinson’s Disease Questionnaire (PDQ)**

Individuals completed a questionnaire and were given an overall score called the single index. The single index scores are depicted in Figure 14. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=0.986).
Figure 14. Single Index scores (M±SEM) of exercise and control groups for the PDQ.

The individual components of the overall PDQ scores are listed in the table 5. The individual components include mobility, activities of daily living (ADL’s), emotional well being (EWB), stigma, social support, cognitive, communication and bodily discomfort (BD). Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups at week 0 and after week 4 for each individual component. The ANOVA revealed no group x time interaction for mobility (p=0.890), activities of daily living (p=0.874), emotional well being (p=0.521), stigma
(p=0.877), social support (p=0.997), cognitive (p=0.998), communication (p=0.493) and bodily discomfort (p=0.320).

**Table 5. Individual components of overall PDQ scores**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exercise Group Pre (Mean ± SD)</th>
<th>Exercise Group Post (Mean ± SD)</th>
<th>Control Group Pre (Mean ± SD)</th>
<th>Control Group Post (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>36.58 (±29.68)</td>
<td>30.75 (±29.5)</td>
<td>25 (±27.81)</td>
<td>20 (±22.73)</td>
</tr>
<tr>
<td>ADL’s</td>
<td>29.99 (±16.88)</td>
<td>27.5 (±17.59)</td>
<td>31.25 (±28.82)</td>
<td>29.57 (±27.04)</td>
</tr>
<tr>
<td>EWB</td>
<td>24.16 (±8.28)</td>
<td>22.92 (±10.06)</td>
<td>24.58 (±19.67)</td>
<td>20.41 (±13.80)</td>
</tr>
<tr>
<td>Stigma</td>
<td>16.28 (±11.49)</td>
<td>12.52 (±9.76)</td>
<td>25.03 (±31.48)</td>
<td>20.64 (±33.23)</td>
</tr>
<tr>
<td>Social Support</td>
<td>3.33 (±5.83)</td>
<td>6.67 (±11.65)</td>
<td>10.0 (±10.25)</td>
<td>13.33 (±14.79)</td>
</tr>
<tr>
<td>Cognitive</td>
<td>25.02 (±16.66)</td>
<td>21.28 (±15.93)</td>
<td>32.53 (±20.80)</td>
<td>28.77 (±19.13)</td>
</tr>
<tr>
<td>Communication</td>
<td>29.99 (±24.90)</td>
<td>30.0 (±21.94)</td>
<td>27.5 (±21.17)</td>
<td>24.17 (±21.31)</td>
</tr>
<tr>
<td>BD</td>
<td>28.35 (±26.71)</td>
<td>20.83 (±17.23)</td>
<td>18.33 (±18.33)</td>
<td>17.49 (±11.44)</td>
</tr>
</tbody>
</table>

**H-Reflex**

In six subjects (N=3 control, N=3 exercise), the H-reflex was elicited pre and post testing. The maximum H/M ratios of all six subjects are depicted in table 6. Analysis of variance with repeated measures (ANOVA) was conducted to determine differences between the two groups and also differences at week 0 compared to week 4. The ANOVA revealed no group x time interaction (p=.673).

**Table 6. Maximum H/M ratios of six subjects**

<table>
<thead>
<tr>
<th></th>
<th>Exercise Group Pre</th>
<th>Exercise Group Post</th>
<th>Control Group Pre</th>
<th>Control Group Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum H/M ratio</td>
<td>.14 (± .05)</td>
<td>.20 (± .06)</td>
<td>.09 (± .08)</td>
<td>.12 (± .07)</td>
</tr>
<tr>
<td>(Mean ± SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The H-reflex and M-wave recruitment curve of one exercise group subject pre testing is depicted in Figure 15 and post testing is depicted in Figure 16. An analysis via paired sample t-test with Bonferroni adjustments showed that the individuals’ H-reflex improved significantly from pre to post testing (p=0.018) and the M-wave improved significantly from pre to post testing (p=0.040).

Figure 15. H-reflex and M-wave recruitment curve before exercise intervention.
Figure 16. H-reflex and M-wave recruitment curve after exercise intervention.
CHAPTER V
DISCUSSION

There have been numerous studies which have examined the benefits of exercise, including aerobic, resistance and balance training on motor symptoms in PD. However there is still little consensus about the mode, duration, intensity or frequency of the exercise that is required. Furthermore, few studies have examined how cycling affects balance in individuals with PD. This study is unique because it uses an interval active assisted cycling paradigm, that to our knowledge has never been used before.

Motor Function

This study showed a significant improvement in overall UPDRS scores of the exercise group before the training program compared to after the training program. We also showed a significant improvement in all the individual components, except gait, of the UPDRS scores. This study also showed improvements in posture tremor in the exercise group. These results are interesting in that a lower body exercise improves upper body motor function, lower body motor function, bradykinesia and posture.

Previous studies have shown improvements in UPDRS scores in subjects with PD. A four week body weight supported treadmill training program showed significant improvements in UPDRS scores compared to a program of physical therapy (Miyai, et al., 2000). The mechanism remains unknown but it is postulated that the improvements can be due to central pattern generators (Calancie et al., 1994; Wickelgren, 1998). It can also be postulated that the improvements in the UPDRS scores were due to the more work individuals with PD were able to perform than in the physical therapy program.

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This information can be related to the current study due to the fact that our subjects were able to perform more work with the help of the motor of the bike. A six week intensive treadmill training program also showed improvements in UPDRS scores (Herman, et al., 2007). Again the mechanism for the improvements are unknown but it was postulated that possibly the treadmill provided an external rhythm that compensated for the defective internal rhythm of the basal ganglia. It was also postulated that the treadmill training (task repetition) may have induced a motor learning effect. These theories of mechanisms of improvement can be carried over to the current study. The rhythmic cycling of the bike could have produced a motor learning effect that helped with the improvements of the UPDRS scores.

On the other hand the current study showed no improvements in resting and kinetic tremors in the exercise group. This could be due to the low values of the tremor scores signifying that the individuals in this study do not have bad tremor symptoms. If the tremor values are low to begin with than there is very little room for overall improvement.

**Balance**

This study showed no significant improvements in the exercise group compared to the control group in the Berg balance scale or in the Biodex Balance System SD tests. There were also no significant improvements in balance in the exercise group before the exercise intervention compared to after the exercise intervention. This data does agree with a couple previous studies (Ashburn et al., 2007; Toole, Maitland, Warren, Hubmann, & Panton, 2005) but it still conflicts with the other studies that have been done.
Research has shown conflicting results in balance gains in subjects with Parkinson’s disease. After a six week weight treadmill training program there was an improvement in the Sensory Orientation Test (SOT) but no improvement in the Berg balance scale (Toole, et al., 2000) but another study showed an increase in the Berg balance scale after an eight week incremental speed treadmill training program (Cakit, Saracoglu, Genc, Erdem, & Inan, 2007). There were no improvements in the Berg balance scale after a six week physiotherapy program (Ashburn, et al., 2007) but there was an increase in the Berg balance scale after a ten week Tai Chi program (Hackney, Kantorovich, Levin, & Earhart, 2007).

The mechanisms for the improvements in the above studies still are unknown. It could be postulated that postural stability gains could be due internal generation of movement (Hackney & Earhart, 2010). In other words studies that have individuals producing the movement themselves show gains in balance, unlike the current study in which the motor produced a majority of the movement for the individuals. Another possible explanation for these findings is that previous studies that reported improvements in balance have utilized upright exercises, whereas our subjects participated in seated cycling.

**Parkinson’s Disease Questionnaire (PDQ)**

In this study we showed no significant improvements in PDQ scores between the exercise group and control group. We also showed no significant improvements in PDQ scores in the exercise group before the training program compared after the training program. Another study showed no significant improvements in the overall PDQ score
of PD subjects after a seven week cycling program or a seven week physiotherapy program (Burini, et al., 2006)

A reason behind the PDQ scores not changing could be due to the timing the PDQ is given. A study looking at validation of the PDQ showed that 53% of individual’s responded the same and 38.6% of the individual’s responded worse (Peto, Jenkinson, & Fitzpatrick, 1998). The reasoning for no substantial changes occurring for the better (or worse) in the scores was the short time period within taking the PDQ (four months) (Peto, et al., 1998). This can be related to the present study since we only allowed for four weeks between the two time periods that the PDQ was given to the individual’s.

Another important factor in the findings of this current study is that even though UPDRS scores did significantly improve there was no improvement in the subject’s quality of life. This could be due to that the PDQ and the different clinical scales are designed to assess different aspects of PD (Peto, et al., 1998). It can also be stated that in the current study that even though quality of life did not significantly improve it did not significantly decrease either, which is an important factor since Parkinson's disease is such a progressive disease.

**H-Reflex**

This study showed that the H-max/M-max ratio in PD subjects before testing was .14 ±.05 and is lower than the normal value of 0.5 (Kamen & Gabriel, 2010). Even though after the exercise program, the H-max/M-max ratio did not significantly improved for the exercise group, the ratio did get better and approached the normal level. These improvements are possibly due to an increase excitability of the motor neuron pool in PD
subjects (McLellan, 1973). The overall results could possibly be due to an adaptive plasticity effect of the central nervous system (Wolpaw & Tennissen, 2001).

By stimulating the H-reflex, adaptive plasticity of the central nervous system can be examined (Wolpaw & Tennissen, 2001). A further issue would be the extent and significance of the short-term H-reflex changes that are seen during different types of movement (Zehr, 2002). It can be stated that by using the H-reflex, changes in the human reflex pathways and the plasticity of the neuromuscular system can be evaluated.

Previous studies have shown an increase H-max/M-max ratio in PD subjects (Delwaide, 1984; McLellan, 1973), while another study has shown a decrease in H-max/M-max ratio in PD subjects (Bathien & Rondot, 1977). Yet, some studies have shown that the H-reflex recruitment curve and the H-max/M-max ratio have not shown any significant differences between normal and PD subjects (Dietrichson & Sorbye, 1971; Hoffmann, 1963). This ambiguous data can be due to stimulus duration, body position, muscle relaxation, severity of disease and certain symptoms associated with PD.

**Summary and Conclusions**

Few studies have investigated the effect of a cycling program on balance, motor function, h-reflex sensitivity and quality of life in individuals with Parkinson’s disease. In the present study, UPDRS and postural tremor was improved following a four week interval active-assisted cycling program. The mechanisms that are responsible for the improvements are still unknown. It can be postulated that the rhythmic cycling helped produce a motor learning effect that were responsible for the improvements in the UPDRS scores.
In the present study there were no improvements in balance or the quality of life in individuals with Parkinson’s disease. Previous studies that reported improvements in balance have utilized upright exercises, whereas our subjects participated in seated cycling. Other explanations for not seeing improvements are the variability of the symptoms and disease state of the individuals in the current study.

Future directions of this study would be to look at a longer training program to determine the duration of exercise that would show the most improvements in motor function and balance in individual’s with PD. Another future direction would be to reduce the variability of the subjects by having inclusion criteria of certain symptoms (balance or tremor) of PD. A last future direction would be to compare the interval active-assisted paradigm to another training program to determine which mode of exercise produces the greatest improvements in symptoms of PD.

**Limitations**

There are several limitations in this study. First, there was no follow-up testing session’s right after exercise and in the few weeks following the exercise training program. This would help to determine how long the effects of the training program would ultimately last in an individual with Parkinson’s disease. Second, there was a wide variety of PD symptom severity. This variability resulted in a large standard deviation in the dataset and contributed to the lack of significant improvement between pre and post tests. Future studies should narrow the inclusion criteria of PD subjects to help control for this variability. Finally, the study had the PD subjects “ON” their medications for testing and training.
APPENDICES
APPENDIX A

LETTER OF INFORMED CONSENT
Appendix A

Letter of Informed Consent

CONSENT TO PARTICIPATE AS A VOLUNTEER IN A RESEARCH STUDY

TITLE: Effects of interval active-assisted cycling on balance in individuals with Parkinson’s disease.

Principal Investigator: Emily Fickes, MS

You are being invited to participate in a research study. This consent form will provide you with information on the research project, what you will need to do, and the associated risks and benefits of the research. Your participation is voluntary. Please read this form carefully. It is important that you ask questions and fully understand the research in order to make an informed decision. You will receive a copy of this document to take with you.

PURPOSE
The purpose of this study is to determine whether multiple sessions of interval active-assisted cycling is an effective way to improve balance, motor function and lower body reflexes in individuals with Parkinson’s disease.

PROCEDURES
We are looking for individuals 50-79 years of age with mild to moderate idiopathic Parkinson’s disease. If you chose to participate then you will be asked to visit the lab for twelve sessions over a four week period (three times per week). You will then be randomly placed into one of two groups: 1) control (no exercise) or 2) interval active-assisted cycling. At the first session, your motor function, balance and lower body reflexes
will be tested. During the remaining sessions, you will complete a 5 minute cycling warm-up session followed by 30 minute cycling exercise and finishing with a 5 minute cycling cool-down. If you are assigned to the control group you will be required to report to the lab only on testing days and will not complete any exercise. Assessments will be repeated every two weeks during the study.

**BENEFITS**

The potential benefits of participating in this study may include improved movement and/or balance for a period of time after the sessions. Furthermore, your participation in this study will help us to better understand how interval active-assisted cycling can be used for rehabilitation in Parkinson’s disease.

**RISKS AND DISCOMFORTS**

There are risks or discomforts associated with this study such as muscles soreness and skin tingling. Also as with any exercise session there could be a risk for a heart attack. Every effort will be made to minimize risks using information from your medical health survey. If you experience any sensation that is unusual or uncomfortable, please tell the staff and they will stop the session.

There is a risk of falling since some of the research involves standing or moving around the room. To minimize this risk, two research assistants will be with you at all times and precautions will be taken to ensure your stability. We will also transport you in a wheelchair, if necessary, for your safety.

Medical treatment by the University Health Center is provided only to currently registered students. Please be advised that for all other injuries, emergency services will be called for those occurring on the Kent State University campus. You or your medical insurance will be billed for this service. No other medical treatment or financial compensation for injury from participation in this research project is available.
PRIVACY AND CONFIDENTIALITY
Your study related information will be kept confidential within the limits of the law. Any identifying information will be kept in a secure location and only the researchers will have access to the data. Research participants will not be identified in any publication or presentation of research results; only aggregate data will be used. Your research information may, in certain circumstances, be disclosed to the Institutional Review Board (IRB), which oversees research at Kent State University, or to certain federal agencies. Confidentiality may not be maintained if you indicate that you may do harm to yourself or others.

COMPENSATION
Individuals in the exercise group will receive a gift card for $10 per training week ($40 at completion of study). Individuals in the control group will receive $5 per testing session ($15 at completion of study).

VOLUNTARY PARTICIPATION
Taking part in this research study is entirely up to you. 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. You will be informed of any new, relevant information that may affect your health, welfare, or willingness to continue your study participation.

CONTACT INFORMATION
If you have any questions or concerns about this research, you may contact Emily Fickes, MS at 330.806.2581. This project has been approved by the Kent State University Institutional Review Board. If you have any questions about your rights as a research participant or complaints about the research, you may call the IRB at 330.672.2704.
CONSENT STATEMENT AND SIGNATURE

I have read this consent form and have had the opportunity to have my questions answered to my satisfaction. I voluntarily agree to participate in this study. I understand that a copy of this consent will be provided to me for future reference.

________________________________  _____________________
Participant Signature     Date
APPENDIX B

UNIFIED PARKINSON’S DISEASE RATING SCALE
Appendix B

Unified Parkinson’s Disease Rating Scale

III. MOTOR EXAMINATION

18. Speech
0 = Normal.
1 = Slight loss of expression, diction and/or volume.
2 = Monotone, slurred but understandable; moderately impaired.
3 = Marked impairment, difficult to understand.
4 = Unintelligible.

19. Facial Expression
0 = Normal.
1 = Minimal hypomimia, could be normal "Poker Face".
2 = Slight but definitely abnormal diminution of facial expression.
3 = Moderate hypomimia; lips parted some of the time.
4 = Masked or fixed facies with severe or complete loss of facial expression; lips parted 1/4 inch or more.

20. Tremor at rest (head, upper and lower extremities)
0 = Absent.
1 = Slight and infrequently present.
2 = Mild in amplitude and persistent. Or moderate in amplitude, but only intermittently present.
3 = Moderate in amplitude and present most of the time.
4 = Marked in amplitude and present most of the time.

21. Action or Postural Tremor of hands
0 = Absent.
1 = Slight; present with action.
2 = Moderate in amplitude, present with action.
3 = Moderate in amplitude with posture holding as well as action.
4 = Marked in amplitude; interferes with feeding.

22. Rigidity
0 = Absent.
1 = Slight or detectable only when activated by mirror or other movements.
2 = Mild to moderate.
3 = Marked, but full range of motion easily achieved.
4 = Severe, range of motion achieved with difficulty.
23. **Finger Taps** (Patient taps thumb with index finger in rapid succession.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

24. **Hand Movements** (Patient opens and closes hands in rapid succession.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

25. **Rapid Alternating Movements of Hands** (Pronation-supination movements of hands, vertically and horizontally, with as large an amplitude as possible, both hands simultaneously.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

26. **Leg Agility** (Patient taps heel on the ground in rapid succession picking up entire leg. Amplitude should be at least 3 inches.)
0 = Normal.
1 = Mild slowing and/or reduction in amplitude.
2 = Moderately impaired. Definite and early fatiguing. May have occasional arrests in movement.
3 = Severely impaired. Frequent hesitation in initiating movements or arrests in ongoing movement.
4 = Can barely perform the task.

27. **Arising from Chair**
(Patient attempts to rise from a straightbacked chair, with arms folded across chest.)
0 = Normal.
1 = Slow; or may need more than one attempt.
2 = Pushes self up from arms of seat.
3 = Tends to fall back and may have to try more than one time, but can get up without help.
4 = Unable to arise without help.

28. Posture
0 = Normal erect.
1 = Not quite erect, slightly stooped posture; could be normal for older person.
2 = Moderately stooped posture, definitely abnormal; can be slightly leaning to one side.
3 = Severely stooped posture with kyphosis; can be moderately leaning to one side.
4 = Marked flexion with extreme abnormality of posture.

29. Gait
0 = Normal.
1 = Walks slowly, may shuffle with short steps, but no festination (hastening steps) or propulsion.
2 = Walks with difficulty, but requires little or no assistance; may have some festination, short steps, or propulsion.
3 = Severe disturbance of gait, requiring assistance.
4 = Cannot walk at all, even with assistance.

30. Postural Stability (Response to sudden, strong posterior displacement produced by pull on shoulders while patient erect with eyes open and feet slightly apart. Patient is prepared.)
0 = Normal.
1 = Retropulsion, but recovers unaided.
2 = Absence of postural response; would fall if not caught by examiner.
3 = Very unstable, tends to lose balance spontaneously.
4 = Unable to stand without assistance.

31. Body Bradykinesia and Hypokinesia (Combining slowness, hesitancy, decreased arm swing, small amplitude, and poverty of movement in general.)
0 = None.
1 = Minimal slowness, giving movement a deliberate character; could be normal for some persons. Possibly reduced amplitude.
2 = Mild degree of slowness and poverty of movement which is definitely abnormal. Alternatively, some reduced amplitude.
3 = Moderate slowness, poverty or small amplitude of movement.
4 = Marked slowness, poverty or small amplitude of movement.
APPENDIX C

BERG BALANCE SCALE
Appendix C

Berg Balance Scale

Berg Balance Test

Name

Date

Location Rater

GENERAL INSTRUCTIONS
Please demonstrate each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.
In most items, the subject is asked to maintain a given position for specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.
Equipment required for testing are a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5 and 10 inches (5, 12.5 and 25 cm). Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item #12.
1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hands for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding.
( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted
If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit
5. TRANSFERS
INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cueing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays steady
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently and to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently >25 cm (10 inches)
( ) 3 can reach forward >12.5 cm safely (5 inches)
( ) 2 can reach forward >5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/ requires external support
9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right.
(Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only in 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cueing
( ) 0 needs assistance while turning

12. PLACING ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps >20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete >2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try
13. STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT)
Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding.
( ) 4 able to lift leg independently and hold >10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or >3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assist to prevent fall

ITEM DESCRIPTION SCORE (0-4)
1. Sitting to standing ______
2. Standing unsupported ______
3. Sitting unsupported ______
4. Standing to sitting ______
5. Transfers ______
6. Standing with eyes closed ______
7. Standing with feet together ______
8. Reaching forward with outstretched arm ______
9. Retrieving object from floor ______
10. Turning to look behind ______
11. Turning 360 degrees ______
12. Placing alternate foot on stool ______
13. Standing with one foot in front ______
14. Standing on one foot ______

TOTAL (maximum 56) ______
0–20, wheelchair bound
21–40, walking with assistance
41–56, independent
APPENDIX D

PARKINSON’S DISEASE QUESTIONNAIRE
Appendix D

Parkinson’s Disease Questionnaire

<table>
<thead>
<tr>
<th>Please tick one box on each line</th>
<th>Not at all</th>
<th>With help</th>
<th>On your own with difficulty</th>
<th>On your own easily</th>
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<tbody>
<tr>
<td><strong>Do you?</strong></td>
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<tr>
<td>1. Walk around outside?</td>
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<td>2. Climb stairs?</td>
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<td>3. Get in and out of a car?</td>
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<td>4. Walk over uneven ground?</td>
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<td>5. Cross roads?</td>
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<td>6. Travel on public transport?</td>
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<td>7. Manage to feed yourself?</td>
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<td>8. Manage to make yourself a hot drink?</td>
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<td>9. Take hot drinks from one room to another?</td>
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<td>10. Do the washing up?</td>
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<td>11. Make yourself a hot snack?</td>
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<td>12. Manage your own money when you’re out?</td>
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<td>13. Wash small items of clothing?</td>
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<td>14. Do your own housework?</td>
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<td>15. Do your own shopping?</td>
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<td>16. Do a full clothes wash?</td>
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<td>17. Read newspapers or books?</td>
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<td>18. Use the telephone?</td>
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<td>19. Write letters?</td>
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<td>20. Go out socially?</td>
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<td>21. Manage your own garden?</td>
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<td>22. Drive a car?</td>
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Forms Completed by:
Date Completed:
REFERENCES
REFERENCES


