THE EFFECTS OF BACKWARD CYCLING ON POSTERIOR PROTECTIVE STEPPING RESPONSES IN PEOPLE WITH PARKINSON DISEASE

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The Effect of Backward Cycling on Posterior Protective Stepping Responses in People with Parkinson Disease

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Abstract

The purpose of this study was to assess the effects of backward cycling on posterior protective stepping responses in people with Parkinson disease. Secondary aims were to assess changes in gait parameters, balance, and aerobic capacity and to assess the acceptability of backwards cycling as an intervention. Twenty-two people (18 males, 4 females) with a history of idiopathic Parkinson disease in Hoehn & Yahr stages II or III completed a 6-week backward cycling program. Each participant cycled for 30 minutes at a moderate intensity twice a week for 12 total sessions. Pre-test, post-test, and 1-month follow up assessments were completed. Data collected included the Mini-BESTest, 6 Minute Walk Test, posterior stepping response variables (number of steps, time to steady, and maximal excursion), and gait parameters in both the forward and backward directions (gait velocity, right and left step length, and right and left step width). Statistical analysis was performed to assess difference across time and within groups. A repeated measures ANOVA with Bonferroni post hoc analysis was used for normally distributed data. A Friedman ANOVA with a Wilcoxon signed-ranks post hoc test was used for non-normally distributed data. Significant within-group differences were shown in forward and backward gait velocity ($p = .017$, $p = .001$), forward right and left step length ($p = .011$, $p = .007$), number of steps during a posterior stepping response ($p = .019$), and the Mini-BESTest ($p = .003$). Pair-wise post hoc analysis revealed differences between baseline measurements and 1-month follow up in forward right and left step length ($p = .049$, $p = .039$), backward gait velocity ($p = .007$), number of steps during a posterior stepping response ($p = .013$), and the Mini-BESTest ($p < .001$). These results show that a backward cycling program is feasible and can have a positive effect on posterior protective stepping responses as well as quality of gait and balance.

Keywords: Parkinson disease, balance, gait, stepping responses, cycling

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The Effect of Backward Cycling on Posterior Protective Stepping Responses in People with Parkinson Disease

Parkinson disease (PD) is a progressive, neurodegenerative disorder characterized by the cardinal signs of bradykinesia, tremors, rigidity, and postural instability (Goodman & Fuller, 2015). People living with PD often experience recurrent falls, which can be detrimental to function and quality of life (Allen, Schwarzel, & Canning, 2012). Reactive stepping responses are commonly affected by the disease progression due to decreased limits of stability and bradykinetic movements (Horak, Dimitrova, & Nutt, 2005; Schoneburg, Mancini, Horak & Nutt, 2013). Medications are commonly used to manage the symptoms of PD; however, this approach has limited effects on stepping responses (de Kam et al., 2014), and in some cases, has been shown to worsen reactive stepping responses (Horak et al., 2005).

There are few studies assessing the effects of exercise on posterior stepping responses in people with PD. Two known studies investigating the outcomes of interventions on stepping responses in persons with PD have resulted in improved function, including increased limits of stability and quicker reaction times to perturbations. However, the studies either utilized specialized equipment for the actual intervention (Shen & Mak, 2012) or a high-frequency protocol in which repetitions of up to 230 were used (Jobges et al., 2014), decreasing their feasibility for use in the clinic or home. There are several studies which suggest that exercise improves mobility and balance in people with PD; however, no study specifically addresses or measures change in posterior stepping responses (Nadeau et al., 2017; Ridgel, Phillips, Walter, Discenzo, & Loparo, 2015; Uygur et al., 2015).

Electromyographic (EMG) studies have revealed similar muscle activation patterns between backwards cycling and posterior stepping responses (Chvatal, Torres-Oviedo,

Safavynia, & Ting, 2011; Eisner, Bode, Nyland, & Caborn, 1999). There are no known published studies assessing the effects of backwards cycling in people with PD. The purpose of this study was to assess the effect of backwards cycling on participant function, including posterior protective stepping responses, and to determine if backward cycling would be an acceptable form of intervention based on the number of adverse events and retention rate. The following primary objective was addressed: to determine if backward cycling has an effect on posterior protective stepping responses in people with PD. In addition, the following secondary objectives were addressed: (a) to determine if backward cycling significantly affects forward and backward gait parameters, balance, and aerobic capacity; and (b) to assess the acceptability of backwards cycling as an intervention through recording adverse events and retention rate.

Stationary bicycles are common in both physical therapy settings as well as in the community; therefore, this type of equipment is readily available and easy to access. If a backwards cycling exercise program can improve posterior protective stepping responses in people with PD, then results of this study may help guide clinicians to choose more appropriate, effective, and safe home program exercises for the PD population.

Literature Review

Parkinson Disease

Parkinson disease is the second-most common neurodegenerative disorder in the United States, affecting more than 800,000 adults (Goodman & Fuller, 2015). The number of people living with PD is expected to steadily rise to 1.06 million by 2030, 1.24 million by 2040, and 1.34 million by 2050 (Kowal, Dall, Chakrabarti, Storm, & Jain, 2012). In 2010, the disease carried a national economic burden of over $14.4 billion dollars (Goodman & Fuller, 2015), which is $8.1 billion higher than a comparable population without PD (Kowal et al., 2012).

Additionally, hip fractures resulting from falls carry an economic burden of $192 million per year in the United States; many falls occurring from a backward perturbation or during backward walking (Hackney & Earhart, 2009a) in the PD population. People with PD are more at risk for fractures due to a higher prevalence of osteoporosis and lower bone mineral density (Coomber, Alshameeri, Masia, Mela, & Parker, 2017) and also carry a higher mortality rate than the healthy population (Coughlin & Templeton, 1979). People with PD also have more risk of recurrent fractures due to the increased fall risk (Zuckerman, 1996). Parkinson disease becomes increasingly common with age and affects one in every 100 people over the age of 75 years (Goodman & Fuller, 2015). The combination of the motor deficits resulting from PD along with age-related changes of decreased muscle strength, impaired balance, and visual deficits can severely affect mobility (Christofoletti, McNeely, Campbell, Duncan, & Earhart, 2016).

The impact of PD also involves the caregiver, with over 40% of caregivers reported declining health as a result of the burden of care (Schrag, Hovris, Morley, Quinn, & Jahanshahi, 2006). Additionally, over 50% of caregivers reported depression due to their caregiving roles; it has been shown that depression is associated with higher caregiver burden and lower health-related quality of life (Martinez-Martin et al., 2007; Schrag et al., 2006). Certain common PD factors, including falls, have been correlated with increased caregiver burden. One major predictor of institutionalization, such as in a nursing home, is caregiver distress (Schrag et al., 2006). It can be inferred that alleviating the impact of PD on the caregiver can decrease their burden as well as improve health-related quality of life and delay institutionalization for the person living with PD.

Parkinson Disease and Falls

Recurrent falls are a problem for people with PD and can lead to injury, reduced activity levels, increased caregiver burden, and increased fear of falling (Allen et al., 2012). People with PD have a two-fold risk of falling compared to the healthy population and recurring fall rates have been shown to be high, with one study reporting 70% falling at least once a year and another reporting 87% experiencing at least one fall in 20 years (Allen et al., 2012; Ashburn, Stack, Pickering, & Ward, 2001; Hely, Reid, Adena, Halliday, & Morris, 2008). Falls in PD can have significant effects on quality of life due to fractures, hospitalizations, loss of functional ability, and activity restrictions (McVey et al., 2009). An analysis of Medicare claims showed that people with PD were 1.3 times more likely to sustain an injury from a fall that required medical attention and that these injuries drove up medical costs (Grimbergen, Munneke, & Bloem, 2004). In fact, in people with PD, 30% of emergency room admissions were trauma based, with falls being the most frequent cause (Martignoni et al., 2004). A retrospective study by Wielinski et al. (2005) reported that 21.6% of patients with PD who fell sustained a fracture and of those, 40.6% required surgery. Additionally, 65% of patients who fell sustained some type of injury other than a fracture, with 75.5% of this cohort needing health care services. People with PD are particularly vulnerable to backwards falls due to a smaller stability margin (Horak et al., 2005). Several reasons for increased risk for falls exist for the PD population, including poor postural responses, proprioceptive deficits, freezing of gait, and the decreased ability to dual task (Grimbergen, Munneke, & Bloem, 2004).

During a reactive stepping response, the time to initiate a step is normal in people with PD, however more time is required to reach maximum movement force. Additionally, the overall force production is reduced in people with PD due to bradykinesia. This results in a person with

PD not adequately being able to return their center of mass within their limits of stability, increasing the risk for a fall (Schoneburg et al., 2013). Another study resulted in a similar conclusion in that people with PD have a backward preponderance for falls following postural perturbations, as well as abnormal co-contraction of both the agonist and antagonist muscles in the legs and trunk (Grimbergen et al., 2004). McVey et al. (2013) reported that as the disease progresses from mild to moderate, posterior stepping responses also worsen, resulting in the need for more steps to recover balance and more inconsistency in choice of stepping foot.

Dopaminergic medication is frequently used to improve motor symptoms resulting from PD, however it has been shown that backwards stepping abnormalities are not improved by pharmacological management (de Kam et al., 2014). Bryant, Rintala, Hou, Lai, and Protas (2011) reported no statistically significant change in forward and backward gait speed, cadence, and stride length between people with PD off medications and on medications. All participants were either taking a carbidopa/levodopa or carbidopa/levodopa/entacapone combination. The dose of medications among the participants ranged from 100 to 300 mg, with a mean of 152.38 mg. A study by de Kam et al. (2014) focused on stepping responses and reported that people with PD had poorer stepping responses with forward and backward perturbations than healthy controls, and that the addition of dopaminergic medications did not improve these stepping responses. Grimberger et al. (2004) confirmed this finding, stating that postural reactions are particularly resistant to dopaminergic medications. In some cases, stepping responses actually worsened significantly on levodopa medication (Schoneburg et al., 2013), increasing the risk for falls and injury. Lastly, the use of levodopa and other dopaminergic medications can eventually lead to dyskinesias, which can compound any existing motor impairments, increasing risk for falls (Kleiner-Fisman et al., 2006).

Deep brain stimulation (DBS) has increased in frequency since its introduction in the 1990s and has shown to be most effective at alleviating levodopa-responsive symptoms such as tremor, on-off fluctuations, and dyskinesias (Weaver et al., 2009). Deficits in gait and balance, however, are least likely to be affected by DBS and in some cases, could worsen (Okun, 2012). Weaver et al. (2009) compared a group receiving dopaminergic medications to people receiving DBS and found that the DBS group had significantly more adverse events compared to the medicine group, including falls, gait disturbance, depression, and dystonia. Additionally, recent studies demonstrated that although DBS can have an immediate effect on motor symptoms in PD, there is then a gradual decline in the effectiveness on gait disturbances and postural instability (Potter-Nerger & Volkmann, 2013; St. George, Nutt, Burchiel, & Horak, 2010; van Nuenen et al., 2008). Due to the ineffectiveness of medications and DBS on improving postural instability, including stepping responses, interventions are needed to improve this reactive strategy to decrease risk for falls and injury.

Parkinson Disease Interventions

There exists a large range of interventions used in the clinic in order to address motor symptoms of PD, including treadmill training, general exercise, and dance. A meta-analysis on the effect of exercise and motor training in people with PD revealed that several types of interventions had a positive effect on balance; however, the effect was small and a conclusion could not be made on whether exercise could reduce falls in the PD population (Allen, Sherrington, Paul, & Canning, 2011). A recent systematic review of PD interventions to maximize physical function and minimize secondary complications found insufficient evidence to support the use of one approach due to the wide variety of interventions used (Tomlinson et al., 2014). This allows one to infer that not one intervention is superior over the other.

Strength training. It has been shown that people with PD have decreased muscle strength and power compared to a healthy population, which can lead to postural instability and falls (van der Kolk & King, 2013). Studies have shown positive effects of strength training in improving muscular strength and endurance (Corcos et al., 2013; Toole, Hirsch, Forkink, Lehman, & Maitland, 2000; van der Kolk & King, 2013), however evidence remains unclear on the effect of strength training on balance and falls (Cruickshank, Reyes, & Ziman, 2015).

Treadmill training. Treadmill training, either with use of a safety harness or without it, is a common intervention in rehabilitation settings. Its use with people with PD in the clinic has shown consistency in improvements with forward gait speed (Cakit, Saracoglu, Genc, & Erdem, 2007; Herman, Giladi, Gruendlinger, & Hausdorff, 2007; Herman, Giladi, & Hausdorff, 2008; Mehrholz et al., 2015) and stride length (Mehrholz et al., 2015; Miyai et al., 2002; Protas et al., 2005). Treadmill training has also demonstrated positive effects on outcome measures, such as the Unified Parkinson's Disease Rating Scale (UPDRS) (Ganesan, Sathyaprabha, Gupta, & Pal, 2014; Herman et al., 2007), Berg Balance Scale (Cakit, Saracoglu, Genc, & Erdem, 2007; Ganesan et al., 2014), and Dynamic Gait Index (Cakit et al., 2007). Most of the aforementioned outcome measures do not include reactive balance assessments nor a backwards walking component. Herman, Giladi, and Hausdorff (2008) reviewed 14 studies involving treadmill training and PD. None of the 14 studies assessed backwards walking or backwards stepping abilities. Additionally, only one study included backwards walking in the intervention (Protas et al., 2005); the rest of the studies only included a forward walking intervention. Several studies used the UPDRS as an assessment of motor function and while the UPDRS does include a postural stability assessment in the form of a posterior pull test, a total UPDRS score does not

give a sense of reactive abilities. One could score poorly on the postural stability section, and still rate highly on the overall test.

Only one study could be found which included a backwards walking assessment. Tseng, Yuan, and Jeng (2015) looked at the effect of treadmill training on backwards walking in people with PD and found significant improvements in backward gait velocity and stride length, despite the intervention being only forward walking. To this date, no known studies have assessed the effectiveness of treadmill training and stepping responses. Forward walking treadmill training has resulted in increased stride length; however, a past study has concluded that effective stepping responses are independent of the length of the step (King, Luchies, Stylianou, Schiffman, & Thelen, 2005); therefore, no conclusion can be made on the effects of treadmill training on posterior stepping responses.

Dance. There have been several studies assessing the effect of dance on gait and balance in people with PD. One recent systematic review assessed dance as an intervention for PD and reviewed a total of five studies. The authors concluded that no meaningful change was experienced with forward gait velocity; there was no mention on backward gait within this review (Sharp & Hewitt, 2014). Another systematic review looked at Argentine tango and PD and reviewed 13 studies. Of these 13 studies, four included a backward gait assessment. Positive results in backward gait were seen after a dance program in people with PD, however there was no significant or clinically meaningful change seen in backward gait velocity in three of the four studies which included a backwards gait component (Duncan & Earhart, 2014; Hackney & Earhart, 2009b; Hackney & Earhart, 2009c); Hackney and Earhart (2009b) did report significant difference in backward stride length. Hackney, Kantorovich, Levin, and Earhart (2007) compared a tango program to a more traditional strength/flexibility exercise program and found

no significant differences between groups. No specific stepping response measure was used in any of the mentioned studies. Stepping responses were instead included as a subsection within the Mini-BESTest, therefore no conclusion can be made on the effectiveness of dance on stepping responses.

Cycling. Several studies have reported the positive effects of a cycling exercise program on motor function in people with PD (Nadeau et al., 2017; Ridgel et al., 2015; Uygur et al., 2015). Improvements after a cycling regime included improved aerobic capacity, walking speed, cadence, and improvement of motor function, as measured by the UPDRS Motor III subsection (Nadeau et al., 2017; Ridgel et al., 2015; Ridgel, Vitek, & Alberts, 2009). Nadeau et al. (2017) reported improvements in forward gait speed and walking cadence however backwards gait and stepping responses were not measured in this study. Most cycling studies did not specifically focus on assessing posterior stepping responses, but instead, the assessment was embedded within the UPDRS Motor III as part of the total score. This makes it impossible to determine how effective an intervention was at improving this specific movement.

One study by Uygur et al. (2014) included a stepping test in their study in the form of the 4-Square Step Test (4SST). The 4SST requires quick directional changes as it requires participants to step forward, backward and sideways in consecutive fashion (Dite & Temple, 2002). The cycling group demonstrated significant improvements in walking velocity and the 4SST, supporting the notion of transfer of cycling exercise to stepping ability in people with PD (Uyger et al., 2014). The 4SST, however, is a test of proactive stepping responses, therefore, there continues to be lack of evidence regarding exercise and posterior, or reactive, stepping responses. To this date, no known interventional studies exist which focuses on the effect of cycling on backwards gait and stepping responses. In the work by Barroso et al. (2014), the

researchers concluded there are shared neuromuscular mechanisms between cycling and walking due to similar muscle synergies. Clinically, this may mean that cycling exercises can transfer to locomotion abilities.

Backwards cycling. Only a few studies could be found pertaining to backwards cycling, all involving healthy adult samples. Cycling in general has been shown to have similar neural control as walking with similar central pattern generator-like output (Zehr, Hundza, Balter, & Loadman, 2009). Two studies assessed the recruitment pattern of the muscles in the lower extremity during backward cycling. Results of both studies were similar in that they showed greater rectus femoris activation in the early quadrant of pedal revolution, followed by activation of the medial and lateral hamstrings in the later quadrants of pedal revolution (Eisner et al., 1999; Neptune, 2000). An EMG study of normal backward stepping responses revealed early activation of the rectus femoris, followed by relaxation, with introduction of the biceps femoris and semitendinosus (Chvatal et al., 2011). Hence, there seems to be similarities of muscle recruitment patterns between backward cycling and backward stepping, giving this intervention potential in terms of improvements in posterior stepping responses. Another study comparing forward and backward cycling found that backward cycling produced higher electromyography (EMG) readings (Zehr et al., 2009).

A cycling program is feasible to carry out in the community (McGough et al., 2016) and although backwards cycling requires greater muscle involvement, in terms of amplitude and duration, it does not require more metabolic demand compared to forward cycling (Bressel, Heise, & Bachman, 1998). This can support the feasibility of a cycling program in the clinic setting. There are no known interventional studies assessing the effects of backwards cycling in either the healthy population or people with PD.

Reactive stepping responses. Few known articles include interventions and assessments focused on reactive stepping responses in people with PD. A study by Protas et al. (2005) included repetitive task-specific, compensatory step training in which individuals with PD were asked to step to recover balance after a perturbation. Perturbations were presented in all directions (forward, backwards, and to each side) and outcomes included a gait analysis and a step test. The step test required the person to step up and down an 8.8 cm step for five repetitions as quickly as possible. Significant improvements were demonstrated in the step test as well as gait speed and cadence. The step test, however, is a proactive balance test, therefore difficult to ascertain if the intervention improved reactive posterior stepping responses. Furthermore, only forward walking was assessed during the gait analysis, therefore no conclusion can be made on improvements in the backward direction.

Jobges et al. (2004) also included a reactive stepping intervention and assessment. The intervention consisted of repetitive pulls and pushes in the backward and sideways directions. The participants completed two 20-minute sessions each day with approximately 180 to 230 perturbations per session. The intervention group showed significant increase in compensatory step length and decreased initiation time to step, however the twice a day schedule (which would be difficult to reproduce in the clinic) with the high number of repetitions decreases the feasibility of this intervention.

Barajas and Peterson (2018) assessed reactive step training in people with PD and found improvements in the margin of stability however the intervention utilized a hydraulic force platform, which would not be feasible in the home or traditional clinic setting. Van Ooteghen, Frank, and Horak (2017) also utilized a hydraulic platform and safety harness, again limiting its feasibility for use in the home or clinic. Additionally, the participants were instructed to “avoid

stepping if possible". (Van Ooteghen, Frank, & Horak, 2017, p. 3). This may not fully reflect an actual protective stepping response.

Intervention summary

Most of the aforementioned interventions focused on forward movement directions, therefore effectiveness of these interventions in improving backwards stepping is unable to be determined. A meta-analysis completed by Allen, Sherrington, Paul, and Canning (2011) assessed the effect of exercise on balance and falls with people with PD and revealed that all included studies in the analysis did not include a backwards gait component, nor a stepping response component. Dance interventions do include multi-directional stepping, however its effectiveness on posterior stepping responses is still unknown. No other known studies have specifically focused on interventions to improve protective stepping responses in people with PD. Several studies focused on improved gait parameters, however low to moderate correlations between gait and stepping responses has been shown and that no consistency between direction of gait and direction of postural responses exist. This may infer that gait deficits in a particular direction is not predictive of postural responses in that direction. (Sutter, Seidler, Duncan, Earhart, & McNeely, 2017).

Exercise and Safety in the Home

Exercise adherence at home is an important aspect of rehabilitation, however perceived barriers can decrease compliance among individuals. Researchers found that perceived barriers to exercise can be predictive of exercise compliance (Ellis et al., 2013); therefore, one focus for therapists should be to minimize these perceived barriers. Several perceived barriers to exercise have been identified in the PD population, including fear of falling, difficulty carrying out the

exercise, and being tedious for others (Ellis et al., 2013; Pickering, Fitton, Ballinger, Fazakarley, & Ashburn, 2012).

Treadmill training is a common intervention in the clinic setting to improve motor symptoms with people with PD; however, there are limited studies confirming the safety of use of a treadmill in the home or community by people with PD (Bello et al., 2013; Canning et al., 2012; Carda et al., 2012; Nadeau, Pourcher & Corbeil, 2013). Most studies showing no adverse effects with use of a treadmill utilized either a safety harness (Bello et al., 2013; Carda et al, 2012) or limited their participants to those in the Hoehn and Yahr (H&Y) PD stages of I and II (Canning et al, 2012; Nadeau, Pourcher, & Corbeil, 2013). A safety harness would likely not be a feasible option for home use. For those people living with later stages of PD who are starting to experience postural instability (Stages III & IV), independent treadmill training in the home and community may not be a safe option for motor training. A pilot study involving treadmill training which included five people with PD in H&Y stages II or greater, resulted in four falls and seven near falls, for a total of 11 adverse events (Skidmore et al., 2008). For safety reasons, there is a need for alternative exercises for people in later stages of PD to safely perform at the home and community to improve balance and stepping responses outside of the clinic.

A meta-analysis on the effects of exercise and motor training in people with PD revealed that several types of interventions had a positive effect on balance (Allen, Sherrington, Paul, & Canning, 2011); however, interventions mostly consisted of exercises in standing (e.g., treadmill training, highly challenging balance training, walking over ground), which may decrease its safety in the PD population. Stationary cycling has been shown to be both feasible and safe for people with PD (McGough et al., 2016); therefore, riding a stationary bike may be more appropriate for the home and community setting. Stationary cycling can also address identified

perceived barriers to exercise, including fear of falling and being less tedious for caregivers. Backwards stationary cycling could be a safe option for people with PD to exercise as it can allow a person to improve postural instability in a position that does not increase fall risk.

Method

Study Design

This was a quasi-experimental, pretest-posttest single group design pilot study with one-month follow-up. The study was approved by both the University of Indianapolis Human Research Protections Program (HRPP) and the Midwestern University Office of Research and Sponsored Programs (ORSP), and was conducted at the Midwestern University's Physical Therapy Institute.

Participants

Participants were recruited from local neurologic rehabilitation centers, Parkinson disease-specific exercise groups, and Parkinson disease-specific support groups. To be included in the study, individuals had to meet the following inclusion criteria: (a) be between the ages of 20 and 80 years, (b) have been diagnosed with idiopathic PD, (c) be in stages II or III of the Hoehn and Yahr (H&Y) PD Staging Scale (Goetz et al., 2004), (d) be able to walk unassisted without an assistive device for at least 20 feet, (e) not currently enrolled in physical therapy, and (f) be able to understand and speak English. Exclusion criteria were (a) the presence of PD-dementia (PD-D), as assessed by a score of less than 21/30 on the Montreal Cognitive Assessment (MoCA) (Dalrymple-Alford et al., 2010), (b) diagnosis of parkinsonism or a Parkinson plus syndrome, (c) the presence of another neurologic disorder, and (d) any other injury or issue which would limit the ability to participate in any capacity, including pregnancy. Hoehn and Yahr staging was determined by the administration of the Movement Disorder

Society Unified Parkinson's Disease Rating Scale Part III: Motor Examination (MDS-UPDRS III).

Data Collection

Data were collected at baseline, within one-week of the conclusion of the 6-week intervention (one-week post-test), and one-month post-intervention (one-month follow-up) by trained research assistants not involved with the intervention. The MoCA and UPDRS-III data were collected to determine study eligibility and were performed by the primary investigator (S. O.). All data were input into a Microsoft Excel spreadsheet under a unique study identification number. Demographic and past medical history related to PD were collected at baseline including age, gender, number of years since diagnosis, and medication schedule. In addition, the following outcomes data were collected at baseline: forward and backward gait analysis measurements, including gait velocity, step length, and step width, posterior stepping response (PSR) measures, including the maximal stepping excursion (PSR-MSE), time to steady (PSR-TTS), and number of steps (PSR-StepNo) to steady, Mini-Balance Evaluation Systems Test (MBT), and the six-minute walk test (6MWT). With the exception of the MBT and 6MWT, three trials of each outcome variable were conducted and the mean score was calculated. All outcome measures were reassessed within one week following the 6-week intervention program, and at a one-month follow-up, except for the MoCA and UPDRS-III.

All data were entered into an electronic data collection sheet on a password-protected laptop. The primary investigator and research assistants were the only individuals with access to the laptop and password. Data were recorded using a randomly assigned unique identification number linked to each participant. The only link between the identification number and the participant's name was kept on a document created on a password-protected computer in a file

location separate from the data file. The laptop was kept in a locked office when not in use. The primary investigator had possession of the office key.

Operational Variables

Participants were designated as H&Y stage II if they had bilateral involvement and were able to recover balance during the pull test (embedded within the MDS-UPDRS III) in two steps or less. Participants were designated as H&Y stage III if there was mild to moderate involvement and three or more steps were required, or assistance was needed to recover from the pull test. Posterior stepping responses was defined as stepping responses measured during administration of reactive postural responses within the MBT. Data collected related to posterior stepping responses was time to steady, maximal stepping excursion, and number of steps needed to steady. An adverse event was defined as any negative result of the intervention, including any injury or medical event directly related to the intervention.

Instruments

Montreal Cognitive Assessment. The MoCA is a brief, validated instrument for mild cognitive impairment and tests various cognitive abilities including executive function, attention, and memory (Gill, Freshmen, Blender, & Ravina, 2008). The MoCA has been shown to be a valid and reliable tool for the screening of cognitive impairments in people with PD, with good intrarater and interrater reliability (ICC = .79 and .81, respectively) and good convergent validity with a neuropsychological battery (r = .72) (Gill et al., 2008). The MoCA has also been shown to be able to detect PD-D with a cut-off score of less than 21/30. (Dalrymple-Alford et al., 2010).

Movement Disorder Society Unified Parkinson's Disease Rating Scale Part III. The MDS-UPDRS III is a comprehensive, clinical rating scale for people with PD and is the most widely used PD-specific measure to assess both motor and non-motor functions (Goetz et al.,

2008). Section III of the MDS-UPDRS is the motor examination section and can be used to determine the H&Y stage of an individual with PD (Scanlon, Katzen, Levin, Singer, & Papapetropoulos, 2007). It has demonstrated excellent test-retest reliability in both the total score and for the motor subsection score only (ICC = .92 and .90, respectively) (Siderowf et al., 2002). This measure has been shown to have strong concurrent validity with the original UPDRS scale (r = .96) as well as high internal consistency (α = .79 to .93) (Goetz et al., 2008).

Posterior stepping responses. Posterior stepping responses were measured during administration of the MBT subsection of reactive postural control, in which the push and release test is used. The push and release test has been shown to hold its sensitivity over repeated trials (Jacobs, Horak, Tran, & Nutt, 2006) and it has been shown to be more accurate in identifying fallers than the pull test (Valkovic, Brozova, Botzel, Ruzicka, & Benetin, 2008). It also has good interrater reliability (ICC = .84) (Jacobs et al., 2006). The variables collected during the posterior stepping response were the maximal stepping excursion (PSR-MSE), the number of steps needed to steady (PSR-StepNo), and the time to steady (PSR-TTS). In the past, stepping responses have been measured by use of force plates and motion analysis systems. The force plates center of pressure changes and the motion analysis system could capture data such as step length and step height (McVey et al., 2009). One recent study looked at maximum step length, as measured by the Maximum Step Length Test (MSLT), and measured the stepping distance by a measuring tape (Duncan, McNeely, & Earhart, 2017). In this study, the maximal stepping excursion during the posterior stepping response (PSR-MSE) was measured by a measuring tape. Time to steady was measured in seconds and the number of steps was measured by visual counting.

GAITRite®. The GAITRite® system is a portable walkway used for gait analysis to collect objective data on spatiotemporal gait parameters (Bilney, Morris, & Webster, 2003). The

GAITRite® system has good to excellent test-retest reliability (ICC = .79 to .98) (van Uden & Besser, 2004), excellent concurrent validity with paper-and-pencil gait analysis methods on spatial measures (right step length ICC = .97; left step length, ICC = .99), and excellent concurrent validity with video-based methods on temporal measures in healthy populations (right step time ICC = .97; left step time ICC = .95) (McDonough et al., 2001). This system also demonstrated good test-retest reliability for gait speed, cadence, and stride length (ICC = .92 to .97).

Mini-Balance Evaluation Systems Test. The MBT is a 14-item comprehensive balance measure that assesses four systems of balance: anticipatory postural adjustments, reactive postural responses, sensory orientation, and dynamic gait (Duncan et al., 2012). In a review of psychometric properties of the MBT, it demonstrated good-to-excellent criterion validity with the BESTest (r = .96), the Berg Balance Scale (r = .79 to .94), the Brief BESTest (r = .94) and the Fullerton Advanced Balance Scale (ρ = .87) (Di Carlo, Bravini, Vercelli, Massazzi, & Ferriero, 2016). It also demonstrated moderate concurrent validity with the activities-specific balance confidence scale (r = .53 to .66) and moderate-to-high correlation with the timed up and go test (r = -.66 to -.89). It has excellent test-retest reliability (ICC = .92 to .98) and interrater reliability (ICC = .86 to .99). The MBT has an established minimal detectable change (MDC) score (3.5 points) as well as a minimal clinically important difference (MCID) value (4 points) (Di Carlo, Bravini, Vercelli, Massazza, & Ferriero, 2016).

Six-minute walk test. The 6MWT is a submaximal test of endurance which measures the distance a person can walk in six minutes. It has excellent test-retest reliability for people with PD (ICC = .96) and has an established MDC value for PD of 82 meters (Steffen & Seney, 2008). Construct validity has been demonstrated in patients with heart failure (r = .63 to .79) (Demers,

McKelvie, Negassa, & Yusuf, 2001), however, no known studies have established validity of the 6MWT with the PD population.

Procedures

Recruitment. Participants were recruited using a combination of convenience and snowball sampling. Recruitment locations were local neurologic rehabilitation centers, Parkinson disease-specific exercise groups, and Parkinson disease-specific support groups. Recruitment methods included informational emails and phone calls (Appendix A). The informational emails had general information regarding the study, inclusion criteria, and instructions to contact the primary investigator for any questions or to express interest in the study. Potential participants contacted the primary investigator directly by phone or email.

Eligibility determination. All interested participants were screened by phone or email to determine if preliminary criteria for the study were met, including diagnosis of PD, the ability to walk without assistance for 20 feet, and the absence of any other neurologic condition or injury. A standard script with questions was used (Appendix B). If interested individuals did not meet study criteria, they were informed of this during the phone call or email and no follow-up appointment was made. All interested individuals who met the preliminary inclusion criteria during eligibility determination were scheduled a baseline testing appointment where they were screened to determine if they met the H&Y stage and PD-D status inclusion requirements.

Confidentiality. Prior to baseline testing, each participant was assigned a randomly generated unique identification number that was used to record data. The unique identification number allowed confidentiality of data as well as to blind the primary investigator of each participant's results. Unique identification numbers were generated using an online number randomizer program. All data were stored electronically on a password-protected laptop. When

not in use, the laptop was stored in a locked filed cabinet, and the key kept by the primary investigator.

Informed Consent. At the start of the baseline appointment, the primary investigator explained all details of the study, answered any questions, and obtained written informed consent. It was explained that further testing by the MDS-UPDRS III and MoCA would be necessary to confirm eligibility and that signing of the informed consent did not guarantee participation in the study. After consent was obtained, administration of the MoCA and MDS-UPDRS III proceeded.

Screening

The screening process was conducted by the primary investigator and took place at the Midwestern University Physical Therapy Institute (MWU PTI). During this appointment, after written informed consent was obtained, the MoCA and MDS-UPDRS III were administered. If eligibility was confirmed, the baseline measures were then collected. Individuals who did not meet the H&Y and PD-D inclusion criteria during the screening process were not enrolled in the study and all data collected were destroyed.

Montreal Cognitive Assessment. Each participant was assessed for PD-D by completing the MoCA. The primary investigator administered the MoCA to each participant in a private examination room. The primary investigator followed all testing protocols set by the developers of the measure. All participants scored at least a 21/30 continued with baseline testing.

Movement Disorders Society Unified Parkinson's Disease Rating Scale. The primary investigator administered section III of the MDS-UPDRS. The primary investigator is certified in administration of the MDS-UPDRS through the Movement Disorders Society. This test also

allowed the primary investigator to determine the H&Y stage for each participant. Two participants did not meet the criteria of the H&Y stage (they were staged at I), therefore did not continue with baseline testing.

Demographic and medical history data. Following informed consent and screening, data on demographics and past medical history related to PD were collected. Data collected included gender, age, years since diagnosis, PD-related medications and dosage, and first signs and symptoms.

Testing. Following confirmation of eligibility, baseline testing began. All baseline tests were administered in the same order for each participant and at each stage of assessment: MBT, PSR, gait analysis using the GAITRite®, and the 6MWT. After participating in a 6-week backward cycling intervention program, participants were retested within one week of their last cycling visit and again approximately one month after their last cycling visit. The same testing procedures were used for both post-intervention testing sessions. For all time periods, data were recorded in a de-identified electronic data sheet. All adverse events occurring at any time during the 6-week intervention program were also recorded.

Mini-BESTest. The MBT was administered by a trained research assistant. Prior to this study, interrater and intrarater reliability was established for all research assistants involved in the data collection aspect of this study. Interrater reliability was excellent (ICC = .96) and intrarater reliability was good-to-excellent (ICC = .81 to 1.00). The test was conducted using the instructions included within the test. A gait belt was donned on each participant for safety. The total score was calculated out of a maximal score of 28 and recorded.

Posterior stepping response. Posterior stepping responses were measured during administration of the MBT subsection of reactive postural control. For this test, the participant

was instructed to stand with feet shoulder width apart and arms down at sides. The administrator then placed both hands on the participant's shoulder blades, and asked him or her to lean back into the administrator's hands beyond their backward limit. They were then instructed to do whatever was necessary, including taking a step, to avoid a fall once the administrator's hands were removed. Prior to performing this component of the MBT, the participant's heels were lined up on a taped placed on the ground. The participant first listened to the instructions, as stated on the MBT. The participant was then instructed to stop and stay in place after steadying. A research assistant then placed a piece of tape directly behind the heel that was the furthest back. The participant was then instructed to return to the start line and this was repeated for two more trials, for a total of three. A research assistant then measured (in centimeters) the distance between the start tape and the three pieces of tape on the ground. This was recorded as the PSR-MSE. All three trials were also videotaped to allow the research assistant to watch each trial to collect data on time to steady and the number of steps. For PST-TTS data, the time started as soon as the tester removed their hands from the participant's shoulder blades and stopped as soon as the participant successfully stopped their backward momentum. The time, in seconds, was then recorded. If the patient needed assistance to prevent a fall, no time was entered. For the PSR-StepNo, the research assistant watched the video and counted the number of steps needed to steady.

Gait analysis. Forward and backward gait parameters were assessed utilizing the GAITRite®. The password-protected research laptop contained the GAITRite® software, therefore before the gait trials, the laptop was connected to the GAITRite® mat. Participants were entered into the system as "Participant" along with their first name and their unique identification number as their last name. Date of birth was also entered per system requirement.

To assess forward walking, the participant was instructed to stand at the end of the walkway, facing the walkway. A gait belt was donned if deemed necessary. A research assistant stood behind the participant, as to not influence walking speed. Another research assistant controlled the laptop connected to the GAITRite® in order to capture the data of each trial. The participant was instructed to walk at a comfortable pace beyond the other end of the walkway. Three trials were completed and trial data were saved within the GAITRite® program. To assess backwards walking, the participant was instructed to stand at the end of the walkway, facing away. A research assistant was positioned behind the participant (to the side of the mat) as to not influence walking speed. The participant was instructed to walk backwards along the walkway at a self-selected pace and then instructed to stop once beyond the end of the walkway. Three backwards walking intervals were completed and trial data were saved within the GAITRite® program. The participant was allowed to rest up to two minutes in between each walking interval if needed. Variables recorded for this study were gait velocity (centimeter/second), mean step length (cm), and mean step width (cm), and were obtained through the GAITRite® software. Side-specific variables, including right and left step length and step width, were provided through the software.

Six-minute walk test. Prior to testing, measures of exercise responses w taken, which included heart rate (HR), blood pressure (BP), and oxygen saturation (SO2). The same exercise measures were also taken immediately after completion of the 6MWT. A walkway of a 50-foot length was marked off with a red cone at each end. Instructions were used according to the recommendations set by the American Thoracic Society (2002):

> 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. 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.

A gait belt was used if deemed necessary. The research assistant stood at a location near the starting point for the duration of the test, as to not influence the walking pace. If a participant required close supervision, an additional research assistant walked alongside, but behind the participant as to not influence walking pace. The assistant announced when each minute had passed, and did not provide other verbal cues throughout the test. After completion of the test, the participant was seated in a chair and exercise response measures were taken and recorded. The participant was instructed to rest until exercise measures returned back to within 10% of baseline results (Noonan & Dean, 2000). The total number of feet the participant ambulated was calculated and recorded on a de-identified electronic data sheet.

Intervention

Upon completion of baseline testing, participants were scheduled to return to the MWU PTI for 12 total sessions over a six-week period, at an average frequency of two times per week. Each participant received an electronic copy of their schedule, and a hard copy if they wished, as well as contact information in case they needed to cancel or reschedule. Participants were instructed to come to each session dressed comfortably with appropriate athletic shoes. The

MWU PTI provided water as needed throughout each session, as well as a small exercise towel. For the intervention, a Schwinn Airdyne stationary bicycle (SAB) was used. The SAB has been used in the treatment of various medical conditions, including being part of cardiac rehabilitation (Butler, Palmer & Rogers, 1992), the treatment of Guillain-Barre Syndrome (Arsenault et al., 2016), and traumatic brain injury (Sartor-Glittenberg & Brickner, 2014). It also has been used to determine aerobic capacity in people with multiple sclerosis (Beier, Bombardier, Hartoonian, Motl, & Kraft, 2014). Despite no known publications describing the use of the SAB with the Parkinson population, its safety has been demonstrated among other neurologic disorders. Additionally, the SAB provides consistent pedaling resistance both in the forward and backward directions. This was not the case with some other types of upright, stationary bicycles in which resistance of pedaling was only felt in forward pedaling.

During the first session, the participant was introduced to the SAB by a research assistant. The seat height for each participant was set at a height which allowed 25° to 30° of knee flexion when the pedal was at the bottommost point. This represented the most desirable position to ease forces placed on the knee during cycling (Asplund & St. Pierre, 2004). The knee flexion angle was determined by having the participant sit on the SAB, move one pedal to the bottommost position, and measuring the knee angle with a goniometer. Prior to cycling, exercise response measures were taken, including HR, BP, respiratory rate (RR), and SO2, and recorded. The seat height for each participant was also recorded in order to maintain consistency during each session. Each participant was asked to pedal backwards at a self-selected pace for five minutes in order to warm up. After this period, the participant was instructed to pedal at a moderate intensity for 30 minutes. Participants were allowed to take a short rest break if they felt necessary, or when the researchers felt it was necessary during the 30-minute interval; however,

the timer was stopped during the duration of any rest breaks to ensure that the total work time equated to 30 minutes. All rest breaks, including number required and the duration of each break, was recorded. Immediately following onset of the exercise interval, the participant was asked to rate their intensity by use of a visual Borg Rating of Perceived Exertion scale (Borg RPE). The Borg RPE is a 15-point scale from 6 to 20, with 6 being the lightest intensity and 20 being maximal intensity (Borg, 1982). The Borg RPE was chosen for this study as research has demonstrated that people with PD may demonstrate abnormal cardiac responses to exercise, including decreased HR (Werner, DiFrancisco-Donoghue, & Lamberg, 2006). The Borg RPE has been shown to be a reliable and valid measure of exercise intensity (Day, McGuigan, Brice, & Foster, 2004; Foster et al., 2001; Herman, Foster, Maher, Mikat, & Porari, 2006). For this study, moderate intensity was defined as an RPE rating of 12-14. The RPE obtained and recorded every 5 minutes of cycling to ensure moderate intensity was maintained throughout the session. If the reported RPE rating was greater than 14, the participant was asked to decrease speed until they rated their exertion as a 14 or below. If the participant reported a rating of less than 12, they were asked to increase their speed until the rating fell within the desired range. A bottle of water was within reach of the participant at all times. After completion of 30 minutes, the participant was given a choice of either decreasing the intensity and pedaling at a self-selected pace for five additional minutes for a cool-down period, or to walk for five minutes. Following completion of the cool-down period, the participant was seated in a chair and exercise response measures was taken. The participant was instructed to rest until all measures returned to within 10% of baseline measures. A trained research assistant monitored each session and recorded all necessary data, including pre-exercise response measures, perceived exertion rating, and post-exercise response measures (Appendix C).

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY). All comparisons were two-tailed using a significance level of less than .05 to be considered statistically significant. Descriptive statistics were conducted on participant demographics and baseline and post-intervention data. Nominal and ordinal data are presented as frequencies and percentages. Normally distributed interval and ratio data are reported as means and standard deviations while non-normally distributed data are reported as medians and interquartile ranges. Normal distribution of data was determined using the Shapiro-Wilk test. Sphericity was determined by the Mauchly's test of sphericity.

For outcome measures in which three trials were conducted, the calculated mean score of the three trials was used for analyses. To determine if there were statistically significant differences in the outcome variables over time both parametric and non-parametric tests were conducted. For normally distributed data with assumption of sphericity, repeated measures ANOVAs were conducted. This included forward and backward gait velocity, forward step length, forward step width, and backward right step length. For data that did not meet the assumption of sphericity, the Greenhouse-Geisser test was used (PSR-MSE, backward left step length, backward left and right step width). If significance was demonstrated, post-hoc tests with Bonferroni correction was run to locate the source of difference. For data not normally distributed, a Friedman ANOVA test was run to determine difference in the repeated measures at each time frame (MBT, PSR-TTS, and PSR-StepNo). If significance was found, pairwise Wilcoxon signed-ranks post-hoc tests were conducted using the Bonferroni correction to adjust the significance level ($p < .017$) to control for possible alpha inflation.

Effect size estimates for each normally distributed variable are reported using partial-eta squared (η^2_p). For pairwise comparisons, effect size estimates are reported using Cohen's *d*. Due to data not being normally distributed, effect sizes for MBT, PSR-TTS, and PSR-StepNo were calculated based on the formula recommended by Cohen (1988) and Rosenthal (1994). Effect sizes were transformed to Cohen's *d* based on calculations reported by Cohen (1988) and Rosenthal (1994), (as reported by Lenhard & Lenhard, 2016). Effect sizes for Cohen's *d* were interpreted based on guidelines proposed by Cohen (1988, 1992) with 0.20 - < 0.50 = small effect; 0.50 - < 0.80 = medium effect; $\geq$ 0.80 = large effect.

Results

Twenty-six participants were enrolled in the study. Prior to starting the intervention, two participants opted out, one due to not being able to commit the time and the other due to a death in the family. Twenty-four people started the intervention program with one person discontinuing after two intervention sessions due to leg cramping. Twenty-three participants completed the intervention program and subsequent posttest. For one-month follow-up testing, one participant was not able to be reached; therefore, 22 participants completed the one-month follow-up test. Baseline demographics are presented in Table 1.

Primary Objective

The primary objective was to determine if backward cycling had an effect on posterior protective stepping response in people diagnosed with PD. Results are presented in Table 2.

Posterior stepping response. A Friedman ANOVA revealed there was a significant decrease in the number of steps needed to steady following a backward loss of balance (PSR-StepNo) across the three time periods, X^2 (2, N = 22) = 7.96, p = .019 with a medium effect size (d = 0.74), representing a moderate magnitude of change. Pairwise post hoc analyses using the

Wilcoxon signed-ranks test revealed a significant median decrease between baseline and one-month follow-up of 0.50 steps, with a large effect size (d = 0.81), representing a large magnitude of change.

A Friedman's ANOVA revealed no significant difference in PSR-TTS across three measures, $X^2(2, N = 19) = 5.15$, $p = .076$; however, a medium effect size (d = 0.58) was determined, representing a moderate magnitude of change.

A repeated measures ANOVA revealed no significant difference in mean MSE over time, $F(2, 40) = 3.48$, $p = .065$, with a small effect size ($\eta^2_p = 0.15$), representing a small magnitude of change.

Secondary Objectives

The secondary objectives were to determine if backward cycling significantly affects backward gait parameters, forward gait parameters, balance, and aerobic capacity; and to assess the acceptability of backwards cycling as an intervention through recording adverse events and retention rate.

Backward gait parameters. A repeated measures ANOVA revealed a significant increase in mean backward gait velocity over time, $F(2, 42) = 7.91$, $p = .001$ with a medium effect size ($\eta^2_p = 0.27$), representing a moderate magnitude of change. Post hoc analysis identified a statistically significant increase between baseline and one-month follow-up, mean difference 12.60 cm/s, $p = .011$ with a small effect size (d = 0.26), representing a small magnitude of change. No significant difference was found between baseline and one-week testing, with a mean difference of 6.92 cm/s and small effect size (d = 0.34), representing a small magnitude of change. No significant difference was found in mean left step length over time, $F(2, 42) = 1.11$, $p = .327$ with a negligible effect size ($\eta^2_p = 0.05$) representing a trivial amount of

change. No significant difference was found in mean right step length over time, $F(2, 40) = 2.56$, $p = .090$ with a small effect size ($\eta^2_p = 0.11$), representing a small magnitude of change. No significant difference was found in mean left step width over time, $F(2, 42) = 1.05$, $p = .342$ with a negligible effect size ($\eta^2_p = 0.05$) representing a trivial amount of change. No significant difference was found in mean right step width over time, $F(2, 42) = 0.78$, $p = .425$ with a negligible effect size ($\eta^2_p = 0.04$), representing a trivial amount of change.

Forward gait parameters. A repeated measures ANOVA revealed a significant increase in mean forward gait velocity over time, $F(2, 42) = 4.52$, $p = .017$, with a small effect size ($\eta^2_p = 0.18$), representing a small magnitude of change; left step length, $F(2, 40) = 5.65$, $p = .007$, with a medium effect size ($\eta^2_p = 0.22$), representing a moderate magnitude of change; and right step length, $F(2, 42) = 4.99$, $p = .011$, with a small effect size ($\eta^2_p = 0.19$), representing a small magnitude of change. Post hoc analyses identified a statistically significant increase between baseline and one-month follow-up in left step length, mean difference 3.39 cm, $p = .039$, with small effect size ($d = 0.31$), and right step length, mean difference 3.01 cm, $p = .049$, with a small effect size ($d = 0.29$), both effect sizes representing a small magnitude of change. No significant difference was found in left step width, $F(2, 42) = 1.69$, $p = .197$ with a negligible effect size ($\eta^2_p = 0.07$) and mean difference of 0.47 cm between baseline and one-week testing, with a negligible effect size ($d = 0.14$), both effect sizes representing a trivial amount of change. No significant difference was revealed in right step width, $F(2, 42) = 0.84$, $p = .437$, with a negligible effect size ($\eta^2_p = 0.04$), and a mean difference of 0.01 cm and negligible effect size ($d = 0$), both effect sizes representing a trivial amount of change.

Balance. A Friedman's ANOVA revealed that there was a significant increase in MBT scores over time, $X^2(2, N = 22) = 11.4$, $p = .003$ and a large effect size ($d = 0.91$), representing a

large magnitude of change. Pairwise post hoc analysis using the Wilcoxon signed-ranks test revealed a statistically significant difference between baseline and 1-month follow-up (Z = -3.50, p < .001). The median difference of 3.00 points resulted in a very large effect size (d = 1.24), representing a very large magnitude of change. There was no significant difference between baseline and 1-week post-test, Z = -2.24, p = .025, however, there was a medium effect size (d = 0.72), representing a moderate magnitude of change.

Aerobic capacity. A repeated measures ANOVA revealed no significant difference in mean 6MWT distance over time, $F(2, 42) = 1.10$, p = .342, with a small effect size ($\eta^2_p = 0.15$), representing a small magnitude of change.

Acceptability. One adverse event was recorded and involved a participant experiencing leg cramping during the first two intervention sessions therefore, this participant opted to discontinue the intervention. Twenty-four participants started the intervention program, and 23 participants completed the entire intervention program, for a 95.8% retention rate.

Discussion

The purpose of this study was to explore the use of backwards cycling in people with PD. The objectives were to determine the effects on participant function and to determine if backward cycling would be an acceptable form of intervention based on the number of adverse events and retention rate. It is known that people with PD have postural instability and consequential fall risk, and this fall risk can increase as the disease progresses (Gray & Hildebrand, 2000). Postural instability in the backward direction is particularly prevalent in the PD population (Carpenter, Allum, Honegger, Adkin, & Bloem, 2003; Horak, Dimitrova, & Nutt, 2005). A survey by Ashburn, Stack, Ballinger, Fazakarley, and Fitton (2008) which included 124 people living with PD, revealed that out of the eight bone fractures which occurred due to

falling, six out of eight (75%) were due to backward or sideward landings. Protective stepping responses, or reactive postural control, refer to a person's ability to produce an effective stepping strategy to realign the body's center of mass with the limits of stability (Schoneburg et al., 2013). It is known that these stepping responses are slower and smaller in people with PD, therefore increasing risk for falls (Shoneburg et al., 2013). To date, this is the first study to assess a backward cycling program for the PD population.

For posterior protective stepping responses, we selected to highlight the number of steps, maximal excursion distance, and time to steady. At baseline, participants required a mean of 2.48 steps to steady from a posterior loss of balance (LOB). This is consistent with a previous study, which included moderately affected people with PD, and reported a mean of 2.43 steps needed to recover from a posterior LOB (McVey et al., 2013). After completion of a 6-week backward cycling program, the number of steps significantly decreased from a median of 2.00 steps to 1.50 steps. This median change persisted through the 1-month follow-up. Both baseline to 1-week post-test comparisons and baseline to 1-month follow-up comparisons demonstrated a medium to large effect size ($d = 0.63$ and $d = 0.81$ respectively). This significant reduction in the number of backwards steps following a posterior LOB may be relevant in the PD population, as retropulsion has been shown to be a fall risk factor (Lindholm, Hagell, Hansson, & Nilsson, 2014) as well as a self-identified deficit in people with PD (Ashburn et al., 2008). Additionally, the reduction in number of steps needed to maintain balance after this backwards cycling program may be of interest to clinicians who work with the PD population with goals of improving posterior reactive stepping responses in people who exhibit more than one step.

There was downward trend observed in the maximum stepping excursion, meaning the participants were able to steady themselves in a shorter distance following a posterior loss of

balance; however, this was not a significant change from baseline. The mean maximal stepping excursion at baseline of 54.80 cm decreased to 43.12 cm at one-week post-test (medium effect size, $d = 0.56$), with a slight upward trend at 1-month follow-up of 46.23 cm. One factor that could explain this variable not reaching significance is that participants were able to steady themselves with less steps, therefore possibly being able to step with an increased step length in order to do so. In other words, a person may be able to catch themselves in less steps due to being able to step longer. While this could significantly improve the number of steps, this could limit how much change the MSE could potentially achieve. Additionally, at baseline, the median number of steps was two, leaving little room for improvement as one step is the minimum value for this test. Therefore, if the number of steps is near a ceiling, the MSE may not have room for an appreciable change.

While not statistically significant, this effect may be clinically relevant. It is known that retropulsion is an independent risk factor for falls in people with mild PD (Lindholm, Hagell, Hansson, & Nilsson, 2015); therefore, a backward cycling program shows potential as being an effective intervention to improve posterior protective stepping responses.

The time to steady variable also showed a downward trend, meaning that participants were able to steady themselves after a loss of balance in less time. The median time to steady at baseline was 0.89 seconds and decreased to 0.35 seconds at one-week follow-up, with a medium effect size ($d = 0.72$). This change was maintained at the one-month follow-up, with a median of 0.41 seconds to steady, and a medium effect size ($r = 1.24$) compared to baseline. Therefore, following the backward cycling intervention, the participants were quicker to steady themselves, and this improvement maintained through the 1-month follow-up, with little to no change. Although the change was not statistically significant, the medium effect size in reduction of time

to steady may be relevant to clinicians working with the PD population who have goals in improving stepping responses.

In terms of the posterior protective stepping responses overall, following a posterior LOB, participants were able to steady themselves in less distance, less steps, and in less time. There have been studies showing improvements in stepping abilities and responses (Barajas & Peterson, 2018; Jobges et al., 2004; Protas et al., 2005) however what is lacking is an intervention in which a person with PD can perform on their own outside of therapy care. All of these previous studies utilized an intervention in which external perturbations were used, produced by either a person or expensive equipment. These types of interventions are not feasible for a person at home or in the community. A stationary bicycle, however, is common in homes, community fitness and recreation centers, therefore readily available. Additionally, the type of stationary bicycle used in this study is relatively inexpensive compared to other recumbent-type bicycles found in therapy clinics. Therefore, this intervention is a feasible, safe mode of exercise that people living with PD can perform at home or community in order to improve and/or maintain posterior protective stepping responses to optimize their safety.

In terms of effects on gait variables, backward cycling resulted in significant improvements in backward gait velocity, forward gait velocity, and forward step length. The mean difference for both forward and backward gait velocity improved from baseline to one-week post-test but continued improving from one-week post-test to one-month follow up. This seems to indicate that there was continued improvement four weeks beyond cessation of the intervention. This continued improvement may be due to two factors. First, one unintended result of this study is that at 1-month follow-up testing, several participants reported including backward cycling in their own exercise program. This continuation of this particular intervention

may have had a continued positive effect on several study variables between post-test and one-month follow-up. Secondly, it is known that exercise has been shown to have a neuroprotective effect on the brain as well as result in exercise-induced neuroplasticity (Mak, Wong-Yu, Shen, & Chung, 2017). Additionally, exercise has been shown to increase the binding potential of dopamine receptors in early PD as well as a neurorestorative effect (Petzinger et al., 2013). This would result in improved motor function, including automatic movements (Petzinger et al., 2013). Therefore, the continuation of improvement following the intervention could be due to lasting motor function improvements due to the neuroplastic and neurorestorative effects of exercise.

The mean difference in backward gait velocity from baseline to 1-month follow-up was 12.85 cm/s, or 0.13 m/s. Although no MDCs have been established for backwards walking in PD, this value approached the MDC for forward gait velocity in this population (MDC=0.18 m/s) (Steffen & Seney, 2008). This may be of interest to clinicians who are treating patients with PD who have goals in improving backward gait, which has been shown to be affected in PD (Hackney & Earhart, 2009). Additionally, walking ability has been identified as a primary concern for people with PD, and that gait speed is a particularly important factor (Hass et al., 2014).

Balance significantly improved following a backwards cycling program. Participants' MBT scores from baseline (Median = 23) to one-week post-test (Median = 25) improved by a median difference of 2 points, and this improvement continued through the one-month follow-up, with a median MBT score of 26. This 3-point difference from baseline to one-month follow-up closely approached the MDC established for PD, of 3.5 points (Di Carlo et al., 2016). Overall, there seems to be a ceiling effect due to the relatively high baseline score of the MBT. The mean

age of the study participants was 68.8 years with a median MBT score of 23 at baseline. The normative mean MBT value for the 60-69 age group is 24.7 (O'Hoski et al., 2014), therefore, the baseline value was close to the normative value, leaving little room for improvement. Additionally, we selected to include people in H&Y stage II and III, however it is stage III where people with PD start demonstrating postural instability, with stage II being defined as bilateral involvement without impairment of balance (Goetz et al., 2004). By including stage II, this skewed the MBT scores towards a higher total. In our study, the mean MBT scores for participants in H&Y stage II was 23.55 and the mean for participants in H&Y stage III was 21.75. Therefore, the inclusion of H&Y stage II may have introduced a ceiling effect, therefore limiting the potential magnitude of change.

Looking further into the MBT subscales, one reason for the increase in the MBT could be attributed to improvements within the reactive postural control subsection. Calculating the means of these subscores, baseline for reactive postural control was 4.17 points, which increased to 4.95 points at one-week post-test and this increase remained at one-month follow-up with a mean of 5.10 points.

In terms of aerobic capacity, no significant changes were found, despite participants exercising at a moderate intensity each session. This may be due to the frequency of the intervention delivery. The American College of Sport Medicine Guidelines for Exercise Testing and Prescription recommends an exercise frequency of at least 3 days per week when exercising at a moderate intensity in order to improve or maintain aerobic capacity (Whaley, Brubaker, & Otto, 2006). The participants in this study only exercised at a frequency of twice per week. For clinicians with goals of improving aerobic capacity, an increase in frequency may be needed or

inclusion of aerobic exercise in a patient's home exercise program would be warranted to complement the therapy sessions.

Overall, results from our study are consistent with other studies looking at the effects of forward cycling and PD in terms of gait variables, with significant improvements in forward gait velocity, cadence, and balance (Nadeau et al., 2017; Uyger et al., 2015). Interestingly, our study with a focused backward direction intervention produced improved gait variables in the forward direction as well. This type of result has been reported in other studies. One study looking at the effects of forward treadmill training reported improvements in backward gait variables, including backward gait velocity, and stride length, following a forward treadmill training program (Tseng, Yuan, & Jeng, 2015). Another study using repetitive compensatory step training in the backward and lateral direction also showed significant improvements in forward gait velocity, cadence, and step length (Jobges et al., 2003). These aforementioned studies seem to support the notion that the direction of the intervention may not limit improvements in other directions. However, findings from our previous studies study either do not contain evidence supporting that the intervention can improve stepping responses or the intervention is not feasible in the home and clinic. The safety of the use of a treadmill at home by people with PD has come into question, with a study showing several adverse events during a home treadmill exercise program with people with PD (Skidmore et al., 2008). The feasibility of a compensatory stepping program at home is also challenged, due to the need for external perturbations. The safety of the use of a stationary bicycle in the PD population has been shown in the past (McGough et al., 2016) and it is further supported by our study. In addition, our study demonstrates that with backwards cycling is safe, feasible, and potentially effective at not only improving protective stepping responses, but also gait and balance.

This six-week backward cycling program resulted in one adverse event. One participant experienced leg cramps after two intervention sessions and decided to discontinue the program. The participant reported his leg cramping in both quadricep muscles. There are two possible explanations for the cramping experienced by this participant: muscle overload/fatigue or an electrolyte deficit (Bergeron, 2008). Following the first session, the participant was instructed to stay hydrated during the days between sessions as well as consider an electrolyte sport drink; however, the cramping persisted. During backward pedaling, it has been shown that the rectus femoris works both eccentrically and concentrically (Neptune, Kautz, & Zajac, 2000). It has also been shown that although backward cycling does not require more metabolic demand compared to forward cycling; there is greater muscle involvement terms of amplitude and duration (Bressel, Heise, & Bachman, 1998). Therefore, the act of pedaling backwards may have been too great of a load for this participant, therefore may have required a slower, gradual increase in duration of the pedaling to condition the leg muscles. It is important to note that if a new intervention like backwards cycling is introduced into a patient's treatment therapy, therapists should encourage cessation of an external exercise program until exercise tolerance is increased, possible gradual increase of the duration of the exercise, and to promote proper hydration.

Every participant was able to get on and off the upright bicycle with no more than supervision. The main complaints during the intervention was discomfort of the bicycle saddle; however, this discomfort waned as the intervention sessions continued. Several participants reported they continued backward cycling in their own fitness centers immediately following completion of the research program, further supporting the acceptability of the intervention.

Limitations

Several limitations exist within this study. The sample size was relatively small therefore potentially underpowered. It also lacked a control group, which could negatively affect internal validity. The addition of a control group would allow comparisons to more traditional forms of exercise interventions. Additionally, the 6-week duration of the intervention program was relatively short. A systematic review of exercise interventions for people with PD included 14 studies, 10 (71%) of which had intervention durations of greater than six weeks (Goodwin et al., 2008). We selected this duration, as well as the frequency of twice a week, intentionally in order to create a feasible program within any outpatient therapy setting. Although attempts to schedule participants in peak medication times was the goal for both the assessments and interventions, this was not able to be consistent due to scheduling logistics and availability. Many participants, however, were scheduled on the same day and time each week, therefore some amount of consistency was able to be achieved.

Strengths

This study introduced a multi-faceted method of objectively measuring posterior protective stepping responses. Taking this approach, therapists can gain more insight into the specific issue affecting individuals from effectively steadying themselves following a posterior LOB. For example, a patient may be able to steady themselves, however if the maximal excursion distance is excessive, this may continue to be a fall risk, therefore specific interventions are needed to improve this. Additionally, this study supports an intervention that utilizes relatively inexpensive equipment that has potential at improving posterior stepping responses. This is in stark contrast to most studies regarding stepping responses, which utilize expensive hydraulic force plates.

Clinical Relevance

Adherence to a home exercise program in people with PD is an important factor as consistent exercise has been associated with improved quality of life, motor function, mobility, and decreased caregiver burden (Oguh, Eisenstein, Kwasny,& Simuni, 2014). Factors have been identified for reasons why patients were not complaint with their home exercise programs, including fear of falling, difficulty carrying out the exercise, and being tedious for others. In this present study, backward cycling was feasible, with a high retention rate, and was also safe, with only one adverse event (muscle cramps) being reported. Additionally, each participant was able to get on/off the bicycle and pedal with no more than supervision, therefore has the potential to be an intervention that can be done independently. The intervention also has potential to be effective at improving posterior stepping responses without need of expensive equipment nor the need for another person to produce an external perturbation, therefore increasing the feasibility of home and community use.

Conclusion

This study supports the use of a backwards cycling program as a feasible, safe intervention that can be effective at improving posterior proactive stepping responses in people with PD. Secondarily, a backwards cycling program may also improve overall balance and gait parameters in both the forward and backward direction. Future research is needed to determine the effects of a longer duration program (10-12 weeks) and to determine the optimal dosage in terms of frequency and duration. Additionally, a control group for comparisons to other commonly used interventions would be warranted. Due to the effectiveness and safety, backward cycling could be considered as an intervention for both the clinic and community setting.

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Table 1

Baseline Characteristics (N=23)

Characteristic		Minimum - Maximum
Gender, *n* (%)		
Male	19 (82.6)	
Female	4 (17.4)	
Age, mean (SD)	68.22 (7.74)	56-78
Years since PD diagnosis, mean (SD)	6.39 (4.44)	1-14
Hoehn and Yahr stage, *n* (%)		
Stage II	11 (47.8)	
Stage III	12 (52.2)	
MDS-UPRDS III, mean (SD)	30.70 (13.10)	10-63
MoCA, mean (SD)	26.74 (2.77)	21-30

Note. PD = Parkinson disease; MDS-UPDRS III = Movement Disorders Society-sponsored revision of the Unified Parkinson's Disease Rating Scale part III motor examination; MoCA = Montreal Cognitive Assessment

Table 2

Comparison of Baseline, 1-Week, and 1-Month Follow-up Measures

Variable	Baseline	1-week follow-up	1-month follow-up	*p*
	M (SD)	*M* (SD)	*M* (SD)	
		Posterior Stepping Response		
PSR-MSE (cm)	54.80 (25.13)	43.12 (15.56)	46.32 (13.02)	.065
PSR-TTS (sec)†	0.89 (1.37)	0.35 (0.52)	0.41 (0.79)	.076
PSR-step number†	2.00 (1.50)	1.50 (1.08)	1.50 (1.08)	.019*
		Backward Gait		
Gait velocity (cm/sec)	71.57 (19.36)	78.49 (21.20)	84.43 (24.90)	.001**
Left step length (cm)	41.66 (8.04)	42.92 (9.36)	43.76 (11.15)	.327
Right step length (cm)	43.42 (9.47)	44.35 (11.59)	46.29 (12.28)	.090
Left step width (cm)	18.90 (4.53)	18.50 (5.03)	18.16 (4.70)	.342
Right step width (cm)	19.03 (4.79)	18.71 (4.92)	18.40 (4.60)	.425
		Forward Gait		
Gait velocity (cm/sec)	111.48 (20.27)	118.42 (21.22)	120.03 (23.96)	.017*
Left step length (cm)	63.52 (9.93)	66.58 (10.07)	66.91 (10.61)	.007**
Right step length (cm)	63.72 (8.36)	66.26 (9.23)	66.73 (9.22)	.011*
Left step width (cm)	10.23 (3.00)	10.70 (3.83)	10.84 (3.67)	.197
Right step width (cm)	10.55 (3.22)	10.55 (3.75)	10.94 (3.60)	.437
		Functional Outcome Measures		
6MWT (ft)	1188.14 (217.02)	1221.36 (252.89)	1239.18 (247.33)	.361
MBT†	23.00 (4.25)	25.00 (2.75)	26.00 (3.00)	.003**

Note. PSR-MSE = posterior stepping response – maximal stepping excursion; PSR-TTS = posterior stepping response – time to steady; 6MWT = 6 Minute Walk Test; MBT = Mini-BESTest

[*] $p < .05$

[**] $p<.01$

[†] Reported as median (interquartile range)

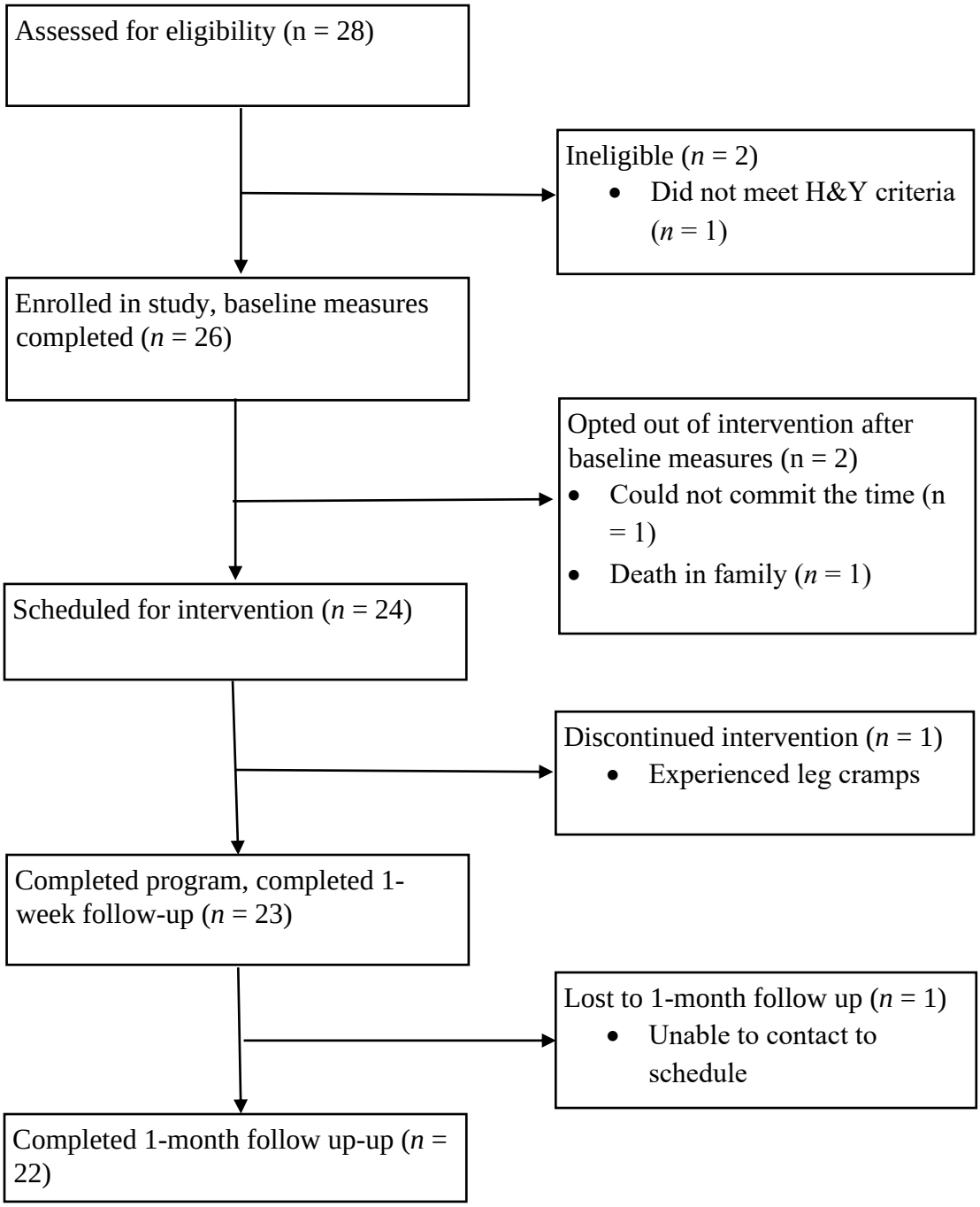

Figure 1. Flow of participants in study.

Appendix A

Hello,
The Midwestern University Physical Therapy Program is seeking volunteers for a research study being conducted at the Midwestern University Physical Therapy Institute. The study is looking for people living with Parkinson's disease to complete a 12-session backward cycling exercise program.

Details:

Study title: The effects of backward cycling on posterior protective stepping responses in people with Parkinson disease
Purpose: To assess if cycling backwards on a stationary bicycle has any effect on stepping responses, balance, gait, and aerobic capacity.
Eligibility criteria:

- Be 20-80 years of age
- Diagnosis of idiopathic Parkinson disease
- Currently in stages II or III of the Hoehn and Yahr Parkinson's disease rating scale
- Be able to walk unassisted without an assistive device for at least 20 feet
- Not currently enrolled in physical therapy
- Be able to understand and speak English

This study is of no cost to any participant. All data will be kept confidential in a password-protected laptop only accessible to the primary investigator, co-investigator, and research assistants.

If you have any questions or are interested in this study, please contact Suzanne O'Neal, PT, DPT, NCS at soneal@midwestern.edu or 623-572-3938.

Thank you very much,
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This research study has been reviewed and approved by the Midwestern University Institutional Review Board (AZ #1128)

Appendix B

I will be asking you some questions that will allow me to confirm your eligibility for this study. You can decline to answer any question and opt out of this study at any time.

1) What is your age?
2) Have you been diagnosed with idiopathic Parkinson's disease?
    a. If no, what is your diagnosis?
3) Are you able to walk without help?
4) Do you need to use an assistive device, such as a cane or a walker, to walk?
5) How far can you walk before you need to stop?
6) Are you currently enrolled in physical therapy?
7) Have you been diagnosed with any other neurologic disorder?
8) Do you have any current illness or injury that may limit your participation in this study?
9) Is there any chance you are pregnant?

Appendix C

Intervention Data Sheet

Session #:	**Date:**

Pre-Vitals
Heart Rate:
Blood Pressure:
Respiratory Rate:
Oxygen Saturation:

Number of rest breaks:	**Duration of each break:**

Rate of Perceived Exertion (RPE) Target: 12-14	
Within first minute	
5 minutes	
10 minutes	
15 minutes	
20 minutes	
25 minutes	

Total exercise time (if different from 30 minutes):

Post-Vitals
Heart Rate:
Blood Pressure:
Respiratory Rate:
Oxygen Saturation: