THESIS

THE IMMEDIATE EFFECTS OF RHYTHMIC ARM SWING AND FINGER TAPPING EXERCISES ON GAIT OF PARKINSON'S PATIENTS

Submitted by

Marion Z. Haase

Department of Music, Theatre and Dance

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Master's Committee:

Advisor: Michael H. Thaut

William B. Davis
Deana B. Davalos

ABSTRACT

THE IMMEDIATE EFFECTS OF RHYTHMIC ARM SWING AND FINGER TAPPING EXERCISES ON GAIT OF PARKINSON'S PATIENTS

This study investigated the immediate effects of a rhythmic arm swing exercise vs. a rhythmic finger tapping exercise on gait parameters of individuals in the early stages of Parkinson's disease (PD). The study design was a randomized control trial involving three experimental conditions: *control group*, *tapping group* and *arm swing group*. Each patient participated in only one of these experimental conditions. Pre-test and post-test of walking at preferred speed were employed for each participant. All participants were rated between 0 and 2 in the Hoehn and Yahr scale. Tapping participants were instructed to tap on a metal plate (while seated) to the beat of an external auditory cue from a metronome set to 120% pre-test walking cadence, for three, 1-minute intervals with 30 seconds of rest in between each interval. The arm swing participants were instructed to swing their arms (while seated) with the beat from a metronome set to 120% pre-test cadence, for three 1-minute intervals with 30 seconds of rest in between each interval. Control group participants were instructed to remain seated for 4 minutes. Hand and arm function were assessed using the Nine Hole Peg Test (NHPT), motor functions were assessed using the Unified Parkinson's Disease Rating Scale (UPDRS) parts III and IV, and balance was assessed using the Berg's Balance Scale. Gait parameters were recorded

at the sampling rate of 500Hz with a computerized foot sensor system. The walking data was analyzed off-line by a personal computer with the interface hardware and analysis software. Changes in velocity, stride length and cadence were recorded during the pre-test and the post-test.

Primary analysis indicated that the tapping treatment increased the absolute cadence in subjects (mean change = 4.400 steps/min, standard error = 1.399 steps/min, p=0.0051), while the arm swing protocol did not have a significant effect on absolute cadence (mean change = -0.356 steps/min, standard error = 1.234 steps/min, p=0.776). The control condition also resulted in no significant change in absolute cadence (mean change = 0.443 steps/min, standard error = 1.399 steps/min, p=0.755). Secondary analysis involving comparison in change of scores between pre and post tests across groups indicated that the tapping treatment's effect was significantly different from the arm swing protocol's results within the parameter of absolute cadence (p=0.0191). Results suggest immediate effects of the arm-swing exercise on gait parameters are not statistically significant, while a pre-gait tapping protocol resulted in immediate effects (increased absolute cadence) that were of statistical significance.

The tapping protocol's effect on cadence suggests that rhythmic finger tapping as a pre-gait exercise may lead to uncued higher step frequencies and gait velocities in Parkinson's disease, and that a seated pre-gait arm-swing exercise may not cause immediate significant changes in gait. A possible explanation for the statistically insignificant change in gait parameters during the arm swing exercise is fatigue – this exercise required more work than the other two conditions, and testing took place immediately after completing the exercise. Other possible confounding variables are the

possibly reduced amplitude of the arm swing during the exercise, and the possibility that arm-swing decoupled from locomotive leg movements may have limited effects on gait. Tapping to a beat, however, may have immediate carryover effects perhaps due to its being a non-locomotive motion that can be isolated as a rhythmic pre-gait exercise.

These findings suggest that a rhythmic tapping exercise may be beneficial to patients with Parkinson's disease, and may increase their walking cadence. However, arm-swing in PD remains a problem due to it's reduced amplitude as a symptom of the disease, and this negatively affects gait parameters. Further research is necessary to investigate new ways to improve arm-swing and consequently gait parameters in PD patients.

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CHAPTER I: INTRODUCTION

Purpose

The purpose of this study was to investigate the immediate effects of rhythmic arm swing and rhythmic finger tapping as pre-gait exercises on cadence, stride length, and velocity of subjects in the early stages of Parkinson's disease (PD). Each participant was randomly assigned to one of three conditions: *control*, *tapping*, *or arm swing*. Each participant partook in his or her assigned study condition once to help determine if rhythmic movement exercises had an immediate effect on cadence, stride length, and velocity more than a control condition, and to compare potential differences in effect between arm swing and finger-tapping conditions.

Need

Parkinson's disease is a neurodegenerative disease affecting 16.5-18 out of 100,000 in the general population annually (Mayeux, Marder, & Cote, 1995). It presents various motor, cognitive, and emotional symptoms that vary from one individual to another (Duvoisin & Golbe, 1989) and as the disease progresses. The greatest risk factor in PD is age, with less than 10% onset before the age of 40 (Rajput & Utti, 1997). As the general population ages, the incidence of PD is projected to rise significantly, increasing the need for appropriate care and interventions for the disease. Parkinson's disease can lead to physical disabilities that can lead to serious complications. The incidence of falls is greater in PD, which leads to related complications (i.e. fractures, head injuries, etc.)

(Elbaz, Bower, & Maraganore, 2002; Fall, Saleh, Fredrickson, & Olsson, 2003; Herlofson, Lie, Arsland, & Larsen, 2004; Hughes, Ross, Mindham, & Spokes, 2004).

The diagnosis of PD requires two of the three cardinal motor signs to be present: bradykinesia (slowness of movement), rigidity and tremor. Variants of parkinsonism should be excluded in diagnosis (i.e., drug-induced parkinsonism) (Rajput, Offord, & Beard, 1984). The cardinal motor symptoms affect gait in various ways, including reduced arm swing, slowing of gait, early fatigue, decreased strength, shuffling gate, freezing of gait and difficulty turning or going around obstacles (Braak, Del Tredici, & Rub, 2003; Braak, Ghenremedhin, & Rub, 2004). These gait disturbances increase the risk of falls in PD and are therefore an important target in therapy.

PD treatment for motor symptoms affecting gait include pharmacological interventions, surgical procedures (including DBS and deep brain lesions), physical therapy, and neurologic music therapy.

Pharmaceutical treatment includes levodopa, and dopamine agonists which have been found to improve stride length, velocity and synchronization of movements (Fernandez & Blin, 1991). However, it has been found that these pharmaceutical interventions have a ceiling effect on gait parameters. Physical therapy has been found to overcome the ceiling effects by improving stride length when auditory cueing is used in training (Dean, Jones, & Ellis-Hill, 2001; De Goede, Keus, Kwakkel, & Wagenaar, 2001; Morris, Iansek, & Matyas, 1994; Thaut, McIntosh, & Rice, 1996).

Physical therapy involves rigorous training including functional mobility exercises, gait training exercises, strength training and other motor exercises to increase safety and maintain the individual’s optimal level of motor function.

Neurologic music therapists also work with the PD population to address sensorimotor goals, including gait, through the use of a neurologic music therapy techniques, including Rhythmic Auditory Stimulation (RAS) specifically for gait training.

This investigation focuses on the question of whether higher movement frequencies induced during rhythmic pre-gait exercises in other motor functions than gait (arm swing, and finger tapping) can transfer to higher step frequencies in subsequent gait performance, also improving overall velocity and stride length. Of particular interest for PD was the arm swing condition. One characteristic of gait kinematics in PD is highly reduced arm swing during locomotion. Thus an important question was if focusing on faster arm swing as a pre-gait exercise, step frequencies would follow during subsequent walking.

Hypothesis

The present study will determine whether a seated pre-gait rhythmic arm-swing, or finger tapping exercise will have an immediate effect, increasing gait parameters, by measuring pre-test and post-test velocity, cadence and stride length with the use of foot switches, and through the use of gait analysis software.

The following null hypothesis is proposed: there will be no statistically significant changes in gait parameters between pre-test and post-test measurements after partaking in a seated pre-gait rhythmic arm swing, or finger tapping exercise when the cue frequencies of the exercise is set at 120% of subject's preferred walking cadence.

CHAPTER II: RELATED LITERATURE

Background

Parkinson's disease (PD) was first described by James Parkinson in 1817 (Parkinson, 2002), when he described six observed patients' walking patterns as having "involuntary tremulous motion, with lessened muscular power" with "a propensity to bend the trunk forwards, and to pass from walking to a running pace: the senses and intellect being uninjured" (p. 223) . Jean-Martin Charcot renamed the disease from its former name of "paralysis agitans" to Parkinson's disease, crediting Parkinson for his findings. He also contributed to the understanding of the disease by describing the slowness of movement as a phenomenon not occurring due to weakness of the muscles (Kempster, Hurwitz, & Lees, 2007). Over 100 years later, in 1919, it was discovered that PD is caused by the loss of cells in the substantia nigra of the basal ganglia. Later, Swedish Arvid Carlsson and colleagues' discovered in the 1950s that the neurotransmitter associated with the substantia nigra is dopamine (Carlsson, 1993). In 1960, Ehringer and Hornykiewicz discovered that the amount of dopamine in the striatum of patients with PD is markedly decreased (Hornykiewicz, 2006). This discovery initiated the trials of levodopa in PD patients, resulting in improvements in akinesia (Birkmayer, 1961). Today, levodopa continues to be one of the pharmaceutical interventions to decrease the symptoms of PD.

According to the National Institute of Neurological Disorders and Stroke, the incidence of Parkinson's disease in the United States is estimated to be 50,000 per year.

Risk factors include race, ethnicity, heredity, environment, gender and age. The disease is more prevalent in men than in women, and the main risk factor for being diagnosed with PD is age – older populations being at higher risk (NINDS; deRijk, Rocca, & Anderson, 1997). As the population in the United States continues to age, with Baby Boomers entering the older ages of higher risk, the incidence of PD may continue to rise.

PD presents three cardinal motor signs: tremor, rigidity, and bradykinesia. Two of these signs must be present for PD to be diagnosed. Other causes of parkinsonism must also be excluded (i.e., drug induced parkinsonism, multiple system atrophy, etc,).

Tremor is the most common sign seen in PD (Rajput, Rozdilsky, & Ang, 1991). It involves a rhythmic movement of the hands, fingers and arms that is present when the arm is at rest. It is increased when the individual is under stress or fatigued, and it is diminished with voluntary movement. Thalamic lesions decrease tremors but it is not clear how this occurs (Djaldetti, Mosberg-Galili, & Sroka, 1999).

Rigidity is the resistance of passive stretch (Hallet, 2003). It is equally present in agonist and antagonist muscles and leads to a stooped posture as the disease progresses due to increased rigidity in the flexor muscles of the cervical and thoracic spine. Rigidity may occur due to abnormal long-latency reflexes and abnormal background muscle contraction. Long-latency reflexes are mediated by the sensorimotor cortex, which in PD has abnormal excitability (Rothwell, Obeso, Traub, & Marsden, 1983; Buhrmann, Gorsler, & Baumer, 2004).

Bradykinesia is the slowness of voluntary movement and can lead to akinesia (absence of voluntary movement) (Marsden, 1989). Bradykinesia presents itself asymmetrically in the body, distally as micrographia and slower finger tapping. In the

limbs, slow walking patterns and reduced arm swing are evidence of bradykinesia. Bradykinesia may be related to the abnormal cortical activation derived from the impaired basal ganglia in PD (Wichmann & DeLong, 2003; Chen, Kumar, Garg, & Lang, 2001). PET studies have correlated nigrostriatal degradation with bradykinesia and rigidity, but not with tremor (Otsuka, Ichiya, & Kuwabara, 1996).

These motor signs result in various gait disturbances including reduced arm swing, slow gait, abnormal posture, decreased cadence, early fatigue, decreased strength, and shuffling gait (Marttila & Rinne, 1977; Bloem, hausdorff, Visser, & Giladi, 2004).

Decreased velocity and shortened stride length are associated with hypokinesia (reduced movement size) (Svehlik, et al., 2009; Sofuwa, Nieuwboer, Desloovere, Willems, Chavret, & Jonkers, 2005; Morris, McGinley, Huxham, Collier, & Iansek, 1999). There is increased hypokinesia in the gait of PD patients when compared to age-matched control subjects (Morris, Iansek, Matyas, & Summers, 1996). Consequently, stride length is reduced (at preferred walking speeds) in patients with PD when compared to a control group (Ebersbach, et al., 1999; Sofuwa, Nieuwboer, Desloovere, Willems, Chavret, & Jonkers, 2005; Svehlik, et al., 2009).

There are several treatments currently used to target the symptoms of PD. Pharmacologically, levodopa is the standard treatment for PD to increase dopamine in the nervous system. Dopamine agonists are also used depending on the individual. Medications do not prevent disease progression but instead aim to decrease the presence of symptoms (National Parkinson's Foundation, 2010).

Surgical treatments are less commonly used. They include thalamotomies and pallidotomies, which target specific regions of the brain (thalamus and globus pallidus) to

treat symptoms like tremors. Functional neurosurgery for advanced Parkinson's includes Deep Brain Stimulation (DBS) which provides bilateral high frequency stimulation that targets specific areas of the brain to diminish PD symptoms (Herzog, Volk,ann, Krack, Kopper, Potter, & Lorenz, 2003; Volkmann, Allert, Voges, Strum, Schnitzler, & Freund, 2004).

Physical therapy as a treatment aims to teach patients to engage in motor tasks safely, as well as to improve functional motor abilities, such as gait, while reducing secondary motor complications (Kwakkel, de Goede, & van Wegen, 2007).

Research in gait rehabilitation of PD has included different approaches to enhance gait parameters. Visual cues have been found to enhance stride length in PD (Morris M. E., Iansek, Matyas, & Summers, 1996). Other findings include the effects of verbal cues to increase the amplitude of arm swing, which has resulted in increased velocity and stride length (Behrman, Teitelbaum, & Cauraugh, 1998). Neurologic music therapy's Rhythmic Auditory Stimulation (RAS) has been found to be beneficial in gait rehabilitation of stroke, traumatic brain injury and Parkinson's, among other neurologic conditions, improving gait parameters such as velocity and cadence (Thaut, McIntosh, Prassas, & Rice, 1993; McIntosh, Brown, Rice , & Thaut, 1997; Hurt, Rice, McIntosh, & Thaut, 1998; Willems, et al., 2006; Thaut, et al., 2007; Hausdorff, Lowenthal, Herman, Gruendlinger, Peretz, & Giladi, 2007). In rehabilitation and at-home care, music therapists have been working in conjunction with physical therapists in order to achieve similar gait rehabilitation goals in Parkinson's patients.

This investigation will serve as a pilot study to answer the following question: can cadence, velocity, and stride length be increased by providing a seated pre-gait arm-

swing rhythmic entrainment exercise, more than the control condition and a seated pre-gait finger-tapping rhythmic entrainment exercise?

Rationale

Human locomotion is unlike other animals in that it is bipedal. Although we do not use our upper extremities to propel ourselves during locomotion, we have a rhythmic, pendular motion in our arms as we walk. In the following sections these topics will be reviewed: the arms' pendular motion during gait and the muscle activation it involves, intralimb neural coupling, and the implications these aspects of human locomotive arm swing have on Neurologic Music Therapy RAS techniques.

The arms move like active, complex pendulums in human locomotion

The alternating swinging of the arms as we walk could be observed as a result of the movement from the rest of the body. However, in 1939, measurements of muscle activation in the arms and shoulders during locomotion resulted in an early suggestion that perhaps the swinging of our arms does not occur passively, that it occurs due to muscular activation in the arms and shoulders (Elftman, 1939).

Hogue (1969), upon further researching muscle activation in normal subjects (15 college students) during locomotion, suggested that the arms do move like pendulums, but that this pendular movement is not due only to gravity, but also the velocity of arm swing caused by muscle activation.

To further understand arm swing's relationship to a pendulum, it is important to understand the basic mechanics of a pendulum. Webb et al (1994) conducted an

experiment using mathematical ideas derived from Searle's notes on pendular activity. They take into account in their analysis the fact that "every pendulum has a natural frequency of oscillation" (Webb, Tuttle, & Baksh, 1994, p. 479). This frequency depends on gravity when referring to a passive pendulum fixed on a fulcrum. Webb calculated natural pendular frequencies of the arms of his study subjects based on characteristics of a cadaver's arm. He noticed, however, that his calculations were oversimplified since the upper limb is not a passively swinging pendulum. He states that the arms are "pendulums that are actively controlled by the neuromuscular system" (p. 485).

Furthermore, due to the muscular activity involved in elbow flexion and extension, the arms should be seen as "complex" pendulums. Therefore, comparing arm swing to a pendulum would necessitate very complex mathematical functions that include all the external and internal factors involved in arm swing.

In addition to the complexity of the physics involved in arm swing when comparing it to pendular activity, Webb also explains that another factor to take into consideration when studying the dynamics of arm swing are the fulcra of the arms. They are not stationary as we see in normal pendulums, instead, they are moving parts of the arm that move with the rest of the body.

In summary, the arms do not hang by our sides and move passively back and forth as a result of our body's movement when we walk. While they have a pendulum-like trajectory, this movement is a result of muscle activation as well as gravity. Understanding the active role of the arms in walking leads us to the next question: why are arm and shoulder muscles active when we walk? In order to answer this question, one

must first gain a basic understanding of the muscle activation that occurs in the arms and shoulders when we walk.

Muscles activated during arm swing in gait

In 1965, Ballesteros recorded the action potentials of several muscles of the arm and shoulder while normal subjects walked. The results indicated that the backward motions of the arm utilized "extensors and outward rotators of the arm at the shoulder" (p. 309). The anterior part of the deltoid and pectoralis major were primary movers during the backswing. As the arm swings forward, flexors and internal rotators play the main role in moving the arm. Ballesteros also points out that abduction of the arm is required in order for the arm to swing. This abduction is carried out by the middle part of the deltoid and supraspinate muscles, assisted by other surrounding muscles.

Murray (1967) also investigated muscle activation during arm flexion and extension in normal men by using reflective targets and measuring the changes in angles as their arms swung. His results indicated that as the arm swings forward, the shoulder and elbow are flexed. They are then extended as the arm swings backward.

In another study by Hogue (1969), electromyography (EMG) measurements were taken from college students. Hogue studied the EMG patterns, the sounds of the muscular activity and videos of the subjects as they walked. During forward swing, the anterior deltoid was activated, as found in Ballestero's earlier study. Hogue, however, found more activation in the middle trapezius than the anterior deltoid, while Ballesteros did not include the trapezius muscle in her measurements. During the backward swing, the teres major displayed a lot of activity in Hogue's study. This muscle was also noted as the

primary muscle in backward swing in Ballesteros' study. Also of importance are the middle and posterior deltoid muscles, which were found to be active throughout the arm swing in Hogues's study. These were the muscles that Ballesteros explained are involved in the abduction of the arm.

To summarize, muscle activation during forward and backward arm swing involves several alternating and some constant muscles. Forward swing is associated with the anterior deltoid along with other supporting muscles. The backward arm swing is associated with the teres major along with other supporting muscles. Throughout the arm swing, some muscles remain inactive. The middle and posterior deltoids are involved in abducting the arm to allow the swing of the arm without bumping into the body.

Function of arm swing in gait

Ohsato (1993) studied rotation of the pelvic girdle in relation to the rotation of the shoulder girdle. It was found that the two girdles rotate in opposing directions. This serves "as a counter-balance function" in walking. This is essential for smooth walking. The rotation of the shoulder girdle was found to be affected by the active pendular movement of the arms. Another observation Ohsato made is that the acceleration of the leg is influenced by the contralateral arm swing.

Lulic et al (2008) investigated the influence of arm swing on gait. Results showed that changes in arm swing affected gait patterns. When arm swing was emphasized, lateral and vertical displacements of the body's center of mass were decreased. Lulic et al state that arm swing may reduce energy expenditure since the body is not oscillating and is moving in almost a straight line.

To summarize, arm swing helps regulate smooth walking by countering the pelvic rotations. The acceleration of the arm swing also influences the acceleration of the contralateral leg. Finally, arm swing reduces energy expenditure during human locomotion by reducing the oscillations of the body's center of mass. These findings are evidence that the arms' swing affects gait patterns.

Intralimb neural coupling

Arm swing has been proposed to be a residual pattern of activity from our quadruped ancestors, and that it is guided by central pattern generators (CPGs) found in the cervical enlargement (Jackson K. M., 1983; Jackson; Jackson, Joseph, & Wyard, 1983). CPGs are neurons involved in intrinsically rhythmic movements such as walking. This means that such generators influence the legs' walking motion, since walking is an intrinsically rhythmic activity. Jackson's suggestion that the arms have CPGs that drive their rhythmic movements, and previous studies' findings that we have CPGs influencing the legs in locomotion, raise the following question: are cervical and lumbosacral spinal cord CPGs interconnected? According to Eke-Okoro (1994), the answer is yes. Eke-Okoro studied changes in H-reflex amplitudes of normal subjects during several conditions. When investigating the effects of deliberate arm positions on the leg's response to the H-reflex test, Eke-Okoro found that actively engaging the arms while resting the legs suppresses the reflex in the legs. This, he states, strongly suggests that there is an interaction between the spinal cord segments that serve the arms and spinal cord segments that serve the legs.

This neural coupling between the arms and the legs was also supported by Huang's (2004) investigation of EMG patterns in several conditions involving arms and leg cyclic movements. The investigators found that when the arms were engaged, it resulted in neuromuscular recruitment of the resting lower limbs. Therefore, neural communication between the arms and the legs exists, probably as remnants of quadruped locomotion patterns our non-bipedal ancestors had.

Dietz (2001) takes this idea of interlimb coupling a step further when he suggests that it is flexible. The coupling between the cervical and thoracic regions of the spinal cord does not occur when the arms are involved in skilled movements (i.e., writing), but it does occur during locomotion. Therefore, communication between our arms and legs depends on the task.

To summarize, there is neural communication between the arms and the legs. This communication depends on the task (locomotor versus skilled movements of the arms). Kawashima et al (2008) investigated how the arms use these communicative pathways to affect the legs in a study involving patients with Spinal Cord Injury (SCI). They found that when the arms were moved passively in patients with incomplete SCI, EMG activity was observed in the legs. This activity resembled EMG activity seen in normal subjects' gait.

Rhythmic Tapping as a Treatment Protocol

In this study the aim is to investigate the effects of a seated rhythmic arm swing exercise to an external rhythmic auditory cue. In an attempt to rule out the effects of rhythm alone on gait parameters, rhythmic tapping to an auditory cue has been added as a treatment condition. Instead of passively listening to a beat, the tapping apparatus and protocol have been added as a means to quantify subjects' attention to the beat via a motor task that has minimal motor implications (tapping a finger to the beat of the metronome). The quantification entails synchronization to the beat – if the subjects are synchronizing to the beat, this serves as evidence that they are attending to the beat.

Studies have investigated the effects of rhythmic finger tapping on gait parameters of healthy and clinical populations, resulting in improvements in gait parameters and lower extremity EMG pattern during gait (Thaut & McIntosh, 1992; Thaut, McIntosh, Prassas, & Rice, 1993). This further supports the tapping protocol as an appropriate treatment protocol to which the rhythmic arm swing protocol can be compared.

While various motor symptoms are evident in PD, such as tremor, dyskinesia, akinesia, bradykinesia, etc., studies have shown that Parkinson's patients are able to tap to the beat during their "on" medication cycle, and early stages of Parkinson's disease (Yahalom, Simon, Thorne, Peretz, & Giladi, 2004; Freeman, Cody, & Schady, 1993; Rubenstein, Giladi, & Hausdorff, 2002), therefore this task is considered to be within the motor abilities of the subjects in this study.

What does this mean in Neurologic Music Therapy?

As mentioned before, several studies have found that rhythmic cueing improves gait parameters in paretic patients, Parkinson's and Huntington's patients. RAS entrains stepping motion by using patient-dependent frequencies, which can be delivered either with a metronome or a musical instrument. Rhythmic entrainment of arms has been investigated, but not in relation to gait.

Rhythmic arm movements have been correlated to CPG activity (Zehr, et al., 2004), and the neurological mechanisms involved in such movements have been differentiated from discrete arm movements (Schaal, Sternad, Osu, & Kawato, 2004). Schaal utilized functional neuroimaging to study cortical activation during discrete and rhythmic wrist flexion and extension. The results from his study showed that rhythmic movement activates a small amount of the primary motor areas, whereas discrete movement of the wrist resulted in multiple bilateral activations of the cortex. Therefore, rhythmic arm movements can be classified as automatic. The significance of this finding is that cortical input in rhythmic arm movements is minimal and relies mostly on CPG activity.

Changes in arm swing amplitude during gait training may add benefits to therapy. So far, it's been established that rhythmic activity in the arms, like arm swing in gait, affects the legs. Arm swing, since it is a rhythmic movement, involves the use of CPG, resulting in less cortical recruitment and activating the neurological intralimb coupling that occurs at the spinal level. Rhythmic arm movement can be influenced by external cues such as in RAS. Ford (Ford, Wagenaar, & Newel, 2007) investigated the effects of auditory rhythms and specific instructions on gait patterns of stoke patients. His results showed that external auditory cues (a metronome) directed at the upper limbs' motion

increased thoracic rotation and transverse pelvic rotation during gait. This resulted in increased velocity.

Further research involving arm swing in RAS could investigate the effects of pre-gait exercises involving arm swing on gait parameters including stride length, stride symmetry, velocity and cadence. It has been found that rhythmic arm movements recruit leg muscles and that arm swing is important in stabilizing the center of mass of the body to decrease energy expenditure during walking. Therefore, involving the arms in RAS may enhance the technique's effects on gait parameters.

Reduced arm swing is an early sign of the disease (Parkinson Study Group, 1989). Decreased arm swing amplitude has been noted during fast walking in Parkinson's (Hong, Earhart, Damiano, & Perlmutter, 2005). In order to address the decreased arm swing in physical therapy, external cues such as visual and verbal commands are used. Verbal instructions have resulted in an increase in velocity when they were directed at the size of steps, however, this response varied widely from one subject to the next (Werner & Gentile, 2003).

Sensory cueing is a powerful tool in gait rehabilitation for PD (Rubinstein, Giladi, & Hausdorff, 2002). Visual cues improve stride length, while auditory cues have been found to improve cadence, with no significant change found when both cues were used simultaneously with Parkinsons patients (Protas, Mitchell, Williams, Qureshy, Caroline, & Lai, 2005). Visual cues have also been found to normalize stride length (Morris M. E., Iansek, Matyas, & Summers, 1996).

External cues serve as triggers in PD to avoid the recruitment of the defective pallidocortical projections (Morris, Iansek, & Matyas, The pathogenesis of gait

hypokinesia in Parkinson's disease, 1994; Cunnington, Ianseck, Bradshaw, & Phillips, 1995). External cues may also emphasize the activity of the parietothalamic premotor cerebellar and prefrontal areas of the brain (Wu & Hallett, 2005; Samuel, Caballos-Bauman, & Blin, 1997)

In neurologic music therapy, one of the key elements for sensorimotor training is rhythm. The brain's auditory processes have direct influence upon motor processes (Thaut, Kenyon, Shauer, & McIntosh, 1999). The temporal aspects of motor commands share many of the neural connections as those that process information on rhythm, which allows for motor planning and execution to be based on an external auditory rhythmic stimuli (Thaut, 2003). Neurologic music therapy techniques take advantage of this by utilizing rhythm as an auditory cue for sensorimotor training.

A neurologic music therapy technique used for gait training is called Rhythmic Auditory Stimuliation (RAS). The external auditory stimulus provided in this technique acts as the timekeeper for the intrinsically rhythmic motions in gait (Thaut, 2008). The clinical protocol of RAS involves several steps:

1. Assessment: during this phase, gait parameters are measured (cadence, velocity and stride length)
2. Resonant Frequency Entrainment: the patient's cadence is matched temporally with the auditory cues (cues may be delivered musically through the use of an instrument (i.e., autoharp or piano) or with the use of a metronome – depending on the client's needs).
3. Frequency modulation: the tempo of the cue is modulated (faster or slower) depending on the client's goal cadence and gait disturbances present.

4. Advanced Gait Training: during this portion of the RAS protocol, the client partakes in pre-gait exercises that target specific maladaptive gait patterns, or specific areas of need. This is facilitated with Patterned Sensory Enhancement techniques that aim to facilitate the movements' spatial, temporal and force components.
5. Fading: RAS is diminished and faded away to ensure the client can maintain the tempo by internalizing the auditory cue.
6. Reassessment: all the gait parameters are re-assessed to determine whether RAS has had an effect on the client's gait.

RAS enables more automatic movement and less stride-to stride variability in Parkinson's. RAS has a carryover effect, which suggests motor plasticity in networks controlling rhythmicity (Hausdorff, Lowenthal, Herman, Gruendlinger, Peretz, & Giladi, 2007).

CHAPTER III: METHODOLOGY

Participants

Subject selection

Subjects were recruited by posting flyers in the Ft. Collins/Loveland and surrounding areas and through presentations at community-based support group meetings. Subjects were randomly assigned to one of three conditions (*control* – seated, no pre-gait exercise; *tapping* – seated pre-gait finger-tapping rhythmic entrainment; and *arm swing* – seated pre-gait arm swing rhythmic entrainment) with the use of block randomization methods. Subjects were informed of the three possible treatment conditions. The ethical review board clearance was obtained for each participant. A total of 26 subjects were recruited to participate in this study (control group n=7, arm-swing group n=8, tapping group n=7).

Subject characteristics

Participants had a diagnosis of Parkinson's disease (this diagnosis was obtained by the participant from his/her physician/neurologist prior to enrolling in the study). Subjects were included in the study when they (1) were rated to be in stages 0-2 of the Hoehn and Yahr Parkinson's scale, (2) were able to walk independently without assistive devices for at least 14 meters at a time, no more than 4 times, (3) had no severe perceptual deficits, (4) had no medical complications, and (5) were interested in participating in the study. Subjects were not matched for age. If subjects were under current pharmacological treatment for Parkinson's symptoms, they were required to be in

the “on-medication” phase of their cycle during testing. Each subject completed an entry questionnaire for screening purposes. Additional assessments included the Berg’s Balance Scale, Nine-Hole Peg Test (NHPT), and the Movement Disorder Society – Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) – parts III and IV (Siderowf, McDermott, Kieburtz, Blindauer, Plureb, & Shoulson, 2002; Metman, et al., 2005; Steffen & Sevey, 2008; Qutubuddin, Pegg, Cifu, Brown, McNamee, & Carne, 2005)

Each participant took part in his/her assigned condition once. The duration of the study for each participant averaged one (1) hour, including assessments, equipment setup, pre-test, training condition and post-test. Table 1 provides detailed information on all subjects and Table 2 provides descriptive statistics outlining the distribution of selected subject characteristics including number of male/female, age, year of diagnosis, height, weight and Parkinson’s medication.

Table 1: Subjects' Characteristics

protocol	subject #	age	DOD	sex	test date	medications	med conditions	hearing	vision	height (ft/in)	weight (lbs)	physical activities	assistive device	Reason for disqualificatio
Arm Swing	3	69	2001	M	5/24/06	stalevo, requip, amantadine, coenzyme q10, baby aspirin, coagular	none	mild hearing loss	glasses	5'10"	208	pd ex group	no	
Arm Swing	5	61		M	6/13/06	PD: comtan, levodopa, amantadine, namenda, pristiq, omptazole, zelapat, exelon patch. HIV: epzicom, sentiess, acyclovir, enablex	HIV	normal	glasses	5'10"	160	walk daily, skiing, yoga	walker if by himself	
Arm Swing	7	75	2008	M	6/14/06	gemfibrozil, sinemet, levothyroxin, otc-niacin, cholestoff, vits and mins	bursitis (shoulder), slower reflex on right knee	normal	glasses	5'10"	213	gym 2x/week, hike, balance, neurointegrated muscular activity, mow lawn, walk 4mi	hiking stick to hike	equipment failure during post-test
Arm Swing	12	68	2004	M	7/15/06	amantadine, selegedine, requip, levodopa, senemet	none	hearing aid	visual hallucinations, double vision, but drives	6'2"	175	walk, weights, yard work	no	
Arm Swing	13	55	2007	F	7/18/06	mirapex, coenzyme q10, mm. activation techniques with pt	none	normal	reading glasses	5'3"	135	phys trainer, ski, hike, walk	no	
Arm Swing	15	58	2009	F	8/9/06	aselect, zonezyme q10	none	normal	contacts	5'4"	135	jazzersize, yoga	no	
Arm Swing	16	63		F	8/10/06	prefest (HRT), synthera, cocutanath	none	normal	reading glasses	5'7"	148	tennis, ex classes	no	
Arm Swing	19	71	2007	M	8/10/06	metformin, glipizide, niacin, azelect, mirapex, zocan, hbp med, vits	diabetes, hbp, congestive heart, on oxygen	normal	glasses	5'8"	240	garden, snow yards, vacuum	no	
Arm Swing	20	78	2008	F	8/11/06	propsetine, atenlol (BP), sinbastatin (chol), amlodapene (PD), lisinoail (BP), symmetiel (PD), thyroid leverthyroxene, femara	rt hip replacement, breast cancer (lt), hbp, macular degeneration	normal	reading glasses	5'2.5"	160	stationary bike, aquarobics	cane for safety	subject stopped walking during post-test to ask how she should walk
Arm Swing	22	74	1992	M	8/22/06	sinemet, requip, simvastatin, baby aspirin	diabetes (diet controlled), neurological tremors, stiffness, etc)	normal	glasses	5'9"	175	walking, weights, stretching, stairs	sometimes	
Arm Swing	23	70	2004	F	8/23/06	mirapex, levodopa, vits, calcium.,, aspirin, magnesium	hernia surg 5 yrs ago, transglobal amnesia (5yrs ago)	normal	glasses	5'2.5"	119	yoga, hiking, walking	no	
Arm Swing	25	60	2006	F	8/27/06	sinemet, comtan, selegiline, amantadine, provigil, simvastatin, vits	DBS	normal	glasses	5'1"	125	yoga, broadway dance, rec. dancing	no	
Control	4	64	1988	F	6/10/06	sinemet, requip, amantadine, klonopin (clonazepan)	none	normal	glasses, double vision when reading	5'2"	100	walk track, pt daily, stationary bike, strtch/balance ex, weights	walker during "off" period	
Control	6	71	2006	M	6/14/06	metformin (pre-diabetes), azilect	recent back surgery	very mild hearing problems	reading glasses	6'4"	230	walking	no	
Control	9	72	1986	M	6/27/06	cenemet, merapex, amantadine	none	slight hearing loss	glasses	5'11"	180	ex 3x/week	hicking stick as precaution	
Control	11	65	1998	F	7/8/06	sinemet, entacapone, levothyroxine, lorazapam, celexa, naproxine, requip, alpha lipoic acid, vits, ropinirole	rt. knee surgery	normal	reading glasses	5'1"	150	cleaning	walking stick sometimes	
Control	17	65	2010	F	8/10/06	primpro, xalatan (ocul. Hpertens), requip, azalect, coq10, magnesium (mm relax), cocumin	arthritis, 2 hip replacements, carpal tunnel	normal	glasses	5'4.5"	130	walk, wii balance, recumbent bike	2 hiking poles in mountains	
Control	18	66	2008	F	8/10/06	azelect, plaquelil (lupus), invastatin (cholest), synthroi (thyroid), coq10, vits	lupus, mitrovalve prolapse, acid stomac	hearing aid	glasses	5'3.5"	110	treadmil, pilates, zumba, pt	no	
Control	26	68	2009	F	8/29/06	sinemet, zaloft, synthrois, mapzid, zocor, coq10, flaxseed oil		normal	glasses	5'8"	172	walking, hiking, weights	no	
Tapping	1	74	2007	F	5/9/06	azilect, pramipexole	heart murmur, BP fluctuation	some frequency hearing loss	glasses	5'5"	160	walking, exercise video, PD ex group	no	
Tapping	2	66	1996	F	5/11/06	mirapex, amantadine, fosamax (osteoporosis)	osteoporosis	normal	glasses	5'10"	170	pd ex group, walk 2x/week, wii balance, ex dvd	no	subject entered "off" state - opted out of experiment midway
Tapping	8	73	2006	M	6/24/06	azelect, cinemet, mirapex	sleep apnea, bladder stone 2007	high end hearing loss	glasses, parkinsonian vision with eye tracking	5'11"	156	yoga, cardio, wii balance	hiking stick to hike	
Tapping	10	49	1996	M	6/29/06	cenemet, amantadine, colarsepan	none	normal	multifocal glasses	5'11"	143	biking, walking	cane on bad day	
Tapping	14	69	2004	M	7/21/06	levo, requip, creatine; prostate flomax, tamsulosin, avodart; depress citalopran	depression and prostate cancer (subsided)	normal	glasses	5'9"	163	yoga, walking	hiking stick to hike	
Tapping	21	62	2006	M	8/11/06	cenemet, azelact, requip, coq10	achile's tendon repair 22yrs ago, diverticulitis, basal cell cancer	normal	glasses	5'8"	160	yoga, mt biking, hike, ski	2 hiking poles in mountains	
Tapping	24	64	2008	M	8/23/06	selegeline, mirepex, finasteride	none	normal	glasses	5'7"	190	cycling, swimming, weight, running	no	

Table 2: Distribution of Sujbect Characteristics

Per Protocol Male/Female Percentages

Condition	# Subjects	# Male	% Male	# Female	% Female
Arm Swing	10	5	50%	5	50%
Control	6	2	33%	4	67%
Tapping	7	5	71%	2	29%
TOTAL	23	12	52%	11	48%

Per Protocol Age Distribution

Condition	Mean	SD	Median	Min	Max	Range
Arm Swing	65	6	66	55	74	19
Control	65	9	67	49	74	25
Tapping	67	3	66	64	72	8
ALL GROUPS	66	6	66	49	74	25

Per Protocol Year of Diagnosis Distribution

Condition	Mean	SD	Median	Min	Max	Range
Arm Swing	2003.3	5.1	2004	1992	2009	17
Control	2000.71	10.2	2006	1986	2010	24
Tapping	2004.5	4.4	2006	1996	2008	12
ALL GROUPS	2002.8	6.7	2006	1986	2010	24

Per Protocol Height Distribution (in)

Condition	Mean	SD	Median	Min	Max	Range
Arm Swing	66.9	4.1	67.5	61	74	13
Control	66.6	5.4	64.5	61	76	15
Tapping	68.5	2.3	68.5	65	71	6
ALL GROUPS	67.2	4.1	68	61	76	15

Per Protocol Weight Distribution (lbs)

Condition	Mean	SD	Median	Min	Max	Range
Arm Swing	162	38.6	154	119	240	121
Control	153.5	45.1	150	100	230	130
Tapping	162	15.4	160	143	190	47
ALL GROUPS	159.3	35.2	160	100	240	140

Parkinson's Medication Distribution (#participants on med)

medication	#Participants	% of N	medication	#Participants	% of N
Stalevo	1	4%	Levodopa	4	17%
Ropinirole	9	39%	Selegiline	4	17%
Amantadine	8	35%	Sinemet	11	48%
Coq10	8	35%	Pramipexole	8	35%
Comtan	2	9%	Rasagiline	8	35%

Materials and Data Collection

Temporal data

Patients walked on a 14m flat walkway with the initial and final 2m exempt from data collection to allow for acceleration and deceleration. Gait parameters were recorded at the sampling rate of 500Hz with a computerized foot sensor system. The foot switches consisted of 4 contact sensors placed at the heel, first metatarsal, fifth metatarsal and the big toe. These were embedded into shoe inserts (Figure 1). The sensor was stored in a portable microprocessor (Figure 2) and then downloaded after the test walk into a personal computer with the interface hardware and analysis software.

Figure 1. Sensor foot switches

Figure 2. Portable microprocessor

Synchronization data

Participants' synchronization during the experimental entrainment periods was recorded using two methods of data collection. For *tapping*, a contact plate on a flat surface was used to determine the subject's finger-tapping synchronization to the

auditory stimulus (Figure 3). The subject was instructed to tap on the beat at the tempo provided by a Boss® DB-90 metronome. The beat was delivered via one Logitech® speaker, placed 1m in front of subject. The tempo was set at 120% of pre-test walking cadence, to the nearest beat-per-minute. A metallic probe was placed on the subject's index finger of the least affected hand, secured with medical tape. This probe was connected to a circuit containing a 9v battery, connected to an analog digital sampler. The circuit closed every time the probe made contact with the target plate, providing a recordable change in voltage. The target was a square metal plate attached to a board, which also contained the 9v battery circuit. This board was placed on a table 30" high, in front of the subject who was seated in an armless chair with back support. The metronome was also connected to the analog digital sampler. The sampler was connected to a computer that recorded the data (both the metronome click frequency and the subject's tapping frequency – see Figure 4 for sample graph of synchronization).

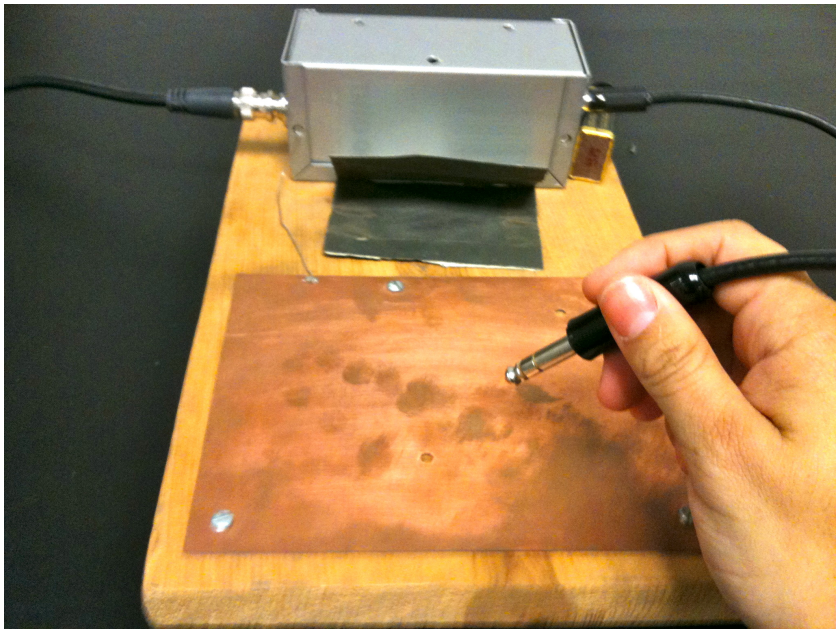

Figure 3. Tapping apparatus

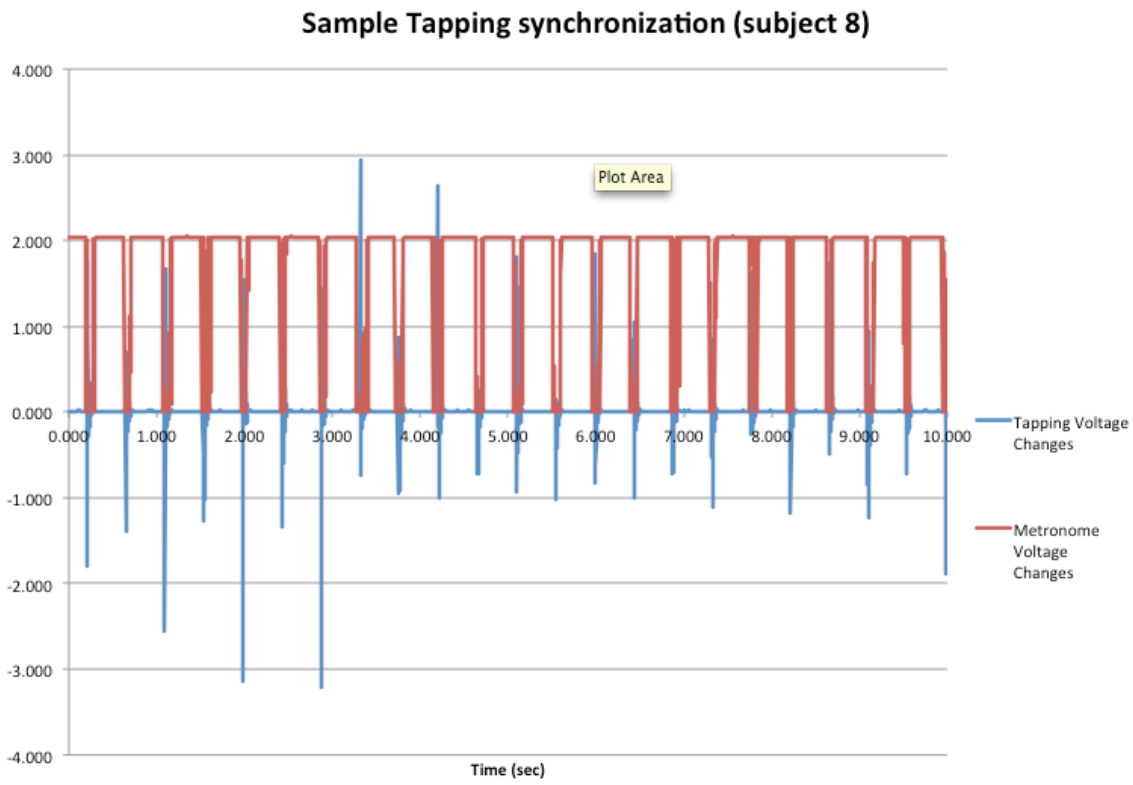

Figure 4. Sample tapping synchronization

For *arm swing*, arm kinematics was recorded using a two-dimensional (2D) video-based motion analysis system (SELSPOT) at a sampling rate of 60 frames per second. One reflective marker was placed on the dorsal part of the wrist of the least affected arm (Figure 5).

Figure 5. Reflective marker

The video camera was connected to a computer with software that coordinated the metronome clicks with the video recording of the reflective target's trajectory. The maximum Y-coordinate reached by the target during the forward swing was compared to occurrence of the metronome's click.

The auditory stimulus was provided the Boss® DB-90 metronome. The beat was delivered via on Logitech® speaker, placed 1m in front of subject. The tempo was set at 120% of pre-test walking cadence, to the nearest beat-per-minute. See Figure 6 for sample graph of arm swing synchronization data.

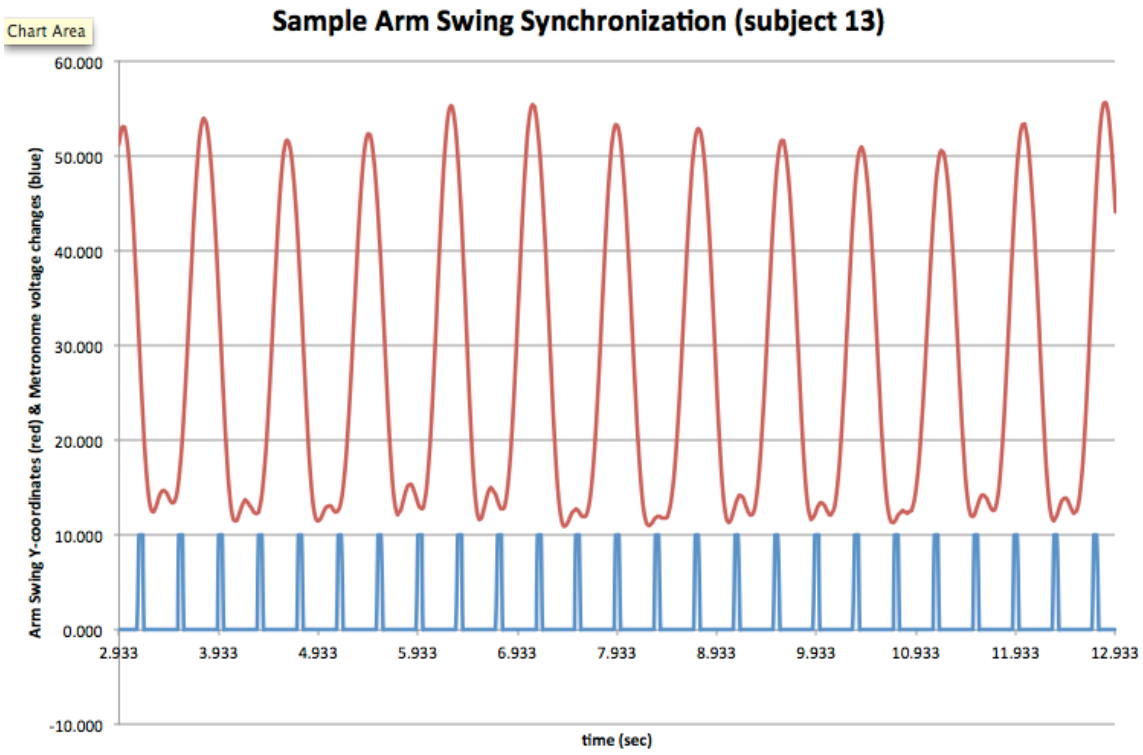

Figure 6. Sample arm swing synchronization graph

Protocol

Control condition

Subject was instructed to walk a 14m straight walkway (no data was gathered in the first and final 2m, to allow for acceleration and deceleration), at his/her preferred walking cadence. During this initial walk, subject's gait parameters were measured using shoe inserts with foot switches embedded in them.

Subject then sat on an armless chair with back support (the same model and type of chair was used in every experimental condition) for the duration of 4 minutes. After this time, the subject was instructed to walk the 14m walkway again at his/her normal walking cadence as post-test.

Tapping

Subject was instructed to walk a 14m straight walkway (no data was gathered in the first and final 2m, to allow for acceleration and deceleration), at his/her preferred walking cadence. During this initial walk, subject's gait parameters were measured using shoe inserts with foot switches embedded in them.

Subject then sat on an armless chair with back support, in front of a table containing the contact plate and tapping probe. The chair was adjusted for each subject, so that he/she could rest the forearm and elbow on the table, in a position that was most comfortable for the subject to tap with the metallic probe in the center of the metal plate. The subject wore the probe on the index finger of his/her least affected hand. The metronome was set at a 20% increase of the subject's pre-test walking cadence. Tapping occurred during three, 1-minute intervals, with a 30-second rest interval in between each interval when no tapping occurred. Tapping frequency was recorded during the middle 10 seconds of the second 1-minute tapping interval.

Tapping on the plate allowed for the analysis of tapping synchronization to the beat, to ensure rhythmic entrainment was occurring.

After the pre-gait rhythmic finger-tapping exercise was completed, the subject had the probe removed from his finger and was instructed to walk down the 14m walkway for a post-test.

Arm swing

Subject was instructed to walk a 14m straight walkway (no data was gathered in the first and final 2m, to allow for acceleration and deceleration), at his/her preferred walking cadence. During this initial walk, subject's gait parameters were measured using shoe inserts with foot switches embedded in them.

The subject then sat in an armless chair with back support. A reflective target was placed on the dorsal portion of the subject's wrist of the least affected side. This arm faced the camera while the subject sat in the armless chair. The subject was placed in front of the camera so that the full amplitude of the arm swing could be recorded. The subject was instructed to swing his/her arms with the beat of the metronome. The metronome was set at a 20% increase of his/her pre-test walking cadence. The subject completed three, 1-minute arm swing intervals with the metronome, with 30-second resting periods between intervals. Arm swing frequency was recorded during the middle 10 seconds of the second 1-minute entrainment interval.

After the rhythmic arm swing pre-gait exercise portion was completed, the subject was asked to walk down the 14m walkway, at his/her normal walking cadence, for a post-test.

Statistical Analysis

General

Summary tabulations display the number of observations, mean, standard deviation, median, range, minimum, and maximum for continuous variables and the number and percent per category for ordinal and categorical data. All endpoints of this study are presented graphically where possible.

Analysis populations

The intent-to-treat (ITT) populations consist of all subjects who have been randomized (n=26). The per-protocol **(**PP) population is defined as all subjects who have been treated according to study protocol (n=23) (i.e., all inclusion/exclusion criteria were satisfied, pre-test and post-test were completed, etc.). The analyses of all primary and secondary endpoints were performed on the PP population.

Baseline comparability

All measurements (variables) collected at baseline have been summarized and compared between study conditions. These include Parkinson's disease severity scores as well as demographic information. Comparisons between study conditions of baseline variables on a continuous scale were performed using a two-sample t-test and non-parametric Wilcoxon Rank Sum test.

Primary endpoints

Absolute cadence (steps/min), absolute velocity (m/min), and absolute stride length (m) were the primary endpoints of this study. They were analyzed in terms of means and standard deviations for the pre-test and post-test assessments. Mean percentage changes between pre-test and post-test assessments were computed and evaluated using an analysis of variance (ANOVA), F-Test across groups. In order to control the type I error (to be less than 5%), the Dunnett's procedure for multiple comparisons was used to compare changes in cadence, velocity, and stride length

measurements between the two experimental conditions and the control group. T-tests were completed as part of the analysis of variance to test if changes were significantly different from zero.

CHAPTER IV: RESULTS

Subject comparability analysis

Comparison of subject characteristics involved the Wilcoxon test on all assessment measurements (UPDRS, NHPT, H&Y, and Berg's balance scale). No significant differences were found between groups. Table 3 outlines mean assessment scores for UPDRS, NHPT and Berg's, and Table 4 outlines the statistical analysis on these mean scores for subject comparability purposes.

Table 3:

Mean Assessment Scores

Nine Hole Peg Test - Dominant Hand (sec)

Condition	Mean	SD	Median	Min	Max	Range
Control	28.61	5.1	27.83	23.27	35.15	11.88
Arm Swing	35.85	15.1	35.25	18.8	73.1	54.3
Tapping	33.42	19.95	29.3	24.68	80.45	55.77
Total	33.53	14.47	30.13	18.8	80.45	61.65

Berg Balance Scale Scores

Condition	Mean	SD	Median	Min	Max	Range
Control	54.4	1.6	54	52	56	4
Arm Swing	53.3	5.1	55	40	56	16
Tapping	54	5.6	56	49	56	7
Total	53.6	3.8	55	40	56	16

Unified Parkinson's Disease Rating Scale Scores (selected scores from Part III & IV assessment)

	Median	Min	Max	Range	Mode
Upper Extremity Rigidity	0	0	3	3	0
Lower Extremity Rigidity	0	0	3	3	0
Leg Agility	0	0	4	4	0
Gait	1	0	2	2	1
Freezing of Gait	0	0	0	0	0
Postural Stability	1	0	3	3	0
Body Bradykinesia	1	0	3	3	1
Postural Tremor	0	0	2	2	0
Kinetic Tremor	0	0	2	2	0
Resting Tremor UE	0	0	2	2	0
Resting Tremor LE	0	0	1	1	0

Table 4: Subject Cmparability Statistics

RANK SUMS							kruskal-wallis test		
assessment	condition	N	sum of scores	expected under H0	st dev under HO	mean score	chi-square	df	p>chi-square
updrs	Tapping	7	77.0	84.000	14.937	11.000	0.526	2	0.769
	Swing	9	104.5	108.000	15.843	11.611			
	Control	7	94.5	84.000	14.937	13.500			
H&Y	Tapping	7	71.5	84.000	12.936	10.214	2.083	2	0.353
	Swing	9	127.5	108.000	13.721	14.167			
	Control	7	77.0	84.000	12.936	11.000			
Berg	Tapping	7	107.0	108.000	14.937	11.889	0.117	2	0.943
	Swing	9	88.5	84.000	14.083	12.643			
	Control	7	80.5	84.000	14.083	11.500			
NHPT	Tapping	7	63.0	84.000	14.967	9.000	4.447	2	0.108
	Swing	9	141.0	108.000	15.875	15.667		(exact)	
	Control	7	72.0	84.000	14.967	10.286			0.107

NUMBER OF POINTS ABOVE MEDIAN							median one-way analysis		
assessment	condition	N	sum of scores	expected under H0	st dev under HO	mean score	chi-square	df	p>chi-square
updrs	Tapping	7	3.0	3.348	1.127	0.429	0.339	2	0.844
	Swing	9	4.0	4.304	1.195	0.444			
	Control	7	4.0	3.348	1.127	0.571			
H&Y	Tapping	7	2.9	3.348	0.799	0.408	1.772	2	0.412
	Swing	9	5.4	4.304	0.847	0.603			
	Control	7	2.7	3.348	0.799	0.388			
Berg	Tapping	7	3.0	3.348	1.127	0.429	0.339	2	0.844
	Swing	9	4.0	4.304	1.195	0.444			
	Control	7	4.0	3.348	1.127	0.571			
NHPT	Tapping	7	71.0	84.000	15.875	9.571	3.596	2	0.166
	Swing	9	138.0	108.000	14.967	15.333		(exact)	
	Control	7	67.0	84.000	14.967	10.143			0.167

Synchronization analysis

Entrainment during treatment (tap or swing) was defined by matching endpoints (for each beat a corresponding tap or swing). All subjects in the arm-swing protocol entrained to the beat. In the tapping protocol, subject 10 had fewer responses than the number of cues provided (4 taps for 19 auditory cues); therefore, he did not entrain to the beat.

Mean synchronization error refers to the mean closeness of time matching between cue and response (phase synchronization) – Subject 10 did not display phase synchronization (Subject 10 mean synchronization error = -3.978 sec) while all other participants displayed phase synchronization (Table 5: tapping group mean synchronization error = 0.026 sec; Table 6: swing group mean synchronization error = 0.071sec).

Table 5: Tapping Synchronization Analysis

Subject #	Mean sync err (sec)	Sync err St dev (sec)	Mean absolute per err (sec)	Abs per error st dev (sec)
1	-0.007	0.016	0.020	0.013
8	-0.024	0.010	0.010	0.009
10*	3.978	3.632	1.795	2.316
14	0.020	0.021	0.026	0.022
19	0.064	0.024	0.016	0.014
21	0.062	0.011	0.014	0.008
24	0.039	0.019	0.019	0.017
Group Means: *(excluding S10)*	0.026	0.017	0.017	0.014

**Subject 10 executed 5 taps (responses) to 19 clicks (stimulus)*

The variability of the synchronization responses is represented by the mean standard error of the synchronization error. Subject 10 demonstrated the greatest synchronization variability (Subject 10 mean standard error = 3.632 sec; Table 5: Tapping group mean standard error = 0.017 sec; Table 6: Arm-swing group mean standard error = 0.241 sec). The mean standard error in the arm swing group is significantly greater than that of the tapping group (Table 7: Z=-2.2613, p=0.0237), which suggests that there is greater variability in the synchronization of arm swing to the beat than in tapping to a beat.

Table 6: Arm Swing Synchronization Analysis

Subject #	Mean sync err (sec)	Sync err St dev (sec)	Mean absolute per err (sec)	Abs per error st dev (sec)
3	0.269	0.218	0.094	0.224
5	0.160	0.438	0.300	0.068
7	0.478	0.412	0.173	0.036
12	-0.198	0.068	0.035	0.019
13	-0.162	0.013	0.010	0.006
15	0.134	0.028	0.026	0.021
16	0.202	0.017	0.012	0.016
20	1.108	0.754	0.218	0.380
22	-0.165	0.018	0.017	0.017
23	-0.168	0.131	0.014	0.016
25	-0.876	0.556	0.150	0.073
Group means:	0.071	0.241	0.095	0.080

Table 7: Variability Analysis

arm swing	Subject #	Sync err St dev (sec)		
	3	0.218		
	5	0.438		
	7	0.412		
	12	0.068		
	13	0.013		
	15	0.028		
	16	0.017		
	20	0.754		
	22	0.018		
	23	0.131	mean	st. dev
	25	0.556	0.241	0.258930628
tapping	Subject #	Sync err St dev (sec)		
	1	0.016		
	8	0.010		
	14	0.021		
	19	0.024		
	21	0.011	mean	st. dev
	24	0.019	0.017	0.00556477

Significant difference between groups

Wilcoxon Two-Sample Test

Z=-2.2613

p=0.0237

Kruskal Wallis Test

Chi-square = 5.3434

df=1

p=0.0208

Absolute period error quantifies the period synchronization (Subject 10 Absolute period error = 1.795sec; Table 5: tapping group mean absolute period error = 0.017sec; Table 6: arm swing group absolute period error = 0.080sec). Once again, Subject 10

displays the least period synchronization, and arm swing's absolute period error is greater than that of the tapping group.

Gait parameters

Primary analysis involved the use of t-tests as part of the one-way analysis of variance to identify differences between pre and post treatment measurements within groups, measuring whether each treatment had an effect on gait parameters. Table 8 lists individual pre/post treatment scores as well as corresponding descriptive statistics. Table 9 provides the statistical analysis of pre/post mean score changes in gait parameters.

Table 3.1 Individual Pre-treatment and Post-treatment Scores

subject	condit	PRE number of stride	POST number of stride	PRE abs velocity (m/m	POST abs velocity (m/mi	PRE abs cadence (step/m	POST abs cadence (step/m	metronome (bp	PRE abs stride length (m)	POST abs stride length (m)	PRE abs gait cycle (sec)	POST abs gait cycle (sec	PRE Rt single limb (se	POST Rt single limb (sec)	PRE Lt single limb (sec	POST Lt single limb (sec)	PRE LT single limb % gait cycle	POST LT single limb % gait cycle
4	C	8	8	63.8	63.8	119.7	119.7	control	1.066	1.066	1.00	1.00	0.375	0.375	0.398	0.398	39.7	39.7
6	C	6	6	67.6	69.7	100.9	102.1	control	1.339	1.364	1.19	1.17	0.474	0.457	0.486	0.457	40.9	38.9
9	c	6	6	75.8	74.8	112.6	113.0	control	1.346	1.324	1.07	1.06	0.371	0.357	0.374	0.294	35.1	27.7
11	c	10	9	40.4	43.4	92.9	95.5	control	0.870	0.909	1.29	1.26	0.378	0.365	0.417	0.407	32.3	32.4
17	c	7	7	75.3	67.5	123.2	119.8	control	1.222	1.128	0.97	1.00	0.357	0.382	0.347	0.347	35.6	34.6
18	c	6	7	68.7	69.9	109.3	114.2	control	1.257	1.225	1.10	1.05	0.427	0.407	0.391	0.377	35.6	35.9
26	c	5	6	79.2	72.5	111.7	109.1	control	1.418	1.329	1.07	1.10	0.398	0.411	0.392	0.378	36.5	34.4
3	S	11	10	38.9	43.8	99.6	100.4	120	0.781	0.873	1.20	1.20	0.346	0.321	0.325	0.352	27.0	29.5
5	S	8	8	34.6	29.1	62.5	55.6	75	1.106	1.048	1.92	2.16	0.691	0.750	0.728	0.815	37.9	37.8
12	s	5	5	80.3	78.7	103.6	101.7	124	1.550	1.548	1.16	1.18	0.408	0.416	0.401	0.399	34.6	33.8
13	s	6	6	86.1	80.9	121.9	120.1	146	1.413	1.347	0.98	1.00	0.374	0.359	0.375	0.382	38.1	38.2
15	s	6	6	67.1	68.9	106.5	104.9	128	1.259	1.315	1.13	1.14	0.422	0.429	0.430	0.439	38.1	38.3
16	s	6	6	71.7	77.0	103.7	109.6	124	1.382	1.406	1.16	1.10	0.417	0.405	0.469	0.442	40.5	40.4
22	s	7	7	71.4	63.1	112.0	113.1	134	1.275	1.115	1.07	1.06	0.380	0.403	0.450	0.410	42.0	38.7
23	s	6	5	74.4	77.9	106.3	108.2	128	1.399	1.440	1.13	1.11	0.404	0.399	0.430	0.430	38.1	38.7
25	s	6	6	75.8	77.5	119.1	118.4	143	1.273	1.310	1.01	1.01	0.382	0.393	0.389	0.388	38.6	38.2
1	T	6	6	78.8	80.6	118.1	121.4	142	1.334	1.328	1.02	0.99	0.370	0.363	0.387	0.371	38.1	37.5
8	T	6	5	76.4	89.4	112.1	121.0	135	1.364	1.477	1.07	0.99	0.366	0.342	0.389	0.356	36.3	35.9
10	t	6	6	67.6	69.5	102.5	104.6	123	1.318	1.329	1.17	1.15	0.480	0.451	0.523	0.497	44.7	43.3
14	t	5	6	75.3	80.3	103.2	112.8	124	1.459	1.425	1.16	1.06	0.446	0.384	0.417	0.390	35.9	36.7
19	t	9	9	48.0	54.4	102.6	111.0	123	0.936	0.980	1.17	1.08	0.404	0.377	0.406	0.380	34.8	35.1
21	t	5	6	79.0	78.6	110.6	111.5	133	1.429	1.410	1.09	1.08	0.414	0.411	0.400	0.390	36.9	36.3
24	t	6	7	75.7	69.5	120.2	117.8	144	1.260	1.180	1.00	1.02	0.345	0.351	0.336	0.341	33.7	33.5
control	Mean	6.857	7.000	67.3	65.9	110.0	110.5	n/a	1.217	1.192	1.10	1.09	0.397	0.393	0.401	0.380	36.5	34.8
	SD	1.676	1.155	13.0	10.5	10.4	9.0	n/a	0.190	0.167	0.11	0.09	0.041	0.034	0.043	0.051	2.9	4.0
	Median	6	7	68.7	69.7	111.7	113	#NUM!	1.257	1.225	1.07	1.06	0.38	0.382	0.392	0.378	35.6	34.6
	Mode	6	6	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	#N/A	1.07	1	#N/A	#N/A	#N/A	#N/A	35.6	#N/A
	Min	5	6	40.4	43.4	92.9	95.5	0	0.87	0.909	0.97	1	0.36	0.357	0.347	0.294	32.3	27.7
	Max	10	9	79.2	74.8	123.2	119.8	0	1.418	1.364	1.29	1.26	0.47	0.457	0.486	0.457	40.9	39.7
	Range	5	3	38.8	31.4	30.3	24.3	0	0.548	0.455	0.32	0.26	0.12	0.1	0.139	0.163	8.6	12
Arm Swing	Mean	6.778	6.556	66.7	66.3	103.9	103.6	124.667	1.271	1.267	1.20	1.22	0.425	0.431	0.444	0.451	37.2	37.1
	SD	1.787	1.590	17.9	18.2	17.2	19.2	20.585	0.222	0.214	0.28	0.36	0.103	0.124	0.115	0.140	4.3	3.3
	Median	6	6	71.7	77	106.3	108.2	128	1.275	1.315	1.13	1.11	0.4	0.403	0.43	0.41	38.1	38.2
	Mode	6	6	#N/A	#N/A	#N/A	#N/A	124	#N/A	#N/A	1.16	#N/A	#N/A	#N/A	0.43	#N/A	38.1	38.2
	Min	5	5	34.6	29.1	62.5	55.6	75	0.781	0.873	0.98	1	0.35	0.321	0.325	0.352	27	29.5
	Max	11	10	86.1	80.9	121.9	120.1	146	1.55	1.548	1.92	2.16	0.69	0.75	0.728	0.815	42	40.4
	Range	6	5	51.5	51.8	59.4	64.5	71	0.769	0.675	0.94	1.16	0.35	0.429	0.403	0.463	15	10.9
Tapping	Mean	6.143	6.429	71.5	74.6	109.9	114.3	132.000	1.300	1.304	1.10	1.05	0.404	0.383	0.408	0.389	37.2	36.9
	SD	1.345	1.272	11.1	11.3	7.4	6.1	8.944	0.174	0.172	0.07	0.06	0.048	0.038	0.057	0.051	3.6	3.1
	Median	6	6	75.7	78.6	110.6	112.8	133	1.334	1.329	1.09	1.06	0.4	0.377	0.4	0.38	36.3	36.3
	Mode	6	6	#N/A	69.5	#N/A	#N/A	123	#N/A	#N/A	1.17	0.99	#N/A	#N/A	#N/A	0.39	#N/A	#N/A
	Min	5	5	48	54.4	102.5	104.6	123	0.936	0.98	1	0.99	0.35	0.342	0.336	0.341	33.7	33.5
	Max	9	9	79	89.4	120.2	121.4	144	1.459	1.477	1.17	1.15	0.48	0.451	0.523	0.497	44.7	43.3
	Range	4	4	31	35	17.7	16.8	21	0.523	0.497	0.17	0.16	0.14	0.109	0.187	0.156	11	9.8

The tapping protocol's absolute cadence increased significantly (mean absolute cadence change = 4.4 steps/min, standard error = 1.300 steps/min, p=0.0051). The mean absolute cadence change for the arm swing group was -0.355 steps/min, with standard error = 1.234, which was not found to be a significant change (p=0.7763). The arm swing exercise appears to have decreased mean absolute cadence, but this change is not statistically significant (p=0.776). Tapping groups' mean absolute cadence change was significantly different (p=0.0191) from that of the arm swing group (mean absolute cadence change in tapping group = 0.443 steps/min, standard error = 1.307 steps/min).

Table 9: Statistical analysis of pre/post mean score changes in gait parameters (between groups)

parameter	condition	mean change	standard error	H0:LSMean =0	H0:LSMean =control
# of strides	control	0.143	0.237	0.553	
	arm swing	-0.222	0.209	0.300	0.416
	tapping	0.286	0.237	0.241	0.875
absolute velocity (m/s)	control	0.143	1.931	0.504	
	arm swing	-0.378	1.703	0.827	0.907
	tapping	3.071	1.931	0.127	0.210
absolute cadence* (steps/min)	control	0.443	1.400	0.755	
	arm swing	-0.356	1.234	0.776	0.874
	tapping	4.400	1.400	**0.005**	0.104
absolute stride length (m)	control	-0.025	0.025	0.334	
	arm swing	-0.004	0.022	0.858	0.758
	tapping	0.004	0.025	0.870	0.628
absolute gait cycle (sec)	control	-0.007	0.023	0.762	
	arm swing	0.022	0.021	0.293	0.545
	tapping	-0.044	0.023	0.072	0.433

**significant change in mean absolute cadence scores for tapping group*

Table 10: Statistical Analysis of mean change in scores for absolute cadence (between

Condition	Cadence LSMean (steps/min)	standard	Pr > |t|
control	0.4429	1.3996	0.7550
arm swing	-0.3556	1.2343	0.7763
tapping	4.4000	1.3996	**0.0051**

H0:LSMean of Control = LSMean of Arm Swing
p=0.6733
H0:LSMean of Control = LSMean of Tapping
p=0.0594
H0:LSMean of Tapping = LSMean of Arm Swing
p=0.0191

Secondary analysis involved a one-way analysis of variance comparing the three conditions to compare changes of scores between pre and post treatment across groups. A significant difference in mean changes between groups was found in absolute cadence (F=3.54, p=0.0483). This difference was due to the significant mean change in absolute cadence in the tapping group as stated before. No other significant differences between groups were found. The percentage change in absolute cadence was compared across groups with no significant difference found (Table 12: F=3.18, p=0.0632).

Table 11: Percentage Change in Absolute Cadence

subject #	condition	% change in treatment	% change in post-test		
4	C	n/a	0.00		
6	C	n/a	0.01		
9	c	n/a	0.00		
11	c	n/a	0.03		
17	c	n/a	-0.03		
18	c	n/a	0.04	Mean	St Dev
26	c	n/a	-0.02	0.01	0.02598347
3	S	0.2	0.01		
5	S	0.2	-0.11		
12	s	0.2	-0.02		
13	s	0.2	-0.01		
15	s	0.2	-0.02		
16	s	0.2	0.06		
22	s	0.2	0.01		
23	s	0.2	0.02	Mean	St Dev
25	s	0.2	-0.01	-0.01	0.04492733
1	T	0.2	0.03		
8	T	0.2	0.08		
10	t	0.2	0.02		
14	t	0.2	0.09		
19	t	0.2	0.08		
21	t	0.2	0.01	Mean	St Dev
24	t	0.2	-0.02	0.04	0.04327609

%'s expressed in decimal points

No Significant difference between groups
F = 3.18
p=0.0632

To summarize, entrainment occurred in both conditions (tapping and arm swing) but arm swing resulted in higher phase synchronization variability than tapping (during treatment) and was also found to result in no significant changes in gait parameters. Gait

parameter changes were found in the tapping protocol with significant increase in mean change in absolute cadence, which was significantly different from the change seen in the arm swing group.

CHAPTER V: DISCUSSION

Studies have shown that auditory cues have benefits in PD gait rehabilitation (Cody, Ashton, Howe, Lovegreen, & Oldham, 2003). The present study investigated the immediate effects of a rhythmic arm swing exercise vs. a rhythmic finger tapping exercise on gait parameters of individuals in the early stages of PD.

Results showed a significant increase in the mean change in absolute cadence in the tapping treatment group, while no significant changes were found in the arm swing and control groups. This is an interesting finding, considering the fact that both treatment groups synchronized to the beat. However, it was found that the arm swing phase synchronization variability was significantly higher than that of the tapping protocol. This could be a possible explanation for difference between tapping and arm swing protocols' results.

Another possible explanations for the statistical insignificant change in gait in the arm swing treatment group is the fact that since this exercise required greater physical demand from the subject (compared to the other conditions), fatigue may be a confounding variable. The mean changes in absolute cadence, velocity, and stride length for the arm swing group decreased. Although this mean decrease in arm swing scores was not found to be statistically significant, it is important to note that the arm swing group was the only group whose mean parameters *decreased*.

It is also possible that the results found in the arm swing group involves the amplitude of the arm swing during the exercise was decreased due to the increased cue

frequency. Studies have shown that increased arm swing amplitude during walking increases gait parameters (Eke-Okoro, Gregoric, & Larsson, 1997).

In the present study, all subjects' auditory cue was set to 120% of their preferred walking cadence. These subjects were all within stages 0-2 of the Hoehn & Yahr scale with a mean absolute pre-treatment cadence (for all groups) of 108±3.5 steps/min. Perhaps the increase of 20% may have created a frequency template that was too high and consequently decreased the amplitude of arm swing, resulting in decreased gait parameters. Future studies may include subject-based increase or decrease in auditory cue frequencies to elicit greater arm swing amplitude.

It is also of interest to better understand the neurological differences between the two tasks and how they relate to gait. Gait kinematics involve arm swing, therefore it may be possible that arm swing as an isolated movement may not have significant effects on gait when it is decoupled from the task itself. Conversely, finger tapping is a motor task that is independent of walking, while it is still a rhythmic movement, it is not one that normally occurs in conjunction with the legs in walking, therefore it is possible to isolate it as a rhythmic entrainment exercise that can result in changes within gait parameters.

It is important to note that the immediate effects in both treatment groups showed that the percentage change in cadence is significantly lower than the 20% increase provided by the auditory cue. While this frequency template provided by the metronome seems to result in a change in tempo as an immediate effect, but does not serve as a template that is matched after treatment. Perhaps this frequency change fades quickly after the exercise is completed.

As mentioned before, a significant change in mean absolute cadence was found in the tapping treatment group. A possible explanation would be the nature of the exercise – a rhythmic exercise that is not part of gait kinematics. Tapping to a beat perhaps demonstrated immediate effects due to the non-ambulatory nature of the exercise and its ability to be isolated from gait kinematics.

However, based on analysis of synchronization variability, the tapping entrainment exercise exhibited significantly less variability than that of the arm swing exercise (during entrainment), and the tapping exercise's better phase synchronization could account for the immediate frequency change (although the percentage of change was not found to be significant in any group) in stepping motion found in the tapping protocol, compared to the lack of significant change in the arm swing protocol (where phase synchronization was significantly higher than in the tapping entrainment).

Arm swing as a seated pre-gait rhythmic exercise did not result in any significant changes in gait parameters. However, diminished arm swing remains a major symptom of PD and it has negative implications on gait parameters. It is important to target arm swing during gait rehabilitation, but based on this study's findings, it may not be of any benefit to decouple the arm swing movement from the leg motion involved in gait.

This pilot study has demonstrated a significant change in the mean absolute cadence of patients within the early stages of PD when they were instructed to simply tap their fingers on a plate with the beat of a metronome set to 120% of their preferred walking cadence. Perhaps such a simple task could be included in the daily gait training routine of an individual with PD. An exercise that can be done safely while seated and has very minimal physical demand, could be an exercise that could help improve the gait

parameters in individuals with PD, in combination with other exercises that have been found beneficial for safe walking.

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APPENDIX I: CONSENT FORM

Consent to Participate in a Research Study
Colorado State University

TITLE OF STUDY: The effects of a seated rhythmic arm swing entrainment exercise on gait parameters of Parkinson's patients.

PRINCIPAL INVESTIGATOR: Dr. Michael H. Thaut, (970) 491-5533, Michael.Thaut@ColoState.EDU

CO-PRINCIPAL INVESTIGATOR: Marion Z. Haase, (713) 408-0597, mzcnatural@gmail.com

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH? You have been invited to participate in this study because you have been recently diagnosed with Parkinson's disease.

WHO IS DOING THE STUDY? The study is being conducted at Colorado State University's (CSU) Center for Biomedical Research in Music (CBRM). Dr. Michael Thaut is the scientific director of CBRM, and professor of music and neuroscience at CSU. Marion Haase is a Board-Certified, Neurologic Music Therapist, working on her Master's in Music Therapy at CSU.

WHAT IS THE PURPOSE OF THIS STUDY? The purpose of this study is to see if patients with Parkinson's disease can benefit from a seated exercise that involves swinging the arms to the beat of a metronome. More specifically, we are interested in seeing if this exercise can help patients with Parkinson's disease (PD) walk more safely, by increasing the speed and the size of their steps.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST? The study will take place at Colorado State University's Center for Biomedical Research in Music at the University's Center for the Arts (UCA room 146). You will participate one time. The study will not take more than 2.5 hours.

WHAT WILL I BE ASKED TO DO? You will be asked to wear dark clothes because you will have to wear a reflective marker that the computer needs to be able to identify, and comfortable walking shoes (no flip-flops, slippers or high heels). Thin shoe inserts will be put in your shoe. These have sensitive switches that will be plugged into a small metal box that will be attached to your back using a belt. This box will record how you walk. This is the order of events:

1) Assessments: We will do three tests to test your balance and your physical abilities. These tests include the Berg's balance test, the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) parts III and IV (for arm function), and the 9-hole peg test (to test arm function).
2) The experiment:
    a. First, you will walk for 14 meters (approximately 15.5 yards) straight. At this time, we will be recording your walking with the foot switches in your shoes.
    b. You will walk to the computer to transfer the information from the box on your back. A chair will be provided while you wait.
    c. You will do one of these three (only one): 1) sit in a chair and swing your arms to a beat from a metronome while wearing a reflective ball on the wrist of your least affected arm (this will be taped using medical tape), 2) sit in a chair and tap a metal probe onto a metal plate to a beat from a metronome, or 3) sit in a chair and rest for 6.5 minutes
    d. You will walk again down the 14 meters (approximately 15.5 yards), followed by going to the computer to transfer the information from the box on your back.

ARE THERE REASONS WHY I SHOULD NOT TAKE PART IN THIS STUDY?
You should not be in this study if:

1) your doctor has rated you to be in stage 3-5 of the Hoehn and Yahr Parkinson's scale
2) you are not able to walk independently without a walker or a cane for at least 14 meters (approximately 15.5 yards) at a time, no more than 4 times
3) you are hard of hearing, or legally blind
4) you have other medical complications (i.e., heart disorders, pulmonary disorders, etc)
5) you walk very quickly
6) You do not wish to participate in this study

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- The shoe inserts have the feel of cardboard, you may find this uncomfortable in your shoes.
- The box strapped to your back may feel uncomfortable, especially while seated (it is like wearing a metal fannypack on your back)
- If you must wear the reflective marker, although medical tape will be used, it may pull on some of your arm hair when taking it off. Tape will also be used to attach the metal probe on those participants who will be tapping a metal plate.
- It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards to minimize any known and potential, but unknown, risks.

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY? There are no known benefits to participating, but this study hopes to find it beneficial for Parkinson's patients to do an exercise while seated which involves swinging the arms to a beat. We hope to find that doing this exercise will enhance walking by helping you take bigger steps and walk at a faster speed.

DO I HAVE TO TAKE PART IN THE STUDY Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

WHO WILL SEE THE INFORMATION THAT I GIVE?
We will keep private all research records that identify you, to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep you name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from your research records and these two things will be stored in different places under lock and key.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY? There is no compensation for participating in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THE RESEARCH? The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 180 days of the injury.

WHAT IF I HAVE QUESTIONS?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, Marion Z. Haase at 713-408-0597 or mzcnatural@gmail.com, or Dr. Michael H. Thaut, the scientific director at CBRM (970) 491-5533, Michael.Thaut@ColoState.edu.

If you have any questions about your rights as a volunteer in this research, contact Janell Barker, Human Research Administrator at 970-491-1655. We will give you a copy of this consent form to take with you.

This consent form was approved by the CSU Institutional Review Board for the protection of human subjects in research on (Approval Date).

WHAT ELSE DO I NEED TO KNOW? You may be part of one of the experimental conditions which will require us to record video of you swinging your arms to the beat.

Your signature acknowledges that you have read the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 3 pages.

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person agreeing to take part in the study

_____ _____

Name of person providing information to participant Date

_____

Signature of Research Staff

APPENDIX II: UNIFIED PARKINSON'S DISEASE RATING SCALE

Part III: Motor Examination

Overview: This portion of the scale assesses the motor signs of PD. In administering Part III of the MDS-UPDRS the examiner should comply with the following guidelines:

At the top of the form, mark whether the patient is on medication for treating the symptoms of Parkinson's disease and, if on levodopa, the time since the last dose.

Also, if the patient is receiving medication for treating the symptoms of Parkinson's Disease, mark the patient's clinical state using the following definitions:

ON is the typical functional state when patients are receiving medication and have a good response.
OFF is the typical functional state when patients have a poor response in spite of taking medications.

The investigator should "rate what you see". Admittedly, concurrent medical problems such as stroke, paralysis, arthritis, contracture, and orthopedic problems such as hip or knee replacement and scoliosis may interfere with individual items in the motor examination. In situations where it is absolutely impossible to test (e.g., amputations, plegia, limb in a cast), use the notation "**UR**" for Unable to Rate. Otherwise, rate the performance of each task as the patient performs in the context of co-morbidities.

All items must have an integer rating (no half points, no missing ratings).

Specific instructions are provided for the testing of each item. These should be followed in all instances. The investigator demonstrates while describing tasks the patient is to perform and rates function immediately thereafter. For Global Spontaneous Movement and Rest Tremor items (3.14 and 3.17), these items have been placed purposefully at the end of the scale because clinical information pertinent to the score will be obtained throughout the entire examination.

At the end of the rating, indicate if dyskinesia (chorea or dystonia) was present at the time of the examination, and if so, whether these movements interfered with the motor examination.

3a Is the patient on medication for treating the symptoms of Parkinson's Disease? ☐ No ☐ Yes

3b If the patient is receiving medication for treating the symptoms of Parkinson's Disease, mark the patient's clinical state using the following definitions:

☐ ON: On is the typical functional state when patients are receiving medication and have a good response.

☐ OFF: Off is the typical functional state when patients have a poor response in spite of taking medications.

3c Is the patient on Levodopa ? ☐ No ☐ Yes

3.C1 If yes, minutes since last levodopa dose: _____

	SCORE
3.1 SPEECH Instructions to examiner: Listen to the patient's free-flowing speech and engage in conversation if necessary. Suggested topics: ask about the patient's work, hobbies, exercise, or how he got to the doctor's office. Evaluate volume, modulation (prosody) and clarity, including slurring, palilalia (repetition of syllables) and tachyphemia (rapid speech, running syllables together). 0: Normal: No speech problems. 1: Slight: Loss of modulation, diction or volume, but still all words easy to understand. 2: Mild: Loss of modulation, diction, or volume, with a few words unclear, but the overall sentences easy to follow. 3: Moderate: Speech is difficult to understand to the point that some, but not most, sentences are poorly understood. 4: Severe: Most speech is difficult to understand or unintelligible.	☐
3.2 FACIAL EXPRESSION Instructions to examiner: Observe the patient sitting at rest for 10 seconds, without talking and also while talking. Observe eye-blink frequency, masked facies or loss of facial expression, spontaneous smiling and parting of lips. 0: Normal: Normal facial expression. 1: Slight: Minimal masked facies manifested only by decreased frequency of blinking. 2: Mild: In addition to decreased eye-blink frequency, Masked facies present in the lower face as well, namely fewer movements around the mouth, such as less spontaneous smiling, but lips not parted. 3: Moderate: Masked facies with lips parted some of the time when the mouth is at rest. 4: Severe: Masked facies with lips parted most of the time when the mouth is at rest.	☐

	SCORE
3.3 RIGIDITY Instructions to examiner: Rigidity is judged on slow passive movement of major joints with the patient in a relaxed position and the examiner manipulating the limbs and neck. First, test without an activation maneuver. Test and rate neck and each limb separately. For arms, test the wrist and elbow joints simultaneously. For legs, test the hip and knee joints simultaneously. If no rigidity is detected, use an activation maneuver such as tapping fingers, fist opening/closing, or heel tapping in a limb not being tested. Explain to the patient to go as limp as possible as you test for rigidity. 0: Normal: No rigidity. 1: Slight: Rigidity only detected with activation maneuver. 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved. 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort. 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.	☐ Neck ☐ RUE ☐ LUE ☐ RLE ☐ LLE
3.4 FINGER TAPPING Instructions to examiner: Each hand is tested separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to tap the index finger on the thumb 10 times as quickly AND as big as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problems. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) the amplitude decrements near the end of the 10 taps. 2: Mild: Any of the following: a) 3 to 5 interruptions during tapping; b) mild slowing; c) the amplitude decrements midway in the 10-tap sequence. 3: Moderate: Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st tap. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L

	SCORE
3.5 HAND MOVEMENTS Instructions to examiner: Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to make a tight fist with the arm bent at the elbow so that the palm faces the examiner. Have the patient open the hand 10 times as fully AND as quickly as possible. If the patient fails to make a tight fist or to open the hand fully, remind him/her to do so. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problem. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task. 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task. 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L
3.6 PRONATION-SUPINATION MOVEMENTS OF HANDS Instructions to examiner: Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to extend the arm out in front of his/her body with the palms down; then to turn the palm up and down alternately 10 times as fast and as fully as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problems. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence. 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence. 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing c) the amplitude decrements starting after the 1st supination-pronation sequence. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L

	SCORE
3.7 TOE TAPPING Instructions to examiner: Have the patient sit in a straight-backed chair with arms, both feet on the floor. Test each foot separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the heel on the ground in a comfortable position and then tap the toes 10 times as big and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problem. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) amplitude decrements near the end of the ten taps. 2: Mild: Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task. 3: Moderate: Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the first tap. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L
3.8 LEG AGILITY Instructions to examiner: Have the patient sit in a straight-backed chair with arms. The patient should have both feet comfortably on the floor. Test each leg separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the foot on the ground in a comfortable position and then raise and stomp the foot on the ground 10 times as high and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problems. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task. 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task. 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the first tap. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L

	SCORE
3.9 ARISING FROM CHAIR Instructions to examiner: Have the patient sit in a straight-backed chair with arms, with both feet on the floor and sitting back in the chair (if the patient is not too short). Ask the patient to cross his/her arms across the chest and then to stand up. If the patient is not successful, repeat this attempt a maximum up to two more times. If still unsuccessful, allow the patient to move forward in the chair to arise with arms folded across the chest. Allow only one attempt in this situation. If unsuccessful, allow the patient to push off using his/her hands on the arms of the chair. Allow a maximum of three trials of pushing off. If still not successful, assist the patient to arise. After the patient stands up, observe the posture for item 3.13 0: Normal: No problems. Able to arise quickly without hesitation. 1: Slight: Arising is slower than normal; or may need more than one attempt; or may need to move forward in the chair to arise. No need to use the arms of the chair. 2: Mild: Pushes self up from arms of chair without difficulty. 3: Moderate: Needs to push off, but tends to fall back; or may have to try more than one time using arms of chair, but can get up without help. 4: Severe: Unable to arise without help.	☐
3.10 GAIT Instructions to examiner: Testing gait is best performed by having the patient walking away from and towards the examiner so that both right and left sides of the body can be easily observed simultaneously. The patient should walk at least 10 meters (30 feet), then turn around and return to the examiner. This item measures multiple behaviors: stride amplitude, stride speed, height of foot lift, heel strike during walking, turning, and arm swing, but not freezing. Assess also for "freezing of gait" (next item 3.11) while patient is walking. Observe posture for item 3.13 0: Normal: No problems. 1: Slight: Independent walking with minor gait impairment. 2: Mild: Independent walking but with substantial gait impairment. 3: Moderate: Requires an assistance device for safe walking (walking stick, walker) but not a person. 4: Severe: Cannot walk at all or only with another person's assistance.	☐

	SCORE
3.11 FREEZING OF GAIT Instructions to examiner: While assessing gait, also assess for the presence of any gait freezing episodes. Observe for start hesitation and stuttering movements especially when turning and reaching the end of the task. To the extent that safety permits, patients may NOT use sensory tricks during the assessment. 0: Normal: No freezing. 1: Slight: Freezes on starting, turning or walking through doorway with a single halt during any of these events, but then continues smoothly without freezing during straight walking. 2: Mild: Freezes on starting, turning or walking through doorway with more than one halt during any of these activities, but continues smoothly without freezing during straight walking. 3: Moderate: Freezes once during straight walking. 4: Severe: Freezes multiple times during straight walking.	☐
3.12 POSTURAL STABILITY Instructions to examiner: The test examines the response to sudden body displacement produced by a quick, forceful pull on the shoulders while the patient is standing erect with eyes open and feet comfortably apart and parallel to each other. Test retropulsion. Stand behind the patient and instruct the patient on what is about to happen. Explain that s/he is allowed to take a step backwards to avoid falling. There should be a solid wall behind the examiner, at least 1-2 meters away to allow for the observation of the number of retropulsive steps. The first pull is an instructional demonstration and is purposely milder and not rated. The second time the shoulders are pulled briskly and forcefully towards the examiner with enough force to displace the center of gravity so that patient MUST take a step backwards. The examiner needs to be ready to catch the patient, but must stand sufficiently back so as to allow enough room for the patient to take several steps to recover independently. Do not allow the patient to flex the body abnormally forward in anticipation of the pull. Observe for the number of steps backwards or falling. Up to and including two steps for recovery is considered normal, so abnormal ratings begin with three steps. If the patient fails to understand the test, the examiner can repeat the test so that the rating is based on an assessment that the examiner feels reflects the patient's limitations rather than misunderstanding or lack of preparedness. Observe standing posture for item 3.13 0: Normal: No problems: Recovers with one or two steps. 1: Slight: 3-5 steps, but subject recovers unaided. 2: Mild: More than 5 steps, but subject recovers unaided. 3: Moderate: Stands safely, but with absence of postural response; falls if not caught by examiner. 4: Severe: Very unstable, tends to lose balance spontaneously or with just a gentle pull on the shoulders.	☐

	SCORE
3.13 POSTURE Instructions to examiner: Posture is assessed with the patient standing erect after arising from a chair, during walking , and while being tested for postural reflexes. If you notice poor posture, tell the patient to stand up straight and see if the posture improves (see option 2 below). Rate the worst posture seen in these three observation points. Observe for flexion and side-to-side leaning. 0: Normal: No problems. 1: Slight: Not quite erect, but posture could be normal for older person. 2: Mild: Definite flexion, scoliosis or leaning to one side, but patient can correct posture to normal posture when asked to do so. 3: Moderate: Stooped posture, scoliosis or leaning to one side that cannot be corrected volitionally to a normal posture by the patient. 4: Severe: Flexion, scoliosis or leaning with extreme abnormality of posture.	☐
3.14 GLOBAL SPONTANEITY OF MOVEMENT (BODY BRADYKINESIA) Instructions to examiner: This global rating combines all observations on slowness, hesitancy, and small amplitude and poverty of movement in general, including a reduction of gesturing and of crossing the legs. This assessment is based on the examiner's global impression after observing for spontaneous gestures while sitting, and the nature of arising and walking. 0: Normal: No problems. 1: Slight: Slight global slowness and poverty of spontaneous movements. 2: Mild: Mild global slowness and poverty of spontaneous movements. 3: Moderate: Moderate global slowness and poverty of spontaneous movements. 4: Severe: Severe global slowness and poverty of spontaneous movements.	☐
3.15 POSTURAL TREMOR OF THE HANDS Instructions to examiner: All tremor, including re-emergent rest tremor, that is present in this posture is to be included in this rating. Rate each hand separately. Rate the highest amplitude seen. Instruct the patient to stretch the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other. Observe this posture for 10 seconds. 0: Normal: No tremor. 1: Slight: Tremor is present but less than 1 cm in amplitude. 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude. 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude. 4: Severe: Tremor is at least 10 cm in amplitude.	☐ R ☐ L

	SCORE
3.16 KINETIC TREMOR OF THE HANDS Instructions to examiner: This is tested by the finger-to-nose maneuver. With the arm starting from the outstretched position, have the patient perform at least three finger-to-nose maneuvers with each hand reaching as far as possible to touch the examiner's finger. The finger-to-nose maneuver should be performed slowly enough not to hide any tremor that could occur with very fast arm movements. Repeat with the other hand, rating each hand separately. The tremor can be present throughout the movement or as the tremor reaches either target (nose or finger). Rate the highest amplitude seen. 0: Normal: No tremor. 1: Slight: Tremor is present but less than 1 cm in amplitude. 2: Mild: Tremor is at least 1 but less than 3 cm in amplitude. 3: Moderate: Tremor is at least 3 but less than 10 cm in amplitude. 4: Severe: Tremor is at least 10 cm in amplitude.	☐ R ☐ L
3.17 REST TREMOR AMPLITUDE Instructions to examiner: This and the next item have been placed purposefully at the end of the examination to allow the rater to gather observations on rest tremor that may appear at any time during the exam, including when quietly sitting, during walking and during activities when some body parts are moving but others are at rest. Score the maximum amplitude that is seen at any time as the final score. Rate only the amplitude and not the persistence or the intermittency of the tremor. As part of this rating, the patient should sit quietly in a chair with the hands placed on the arms of the chair (not in the lap) and the feet comfortably supported on the floor for 10 seconds with no other directives. Rest tremor is assessed separately for all four limbs and also for the lip/jaw. Rate only the maximum amplitude that is seen at any time as the final rating. Extremity ratings 0: Normal: No tremor. 1: Slight.: < 1 cm in maximal amplitude. 2: Mild: > 1 cm but < 3 cm in maximal amplitude. 3: Moderate: 3 - 10 cm in maximal amplitude. 4: Severe: > 10 cm in maximal amplitude. Lip/Jaw ratings 0: Normal: No tremor. 1: Slight: < 1 cm in maximal amplitude. 2: Mild: > 1 cm but < 2 cm in maximal amplitude. 3: Moderate: > 2 cm but < 3 cm in maximal amplitude. 4: Severe: > 3 cm in maximal amplitude.	☐ RUE ☐ LUE ☐ RLE ☐ LLE ☐ Lip/Jaw

3.18 CONSTANCY OF REST TREMOR	SCORE
Instructions to examiner: This item receives one rating for all rest tremor and focuses on the constancy of rest tremor during the examination period when different body parts are variously at rest. It is rated purposefully at the end of the examination so that several minutes of information can be coalesced into the rating. 0: Normal: No tremor. 1: Slight: Tremor at rest is present < 25% of the entire examination period. 2: Mild: Tremor at rest is present 26-50% of the entire examination period. 3: Moderate: Tremor at rest is present 51-75% of the entire examination period. 4: Severe: Tremor at rest is present > 75% of the entire examination period.	☐

DYSKINESIA IMPACT ON PART III RATINGS

A. Were dyskinesias (chorea or dystonia) present during examination? ☐ No ☐ Yes

B. If yes, did these movements interfere with your ratings? ☐ No ☐ Yes

HOEHN AND YAHR STAGE	
0: Asymptomatic. 1: Unilateral involvement only. 2: Bilateral involvement without impairment of balance. 3: Mile to moderate involvement; some postural instability but physically independent; needs assistance to recover from pull test. 4: Severe disability; still able to walk or stand unassisted. 5: Wheelchair bound or bedridden unless aided.	☐

Part IV: Motor Complications

Overview and Instructions: In this section, the rater uses historical and objective information to assess two motor complications, dyskinesias and motor fluctuations that include OFF-state dystonia. Use all information from patient, caregiver, and the examination to answer the six questions that summarize function over the past week including today. As in the other sections, rate using only integers (no half points allowed) and leave no missing ratings. If the item cannot be rated, place UR for Unable to Rate. You will need to choose some answers based on percentages, and therefore you will need to establish how many hours generally are awake hours and use this figure as the denominator for "OFF" time and Dyskinesias. For "OFF dystonia", the total "Off" time will be the denominator. Operational definitions for examiner's use.

Dyskinesias: Involuntary random movements
Words that patients often recognize for dyskinesias include "irregular jerking", "wiggling", "twitching". It is essential to stress to the patient the difference between dyskinesias and tremor, a common error when patients are assessing dyskinesias.

Dystonia: contorted posture, often with a twisting component:
Words that patients often recognize for dystonia include "spasms", "cramps", "posture".

Motor fluctuation: Variable response to medication:
Words that patients often recognize for motor fluctuation include "wearing out", "wearing off", "roller-coaster effect", "on-off", "uneven medication effects".

OFF: Typical functional state when patients have a poor response in spite of taking mediation or the typical functional response when patients are on NO treatment for parkinsonism. Words that patients often recognize include "low time", "bad time", "shaking time", "slow time", "time when my medications don't work."

ON: Typical functional state when patients are receiving medication and have a good response:
Words that patients often recognize include "good time", "walking time", "time when my medications work."

A . DYSKINESIAS [exclusive of OFF-state dystonia]

SCORE

4.1 TIME SPENT WITH DYSKINESIAS

Instructions to examiner: Determine the hours in the usual waking day and then the hours of dyskinesias. Calculate the percentage. If the patient has dyskinesias in the office, you can point them out as a reference to ensure that patients and caregivers understand what they are rating. You may also use your own acting skills to enact the dyskinetic movements you have seen in the patient before or show them dyskinetic movements typical of other patients. Exclude from this question early morning and nighttime painful dystonia.

Instructions to patient [and caregiver]. Over the past week, how many hours do you usually sleep on a daily basis, including nighttime sleep and daytime napping? Alright, if you sleep ___ hrs, you are awake ____ hrs. Out of those awake hours, how many hours in total do you have wiggling, twitching or jerking movements? Do not count the times when you have tremor, which is a regular back and forth shaking or times when you have painful foot cramps or spasms in the early morning or at nighttime. I will ask about those later. Concentrate only on these types of wiggling, jerking and irregular movements. Add up all the time during the waking day when these usually occur. How many hours ____ (use this number for your calculation).

0: Normal:	No dyskinesias.
1: Slight:	≤ 25% of waking day.
2: Mild:	26 - 50% of waking day.
3: Moderate:	51 - 75% of waking day.
4: Severe:	> 75% of waking day.

1. Total Hours Awake: _____
2. Total Hours with Dyskinesia: _____
3. % Dyskinesia = ((2/1)*100): _____

4.2 FUNCTIONAL IMPACT OF DYSKINESIAS | **SCORE**

Instructions to examiner: Determine the degree to which dyskinesias impact on the patient's daily function in terms of activities and social interactions. Use the patient's and caregiver's response to your question and your own observations during the office visit to arrive at the best answer.

Instructions to patient [and caregiver]: Over the past week, did you usually have trouble doing things or being with people when these jerking movements occurred? Did they stop you from doing things or from being with people?

0: Normal:	No dyskinesias or no impact by dyskinesias on activities or social interactions.
1: Slight:	Dyskinesias impact on a few activities, but the patient usually performs all activities and participates in all social interactions during dyskinetic periods.
2: Mild:	Dyskinesias impact on many activities, but the patient usually performs all activities and participates in all social interactions during dyskinetic periods.
3: Moderate:	Dyskinesias impact on activities to the point that the patient usually does not perform some activities or does not usually participate in some social activities during dyskinetic episodes.
4: Severe:	Dyskinesias impact on function to the point that the patient usually does not perform most activities or participate in most social interactions during dyskinetic episodes.

☐

B . MOTOR FLUCTUATIONS

4.3 TIME SPENT IN THE OFF STATE

Instructions to examiner: Use the number of waking hours derived from 4.1 and determine the hours spent in the "OFF" state. Calculate the percentage. If the patient has an OFF period in the office, you can point to this state as a reference. You may also use your knowledge of the patient to describe a typical OFF period. Additionally you may use your own acting skills to enact an OFF period you have seen in the patient before or show them OFF function typical of other patients. Mark down the typical number of OFF hours, because you will need this number for completing 4.6

Instructions to patient [and caregiver]: Some patients with Parkinson's disease have a good effect from their medications throughout their awake hours and we call that "ON" time. Other patients take their medications but still have some hours of low time, bad time, slow time or shaking time. Doctors call these low periods "OFF" time. Over the past week, you told me before that you are generally awake ____ hrs each day. Out of these awake hours, how many hours in total do you usually have this type of low level or OFF function ____ (Use this number for your calculations).

0: Normal:	No OFF time.
1: Slight:	≤ 25% of waking day.
2: Mild:	26 - 50% of waking day.
3: Moderate:	51 - 75% of waking day.
4: Severe:	> 75% of waking day.

1. Total Hours Awake: _____
2. Total Hours OFF: _____
3. % OFF = ((2/1)*100): _____

☐

	SCORE
4.4 FUNCTIONAL IMPACT OF FLUCTUATIONS Instructions to examiner: Determine the degree to which motor fluctuations impact on the patient's daily function in terms of activities and social interactions. This question concentrates on the difference between the ON state and the OFF state. If the patient has no OFF time, the rating must be 0, but if patients have very mild fluctuations, it is still possible to be rated 0 on this item if no impact on activities occurs. Use the patient's and caregiver's response to your question and your own observations during the office visit to arrive at the best answer. *Instructions to patient [and caregiver]: Think about when those low or "OFF" periods have occurred over the past week. Do you usually have more problems doing things or being with people than compared to the rest of the day when you feel your medications working? Are there some things you usually do during a good period that you have trouble with or stop doing during a low period?* 0: Normal: No fluctuations or No impact by fluctuations on performance of activities or social interactions. 1: Slight: Fluctuations impact on a few activities, but during OFF, the patient usually performs all activities and participates in all social interactions that typically occur during the ON state. 2: Mild: Fluctuations impact many activities, but during OFF, the patient still usually performs all activities and participates in all social interactions that typically occur during the ON state. 3: Moderate: Fluctuations impact on the performance of activities during OFF to the point that the patient usually does not perform some activities or participate in some social interactions that are performed during ON periods. 4: Severe: Fluctuations impact on function to the point that, during OFF, the patient usually does not perform most activities or participate in most social interactions that are performed during ON periods.	☐
4.5 COMPLEXITY OF MOTOR FLUCTUATIONS Instructions to examiner: Determine the usual predictability of OFF function whether due to dose, time of day, food intake or other factors. Use the information provided by the patients and caregiver and supplement with your own observations. You will ask if the patient can count on them always coming at a special time, mostly coming at a special time (in which case you will probe further to separate slight from mild), only sometimes coming at a special time or are they totally unpredictable? Narrowing down the percentage will allow you to find the correct answer. *Instructions to patient [and caregiver]: For some patients, the low or "OFF" periods happen at certain times during day or when they do activities like eating or exercising. Over the past week, do you usually know when your low periods will occur? In other words, do your low periods always come at a certain time? Do they mostly come at a certain time? Do they only sometimes come at a certain time? Are your low periods totally unpredictable?"* 0: Normal: No motor fluctuations. 1: Slight: OFF times are predictable all or almost all of the time (> 75%). 2: Mild: OFF times are predictable most of the time (51-75%). 3: Moderate: OFF times are predictable some of the time (26-50%). 4: Severe: OFF episodes are rarely predictable. (≤ 25%).	☐

C. "OFF" DYSTONIA

4.6 PAINFUL OFF-STATE DYSTONIA

Instructions to examiner: For patients who have motor fluctuations, determine what proportion of the OFF episodes usually includes painful dystonia? You have already determined the number of hours of "OFF" time (4.3). Of these hours, determine how many are associated with dystonia and calculate the percentage. If there is no OFF time, mark 0.

Instructions to patient [and caregiver]: In one of the questions I asked earlier, you said you generally have ___ hours of low or "OFF" time when your Parkinson's disease is under poor control. During these low or "OFF" periods, do you usually have painful cramps or spasms? Out of the total ____ hrs of this low time, if you add up all the time in a day when these painful cramps come, how many hours would this make?

0: Normal: No dystonia OR NO OFF TIME.

1: Slight: < 25% of time in OFF state.

2: Mild: 26-50% of time in OFF state.

3: Moderate: 51-75% of time in OFF state.

4: Severe: > 75% of time in OFF state.

1. Total Hours Off: _____
2. Total Off Hours w/Dystonia: _____
3. % Off Dystonia = ((2/1)*100): _____

Summary statement to patient: READ TO PATIENT

This completes my rating of your Parkinson's disease. I know the questions and tasks have taken several minutes, but I wanted to be complete and cover all possibilities. In doing so, I may have asked about problems you do not even have, and I may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this scale with me.

Part III: Motor Examination

Overview: This portion of the scale assesses the motor signs of PD. In administering Part III of the MDS-UPDRS the examiner should comply with the following guidelines:

At the top of the form, mark whether the patient is on medication for treating the symptoms of Parkinson's disease and, if on levodopa, the time since the last dose.

Also, if the patient is receiving medication for treating the symptoms of Parkinson's Disease, mark the patient's clinical state using the following definitions:

ON is the typical functional state when patients are receiving medication and have a good response.
OFF is the typical functional state when patients have a poor response in spite of taking medications.

The investigator should "rate what you see". Admittedly, concurrent medical problems such as stroke, paralysis, arthritis, contracture, and orthopedic problems such as hip or knee replacement and scoliosis may interfere with individual items in the motor examination. In situations where it is absolutely impossible to test (e.g., amputations, plegia, limb in a cast), use the notation "**UR**" for Unable to Rate. Otherwise, rate the performance of each task as the patient performs in the context of co-morbidities.

All items must have an integer rating (no half points, no missing ratings).

Specific instructions are provided for the testing of each item. These should be followed in all instances. The investigator demonstrates while describing tasks the patient is to perform and rates function immediately thereafter. For Global Spontaneous Movement and Rest Tremor items (3.14 and 3.17), these items have been placed purposefully at the end of the scale because clinical information pertinent to the score will be obtained throughout the entire examination.

At the end of the rating, indicate if dyskinesia (chorea or dystonia) was present at the time of the examination, and if so, whether these movements interfered with the motor examination.

3a Is the patient on medication for treating the symptoms of Parkinson's Disease? ☐ No ☐ Yes

3b If the patient is receiving medication for treating the symptoms of Parkinson's Disease, mark the patient's clinical state using the following definitions:

☐ ON: On is the typical functional state when patients are receiving medication and have a good response.

☐ OFF: Off is the typical functional state when patients have a poor response in spite of taking medications.

3c Is the patient on Levodopa ? ☐ No ☐ Yes

3.C1 If yes, minutes since last levodopa dose: _____

APPENDIX III: BERG'S BALANCE SCALE

Berg Balance Scale

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand 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 stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 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 unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

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 for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

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 assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for 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 cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

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 safely
( ) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable 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

Berg Balance Scale continued…

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 the 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 fingers 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 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is 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 2-5 cm(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

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the 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

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 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE 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 in > 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

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 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

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.
( ) 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 ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

APPENDIX IV: NINE HOLE PEG TEST

NHPT

Subject # _____
Date: _____

Dominant hand L or R
Trial 1 time _____
Trial 2 time _____

Non-dominant hand L or R
Trial 1 time _____
Trial 2 time _____

Circumstances that may have affected performance?
__Dropped a peg
__Has a cold
__Forgot glasses
__Talking
__Other: _____

Was a trial repeated? Y or N
Why?
__Patient dropped everything on floor
__Forgot to start/stop watch
__Forgot to reset watch in between

APPENDIX VI: ENTRY QUESTIONNAIRE

ENTRY QUESTIONAIRE

Subject Number: _____ Date: _____

Age: _____ Sex:_____ Evaluator: _____

Medications: _____

_____

Current or past medical conditions (diabetes, cardiac, neurological, cancer, joint replacements, high blood pressure): _____

_____

Do you have hearing problems, and do you wear a hearing aide? _____

Do you have any vision problems, do you wear glasses? _____

Height: _____ Weight: _____

Current physical activities: _____

Do you use an assistive device to walk? _____

Can you walk 14 meters (about 15.5 yards) on a straight, level walkway without the use of an assistive device?

_____

If yes, would you be able to perform this more than once? _____