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THE EFFECT OF A NOVEL REHABILITATION PROGRAM ON WALKING PERFORMANCE IN PERSONS WITH MULTIPLE SCLEROSIS

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ABSTRACT

THE EFFECT OF A NOVEL REHABILITATION PROGRAM ON WALKING PERFORMANCE IN PERSONS WITH MULTIPLE SCLEROSIS

By

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The purpose of this study was to compare if the addition of the NewGait™ device to traditional therapy in comparison to traditional therapy alone would be more effective at improving walking technique and walking performance in persons with multiple sclerosis. Eighteen patients with multiple sclerosis participated in this study. Pre- and post-testing assessed kinematic gait variables (speed, step length, step width, double limb support time), toe clearance height, ankle range of motion, balance confidence, rating of perceived exertion, and hip-ankle coordination. Participants completed an 8-week physical therapy protocol aimed to improve gait and balance with the experimental group wearing the NewGait™ device. Repeated measures mixed ANOVA revealed significant improvements over time for both groups, with increased walking speed, improved balance confidence, increase in bilateral step length, and a decrease in the percent of time spent in anti-phase and an ankle-driven coordination phase during swing for the unaffected limb ($p < 0.05$). The experimental group experienced larger improvements in balance confidence ($p < 0.05$), and coordination ($p < 0.05$) when compared to the control group. The results of the current study indicate that the use of the NewGait™ during rehabilitation is effective at improving balance confidence lower limb coordination.

Keywords: gait, physical therapy, NewGait™, balance confidence, coordination

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LIST OF SYMBOLS AND ABBREVIATIONS

Multiple sclerosis…….MS

Extended Disability Status Scale…….EDSS

Physical therapy…….....PT

Rating of perceived exertion……...RPE

Range of motion…….……..……..ROM

CHAPTER 1: JOURNAL MANUSCRIPT

INTRODUCTION

Multiple sclerosis (MS) is a progressive, degenerative neurological disease that affects approximately 350,000 people in the United States and around 2 million people worldwide (1). Symptoms of MS include sensory, cognitive, and motor impairment, and are highly variable among persons with MS (1). Fatigue occurs in about 80% of patients, and may be more prominent in a person who otherwise has minimal activity limitations, meaning those who are not very active during the day (2). Numbness or tingling is often the first symptom that a patient experiences, and occurs in the face, body, and extremities. Weakness may result from the deconditioning of the unused muscles or because of damage to the nerves that stimulate the muscles. Another common symptom that persons with MS may experience is cognitive changes. These changes affect the ability to process incoming information, the ability to learn and remember new information, organization, problem solving, and the ability to maintain attention (2).

Multiple sclerosis is characterized by intermittent episodes of multifocal inflammation in the central nervous system and is often recurrent (3). These inflammation episodes result in the demyelination and transection of axons in the brain, optic nerve, and spinal cord (3). This then leads to conduction delay and the blockage of electrical potentials along the neural pathways (3). These inflammatory and neurodegenerative processes and related injury conclude in the progression of physical and cognitive disability in persons with MS.

The prevalence of multiple sclerosis is highest in northern Europe, southern Australia, and the middle section of North America (4). Several studies indicate that MS may be more prevalent in females (5, 6). The mechanisms behind the development of MS are still unknown, however it is

suggested that environmental and genetic factors may play a role, as well as having a greater awareness, and diagnostic techniques (7). The onset of MS typically occurs during early adulthood, with 50% of patients needing assistance to walk within 15 years of diagnosis (1). Measurement of walking ability is often used to assess disease severity and progression, such as with the Kurtzke Expanded Disability Status Scale (EDSS) and gait analysis (8, 9). Walking impairment is one of the most ever-present features of MS and is a significant characteristic of the later or advanced stages of the disease (3). Performing a gait analysis is a common practice in clinical settings because gait impairments may be indicative of early stages of neurological diseases (9). Persons with MS may present with many gait impairments such as taking shorter steps and walking with a slower speed (9). Kinematic parameters that are most commonly used in a clinical setting to measure a person's gait include step and stride length, velocity, step width, step height, swing time for each foot, and support time (9).

A study conducted among persons with MS and their caretakers concluded that 70% of people with MS who had difficulty walking agreed that walking was the most challenging aspect of the disease (10). Walking and gait impairments can have a high negative impact on motor and lifestyle activities. In addition, these impairments are associated with a low quality of life and an increased risk of falls (11).

Several therapy techniques have been effective at improving gait and mobility. One technique, body-weight supported treadmill training paired with robot-assisted gait training, has been shown to help increase total distance walked, walking velocity, and knee extensor strength (11). Results of other studies show significant changes in the timed 25-foot walk test, 6-minute walk test, 10-meter walk test, and EDSS after completing the rehabilitation program (12, 13). Critics of the device note the expensive costs to acquire the system, and discuss how physically

demanding it is for physical therapists who have to help control and assist the walking movements (11). In addition, most participants in these studies return to their baseline values within 6 months of completing treatment (11, 13). Other therapy techniques used to improving walking performance in persons with MS include resistance and balance training programs. Results from the studies on balance training suggest that balance rehabilitation may be a useful tool for persons with MS to reduce the incidence of falls and improve overall balance skills (14, 15). In addition, resistance training may be an effective rehabilitation program to strengthen or re-train weakened muscles, which may help to lower patient EDSS score and improving walking mechanics, including stride time, step length, and foot angle (16, 17). However, like robot-assisted gait training, there are several criticisms of these rehabilitation techniques. These studies typically have low-quality methodology, as they are non-supervised and include home-based training, relying on self-reporting of volume and intensity (18).

The NewGait™ claims to be a non-motorized, exoskeletal device that provides manual feedback, postural support, and muscular assistance to the wearer in order to optimize gait speed and stability. According to Elite Athlete Products, the manufacturer of the device, the separate parts of the device work together to "assist and promote proper locomotion during each phase of the gait cycle" (19). Presently, no one has investigated these claims. The device consists of a harness that extends over the shoulders and straps that wrap around the waist, thighs, and shanks. In addition, there are elastic bands that connect the waist band to the thigh bands, and shank bands to the shoes. Straps and elastic bands can be placed to provide assistance for specific movements, such as promoting hip abduction/adduction, lifting of the toe, and avoiding foot circumduction (19).

The NewGait™ device is similar to the robot-assisted gait training devices in that both devices give support to the wearer to induce a more normal walking pattern (11). The robot-assisted gait devices are fit to an individual by changing the width and length of the components (11). The NewGait™ can be changed for the user by adding or removing straps and elastic bands (20). In addition, the NewGait™ is more transferable to different walking conditions, as its use isn't confined to the constraints of a treadmill, like many robot-assisted gait training systems. Furthermore, the NewGait™ does not require the physical therapist to control the movements, similar to action seen while using exosuit devices, as the NewGait™ is non-motorized (21). So, a NewGait™ wearer could use the device in conjunction with additional gait improvement exercises, like resistance or balance training. Thus, the NewGait™ has the potential to combine the two different rehabilitation techniques by providing the same type of support as robot-assisted gait devices and the exercises of resistance and balance training. Ideally, a patient would see the same type of improvements in gait parameters seen following robot-assisted gait training, such as stride length, speed, and joint range of motion, in addition to positive changes seen in balance and walking performance from resistance and balance training.

The purpose of this study was to compare if the addition of the NewGait™ device to traditional therapy in comparison to traditional therapy alone would be more effective at improving walking technique and walking performance in persons with multiple sclerosis. In addition, the effect of physical therapy on a population of persons with multiple sclerosis was assessed.

METHODS

Participants

Eighteen individuals (14 female, 4 male; height = 168.2 ± 8.3 cm; mass = 77.6 ± 18.9 kg) were recruited from physical therapy clinics in the Upper Peninsula of Michigan and through email

correspondence via the National MS Society database to participate in an 8-week rehabilitation program. During participant recruitment, individuals were asked questions specific to their MS diagnosis and about any orthopedic and/or health problems (APPENDIX A). Inclusion or exclusion for the study was determined using the above-mentioned questionnaire.

To be included in the study, participants needed to be in a stable phase of their MS, have chronic progressive pattern or relapsing-remitting MS with no relapse within the last three months, and have an EDSS score between 5 and 7 (8) (APPENDIX B). Participants were excluded if they had any cardiac related risk factor, major orthopedic problems or contractures of the lower limbs, complete inability to stand or walk for a period longer than three months, significant medical co-morbidities, and cognitive or psychiatric problems that could compromise compliance with physical therapy.

Procedures

This study was approved by Northern Michigan University's Institutional Review Board (HS17-870) (APPENDIX C) and informed consent (APPENDIX D) was obtained from each participant prior to the start of testing. Participants underwent a 3-dimensional kinematic analysis while performing six trials of a 10-meter walk test. Using a 10-meter walk test is favored over other walk tests in most clinical settings, as it was determined to be strongly associated with lower body muscle strength because of the brief and maximal effort needed for the test (22). Subjects completed the trials of the 10-meter walk test during the pre- and post-rehabilitation testing sessions.

Testing Pre- and post-testing took place before and after an 8-week physical therapy (PT) intervention. Participants were asked to wear shorts and comfortable walking shoes with laces. This was to ensure that all reflective markers could be seen by the cameras and that there was an

attachment point on the shoe for the NewGait™ device. Prior to starting the walk tests, participants completed the Activities-specific Balance Confidence Scale survey (APPENDIX E) to assess their confidence while completing lifestyle-type activities. This survey has been validated as an acceptable measure of balance confidence (23). All participants performed three trials of the 10-meter walk test in the lab without the NewGait™ device. Each participant was then fitted with the device for his or her particular gait abnormality by a licensed physical therapist and/or certified prosthetist, who had all used the device in a clinical setting. The participant was allowed to rest for a length of time that was suitable for them (about 5-10 minutes), then performed three trials of the 10-meter walk test while wearing the device.

Group Assignment Following pre-testing, individual participants were matched to another participant with similar gait characteristics and EDSS score. As determined by a flip of a coin, one member of the pair was placed into the control group, while the other was placed into the experimental group. The physical therapist who was present at the time of testing flipped the coin; heads signifying control group, tails being experimental group. Both groups completed an 8-week rehabilitation program. During this time, the experimental group wore the NewGait™ device during the PT sessions, and were not allowed to take the device with them; the devices stay in the rehab clinic. The control group did not wear the device anytime during the eight weeks.

8-Week Rehabilitation Program Within one week of completing pre-testing, participants began an 8-week rehabilitation program. Both groups completed the same PT protocol. Sessions occurred twice a week, for 60 minutes each session. Refer to Appendix F for the PT exercise protocol.

Participant adherence to the 8-week rehabilitation program relied on the relationship built with the physical therapists. The physical therapists helped the participants keep track of their

sessions, and made sure that the participants completed as many of 16 sessions as possible in the eight weeks. This record was returned to the researchers on the day of post-testing. In addition, an incentive was offered for participants; on completion of both pre- and post-testing and the entire 8-week rehab intervention they would receive a complementary NewGait™ device. Participants who met this criteria received their custom fit device with instructions on how to wear and use it.

Data Collection & Analysis Reflective markers were placed on the participants following International Society of Biomechanics recommendations for lower body kinematics (24). A total of 34 reflective markers were placed bilaterally on the individual's anterior superior iliac spine and posterior superior iliac spine, medial epicondyle of the knee, lateral epicondyle of the knee, medial malleolus of the ankle, lateral malleolus of the ankle, first metatarsal, fifth metatarsal, and calcaneus, with additional 4-marker clusters placed mid-thigh and mid-shank. Reflective markers were placed by the same researcher for every patient visit to ensure reliable placement.

Three-dimensional joint kinematics were assessed while the participants performed trials of a 10-meter walk test. For the purpose of this study, data from the control walks (not wearing the NewGait™ device) were reported. Kinematic data were recorded for the ankle and hip joints using an 10-camera analysis system; 4 Raptor-E, 3 Raptor-H, and 3 Kestrel camera models sampling at 250 Hz (Motion Analysis Corporation, Santa Rosa, CA) (25). Cortex (Version 4, Motion Analysis Corporation, Santa Rosa, CA), was used to capture the walking trials. The cameras were set up and calibrated to capture using Cortex, and the program was used to track the files in post-processing. Linear, cubic, and virtual joins were used to fill any gaps in the data points in the trials. Visual 3D software (Version 4.0, C-Motion, Inc, Germantown, MD) was used for the kinematic analysis. Kinematic gait variables included: step width, step length, ankle range of motion (ROM), double limb support time, and toe clearance height.

The gait variables were identified by first creating a conventional gait model using a CODA pelvis (26). A low-pass Butterworth filter with a cut-off frequency of 6 Hz was used (27). A pipeline was created to identify the gait events, as well as to compute the kinematic gait variables. The gait events of heel strike and toe off were identified using kinematic data by transforming the heel and toe markers into a pelvis coordinate system (28, 29). Based off these gait events, the temporal distance gait measures were calculated by taking averages of the variable over the gait cycle (30). Toe clearance height was determined by taking the maximum height of the distal end of the foot during the swing phase (16). Range of motion of the ankle was calculated using the minimum and maximum angles of the ankle joint during both the swing and stance phases of the gait cycle.

While the participants performed a 10-meter walk test, only the middle six meters were used to assess speed, as this allowed for acceleration and deceleration within the total ten meters. Six-meter walk time was assessed using four timing gates (Witty Wireless Training Timer system, Microgate, Mahopac, NY). The first timing gate was placed at the location at which the participant started the walk trial. The second timing gate was placed at the two-meter mark. The third timing gate was placed at the eight-meter mark. The final timing gate was placed at the 10-meter mark, and also signified the end of the walk test. Participant rating of perceived exertion (RPE) using the Borg's RPE scale of 0-10 was taken following the three walking trials without the device, and following the three trials while wearing the device (31).

Coordination was quantified using a modified vector coding technique as described by Needham et al. for the intralimb coupling of the hip and ankle (27). Hip flexion/extension and ankle dorsiflexion/plantarflexion were assessed during the stance and swing phases for each leg (27). Segment angles were processed using the same Visual 3D model created to analyze the gait

variables, and were normalized to 100% of the gait cycle, heel strike to the next consecutive, ipsilateral, heel strike. As described in the methodology by Needham et al., a modified vector coding technique and circular statistics were used to quantify hip-to-ankle coordination during the stance and swing phases (27). Coordination of the knee and ankle was assessed by percentage of the phase spent in one of four coordination patterns: the two joints in-phase, anti-phase, or if the movement was primarily driven by the hip joint, or ankle joint (27, 32).

Gait symmetry index was calculated for all participants to compare pre-post, using the symmetry index formula presented by Patterson et al. (33). A gait symmetry index value of zero indicates full symmetry, while a value of 100 indicates asymmetry (33). Symmetry index is indicated as "high" of between 0-25%, "normal" if between 25-75%, and "low" if between 75-100% (34)

Data were analyzed in terms of side most affected and the side unaffected by the participants multiple sclerosis related impairments, instead of left and right. Affected and unaffected side was subjectively determined by assessing the participant's walking gait and their NewGait™ prescription.

Statistical Analysis

A repeated measures mixed ANOVA was used to assess the difference in change pre-post and to assess a non-repeated comparison between the control and experimental groups; significance level was set at $p < 0.05$. A paired t-test was used to analyze the significant group changes when significant time * group interactions were found. Analysis was performed with SPSS (Version 25, SPSS Inc, Chicago, IL). Cohen's d effect size was calculated to assess the effect of change across the variables (35). Effect sizes 0.20 or below were considered small,

medium if between 0.201 – 0.50, large if between 0.501 – 0.80, and very large if greater than 0.801 (35).

RESULTS

Mean and standard deviations were calculated for gait variables and RPE (Table 1); and coordination variables (Table 2). Results of the repeated measures mixed ANOVA and Cohen's d effect size can be found in Appendix G.

Repeated measures mixed ANOVA revealed a significant increase in speed (Figure 1), increase in balance, and increase in bilateral step length ($p < 0.05$) over time. There was also a significant time * group interaction for balance ($p < 0.05$; Figure 2), with the experimental group producing a significantly larger improvement in balance confidence pre to post ($p < 0.05$).

Coordination was analyzed within each variable, pre-post. During the swing phase, hip-ankle coordination was mainly spent in-phase for the unaffected side and in a hip-driven phase for the affected side (Figures 3 and 4). During the stance phase, hip-ankle coordination was spent primarily in anti-phase for both sides (Figures 3 and 4). There was a significant decrease in the percent of time spent in anti-phase and an ankle-driven phase during swing for the unaffected limb ($p < 0.05$) over time (Figures 3 and 4). The percent of time spent in anti-phase during swing for the unaffected side decreased from 15.89 ± 5.72% to 11.60 ± 4.04% for the control group and 11.04 ± 4.07% to 8.18 ± 3.69% for the experimental group. The percent of time spent in an ankle-drive phase during swing for the unaffected side decreased from 12.08 ± 6.05% to 9.73 ± 5.33% for the control group, and 12 ± 8.86% to 8.64 ± 7.33% for the experimental group (Figures 3 and 4). There was also a significant group effect for the percent of time spent in anti-phase during

swing for the unaffected limb ($p < 0.05$), with the experimental group exhibiting a significantly larger decrease in percent of time spent in the phase pre to post ($p < 0.05$).

There were some meaningful changes across time for each group, as indicated by medium, large, and very large effect sizes. Balance (0.628) and the percent of time spent in anti-phase during swing in the unaffected limb (0.736) exhibited medium to large effect sizes for the control group. The following variables exhibited medium, large, or very large effect sizes for the experimental group: balance (1.462), RPE (0.795), step length on the unaffected side (0.544), bilateral toe clearance (0.525, 0.532, affected and unaffected, respectively), ankle ROM during swing on the unaffected side (0.587), and the percent of time spent in anti-phase during swing in the unaffected limb (0.736).

There were no significant changes across time or group for step length symmetry index. Twelve out of the total 18 participants experienced a decrease in step length symmetry index from pre to post (Figure 5). Four of the 12 participants had a symmetry index classified as normal at the beginning of the study; the remaining eight participants had a high symmetry index at pre. All 12 participants would be classified as having a high step length symmetry both at the end of the study. Only one participant had a classification of low step length symmetry at the post condition.

Participants in this study attended an average of 14 (± 2) physical therapy sessions out of a total of 16. The control group attended 13 (± 2) sessions and the experimental group attended 15 (± 5) sessions. The most common reasons for having to miss a physical therapy session were illness or weather-related.

DISCUSSION

The purpose of this study was to compare if the addition of the NewGait™ device to traditional therapy in comparison to traditional therapy alone would be more effective at improving walking technique and walking performance in persons with multiple sclerosis. In addition, the effect of physical therapy on a population of persons with multiple sclerosis was assessed. The main finding was that an 8-week physical therapy intervention using the non-motorized, exoskeletal NewGait™ device designed to optimize gait was effective at improving balance confidence and the lower limb coordination during the swing phase on the unaffected limb in persons with multiple sclerosis.

Balance confidence has been identified as one of many factors, including lower extremity strength and general health that contribute to walking gait speed (36). Both the control and experimental groups experienced a significant increase in balance confidence following the eight weeks of physical therapy. However, participants in the experimental group experienced a significantly larger improvement in balance confidence than the control group. This suggests that the NewGait™ device may improve balance confidence through promoting postural support and stability, as it claims (20). Many robot-assisted gait devices are often rigid through the lower body, which reduces the muscular activity necessary to maintain postural stability, as the device supports the individual (37). Most robot-assisted gait devices are also described as being assistive, in which the patient actively attempts to complete a movement, and the device assists in doing the motion (38). The non-rigid and assistive characteristics of the NewGait™ may promote postural stability while wearing the device, as the individual has to actively control their body motions while the device assists in the walking motions. Persons with MS experience more postural sway than healthy individuals, which may be paired with poor trunk control (39). The NewGait™ harness that extends over the shoulders and connects to the waist belt may assist with improving trunk

control, potentially improving stability. If an individual feels more steady in their posture and completing activities, such as those asked about in the Activities-specific Balance Confidence survey, they may have a lesser fear of falling and a lesser need for walking assistance devices, like a cane, which may then result in having more balance confidence (40). This suggests that the NewGait™ may be effective at improving balance confidence by means of improving postural stability.

As stated earlier, balance confidence is a factor that contributes to walking speed, and in the present study, the significant improvements in balance confidence following physical therapy may have contributed to the increases in walking speed for most participants (36). Fritz and Lusardi have characterized different walking speeds as indicators of dependence, hospitalization, rehabilitation needs, discharge locations, and ambulation category (41). All of the participants started with a walking speed that would categorize them as needing intervention to reduce their fall risk. Depending on their impairment and progression of MS, they may have been dependent or independent in activities of daily living. Following eight weeks of PT, eight of the participants in the control group and seven participants in the experimental group were able to increase their walking speed to categorize them as independent in activities of daily living and less likely to need interventions to reduce the risk of falls (Figure 1). The remaining three participants (one control, two experimental) also increased their walking speed, but would still be categorized as needing interventions to reduce the risk of falls, however, they may have become more independent in activities of daily living.

Givon and colleagues performed a gait analysis of persons with MS and found that those individuals demonstrated significant impairments compared to healthy subjects, and these gait impairments are present in the participants in the present study (42). Givon et al. saw a short step

length of 0.45 m in persons with MS, compared to 0.72 m in the healthy control subjects (42). In the present study, participants in both groups experienced a shorter step length on their affected side at the start of the study, which were comparable to those reported by Givon et al. (42). Stroke patients, who experience varying gait impairments similar to persons with MS, often have difficulty standing on one foot on the hemiplegic, or affected side, which results in a shorter step length on the unaffected side (43). The experimental group exhibited meaningful change in step length on the unaffected side, which may suggest an increase in stability on the affected side. Research has shown that an increase in walking speed is often associated with shortening stride time or lengthening step and stride length, and a more symmetrical gait pattern that could be more efficient and functional (44, 45). In the present study, six of the control and six of the experimental group participants who experienced an increase in speed after completing the physical therapy intervention also displayed greater step length symmetry. Four of these participants had a step length symmetry index classification of normal at the beginning of the study, while the remaining eight had a high step length symmetry index. All 12 participants experienced a decrease in symmetry index by the end of the study, classified as high (34). This suggests that all 12 participants became more symmetrical in their gait, as specified by step length. Therefore, it is possible that when persons with MS walk with more symmetric step lengths, they may ambulate at a faster speed. This is in agreement with biomechanical changes seen in stroke patients, who walked at faster speeds with symmetric steps (46). The improvements in step length are likely to have influenced changes in step length symmetry, potentially producing positive changes in balance confidence and walking speed.

The assistance that the NewGait™ provides to the lower limbs may have affected the lower limb coordination of the unaffected side during swing by decreasing the amount of time that the

hip and ankle were spending in anti-phase, possibly creating a more normal swing pattern. Aside from slight plantarflexion during the initial swing phase, a normal gait pattern through the swing phase would be described as the ankle moving in dorsiflexion to neutral (47). During late swing and early stance, ankle-hip coordination is characterized as mostly in-phase flexion (hip flexion – ankle dorsiflexion), and as in-phase extension (hip-extension – ankle plantarflexion) during late stance and early swing (48). In the present study, during the swing phase, the unaffected limb was acting in anti-phase, meaning that the hip and ankle joints were acting in different directions. As an example, the hip may be flexing while the ankle is plantarflexing. Even though the joint coupling stayed in anti-phase, the percent of time spent in this phase significantly decreased to a greater extent in the experimental group than the control group, and it may be proposed that the participants in the experimental group were moving towards a more normal, in-phase coordination pattern during swing (48). Significant changes in coordination were only observed on the unaffected side, and when paired with significant ($p < 0.05$) and large ($d > 0.5$) improvements in step length on the unaffected side, it may be suggested that the affected side had become more stable, allowing for a longer swing phase on the unaffected side. This suggests that the NewGait™ had an effect on the coordination, possibly by way of decreasing the amount of time that the hip and ankle were spending in anti-phase during swing to induce a more normal swing pattern.

A limitation of the current study is the small power due to a small sample size. Due to the study design, the number of participants in each group was small, as the total number had to be divided equally into the control and experimental groups. However, a strength of the current study was that an attempt was made to match the participants to another participant with similar gait impairments. Another limitation would be not having a true control group who did not participant in any rehabilitation therapy. The addition of this control group would aid in assessing the actual

effectiveness of the PT program. A final limitation of the study was that center of mass movement was not measured as a way to quantify postural stability. In addition, the measurement of muscular activity in the lower limbs may help to further discover the biomechanical mechanisms behind the changes seen due to the NewGait™, as changes in gait are often paired with changes in muscle activity (9, 16, 49).

CONCLUSION

Preliminary results in this study of the NewGait™ suggest that the device may be effective at improving balance confidence and lower limb coordination in persons with multiple sclerosis. The NewGait™ may have helped the wearer to increase their postural support and stability, causing an increase in balance confidence. The improvements in step length that caused change in step length symmetry may have also influenced the positive changes observed in balance confidence, which resulted in an increase in walking speed. In addition, the assistive qualities of the NewGait™ may have helped to better coordinate the lower limbs, possibly through decreasing the amount of time that the ankle was plantarflexing to induce a more normal swing pattern.

Future research should include a follow-up testing session with the participants to assess the long-term effectiveness of the NewGait™. In addition, a larger sample size and additional control group should be considered. Finally, future research should test the NewGait™ across other populations that experience gait impairments, and include other research variables, such as muscular activity, to provide a more in-depth assessment of changes in gait impairment, and to further discover the mechanics behind the changes seen due to the NewGait™ device.

TABLES

TABLE 1. Mean ± standard deviation for gait variables and RPE pre- and post-intervention.

		Control (n = 9)		**Experimental (n = 9)**	
		Pre	**Post**	**Pre**	**Post**
Speed (m/sec) *		0.87 ± 2.93	1.00 ± 3.66	0.72 ± 1.35	0.87 ± 1.31
Balance (%) *†		54.01 ± 12.55	62.87 ± 15.63	10.38 ± 21.67	71.66 ± 21.12
RPE		4.11 ± 2.27	3.83 ± 1.90	3.56 ± 0.88	2.61 ± 1.50
Affected Step Length (m) *		0.49 ± 0.20	0.55 ± 0.17	0.45 ± 0.21	0.56 ± 0.26
Unaffected Step Length (m) *		0.55 ± 0.13	0.60 ± 0.11	0.47 ± 0.20	0.59 ± 0.22
Step Length Symmetry Index (%)		22.59 ± 18.85	17.43 ± 24.18	19.18 ± 15.51	14.62 ± 13.31
Step Width (m)		0.15 ± 0.04	0.16 ± 0.03	0.17 ± 0.03	0.16 ± 0.26
Double Limb Support Time (s)		0.45 ± 0.14	0.42 ± 0.11	0.49 ± 0.18	0.43 ± 0.23
Affected Toe Clearance (cm)		3.46 ± 1.35	3.6 ± 1.43	4.99 ±3.07	3.49 ± 2.66
Unaffected Toe Clearance (cm)		2.89 ± 1.52	3.34 ± 1.51	5.16 ± 3.02	3.69 ± 2.47
SWING	Affected Ankle ROM (°)	21.44 ± 11.22	18.13 ± 8.83	18.64 ± 8.56	19.93 ± 9.50
	Unaffected Ankle ROM (°)	23.19 ± 7.92	21.87 ± 6.43	16.94 ± 4.35	20.15 ± 6.58
STANCE	Affected Ankle ROM (°)	28.35 ± 11.46	28.2 ± 10.20	25.95 ± 4.79	25.4 ± 4.74
	Unaffected Ankle ROM (°)	26.81 ± 4.61	28.05 ± 4.17	26.41 ± 6.98	24.51 ± 4.79

**Significant effect for time, $p < 0.05$*

†*Significant effect for pre/post for the experimental group, $p < 0.05$*

TABLE 2. Mean ± standard deviation for coordination variables presented as percent of time spent in each phase.

		Control (n = 9)		Experimental (n = 9)	
		Pre	**Post**	**Pre**	**Post**
SWING - AFFECTED	In-Phase	33.64 ± 16.83	32.87 ± 17.47	32.53 ± 18.36	37.55 ± 21.45
	Anti-Phase	12.64 ± 5.81	10.95 ± 8.04	13 ± 5.56	11.60 ± 6.73
	Hip-Driven	42.60 ± 22.76	44.17 ± 22	45 ± 19.19	43.07 ± 19.50
	Ankle-Driven	10.99 ± 8.31	10.64 ± 7.24	9.48 ± 7.30	7.66 ± 4.80
SWING - UNAFFECTED	In-Phase	43.02 ± 7.89	45.84 ± 9.57	40.62 ± 14.14	44.79 ± 13.53
	Anti-Phase *†	15.89 ± 5.72	11.60 ± 4.04	11.04 ± 4.07	8.18 ± 3.69
	Hip-Driven	29.01 ± 8.32	32.83 ± 13.07	36.01 ± 13.53	38.38 ± 12.38
	Ankle-Driven *	12.08 ± 6.05	9.73 ± 5.33	12 ± 8.86	8.64 ± 7.33
STANCE - AFFECTED	In-Phase	9.88 ± 4.51	10.86 ± 4.62	10.78 ± 4.58	8.70 ± 4.14
	Anti-Phase	46.71 ± 11.47	42.17 ± 14.70	46.76 ± 12.65	44.64 ± 14.87
	Hip-Driven	23.97 ± 15.38	27.83 ± 18.09	24.58 ± 10.57	27.03 ± 10.38
	Ankle-Driven	19.45 ± 9.57	19.14 ± 9.77	17.89 ± 5.36	17.23 ± 5.01
STANCE - UNAFFECTED	In-Phase	8.42 ± 3.39	8.49 ± 3.98	9.72 ± 4.01	8.26 ± 3.89
	Anti-Phase	49.02 ± 13.27	46.57 ± 13.77	47.56 ± 9.61	45.93 ± 16.78
	Hip-Driven	24.06 ± 10.06	23.77 ± 9.62	24.2 ± 13.3	29.38 ± 16.19
	Ankle-Driven	18.6 ± 8.65	21.17 ± 8.74	18.52 ± 5.58	16.43 ± 4.78

**Significant effect for time, $p < 0.05$*

†*Significant effect for the experimental group, $p < 0.05$*

FIGURES

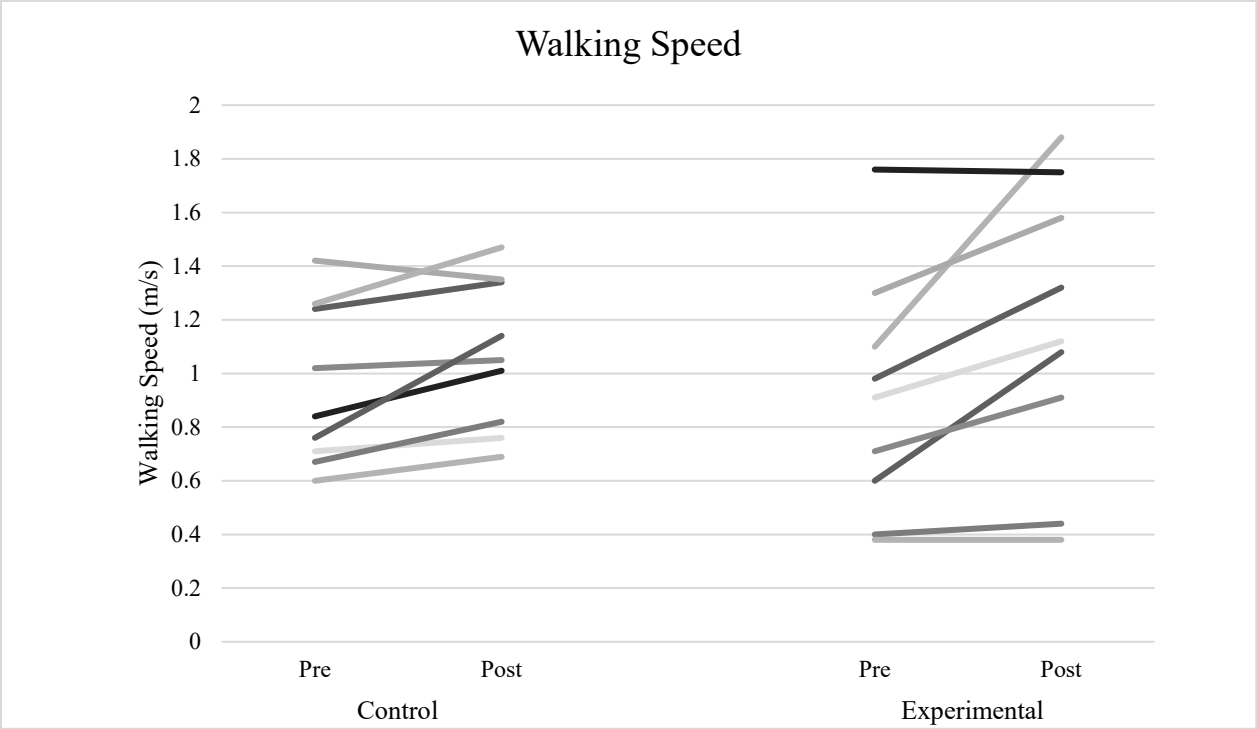

FIGURE 1. Walking speed pre-post for the control and experimental groups.

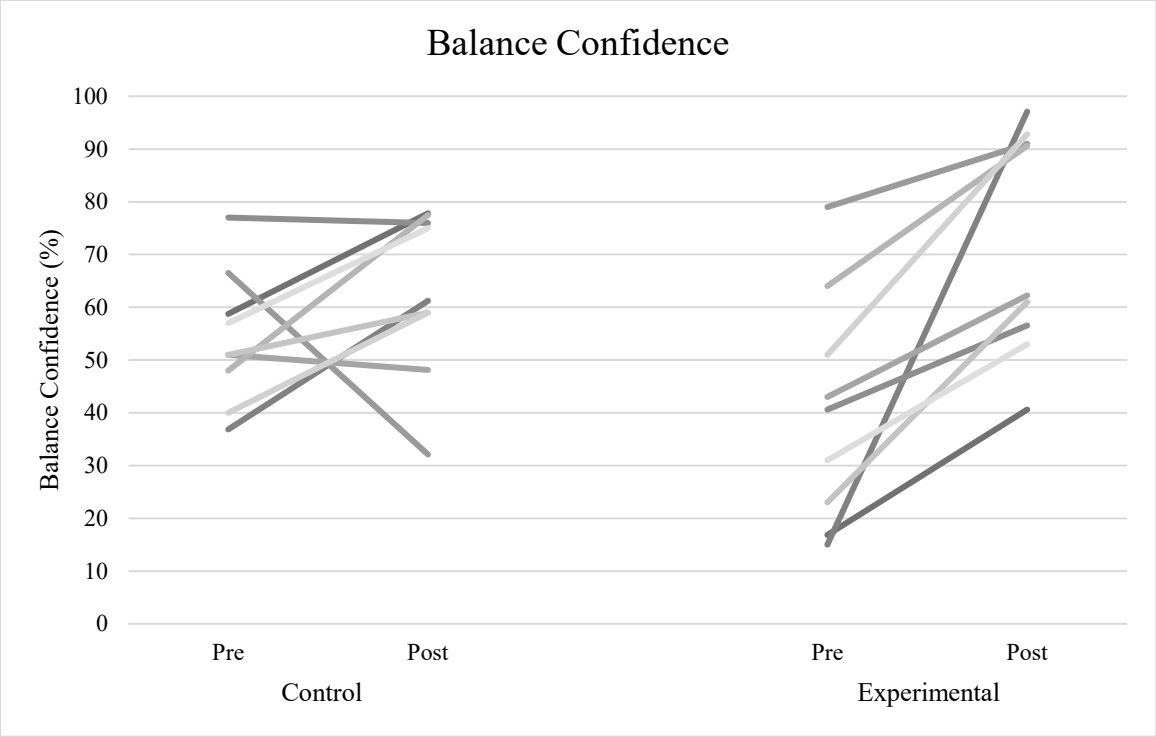

FIGURE 2. Activities-specific Balance Confidence scores for the control and experimental groups, pre and post.

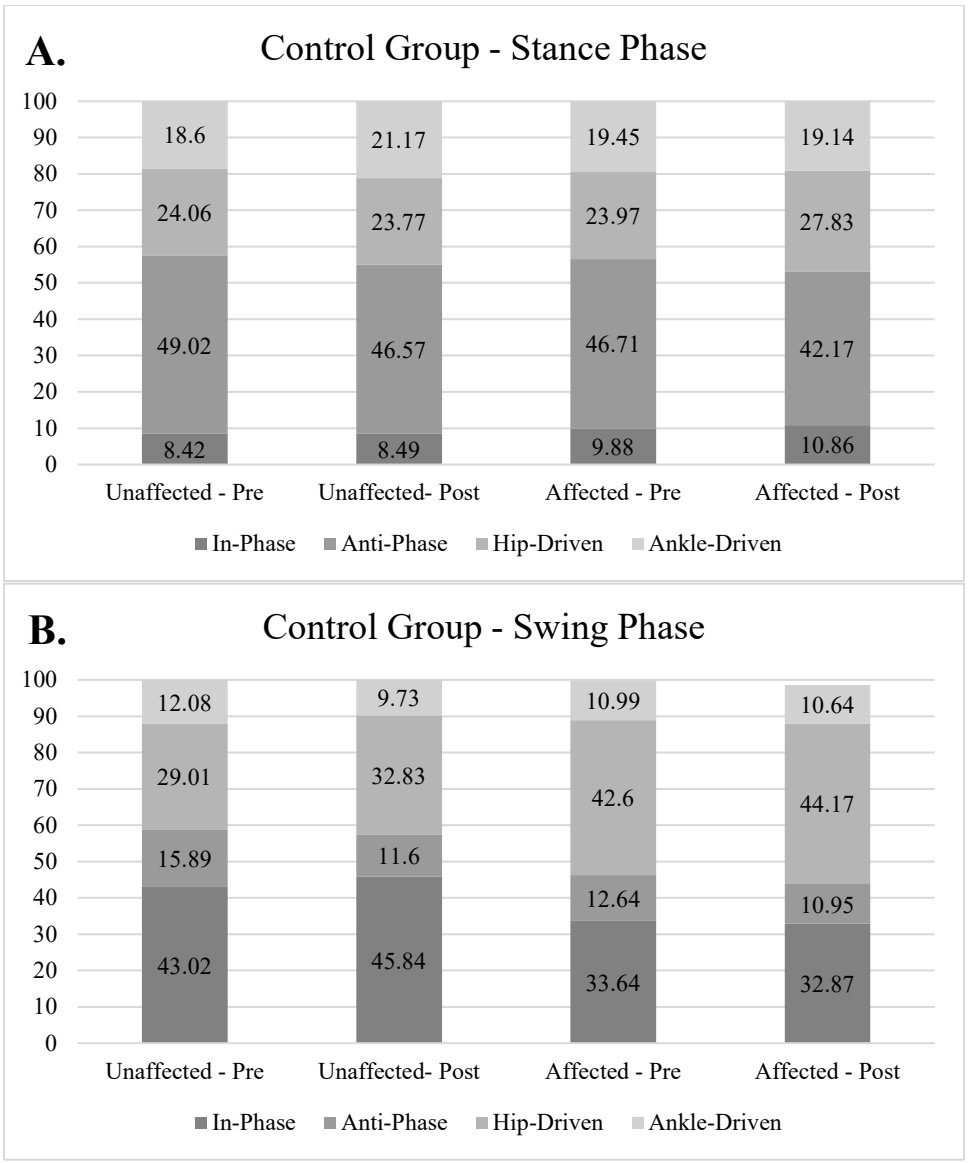

FIGURE 3. Mean percent of time spent in coordination phases for the stance (A) and swing (B) phase for the control group.

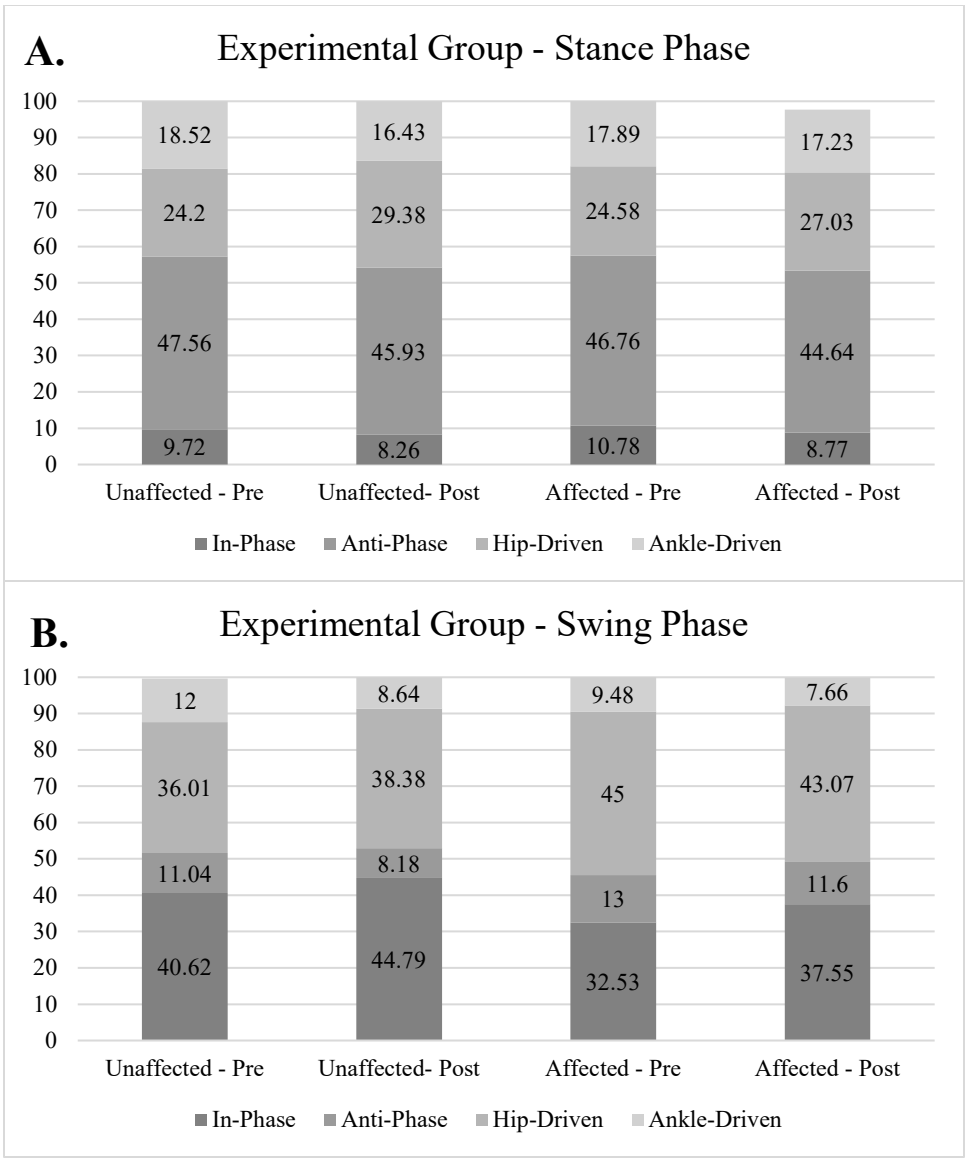

FIGURE 4. Mean percent of time spent in coordination phases for the stance (A) and swing (B) phase for the experimental group.

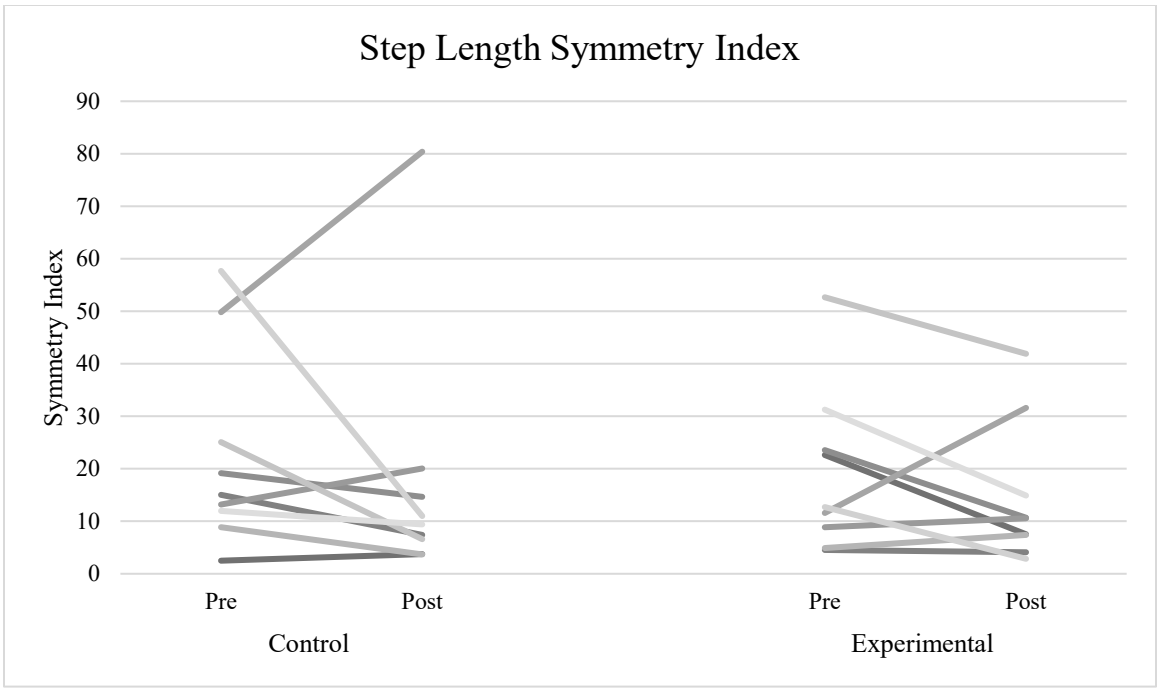

FIGURE 5. Step length symmetry index pre-post for the control and experimental groups.

CHAPTER II: LITERATURE REVIEW

The purpose of this literature review is to give the reader background on the neurodegenerative disease multiple sclerosis. In addition, walking gait and performance rehabilitation programs and devices will be discussed. Finally, analysis methodology for assessing gait and walking performance will be explained. This literature review is separated into five sections: (1) background on multiple sclerosis, (2) walking, (3) techniques used to improve walking and gait, (4) Speedmaker™ and NewGait™ devices, and (5) analysis methods. Databases used to search for literature include Google Scholar, PubMed, and Northern Michigan University's OneSearch. Common search terms included a combination of "multiple sclerosis", "gait", "balance", "rehabilitation", and "gait coordination".

Background on Multiple Sclerosis

Symptoms Multiple sclerosis (MS) is a progressive, degenerative neurological disease that presents symptoms of sensory, cognitive, and motor impairment (1). Common symptoms reported by the National Multiple Sclerosis Society include fatigue, numbness or tingling, weakness, and cognitive changes (2). Fatigue occurs in about 80% of patients, and may be more prominent in a person who has minimal activity limitations, meaning that they are more active during the day. One of the most common symptoms that is first experienced is numbness or tingling of the face, body, or extremities. Weakness results from deconditioning of the unused muscles, or damage to the nerves that stimulate the muscles. Changes in a person's ability to process incoming information, learn and remember new information, organize, problem solve, and focus their attention are all common changes seen with cognitive changes in a person with MS (2).

Pathology and Physiology In persons with multiple sclerosis, pyramidal tract lesions may cause weakness and spasticity, and dorsal column and cerebellar lesions may lead to decreases in

proprioception and coordination. Vestibular and visual dysfunction, cognitive and mood disturbances, and pain may also occur due to neurological degeneration (50).

Multiple sclerosis is initially characterized by intermittent episodes of multifocal inflammation in the central nervous system (3). The recurrent inflammation leads to the demyelination and transection of axons in the brain, optic nerve, and spinal cord. This axon damage results in delays in conduction and blockage of electrical potentials along the neural pathways (3).

Epidemiology Across the world, the prevalence of MS is highest in northern Europe, southern Australia, and the middle part of North America (7). The factors behind the variation in prevalence of MS worldwide are yet to be completely understood. It is suggested that environmental and genetic factors may play a role, as well as having a greater awareness and diagnostic techniques, but they are all still under investigation (7). In the United States, Olmstead County, Minnesota has the highest occurrence of MS with a prevalence of 191.2 per 100,000 people (4). Lubbock, Texas has the lowest recorded prevalence of 39.9 per 100,000 people (4). Multiple sclerosis is more prevalent in females. Two separate studies by Svenson et al. (1994 and 2007) report an increase in the female to male MS prevalence ratio; 2.0 in 1984-1989 to 2.6 in 1994-2002 (5, 6).

Walking & Multiple Sclerosis All of the aforementioned symptoms contribute to walking difficulties with their relations to weakness, spasticity, and loss of balance, sensory deficit, and fatigue. LaRocca found that 70% of people with MS who had difficulty walking, agreed that walking was the most challenging aspect of the disease (10). Walking related impairments have a high negative impact on motor and lifestyle activities, and are associated with a low quality of life and an increased risk of falls (11, 51). Gait factors that are affected by MS will be discussed later in the review.

Walking

According to the World Health Organization, walking is defined as moving along a surface on foot, step by step, so that one foot is always on the ground (52). Variations of walking include strolling, sauntering, walking forwards, backwards, or sideways (52). Walking speed has been identified as a determining factor for predicting dependence, hospitalization, needs for rehabilitation, and ambulation category (41). Individuals with a walking speed of 0.6 m/s or slower are categorized as being dependent in activities of daily living, are more likely to be hospitalized, may need intervention to help reduce fall risk, and may require a walking aid device or be a limited community ambulator (41). Individuals with a walking speed of 1 m/s or faster are categorized as being independent in activities of daily living, are less likely to be hospitalized, are less likely to have an adverse falling event, and be a community ambulator or be able to cross streets with a normal walking speed (41).

Walking gait analysis is important in a clinical setting because gait impairments may be indicative of early stages of neurological diseases (9). Persons with MS may present with many gait impairments such as taking shorter steps and walking with a slower speed (9). Kinematic parameters that are most commonly used in a clinical setting to measure a person's gait include step and stride length, velocity, step width, step height, swing time for each foot, and support time (9). Kinetic and other clinical parameters that are assessed are existence of tremors when walking, record of falls, ground reaction forces, muscle activity, momentum, and body posture (9).

Persons with multiple sclerosis may present with a type of gait impairment called cerebellar ataxia, and according to Kurtzke, et al., may occur in about 80% of MS patients (53, 54). Stolze et al. conducted a study to determine features of cerebellar ataxic gait by comparing patients who had a cerebellar disorder with a healthy control and analyzing multiple gait variables (55). Results

showed that subjects with a cerebellar disorder had a significantly reduced step frequency with a longer stance and double limb support time. In addition, the balance related variables of step width and foot rotation angles were increased, which suggests the need for stability during walking (55). This is in agreement with Martin et al. (49) and Benedetti et al. (56) who both report an increase in double limb support time, which in conjunction with slower walking speeds, suggests that persons with MS try to produce a more conservative and stable gait to compensate for having less balance control. Martin and colleagues assessed the gait impairments in persons with MS who were recently diagnosed and presented with mild neurological signs of the disease (49). In these patients, walking speed and stride length were reduced, and ankle range of motion was limited, all in comparison to a matched control subject. In addition, the change in ankle range of motion was not met with a similar change in knee range of motion (49). Benedetti et al. described gait in persons with MS as protective and favoring stability and balance at the expense of speed. Specifically, gait patterns have an increased hip range of motion due to an excess of hip flexion at the end of the swing phase and at the heel strike, in conjunction with a reduction in ankle range of motion (56). In summary, cerebellar ataxia produces gait impairments in regards to a slower walking cadence and changes in balance related variables (49, 55–59).

Techniques Used to Improve Walking and Gait

Interventions using equipment and exercise have been effective in improving gait and mobility in persons with MS. One specific rehabilitation technique that has been used is body-weight supported treadmill training, which is often paired with robot-assisted gait devices (11, 12). The theory behind robot-assisted gait training is that the consistent, repetitive task-specific training helps the patient to relearn and reinforce the walking movements (12). Robot-assisted gait training has not been extensively researched in persons with MS, but has been studied in individuals with

spinal cord injuries and stroke patients (60, 61). In a single-subject study by Gardner and colleagues, the training device helped to increase walking speed and stride length in running after 6 weeks of training (60). Beer et al. conducted a study that compared robot-assisted gait training with conventional walking therapy (11). Participants in the robot-assisted gait training group used the Lokomat, a robot-driven orthosis device, with the Locobasis for body weight support, all in combination with a treadmill system. Those in the conventional walking therapy group walked over ground with a walking aid if needed and with the assistance of a physical therapist. Results of this study showed significant improvements in distance walked, walking velocity, and knee extensor strength in the robot-assisted training group. However, when reassessed at 6 months post-intervention, all values had returned to baseline in both groups, so no long term effect was seen (11). Lo and Triche tested two protocols of body weight supported treadmill training; one that did not use robotic assistance and one that did use a robot-driven gait orthotic (12). Due to the crossover design, all subjects experienced both conditions for a total of 6 sessions each, with a 6-week washout period between protocols. Results of the study showed no differences between treatment groups, however there were significant within-subject improvements, specifically in the timed 25-foot walk test (+31%), 6-minute walk test (+38.5%) and EDSS (+1) (12). There was also a significant improvement in double support time, but this change could be attributed to the treadmill which does not allow for a prolonged stationary stance, otherwise the patient would be forced off the back of the treadmill (12).

Schwartz and colleagues (13), conducted a similar study to that of Beer and colleagues (11) that compared robot-assisted gait training to conventional walking therapy. Results showed a significant improvement in two of three tested gait parameters, 6- and 10-meter walk times, for the conventional walking group. The robot-assisted training group only saw significant

improvement in the third gait parameter, timed up-and-go test (13). However, after 6 months, all improvement returned to baseline, with the exception of the timed up-and-go test in the robot-assisted training group. Berg balance tests results were sustained in the conventional walking group at three months post-intervention (13). At six months post, the balance test results for the conventional walking group had decreased slightly, but were still higher than baseline values; the robot-assisted training group had returned to baseline. The authors suggest that conventional walking training may produce more long-term effects on balance mechanism than robot-assisted gait training (13).

Despite the lack of long-term effects, these studies suggest that robot-assisted gait training may be effective at producing short-term results. Possible advantages include improvement in many gait variables, which may lower anxiety due to a lower risk of falls (12, 57, 62). In addition, it may not induce as much fatigue or weakness because of the assistive qualities of the device (12). However, it has been noted by Beer et al. that body-weight supported treadmill mechanisms, like those used in robot-assisted gait training, are physically demanding for physical therapists who have to control and assist the walking movements (11). In addition, the equipment for body-weight supported treadmill training and robot-assisted gait training are very expensive, which may not be feasible for many clinics. Future studies that center on robot-assisted gait-training should focus on a long-term program that has the potential to carry over longitudinal effects. Conversely, exercise interventions may be less demanding for therapists and more available to patients at lower costs, would be recommended.

Cattaneo and coworkers examined the effects of balance retraining in persons with MS (14). Participants were split into two experimental groups and one control group. One experimental group completed balance exercises to improve motor and sensory strategies and the other

experimental group completed balance exercises to improve motor strategy. The control group completed exercises that were not specifically aimed to improve balance. Following the three week intervention, results showed a statistically significant decrease in the frequency of falls among the two experimental groups. Significant differences were also observed in the results of the Berg Balance Scale and Dynamic Gait Index. No relevant improvements were seen in the Activities-specific Balance Confidence, Dizziness Handicap Inventory, and the number of subjects who had a fall in the control group (14). A separate study by Monjezi et al. examined the effect of dual- and single-task balance training in persons with MS (15). Subjects in the dual-task training group completed balance activities while simultaneously participating in cognitive tasks, and the single-task group only completed balance activities. Outcome was measured using the 10-meter walk test and timed up-and-go under single-task and dual-task conditions. In addition, the Activities-specific Balance Confidence survey, Berg Balance Scale, and Functional Gait Assessment were used. Results showed no significant difference between groups. However, in both groups there was a significant improvement for dual 10-meter walk test and dual timed up-and-go. In addition, there were significant improvements for Activities-specific Balance Confidence, Berg Balance scale, and Functional Gait Assessment for both groups (15). The results of this pilot study show that any degree of balance training is beneficial for improving balance in persons with MS. The results for these two studies on balance suggest that balance rehabilitation may be a useful tool for persons with MS to reduce the incidence of falls and improve overall balance skills (14).

Gutierrez and coworkers concluded that resistance training may be effective at improving walking and functional capacity in persons with MS who are moderately disabled (16). Subjects participated in an 8-week progressive resistance training program and had kinematic gait variables and strength tested pre- and post-intervention. Results showed significant decreases in time spent

in stance phase and increases in time spent in swing phase in the most-affected limb. The less-affected limb presented with significant increase in step length and foot angle, with a decrease in toe clearance. In both limbs, there were significant decreases in time spent in double support and increases in stride length (16). These results indicate that this resistance training protocol may help persons with MS to produce a more normal stride pattern. These changes, in conjunction with additional results of improvements in fatigue, self-reported EDSS score, and lower extremity isometric muscle strength suggest that resistance training is effective at improving walking and functional capacity in persons with MS (16).

In a study conducted by White et al., persons with MS participated in a progressive resistance training program in efforts to improve strength and functional capacity (17). At the beginning of the 8-week intervention, subjects completed exercises at 50% of their tested maximum. Resistance was gradually increased by 2-5% as individuals were able to complete 15 repetitions in consecutive sessions. Significant improvements were seen in knee extension (7.4%), plantarflexion (52%) and stepping performance (8.7%). In addition, there was a decrease in self-reported fatigue and disability score. Overall, the results suggest that a progressive resistance training program that is individualized to the person may be effective at improving walking and decreasing fatigue in persons with MS (17).

While many studies that examine the effects of exercise on persons with MS show positive improvements, they often have a low-quality methodology, meaning that many studies are non-supervised and include home-based training, relying on self-reporting of volume and intensity. This characteristic often makes making conclusions difficult and hard to compare with other studies (18). Optimally, exercise interventions would be tailored to the individual and be constantly re-evaluated to ensure that the patient is making improvements. One important factor lacking in

the robot-assisted gait-training and many exercise program studies is the lack of long-term effects. Subjects often return to their baseline within months of completing the study.

Speedmaker™ and NewGait™

The Speedmaker™ is a training device created by Elite Athlete Products that is claimed to be able to improve sprint performance (63). According to the company, the product helps to elicit post-activation potentiation, improve knee height, and upper leg drive to improve performance (63). The device consists of a harness that straps over the shoulder, around the abdomen, and lower thigh. Resistance bands are connected to the abdomen and thigh strap and run across the anterior portion of the hip.

Clark et al. examined the effect that the Speedmaker™ had on sprinting and jump performance in track and field athletes (64). The athletes trained with the device for five weeks, and completed pre and post-tests consisting of a warm-up of three 45 meter sprints at 80, 90, and 100% maximum. Three minutes following the sprints, the athletes performed three maximum countermovement jumps and two additional 45 meter sprints; kinematics were assessed during the countermovement jumps and following sprints. Results showed a significant improvement in 10 meter sprint times, meaning that the Speedmaker™ may be beneficial to improving the acceleration phase of sprinting. In addition, there was a significant decrease in maximum knee extension angle, which may suggest an improvement in knee range of motion. Gait impairments are often the first symptoms of some neurological diseases, and specifically, persons with MS often ambulate with a slower speed and less knee and ankle joint movement (58). The results of this study could be applied to a clinical population and suggest that a device of this design could help to increase knee range of motion and speed. The subjects in this study trained while wearing

the device, so it may be reasonable that the mechanisms behind the changes seen in the athlete would be reflected in a clinical population who trains with the device during physical therapy.

The NewGait™ is claimed to be a non-motorized, exoskeletal device that provides manual feedback, postural support, and muscular assistance to the wearer in order to optimize gait speed and stability. According to Elite Athlete Products, the manufacturer of the NewGait™ device, the separate parts of the device work together to "assist and promote proper locomotion during each phase of the gait cycle" (19). Presently, no one has investigated these claims. The NewGait™ is a modification of the original Speedmaker™ device with additional straps and elastic bands added to assist the lower limbs during the gait cycle. For patients who experience foot drop, the shank portion of the device is proposed to assist the tibialis anterior in accomplishing dorsiflexion during the swing phase. The waist belt and upper leg portions are proposed to help to stabilize the pelvis, quadriceps, and abductor muscles during the loading phase. During mid-stance, the device is proposed to help to compress the ankle and hip joints to improve proprioceptive feedback and stability, while also helping to prevent excessive extension of the knee. Finally, the elastic bands of the NewGait™ shorten during mid-swing, to potentially allow for hip flexion and ankle dorsiflexion in order to clear the foot from the ground for swing (19).

The NewGait™ has produced anecdotal clinical improvements in walking performance for a variety of populations, including people with spinal cord injuries, mitochondrial diseases, and injuries to the lower limbs (20, 65). A patient with spinal cord injury became more stable in their walking, had better balance, and was more confident in their walking after implementing the NewGait™ into their physical therapy protocol (65). A patient with mitochondrial disease experienced difficulty walking because of pain due to the disease. After putting on the device and

walking around and walking up and down stairs, the patient felt no pain and could walk normally (66).

The NewGait™ device may be comparable to the devices used in robot-assisted gait training, as both devices give support to the wearer to induce a more normal walking pattern (11). In addition, there is an adaptability feature of both the NewGait™ and robot-assisted gait training devices. The robot-assisted gait devices can be fit to an individual by changing the width of the hip orthosis and lengths of the thigh and shank components (61). For the NewGait™, straps can be added or removed based on what assistance the patient needs. In addition, the elastic bands can be changed to provide easier or harder assistance, and clipped in different locations to assist with different movements (20). Thus, each device can be individualized to each patient to allow for the gait to replicate a normal pattern. A difference between the two devices is the cost. An entire NewGait™ kit could be purchased for under $500, which is more affordable than the equipment needed for body-weight supported treadmill training and robot-assisted gait training, which could add up to more than $10,000. This factor may be more appealing to physical therapists, especially those who work in clinics that do not have a large budget.

The NewGait™ is of similar construction to a device created for the rehabilitation of stroke patients. Bae et al. created a stroke-specific soft exosuit that provides unilateral assistance on the paretic side (21). Specifically, the exosuit provides assistance to the ankle during push off and dorsiflexion assistance during the swing phase (21). Like patients with MS, stroke patients experience varying gait impairments, and like the NewGait™ this soft exosuit is customizable to every individual to address their specific impairment (21). Pilot testing results of the soft exosuit concluded that the device could improve gait symmetry and paretic limb progression in patients with chronic stroke (21). Patients experienced an improvement in step time symmetry, stance time

symmetry, and a decrease in stride time (21). Bae and colleagues suggest that the soft exosuit device may be able to promote a more efficient walking pattern in stroke patients (21). Since the NewGait™ is similar in structure as the soft exosuit developed by Bae et al., it may be reasonable to suggest that the NewGait™ may produce similar results for improving walking gait.

To compare with robot-assisted gait training devices, the NewGait™ is more transferable to different walking conditions, as its use isn't confined to the constraints of a treadmill or to the motorized controls used by physical therapists on exosuit devices. So, a NewGait™ wearer could use the device in conjunction with additional gait improvement exercises, like resistance or balance training. Thus, the NewGait™ has the potential to combine the two different rehabilitation techniques by providing the same type of support as robot-assisted gait devices and the exercises of resistance and balance training. Ideally, a patient would see the same type of improvements in gait parameters seen following robot-assisted gait training, such as stride length, speed, and joint range of motion, in addition to positive changes seen in balance and walking performance from resistance and balance training.

Analysis Methods

According to the Oxford Dictionary of Sport Science and Medicine, gait is defined as a style of walking or running and is an important indicator of health and disease (67). In clinical populations, gait analysis is a typical measure to evaluate the progression of many neurological diseases (9). Being able to evaluate gait characteristics over time may be beneficial for early diagnosis of the disease, as well as for monitoring progression of the disease and determining the best treatment options for the patients. Several technologies, such as 2D and/or 3D motion analysis, may be used to assess a person's gait in clinical settings. Muro-de-la-Herran et al. provide a comprehensive list of common gait parameters assessed in a clinical setting that include speed,

step length and width, swing and stance time, and joint angles(9). Another gait factor that is often assessed is toe clearance height (68). Minimum toe clearance height is the distance between the shoe and the ground during the swing phase. Trips and subsequent falls are most likely to happen during this phase of gait, and may be hard to avoid with a low toe clearance height as it may be hard for individuals to regain their stability quickly enough (68). Schulz tested how minimum toe clearance height changes due to different floor surfaces and gait speed (68). Results showed that minimum toe clearance and several other kinematic variables significantly changed with a faster speed. Specifically, knee and hip flexion at the point of minimum toe clearance height during the swing phase significantly increased, while ankle dorsiflexion angles were significantly reduced at the subject's preferred walking speed (68). These results suggest that changes in joint kinematics may result in changes in minimum toe clearance, which may reduce the risk of trips and falls.

When testing gait, an analysis will often be paired with a survey in which the patient gives a subjective evaluation of their gait quality. Evaluations may include, but are not limited to, rating of perceived exertion and balance confidence. Stamford determined the reliability of the Borg RPE scale under different experimental conditions (31). The results of the study showed that RPE represented a strong relationship between heart rate and work intensity. It was concluded to be a sensitive and reliable measure of stress during work (31). The Activities-specific Balance Confidence Scale is a survey in which subjects self-report their perceived level of confidence while performing 16 lifestyle activities (23). Cattaneo et al. tested the validity of six balance disorder scales, including the Activities-Specific Balance Confidence Scale, in persons with MS. In comparison to some of the other tests, this test was shown to better differentiate between fallers and non-fallers. In addition, it appears to be one of the best predictors of fall status (23).

The Dynamic Systems Theory states that gait movement patterns are a result of the organization of the neuromuscular system based on several factors including: morphology, biomechanics, the environment, and task constraints (69). Overall, the theory states that movement patterns are a result of individual muscles working in conjunction with the neuropathways to achieve a functional outcome that must meet the constraints of the system (69). One way of measuring coordination is using a vector coding technique which quantifies the interaction between two segments by determining the vector orientation between two data points (27). The coupling angle is used as the outcome measure and is a value between 0-360°, and can be described as either in-phase (both moving in the same direction) or anti-phase (27).

Coordination is an important measurement that may be used in clinical populations because changes in coordination among joints may be due to health or disease (70). An increasingly common practice in physical therapy is improving gait coordination and restoring normal gait patterns to accomplish a larger goal of improving ambulatory performance (70). Coordination has been studied in patients with Parkinson's and stroke patients (70–72). In stroke patients, poor coordination is shown by an impaired relative timing of interlimb coordination and an increased variability in the resulting coordination pattern (70). Patients typically have a reduced ability to adjust their gait based on immediate demands. For example, after stroke, patients tend to make variations in walking speed by changing their stride length, rather than stride frequency. In unimpaired walking, stride length and frequency contribute equally to walking speed (70). Patients with Parkinson's disease typically show abnormal changing of stride length, and impaired pacing of gait synchronization (72). Gait variability has been widely studied in the MS population, however there are no known reports of gait coordination in persons with MS before and after a rehabilitation program using a gait training device (1, 73, 74)

In summary, walking impairments are characteristic of neurological diseases such as multiple sclerosis, and are often indicators of the severity and progression of the diseases. There have been multiple rehabilitation mechanisms developed to aid in improving walking performance and gait. The purpose of this literature review was to give the reader background on the neurodegenerative disease multiple sclerosis, and to give some information on walking gait rehabilitation programs and devices. Finally, analysis methodology for assessing gait and walking performance was examined.

CHAPTER III: CONCLUSIONS AND RECOMMENDATIONS

The current study provided preliminary evidence to support the effectiveness of the NewGait™ device on improving gait and walking performance in persons with multiple sclerosis. The NewGait™ was demonstrated to be effective at improving balance confidence and coordination of the lower limbs during the swing phase.

Those participants who wore the NewGait™ during physical therapy exhibited a significantly greater increase in balance confidence. This higher rating of balance confidence may have contributed to the individual having more postural support and stability. In comparison to other gait devices, such as those using in robot-assisted gait training that keep the wearer in a rigid position, the NewGait™ is non-rigid. The rigid devices don't require the individual to engage in as much muscle activity to maintain posture, as the device holds them up. However, the NewGait™ may require individuals to engage their muscles to maintain their posture, which may in turn cause an increase in balance confidence. In addition, the significant increases in step length that caused changes in step length symmetry may have influenced the positive changes seen in balance confidence. Many of the participants in the present study were able to increase their walking speed to a level that would characterize them as independent walkers, meaning that they are independent in activities of daily living and are less likely to need interventions to reduce the risk of falls. Increasing balance confidence by increasing step length and step length symmetry may have resulted in an increase in walking speed.

Lower limb coordination may have improved due to the assistive nature of the NewGait™ device. During the swing phase, ankle-hip coordination is characterized by mostly in-phase flexion and extension. Since the percent of time spent in anti-phase during the swing phase on the unaffected side decreased, it may be proposed that the participants were moving towards a more

normal, in-phase coordination pattern. In addition, since the significant changes seen in coordination were on the unaffected side and there was a large effect size seen in step length on the unaffected side, it may be suggested that the affected side had become more stable, allowing for a longer swing phase on the unaffected side. Overall, this suggests that the NewGait™ had an effect on coordination by allowing for a more normal gait pattern.

Limitations of this study include having a small sample size, not including a control group that did not participate in PT, and not measuring center of mass or muscular activity. Future research should consider following up with participants a few months after completion of using the device to see if improvements last or continue, and testing additional variables, i.e. muscle activity, to provide a more in-depth assessment of change in gait impairment, and to further discover the mechanics behind the changes seen due to the NewGait™ device.

Practical Applications

The implementation of the NewGait™ device to improve walking performance in persons with multiple sclerosis may better serve practitioners and/or serve as a supplemental assistance device to already in-place physical therapy programs. After using the NewGait™ device, participants experienced significant increases in balance confidence and lower limb coordination. Balance confidence and step length are important variables in determining walking speed, and if walking speed can be increased, an individual may have the potential to become more independent in activities of daily living. Improving lower limb coordination to be more normal may influence balance confidence and reduce the risk of injury and falls.

The device could be used on a variety of patients who have a type gait impairment that affects balance confidence and coordination, i.e. Parkinson's and stroke patients. Persons with

Parkinson's experience inadequate balance due to the stiffness and rigidity of their muscles and changes in coordination due to taking shuffling steps (75). Stroke patients may have balance difficulties and coordination may be affected due to strength asymmetries (46). So, Parkinson's and stroke patients may benefit from using the device, as the results of the present study show it is effective at improving balance confidence and lower limb coordination. Due to the versatility in wear ability of the device, it may be used outside of a physical therapy clinic, to potentially act as a walking assistive device, allowing those more impaired patients to be mobile at home and in the community, potentially by improving their balance confidence as seen in the present study. Having improved confidence during household and community activity may increase the amount of time that an individual can spend doing those activities.

The results of this study showed that physical therapy has a positive effect on walking performance in persons with multiple sclerosis, and the addition of the NewGait™ device can improve some variables, like balance confidence and coordination, to a greater degree. This suggests that the addition of the NewGait™ to a physical therapy intervention is beneficial to improving walking performance in persons with multiple sclerosis, and using this device may help to improve patients' quality of life by improving their gait and ambulatory status.

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APPENDIX A

PARTICIPANT RECRIUTMENT QUESTIONS

MS condition questions:
We need to establish that they are in a stable phase of their disease i.e. they have not had a recent relapse or they are primary progressive

- *Firstly in relation to your MS, do you know if you have been diagnosed with relapsing remitting MS or primary progressive MS?*
    - *IF RR: Can you tell me when you had your last relapse?*
        - If severe relapses requiring hospitalisation in last 3 months they are **INELIGIBILE**. But we will be enrolling participants until early april.
    - *IF PP: Ok thank you for that.*

Walking ability:
We need to establish if they have an edss score of between 5-7:

- *Now I would like to assess your walking ability.*
- *This is important as it allows us to identify if you have a walking impairment that is at a level where we feel this rehab program will be of benefit to you.*

- ***Q1:*** *Do you use a walking aid?*
    - If yes
        - *What type of walking aid do you use and how often to you use it?*
            - Are they confined to a wheelchair?
                - If they are confined to a wheelchair they are **INELIGIBLE**, their walking impairment is too severe for our study.
                - If they use a walking aid but are not confined to a wheelchair they are **ELIGIBLE**
    - If no they need to answer yes to question 2 in order to be eligible

- ***Q2:*** *Imagine the length of a football field.*
- *Could you walk the length of ONE football field without the use of your walking aid or rest?*
    - If no they are **ELIGIBLE**
    - If yes continue
- *Could you walk the length of TWO football fields without the use of your walking aid or rest?*
    - If no they are **ELIGIBLE**
    - If yes continue
- *Could you walk the length of THREE football fields without the use of your walking aid or rest?*
    - If no they are **ELIGIBILE**

- If yes they are **INELIGIBLE**, their walking impairment is not severe enough for our study.

Comorbidities:

- *My final question to assess your eligibility is to identify if you have any recent orthopedic problems in your legs such as knee or hip replacement surgery.*
- *Have you had a surgeries on your legs in the last 6 months?*
  - If no they are **ELIGIBLE**
  - If yes
    - *Have you been finished PT treatment for this surgery?*
      - If no they are **INELIGIBLE**, their injury is not severe enough for our study.

APPENDIX B

EXTENDED DISABILITY STATUS SCALE (EDSS)

Score	*Description*
1	No disability, minimal signs in one FS
1.5	No disability, minimal signs in more than one FS
2	Minimal disability in one FS
2.5	Mild disability in one FS or minimal disability in two FS
3	Moderate disability in one FS, or mild disability in three or four FS. No impairment to walking
3.5	Moderate disability in one FS and more than minimal disability in several others. No impairment to walking
4	Significant disability but self-sufficient and up and about some 12 hours a day. Able to walk without aid or rest for 500m
4.5	Significant disability but up and about much of the day, able to work a full day, may otherwise have some limitation of full activity or require minimal assistance. Able to walk without aid or rest for 300m
5	Disability severe enough to impair full daily activities and ability to work a full day without special provisions. Able to walk without aid or rest for 200m
5.5	Disability severe enough to preclude full daily activities. Able to walk without aid or rest for 100m
6	Requires a walking aid - cane, crutch, etc. - to walk about 100m with or without resting
6.5	Requires two walking aids - pair of canes, crutches, etc. - to walk about 20m without resting
7	Unable to walk beyond approximately 5m even with aid. Essentially restricted to wheelchair; though wheels self in standard wheelchair and transfers alone. Up and about in wheelchair some 12 hours a day
7.5	Unable to take more than a few steps. Restricted to wheelchair and may need aid in transferring. Can wheel self but cannot carry on in standard wheelchair for a full day and may require a motorized wheelchair
8	Essentially restricted to bed or chair or pushed in wheelchair. May be out of bed itself much of the day. Retains many self-care functions. Generally has effective use of arms
8.5	Essentially restricted to bed much of day. Has some effective use of arms retains some self-care functions
9	Confined to bed. Can still communicate and eat
9.5	Confined to bed and totally dependent. Unable to communicate effectively or eat/swallow
10	Death due to MS

APPENDIX C

IRB APPROVAL

NORTHERN MICHIGAN UNIVERSITY

OFFICE OF GRADUATE EDUCATION AND RESEARCH
1401 Presque Isle Avenue
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Memorandum

TO: Sarah Clarke
School of Health and Human Performance

Randall Jensen
School of Health and Human Performance

DATE: July 7, 2017

FROM: Robert Winn, Ph.D.
Interim Dean of Arts and Sciences/IRB Administrator

SUBJECT: **IRB Proposal** HS17-870
IRB Approval Dates: 7/7/2017 - 7/7/2018
Proposed Project Dates: 9/1/2017 - 9/1/2018
"The effect of the New Gait training device on walking performance in persons with Multiple Sclerosis"

The Institutional Review Board (IRB) has reviewed your proposal and has given it final approval. To maintain permission from the Federal government to use human subjects in research, certain reporting processes are required.

A. You must include the statement "Approved by IRB: Project # HS17-870" on all research materials you distribute, as well as on any correspondence concerning this project.

B. If a subject suffers an injury during research, or if there is an incident of non-compliance with IRB policies and procedures, you must take immediate action to assist the subject and notify the IRB chair (dereande@nmu.edu) and NMU's IRB administrator (rwinn@nmu.edu) within 48 hours. Additionally, you must complete an Unanticipated Problem or Adverse Event Form for Research Involving Human Subjects

C. Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant.

D. If you find that modifications of methods or procedures are necessary, you must submit a Project Modification Form for Research Involving Human Subjects before collecting data.

E. If you complete your project within 12 months from the date of your approval notification, you must submit a Project Completion Form for Research Involving Human Subjects. If you do not complete your project within 12 months from the date of your approval notification, you must submit a Project Renewal Form for Research Involving Human Subjects. You may apply for a one-year project renewal up to four times.

NOTE: Failure to submit a Project Completion Form or Project Renewal Form within 12 months from the date of your approval notification will result in a suspension of Human Subjects Research privileges for all investigators listed on the application until the form is submitted and approved.

All forms can be found at the NMU Grants and Research website:
http://www.nmu.edu/grantsandresearch/node/102

NORTHERN MICHIGAN UNIVERSITY

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MEMORANDUM

TO: Sarah Clarke
School of Health and Human Performance

CC: Randall Jensen
School of Health and Human Performance

FROM: Robert Winn, Ph.D.
Interim Dean of Arts and Sciences/IRB Administrator

DATE: July 3, 2018

RE: Extension for HS17-870
Original IRB Approval Date: 7/6/2017
New Project Expiration Date: 7/2/2019
"The effect of the New Gait training device on walking performance in persons with Multiple Sclerosis"

Your project modification to extend "The effect of the New Gait training device on walking performance in persons with Multiple Sclerosis" has been approved under the administrative review process. Please include your proposal number (HS17-870) on all research materials and on any correspondence regarding this project.

Any changes or revisions to your approved research plan must be approved by the IRB prior to implementation. Unless specified otherwise, all previous requirements included in your original approval notice remain in effect.

If you complete your project within 12 months from the date of your approval notification, you must submit a Project Completion Form for Research Involving Human Subjects. If you do not complete your project within 12 months from the date of your approval notification, you must submit a Project Renewal Form for Research Involving Human Subjects. You may apply for a one-year project renewal up to four times.

If you have any questions, please contact the Office of Graduate Education and Research.

APPENDIX D

NORTHERN MICHIGAN UNIVERSITY SCHOOL OF HEALTH & HUMAN PERFORMANCE

CONSENT TO ACT AS A HUMAN SUBJECT

Subject Name (print):_____ Date: _____

I hereby volunteer to participate as a subject in exercise testing. I understand that this testing is part of a study entitled: "The effect of the New Gait training device on walking performance in persons with Multiple Sclerosis". The purpose of the study is to investigate the effect of a New Gait training device on walking performance and strength in persons with Multiple Sclerosis.

I hereby authorize Sarah Clarke, Randall L. Jensen, and/or assistants as may be selected by them to perform on me the following procedures:

1. I understand that I am being asked to walk 25 ft. six times on two separate days; one prior to a training program and one after.
2. I understand that markers will be placed on my ankles, knees, hips, and shoulders to measure my knee and hip angles while walking. I will be asked to wear shorts and a t-shirt during these tests to ensure all the markers can been seen by the recording cameras.
3. I understand that I will have four sensors placed on each leg, one each on the front of the thigh (Rectus Femoris); and one each on the front and back of my lower leg (Gastrocnemius and Tibialis Anterior). We may need to shave the skin at the sensor site to ensure a good connection. These electrodes will be used to measure muscle activity, via electromyography while walking.
4. I also understand that on the two days (one prior to the training program and one after) I will perform strength testing on a Biodex Isokinetic strength testing device. This testing will involve 5-10 maximal repetitions of knee extension and flexion, performed as rapidly as possible by each leg.
5. If randomly selected to one of two groups, I will train with a New Gait training device for 8 weeks. A second group will perform normal rehabilitation training activities for the 8 weeks. Following the 8 weeks I will be retested as above.

- ☐ The procedures outlined in points 1-5 (above) have been explained to me.
- ☐ I understand that the procedures described in points 1-5 (above) involve the following risks and discomforts: temporary muscle pain and soreness may be expected. In addition there may be minor skin irritation from the electromyography electrodes. However, I understand that I can terminate any test at any time at my discretion. Moreover, I should cease any test if I experience any abnormalities such as dizziness,

light-headedness, or shortness of breath, etc.

- I understand that with any type of physical effort there is a small risk of heart attack. In order to prevent any of the above-mentioned risks, I understand that the examiners shall adopt the necessary measures to prevent them such as: using physical tests in accordance with my conditioning.
- I have been advised that the following benefits will be derived from my participation in this study: aside from the educational benefit of learning about running analysis there are no direct benefits to me.
- I understand that Sarah Clarke, Randall L. Jensen, and/or appropriate assistants as may be selected by them will answer any inquiries that I may have at any time concerning these procedures and/or investigations.
- I understand that all data, concerning myself will be kept confidential and available only upon my written request. I further understand that in the event of publication, no association will be made between the reported data and myself.
- I understand that there is no monetary compensation for my participation in this study.
- I understand that all costs associated with the physical therapy intervention need to be covered by me or my insurance.
- I understand that in the event of physical injury directly resulting from participation, compensation cannot be provided. However, if injury occurs, emergency first aid will be provided and the EMS system activated.
- I understand that I may terminate participation in this study at any time without prejudice to future care or any possible reimbursement of expenses, compensation, or employment status.

If you have any further questions regarding your rights as a participant in a research project you may contact Dr. Robert Winn of the Human Subjects Research Review Committee of Northern Michigan University (906-227-2300) rwinn@nmu.edu. Any questions I have regarding the nature of this research project will be answered by Dr. Sarah Clarke (906-227-1143) sabreen@nmu.edu or Dr. Randall Jensen (906-227-1184) rajensen@nmu.edu.

I have read the above "Informed Consent Statement." The nature, risks, demands, and benefits of the project have been explained to me. I understand that I may ask questions and that I am free to withdraw from the project at any time without incurring ill will or negative consequences. I also understand that this informed consent document will be kept separate from the data collected in this project to maintain anonymity (confidentiality). Access to this document is restricted to the principle investigators.

If you have any questions, concerns or complaints about the research or your rights as a research participant in this study, you should contact the Patient Advocate at U.P. Health System Marquette at 906- 225-3183 or 1-800-562-9753 ext. 3183

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Subject's Signature Date

Thank you very much for your consideration.

Sincerely,

Principal Investigators: Drs. Sarah Clarke and Randall Jensen

APPENDIX E

THE ACTIVITIES-SPECIFIC BALANCE CONFIDENCE (ABC) SCALE

Instructions to Participants: For each of the following activities, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100% If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports.

0% 10 20 30 40 50 60 70 80 90 100%

No Confidence Completely Confident

How confident are you that you will not lose your balance or become unsteady when you…

1. …walk around the house?___%
2. …walk up or down stairs?___%
3. …bend over and pick up a slipper from the front of a closet floor?_%
4. …reach for a small can off a shelf at eye level?_____%
5. …stand on your tip toes and reach for something above your head?_____%
6. …stand on a chair and reach for something?_%
7. …sweep the floor?___%
8. …walk outside the house to a car parked in the driveway?__%
9. …get into or out of a car?____%
10. …walk across a parking lot to the mall?_____%
11. …walk up or down a ramp?__%
12. …walk in a crowded mall where people rapidly walk past you?____%
13. …are bumped into by people as you walk through the mall?_____%
14. …step onto or off of an escalator while you are holding onto a railing?____%
15. …step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing?_____%
16. …walk outside on icy sidewalks?___%

Total ABC Score: _____

Scoring: (Total ABC Score) _____/ 16 = _____ % of self confidence

APPENDIX F

NEWGAIT™ PHYSICAL THERPAY PROTOCOL

Warm Up Cardio on bike [5 min]
Stretching (on mat) Ankle, hip, knee [10 min]
Gait Exercises Using dowel: pushing forward/backward, side stepping, and karaoke Walking through hall or on treadmill (verbal/visual feedback for gait issues) [15 min]
5 minute break
Balance Exercises Static head turns: feet apart, together tandem, single limb, eyes closed Trunk rotations [5 min]
Functional Balance Exercises Step overs, stairs, stair lunges, hip hiking, sit-stand, ball toss perturbations, reaching up/out/floor, turning around 360 degrees, Body Blade, Vectors, alternating toe touches to top of step [5 min]
Mat Exercises Quadruped hip extension, supine or on side hip abduction, bridge [5 min]
Neurological Tests Testing strength of muscles/muscle groups by having patient act against resistance provided by therapist [5 min]
Intensity
Intensity or number of repetitions for each exercise is decided upon by the physical therapist and is subjective based on daily patient assessment of pain and fatigue.

APPENDIX G

SUPPLEMENTAL RESULTS TABLES

TABLE 3. P-value and Cohen's d (d) effect size for gait variables and RPE.

		Time	Time * Group	Group	d	
					Control	Experimental
Speed (m/sec) *		0.0004	0.277	0.468	0.491	0.337
Balance (%) *†		0.001	0.034	0.736	0.628	1.462
RPE		0.089	0.338	0.245	0.133	0.795
Affected Step Length (m)*		0.009	0.382	0.875	0.321	0.465
Unaffected Step Length (m)*		0.003	0.15	0.531	0.387	0.544
Step Width (m)		0.944	0.255	0.707	0.231	0.316
Double Limb Support Time (s)		0.262	0.687	0.762	0.237	0.303
Affected Toe Clearance (cm)		0.289	0.2	0.424	0.106	0.525
Unaffected Toe Clearance (cm)		0.495	0.209	0.103	0.284	0.532
SWING	Affected Ankle ROM (°)	0.56	0.196	0.906	0.330	0.142
SWING	Unaffected Ankle ROM (°)	0.62	0.778	0.513	0.184	0.587
STANCE	Affected Ankle ROM (°)	0.39	0.0504	0.18	0.014	0.116
STANCE	Unaffected Ankle ROM (°)	0.762	0.166	0.389	0.281	0.323

**Significant effect for time, $p < 0.05$*

†*Significant effect for interaction, $p < 0.05$*

TABLE 4. P-value and Cohen's d (d) effect size for coordination variables.

		Time	Time * Group	Group	d	
					Control	Experimental
SWING - AFFECTED	In-Phase	0.237	0.114	0.845	0.052	0.253
	Anti-Phase	0.292	0.919	0.863	0.231	0.226
	Hip-Driven	0.915	0.306	0.949	0.006	0.100
	Ankle-Driven	0.456	0.612	0.478	0.039	0.301
SWING - UNAFFECTED	In-Phase	0.119	0.754	0.749	0.424	0.301
	Anti-Phase *†	0.004	0.509	0.043	0.736	0.736
	Hip-Driven	0.227	0.772	0.256	0.289	0.183
	Ankle-Driven *	0.045	0.708	0.857	0.530	0.414
STANCE - AFFECTED	In-Phase	0.628	0.17	0.758	0.308	0.460
	Anti-Phase	0.284	0.691	0.832	0.435	0.154
	Hip-Driven	0.183	0.759	0.988	0.257	0.234
	Ankle-Driven	0.7	0.888	0.626	0.001	0.128
STANCE - UNAFFECTED	In-Phase	0.492	0.449	0.738	0.122	0.376
	Anti-Phase	0.61	0.918	0.847	0.090	0.123
	Hip-Driven	0.41	0.358	0.607	0.069	0.351
	Ankle-Driven	0.826	0.051	0.469	0.263	0.402

**Significant effect for time, $p < 0.05$*

†*Significant effect for group, $p < 0.05$*