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The Effectiveness of Partial Body Weight Support Treadmill Training on Muscle Activation and Gait with Normal Subjects

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THE EFFECTIVENESS OF PARTIAL BODY WEIGHT SUPPORT TREADMILL TRAINING ON MUSCLE ACTIVATION AND GAIT WITH NORMAL SUBJECTS

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This scholarly project, submitted by Melanie A. Hanson, Cherron M. Kingzett, Amanda M. Klempel, and Jenny M. Silbernagel in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Faculty Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Signatures

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ABSTRACT

Background and Purpose: The purpose of this study was to evaluate gait kinematics of individuals without pathological impairments. Through the use of electromyography (EMG), the firing of muscles was analyzed during ambulation using the partial body weight support treadmill training (PBWSTT). Video motion analysis (VMA) was also used to look at the movements of the lower extremities and the pelvis. Using both of these tools, it was determined if there was a significant change in muscle firing and movements in normal individuals during ambulation with weight support compared to normal weight-bearing. Methods: Four subjects (3 female, 1 male) were recruited for this study. EMG and VMA data was collected for lower extremity muscle activity and gait kinematics during the gait cycle at 0%, slack removed (3%-6%), 15%, and 30% body weight support. Results: The gluteus medius muscle activation was found to be significantly different between conditions ($F(3,8) = 11.446; p = 0.003$). A post-hoc analysis was found to show significant differences in gluteus medius activation between 0% vs 3-6% ($p = 0.017$), 0% vs 15% ($p = 0.016$), 3-6% vs 30% ($p = 0.015$), 15% vs 30% ($p = 0.015$). The gluteus medius was most active at 15% (132.2%) followed by 3-6% (129.65%). The remaining muscles did not show significant difference in muscle activation and weight-bearing percentages. It is also noted that the power for these muscles were quite low. Step length was found to be significantly different between weight bearing conditions ($p = 0.005$). A post hoc analysis was performed, and Scheffe
results showed significant differences in step length between 0% vs 3-6% (p = 0.016) and 0% vs 30% (p = 0.009). Step length was greatest at 0% BWS for all subjects. Ankle dorsiflexion was not found to be significant (p = 2.176, power = 0.383). **Conclusion:** It was found that PBWSTT did not significantly alter the EMG data of normal individuals. This, in turn, will allow future studies to be performed on individuals who have impairments and limitations knowing that further compensation patterns will not be elicited from the use of PBWSTT.
CHAPTER I
INTRODUCTION

Gait dysfunction is a common result of stroke, traumatic brain injury, spinal cord injury and other neurological insults. Many individuals who have suffered from these insults are non-ambulatory for some length of time; therefore, gait training is one of the components of the rehabilitation process. Traditionally, physical therapists have focused on strengthening and single-movement practices. However, current approaches concentrate on task-specific therapies that are a normal part of an individual’s activities of daily living (ADLs). These task-specific therapies may include transfer training which allows individuals to safely sit down and rise from chairs as they would in their home and community and gait training which allows for mobility and independence. The use of partial body weight support treadmill training (PBWSTT) can be included in these task-specific therapies.

PBWSTT allows a patient to perform multiple, complex ambulatory movements which has shown to be more effective than single-movement therapy approaches for gait training. This is done by decreasing the patient’s body weight by a given percentage through the use of a supportive harness. Utilization of the PBWSTT allows a patient to ambulate correctly early on in the rehabilitation process. This is accomplished by providing trunk stabilization, which allows for weight transfer and loading of the lower extremities under supervision and facilitation provided by a physical therapist.
Current literature has shown the use of 30% body weight support (BWS) for rehabilitation provides appropriate support without altering normal gait patterns when compared to full weight bearing. Through the use of electromyography (EMG) and video motion analysis (VMA), this study hopes to prove that PBWSTT at 30% BWS and less will produce gait parameters most resembling the parameters at full weight bearing.

Problem statement

PBWSTT has been used during the rehabilitation process for many neurological disorders. Due to the fact body weight is reduced, there is a possibility that patients may compensate and develop poor habits while ambulating on the treadmill that may persist. Motor re-learning could be affected due to the activation of muscles at inappropriate times during the gait cycle. This could inevitably affect over-ground ambulation after the rehabilitation process is complete.

Purpose of the study

The purpose of this study was to evaluate gait kinematics of individuals without pathological impairments. Through the use of EMG, the firing of muscles was analyzed during ambulation using the PBWSTT. VMA was also used to look at the movements of the lower extremities and the pelvis. Using both of these tools, it was determined if there was a significant change in muscle firing and movements in normal individuals during ambulation with weight support compared to normal weight-bearing.

Significance of the study

This study looked at muscle activation and gait kinematics using EMG and VMA, respectively. Using the information gathered, it was determined if PBWSTT significantly alters normal individuals’ gait patterns at various body weight support
percentages when compared to full weight-bearing. If there were no significant alterations of gait using PBWSTT on normal subjects, this would indicate that current use of PBWSTT on patients with neurological conditions is beneficial. With these results, future studies can be conducted to apply the specific findings from this study to populations who may benefit from such task-specific gait training.

Research questions

1. Is there a difference in muscle activation between full weight-bearing ambulation and body-weight supported ambulation?
2. Is there a difference in gait kinematics between full weight-bearing ambulation and body-weight supported ambulation?

Hypotheses – Null (HO) and Alternate (HA)

1a. HO = There will be no significant difference in muscle activation between full weight-bearing ambulation (0% body weight support (BWS)) and slack removed supported ambulation (3-6% BWS).
   HA = There will be a significant difference in muscle activation between full weight-bearing ambulation (0% BWS) and slack removed supported ambulation (3-6% BWS).

1b. HO = There will be no significant difference in muscle activation between full weight-bearing ambulation (0% BWS) and 15% BWS.
   HA = There will be a significant difference in muscle activation between full weight-bearing ambulation (0% BWS) and 15% BWS.

1c. HO = There will be no significant difference in muscle activation between full weight-bearing ambulation (0% BWS) and 30% BWS.
HA = There will be a significant difference in muscle activation between full weight-bearing ambulation (0% BWS) and 30% BWS.

2a. HO = There will be no significant difference in gait kinematics between full weight-bearing ambulation (0% BWS) and slack removed supported ambulation (3-6% BWS),

HA = There will be a significant difference in gait kinematics between full weight-bearing ambulation (0% BWS) and slack removed supported ambulation (3-6% BWS).

2b. HO = There will be no significant difference in gait kinematics between full weight-bearing ambulation (0% BWS) and 15% BWS.

HA = There will be a significant difference in gait kinematics between full weight-bearing ambulation (0% BWS) and 15% BWS.

2c. HO = There will be no significant difference in gait kinematics between full weight-bearing ambulation (0% BWS) and 30% BWS.

HA = There will be a significant difference in gait kinematics between full weight-bearing ambulation (0% BWS) and 30% BWS.
Biomechanics of Gait

Gait is defined as an alternating, rhythmic movement of the limbs of the body along with the trunk which results in forward movement of the center of gravity.\textsuperscript{14} The goal of normal gait is to move forward while conserving energy and absorbing the impact of the resultant forces from the floor. There are five determinants of gait which help to decrease energy expenditure while ambulating.\textsuperscript{14} The first determinant is pelvic tilt. As a person walks, the pelvis will tilt downward on the stance leg in order to lower the center of mass. The second determinant is knee flexion at mid stance, which also helps to lower the center of mass. The third determinant of gait is knee, ankle and foot interaction which takes place twice during the gait cycle. The first time is during initial contact when the knee flexes, the ankle plantarflexes and the foot pronates for shock absorption. The second time is during mid stance; the interaction helps to slow the descent of the center of mass by extending the knee, plantarflexing the ankle and supinating the foot. The fourth determinant is pelvic rotation. During this action, the pelvis will rotate four degrees forward and backward to prevent the center of mass from dropping significantly. Lastly, the fifth determinant of gait is physiological valgus of the knee which helps to reduce the lateral displacement of the center of mass during gait.
The Gait Cycle

Each gait cycle, defined as the time between initial contact and the following ipsilateral initial contact, consists of eight defined phases. The phases listed below are defined in relation to the right foot and can be identified in Figure One.

1. Initial Contact (IC) – point at which the right heel strikes the ground.
2. Loading Response (LR) – the weight of the person is transferred onto the right limb.
3. Mid Stance (MSt) – body is centered over the right limb.
4. Terminal Stance (TSt) – trunk moves over the right limb and weight is transferred onto the forefoot.
5. Pre-Swing (PSw) – weight is taken off of the right limb and transferred onto the left.
6. Initial Swing (Isw) – as the right foot comes off the floor, the thigh advances forward.
7. Mid Swing (MSw) – right thigh advances as the foot clears the floor.
8. Terminal Swing (TSw) – right knee extends to enable the limb to prepare for initial contact.

Figure 1: Phases of gait cycle (Figure adapted from Ranchos Los Amigos)
Each of these phases of the gait cycle has identifiable components which include specific pelvic and lower extremity muscular activity and joint range of motion (ROM).

Initial contact is considered to take place at 0% of the gait cycle. At this moment, the primary muscles activated are the hip extensors, knee flexors, knee extensors, and ankle dorsiflexors. Expected joint ROM includes: 20° of hip flexion, 5° of knee flexion, and 0° ankle of plantarflexion.

Loading response takes place from 0-12% of the gait cycle. The primary muscles activated include hip extensors, knee flexors and extensors, and ankle dorsiflexors. During this phase, the gluteus maximus, gluteus medius, tensor fascia latae, and adductor magnus have their peak muscle activation. Expected joint ROM includes: 20° of hip flexion, 15° of knee flexion, and 5° of ankle plantarflexion.

Mid stance occurs from 12-31% of the gait cycle. Muscle activation during this phase includes the hip extensors and abductors, knee flexors, and ankle plantarflexors. The expected joint ROM includes: 0° of hip flexion, 5° of knee flexion, and 5° of ankle dorsiflexion.

Terminal stance takes place between 31-50% of the gait cycle. The primary muscles activated are the hip abductors and ankle plantarflexors. Expected joint ROM is as follows: 20° of hip extension, 5° of knee flexion, and 10° of ankle dorsiflexion.

Pre-swing occurs between 50-62% of the gait cycle. Muscles activated at this time include the hip adductors, knee extensors, and ankle plantarflexors. The rectus femoris is at its peak contraction during this phase. Expected joint ROM is 10° of hip extension, 40° of knee flexion, and 15° of ankle plantarflexion.
Initial swing occurs from 62-75% of the gait cycle. Muscles active at this time include the hip flexors, hip adductors, knee flexors, knee extensors, and ankle dorsiflexors. The iliacus, gracilis, and sartorius are at their peak activation during this phase. Expected joint ROM is 15° of hip flexion, 60° of knee flexion, and 5° of ankle plantarflexion.

Mid swing occurs from 75-87% of the gait cycle. Active muscles are the hip extensors, hip flexors, knee flexors, and ankle dorsiflexors. Expected joint ROM is 25° of hip flexion, 25° of knee flexion, and 0° of ankle dorsiflexion.

Terminal swing is the final phase of the gait cycle, and it occurs from 87-100% of the gait cycle. Active muscles include the hip extensors, hip adductors, knee flexors, knee extensors, and ankle dorsiflexors. The long head of the biceps femoris, semitendinosus and semimembranosus are most active during this phase. The expected ROM includes: 20° of hip flexion, 5° of knee flexion, and 0° of ankle dorsiflexion.

Partial Body Weight Support Treadmill Training (PBWSTT)

The gait cycle consists of complex movements that require the ability of an individual to go through these movements in a coordinated fashion. Utilization of PBWSTT allows people with impairments and functional limitations resulting from neurological and musculoskeletal insults to perform this complex cycle more easily as they recover.

Multiple studies have shown gait training using PBWSTT leads to improved recovery when compared to gait training by focusing on one part of the gait cycle at a time. There are three main elements of ambulation that are addressed specifically by PBWSTT: 1) locomotion is achieved with the treadmill belt, 2) equilibrium reflexes are
compensated for through the use of the harness, and 3) the amount of weight-bearing is dependent on the level of assistance needed by the individual.\(^8\) All of these elements lead to a safe walking environment which allows individuals to focus on the aspects of their gait cycle and not on balance.\(^1,4\) PBWSTT makes it easier for people to begin working on task-specific gait training in high volume without requiring time early on after the insult to work on single elements of the gait cycle.\(^12,16,17\) PBWSTT allows individuals with neurological insults to complete up to 1000 gait cycles during a single, 30-minute therapy session.\(^5,8,18\) Using traditional, over-ground gait-training therapy, the individual may only complete 50 or less gait cycles during one session.\(^5\) Individuals with more acute injuries and insults have been shown to have greater benefits from PBWSTT then people with more chronic injuries.\(^19\)

Cerebrovascular Accident

Up to 80% of patients post-cerebrovascular accident (CVA) suffer from gait deficiencies that may lead to wheelchair dependency or severe gait abnormalities.\(^5\) Gait velocity may be reduced up to 50% in these individuals when compared to a healthy adult. This is due to the fact that the phases of their gait cycle are altered.\(^1\) Often times, the individuals are unable to control the muscles of the pelvis and lower extremities due to their neurological impairments. This ultimately affects the individual’s ability to perform the gait cycle appropriately. PBWSTT has been shown to eliminate equilibrium reflexes and forces the patient to go through the complex gait pattern.\(^12\) Early implementation of PBWSTT improves individuals’ function by reducing the tendency to develop substitution patterns in their gait by “utilizing residual pathways and potentially increasing the amount of neurological recovery”.\(^20\) (p\(^{120}\))
Visintin et al\textsuperscript{16} reported that six weeks of PBWSTT caused significant improvement in balance, over-ground walking speed, endurance, and motor recovery when compared to subjects that simply walked on treadmill without body weight support (BWS). The scores for motor recovery and walking speed were still significantly better than the control group after three months. Trueblood\textsuperscript{1} recruited 13 people post-CVA; eight to perform PBWSTT for six weeks (three times per week for 75 minutes per session of individualized PBWSTT) and five for a control group. Each individual was tested before and after the interventions using the Tinetti Gait and Balance and Six Minute Walk test. It was found that there were significant differences between the experimental and control groups in the Tinetti Balance ($p=0.031$) and total Tinetti score ($p=0.011$). There was no significant difference between groups in the Six Minute Walk Test.

Hesse et al\textsuperscript{21} compared seven non-ambulatory patients with hemiparesis in an ABA single case-study design comparing PBWSTT (part A) with Bobath-theory physiotherapy (part B). Each phase of the design lasted for three weeks, and the subjects were assessed using the Function Ambulation Category (FAC), Rivermead Motor Assessment, and gait cycle parameters. These assessments were performed prior to the study and after the completion of each phase of the ABA cycle. Results showed that treadmill training was more effective in restoring gait ability and walking velocity when compared to the Bobath physiotherapy approaches. The FAC levels improved only during the PBWSTT stage of the ABA design.

Spinal Cord Injury

In a study by Field-Fote and Tepavac\textsuperscript{22}, patients with incomplete spinal cord injury (SCI) above the level of T10 (American Spinal Injury Association (ASIA) Level
C) (Appendix A) completed a 12-week walking program that consisted of PBWSTT and electrical stimulation. The speed of the treadmill was increased gradually by 0.1 m/s until the patients reached a speed at which they felt comfortable walking. During the walking program, the BWS and speed were adjusted to allow the subjects to walk without gait abnormalities. Each subject participated in 36 treatment sessions lasting approximately 90 minutes. At the conclusion of the study, it was found that this combination provided the best sensory environment to help individuals with SCIs improve upon their walking ability. On average, over ground walking speed was 84% greater and treadmill walking speed was 158% faster when compared to pre-training levels.

Field-Fote recruited subjects with SCI (ASIA C) who were at least one-year post-injury for a study. In this study, subjects performed PBWSTT 1.5 hours per day, 3 days per week for 3 months along with electrical stimulation of the common peroneal nerve of the weaker lower extremity. The speed of the treadmill and BWS were self-determined by the patient in order to allow for optimal walking kinematics. BWS was never greater than 30%, and the subjects were encouraged to walk as fast as they could while maintaining appropriate gait kinematics. Significant increases were found for each individual in over-ground walking speed (improved from 0.12 +/- 0.8 m/s to 0.21 +/- 0.15 m/s) and treadmill speed (improved from 0.23 +/- 0.12 m/s to 0.49 +/- 0.2 m/s) and treadmill distance (improved from 93 +/- 84 meters to 243 +/- 139 meters).

A study by Nymark et al was conducted with subjects who had variable SCI that ranged from C2-T10. In addition to PBWSTT, these subjects performed traditional therapies such as weight-shifting, balance, endurance, stretching, and strengthening.
PBWSTT was primarily utilized during spontaneous neurological recovery to regain a more appropriate gait cycle. Four of the five subjects demonstrated improvements in strength, endurance, and ability to ambulate without body-weight support. The four subjects also had improvements in joint motion and EMG results that correlated with improved gait function.\textsuperscript{20} Visintin and Barbeau stated that:

BWS has been shown to facilitate gait and elicit a more normal gait pattern with respect to sagittal angular displacement patterns, temporal distance parameters, and EMG activity of lower limb muscles in a group of spastic paretic subjects during PBWSTT.\textsuperscript{24 (p 541)}

Orthopedic and other diagnoses:

Threlkeld et al\textsuperscript{10} also support the use of PBWSTT to facilitate functional ambulation after neurologic pathologies as well as assist in recovery following musculoskeletal injuries. Hesse et al\textsuperscript{11} studied the effects of PBWSTT versus traditional physical therapy in patients post-total hip arthroplasty. Eighty subjects who could walk independently with crutches were recruited for this study. The control group received 45 minutes of physical therapy days one through ten. Their traditional physical therapy consisted of passive knee and hip joint range of motion, strengthening of hip adductors and extensors according to the proprioceptive neuromuscular facilitation (PNF) concepts, and gait retraining on level ground and stairs at each session. The treatment group received PBWSTT for 25 minutes followed by 20 minutes of physical therapy on days 1-5 and 35 minutes of PBWSTT followed by 10 minutes of physical therapy on days 6-10. These individuals received passive knee and hip joint mobilization at each session. The
Harris score was utilized for assessing these subjects both pre and post-training, and it was found that the PBWSTT group scored 13.6 points higher than the traditional physical therapy group after training was completed. Subjects in the PBWSTT also ceased using crutches five weeks earlier (three weeks versus eight weeks) than the physical therapy group.11

People with a diagnosis with Parkinson’s disease may also benefit from the use of PBWSTT. Miyai et al25 worked with 10 patients with Parkinson’s disease; the subjects performed either PBWSTT or physical therapy for four weeks. Physical therapy consisted of general conditioning, range of motion, ADL training, and gait training. The PBWSTT consisted of walking with 20% BWS for 12 minutes, 4.5 minutes rest, walking with 10% BWS for 12 minutes, 4.5 minutes rest, and then walking with 0% BWS for 12 minutes. Results using the Unified Parkinson’s Disease Rating Scale (UPDRS) were determined before and after treatment; the PBWSTT group had a significant decrease in their UPDRS scores when compared to the physical therapy group.

Schindl et al7 took baseline measurements at six weeks and three weeks pre-study, beginning of the study, and following the study of the functional ambulation category (FAC) and the standing and walking sections of the gross motor function measure (GMFM). The study looked at 10 children with cerebral palsy over a span of three months over which PBWSTT was performed three times a week, 30 minutes per treatment session. The BWS ranged from 0% to 40%. At the conclusion of the study, results showed both the FAC and GMFM scores improved significantly after PBWSTT.
General Parameters:

There are multitudes of body-weight percentages and treadmill speed combinations that may be used with PBWSTT. Body-weight support can range from 10% to 70%, but many of these amounts may not be practical for therapeutic uses. Body-weight support can range from 10% to 70%, but many of these amounts may not be practical for therapeutic uses. Gait kinematics at body weight support levels up to 30% most closely resemble gait kinematics at 0% body weight support. When utilizing a harness to provide body weight support greater than 30%, individuals are unable to generate the appropriate forces required for forward propulsion both for treadmill and overground walking. According to Threlkeld et al BWS levels of 50% and 70% produced a "decrease in cadence, an increase in step length, a reduction in stance phase, and a decrease in double limb support." Due to this observation, utilizing high levels of BWS would be detrimental to the concept of PBWSTT. Ideally, one would decrease the amount of BWS as the individual is able to distribute the weight appropriately throughout the entire gait cycle and perform the gait cycle without abnormal postures.

Treadmill speeds vary a great deal, but it is essential for the treadmill to increase speed by 0.1 miles per hour at a time. In the majority of studies, the initial speed chosen for individuals is dependent upon their self-selected over-ground walking speeds. If the individual was not able to ambulate over ground, a self-selected comfortable speed was chosen by the patient after the application of the harness and required BWS. The required BWS was determined by one of two ways: predetermined BWS amounts or BWS amounts that were most comfortable for the subjects while allowing for appropriate gait kinematics such as lower extremity loading responses. The speed of the treadmill was then adjusted to the comfort level of the patient, which was typically
slower than the demonstrated over ground speed. Therapists were able to perform manual gait corrections with the patient at the slower speed while also allowing for longer, uninterrupted therapy sessions.21 Hesse and company27 encourage BWS to decrease and treadmill speed to increase as soon as possible during rehabilitation to help engage the weight-bearing muscles and long-term cardiovascular benefits. Sullivan, Knowlton and Dobkin2 studied the effects of treadmill speed on locomotor recovery in patients who had sustained a CVA. This study had three treadmill training groups: 1) slow (0.5 mph), 2) fast (2.0 mph), and 3) variable (0.5, 1.0, 1.5, 2.0 mph). Comparing pre and post-training outcomes, the greatest improvement in self-selected over ground walking speed was found with the fast training group. The authors concluded that when individuals train at a speed comparable to an average adult’s walking velocity (2.7 mph), their self-selected overground walking velocity improved significantly.2

In light of this information, PBWSTT can be used as an effective tool for treating various impairments and functional limitations. This enables the health professional to treat the patient at a functional level when compared to traditional physical therapy that has focused on one aspect of the gait cycle at a time. Using subjects without presence of an active pathology or a history of orthopedic pathology, this study will help in determining whether PBWSTT allows individuals to maintain proper gait kinematics and muscle activation during training sessions.
CHAPTER III
METHODOLOGY

Prior to the initiation of this study, the project was reviewed and approved by the University of North Dakota Institutional Review Board (see Appendix B). The methods used in this study are described below.

Subjects

Four subjects (three female, one male) were recruited at the School of Medicine and Health Sciences Physical Therapy Department. This was completed by placing a sign-up sheet on the physical therapy students’ bulletin board. All subjects were required to be 18 years of age or older and fulfill a two-hour commitment of time. Subjects had to be able to ambulate without the use of an assistive device and have prior treadmill experience. Participants were excluded from the study if they had a history of lower extremity orthopedic surgeries, injuries or use of orthotics.

Prior to participation in the study, each subject was given a copy of an information and consent form (Appendix B). They were asked to read and sign the consent form indicating they understood the study and its objectives. Participants had to be able to read and understand the document and be competent and independent in their decision-making. Participants were provided with a copy of the consent form to take with them in case they had further questions or concerns. They also were required to verbally answer the PAR-Q questionnaire to rule out any cardiovascular conditions (Appendix C).
Instrumentation

Surface electrodes were utilized to record EMG activity. EMG activity was collected with a Noraxon Telemyo8 telemetry unit (Noraxon USA, 13430 North Scottsdale Rd., Scottsdale, AZ 85254) and transmitted to a Noraxon Telemyo8 receiver and then digitized by an analog digital interface board in Peak Analog Module. The Peak Motus5 system (Peak Performance, Englewood, CO) was used to store and analyze the EMG data. Final data are presented as percent of normalized EMG activity as an average of three gait cycles at each of the support trials.

Motion analysis reflective markers were placed on each subject (see Procedure on page 18 for details). Four high-speed video cameras (Peak Performance High-Speed Video System, Englewood, CO, and Pulnix TM-640 Sequential Scanning Camera, Sunnyvale, CA) operating at 60 frames per second were set up to tape the activity. Four hi-fi videocassette recorders (JVC BR-S3784 Hi-Fi VCR) recorded each trial onto super VHS tapes and encoded with a SMPTG time code generator. The Peak Calibration Frame (Peak Performance, Englewood, CO) was used to calibrate the cameras before the study began. A Lite-Gait body weight support system and a Gate Keeper Treadmill was used to apply the treadmill training. Following the recording of all trials, all subjects’ movements were digitized using the Peak Motus software package. The tapes were played back on a Sanyo model GVR-S955 (Sanyo, 1200 W Artersia Blvd, Campton, CA 90220) videocassette recorder for the purpose of digitization. Raw data coordinates were filtered using a Butterworth filter and conditioned at a cutoff frequency of six hertz.
Procedure

Following reading and signing the consent form and passing of the Par-Q questionnaire, the electrode placement sites were determined and marked on the right side of body of each subject with a permanent marker according to EMG placement standards. After each area was marked, it was prepared by shaving the existing hair with an electric clipper and vigorously rubbing the skin with rubbing alcohol. Two electrodes were placed at seven locations while maintaining 1-2 millimeters distance between each electrode. The gluteus medius electrodes were located at the proximal 1/3 distance between the iliac crest and greater trochanter. The erector spinae electrodes were horizontally aligned with the L3-4 interspace, four centimeters lateral to the mid-line. The biceps femoris electrodes were placed at the midpoint between the ischial tuberosity and the lateral femoral condyle. The electrodes for the gastrocnemius were placed over the muscle belly 1/4 the distance between the fibular head and calcaneous. The vastis lateralis electrodes were placed along a line 1/4 the distance from the lateral knee joint line to the anterior superior iliac spine (ASIS). The rectus femoris electrodes were placed at the midpoint between the ASIS and superior pole of the patella. The anterior tibialis electrodes were placed over the muscle belly 1/3 of the distance from the inferior patellar pole to the lateral malleolus. A ground electrode was placed on the fibular head.

Next, the harness was put on the subject using the greater trochanters as a reference to where the bottom of the harness should be located. After doing so, the motion analysis reflective markers were placed bilaterally on the following bony landmarks using double stick tape and rubber bands: greater trochanters, lateral femoral condyles, lateral malleoli,
ASIS, and the sacrum. Two small markers were also placed level with each other on the subject’s shoes at the lateral calcaneous and head of the fifth metatarsal. A foot switch was taped under the plantar surface of the right heel of all subjects. All wires were connected to the electrodes and footswitch, and the subject’s weight was taken (with harness donned) using a standard medical scale. After the weight was determined, 15% and 30% BWS levels were calculated and recorded. Each subject was randomly assigned the order of BWS during testing before the study began. This was done by pulling the order out of a hat, and the random assignments were for slack removed, 15% BWS and 30% BWS. All subjects walked with 0% BWS to begin their testing. See Appendix D for picture of the set-up.

Maximal voluntary contractions (MVC) for each muscle were recorded while performing manual muscle testing of the aforementioned muscles. The harness was attached to the support system, and each subject was instructed to stand with his/her feet shoulder-width apart. Each subject was also told to keep their hands off the treadmill hand-rails and to look away from the scale when BWS was increased.

During each phase of the study, the subjects walked for three minutes. The first minute was to allow the subjects to adjust to the BWS amount. The data was then randomly collected for 8-second intervals – once during the second minute of walking and once during the third minute. After each phase, the subjects were allowed to rest for 1-2 minutes while the BWS amounts were adjusted according to the predetermined, randomized order. Throughout the study, subject’s exertion levels were inquired about.

As previously mentioned, the EMG activity was collected using the TeleMyo 900 telemetry unit. It was transmitted from the telemetry transmitter to the TeleMyo 900
receiver which was interfaced with an analog to digital interface unit (Peak Performance Inc., Englewood, CO) utilizing a NorBNC board (Noraxon USA). The EMG files were then imported from the Peak Performance system into the Myoresearch EX software program (Noraxon USA) using a laptop computer. Using the Myoresearch XP (Noraxon, USA) software program, the EMG data was integrated and smoothed. EMG data was filtered, rectified, and normalized to the unweighted walking trial for each subject. Final data are presented as percent of normalized EMG activity as an average of three gait cycles at each of the support trials. The EMG data was analyzed using MyoResearch software package to make comparisons between muscle activity and weight bearing support levels.
CHAPTER IV
RESULTS

The purpose of this study was to evaluate muscle activation and gait kinematics during PBWSTT of individuals without pathological impairments. VMA and EMG were utilized in order to determine if there was a significant change in these variables between full weight bearing and multiple levels of body weight support. Our research questions were as follows: 1) Is there a difference in muscle activation between full weight-bearing ambulation and body-weight supported ambulation? and 2) Is there a difference in gait kinematics between full weight-bearing ambulation and body-weight supported ambulation?

Data from subjects 1-4 was analyzed. The small sample size (n = 4) resulted in the need to run both parametric and non-parametric statistical measure. It was found that the non-parametric measures supported the parametric results; therefore, parametric results are reported in this study.

Muscle Activation

In order to answer research question number one, the researchers looked at the EMG of seven muscles. The muscles included were the gluteus medius, erector spinae, biceps femoris, gastrocnemius, vastus lateralis, rectus femoris, and anterior tibialis. The data from each muscle group was compared between all four subjects at all four levels of body-weight support (0%, 3-6%, 15%, and 30%). This was computed using a repeated
measure, single-factor analysis of variance (ANOVA) in SPSS (Chicago, IL 60606). The required level of significance was set at $p = 0.05$. Table 1 illustrates the EMG means and standard deviations found for each of the seven muscle groups.

Table 1: EMG Means and Standard Deviations for Tested Muscles (numbers are compared to baseline (100%))

<table>
<thead>
<tr>
<th>Percentage Weight Bearing Removed</th>
<th>Gluteus Medius</th>
<th>Erector Spinae</th>
<th>Biceps Femoris</th>
<th>Gastrocnemius</th>
<th>Vastus Lateralis</th>
<th>Rectus Femoris</th>
<th>Anterior Tibialis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean % (std dev)</td>
<td>mean % (std dev)</td>
<td>mean % (std dev)</td>
<td>mean % (std dev)</td>
<td>mean % (std dev)</td>
<td>mean % (std dev)</td>
<td>mean % (std dev)</td>
</tr>
<tr>
<td>0%</td>
<td>100 (0)</td>
<td>100 (0)</td>
<td>100 (0)</td>
<td>100 (0)</td>
<td>100 (0)</td>
<td>100 (0)</td>
<td>100 (0)</td>
</tr>
<tr>
<td>3-6%</td>
<td>129.65 (18.84)</td>
<td>109.58 (37.63)</td>
<td>111.73 (57.48)</td>
<td>117.15 (23.93)</td>
<td>109.25 (6.32)</td>
<td>89.05 (7.87)</td>
<td>109.25 (24.94)</td>
</tr>
<tr>
<td>15%</td>
<td>132.20 (17.49)</td>
<td>131.90 (18.04)</td>
<td>128.23 (61.18)</td>
<td>132.20 (33.29)</td>
<td>107.13 (20.42)</td>
<td>85.48 (7.45)</td>
<td>111.83 (26.61)</td>
</tr>
<tr>
<td>30%</td>
<td>99.35 (14.77)</td>
<td>125.28 (12.22)</td>
<td>113.68 (55.83)</td>
<td>110.90 (14.50)</td>
<td>119.95 (19.74)</td>
<td>88.85 (24.86)</td>
<td>118.48 (10.52)</td>
</tr>
</tbody>
</table>

The gluteus medius muscle activation was found to be significantly different between subjects ($F(3,8) = 11.446; p = 0.003$). The power for this test was 0.977 and partial eta squared was 0.811. A post-hoc analysis was then performed, and Scheffe results were found to show significant differences in gluteus medius activation between 0% vs 3-6% ($p = 0.017$), 0% vs 15% ($p = 0.016$), 3-6% vs 30% ($p = 0.015$), 15% vs 30% ($p = 0.015$).

The remaining six muscles did not show significant difference between muscle activation and weight-bearing percentages (see Table 2). It is also noted that the power for these six muscles was quite low.
Table 2: ANOVA Results for Muscle Activation

<table>
<thead>
<tr>
<th></th>
<th>Degrees of Freedom</th>
<th>F</th>
<th>Significance (p)</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erector Spinae</td>
<td>3,8</td>
<td>1.585</td>
<td>0.267</td>
<td>0.275</td>
</tr>
<tr>
<td>Biceps Femoris</td>
<td>3,8</td>
<td>0.375</td>
<td>0.773</td>
<td>0.096</td>
</tr>
<tr>
<td>Gastrocnemius</td>
<td>3,8</td>
<td>1.849</td>
<td>0.217</td>
<td>0.316</td>
</tr>
<tr>
<td>Vastus Lateralis</td>
<td>3,8</td>
<td>0.525</td>
<td>0.677</td>
<td>0.116</td>
</tr>
<tr>
<td>Rectus Femoris</td>
<td>3,8</td>
<td>0.555</td>
<td>0.659</td>
<td>0.121</td>
</tr>
<tr>
<td>Anterior Tibialis</td>
<td>3,8</td>
<td>1.022</td>
<td>0.433</td>
<td>0.188</td>
</tr>
</tbody>
</table>

Motion Analysis

To answer research question number two, the researchers looked at both step length and ankle dorsiflexion. The data was compared between all four subjects at all four levels of body-weight support (0%, 3-6%, 15%, and 30%). This was computed using a repeated measure, single-factor analysis of variance (ANOVA) in SPSS (Chicago, IL 60606). The required level of significance was set at \( p = 0.05 \). Step length was found to be significantly different between weight bearing conditions (\( F(3,9) = 8.923; p = 0.005 \); partial eta squared = 0.748; power = 0.948). Post Hoc analysis was performed, and Scheffe results showed significant differences in step length between 0% vs 3-6% (\( p = 0.016 \)) and 0% vs 30% (\( p = 0.009 \)) (see Table 3).

Table 3: Average Step Length (meters) for Each Subject at Each Level of Weight Bearing Removed

<table>
<thead>
<tr>
<th>Percentage Weight Bearing Removed</th>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>0.50</td>
<td>0.52</td>
<td>0.50</td>
<td>0.49</td>
</tr>
<tr>
<td>3-6%</td>
<td>0.47</td>
<td>0.49</td>
<td>0.48</td>
<td>0.47</td>
</tr>
<tr>
<td>15%</td>
<td>0.49</td>
<td>0.49</td>
<td>0.48</td>
<td>0.48</td>
</tr>
<tr>
<td>30%</td>
<td>0.47</td>
<td>0.47</td>
<td>0.48</td>
<td>0.48</td>
</tr>
</tbody>
</table>
Ankle dorsiflexion between subjects was not found to be significant ($F(3,9) = 2.176; p = 0.161$; partial eta squared = 0.420; power = 0.383) (see Table 4).

Table 4: Amount of Ankle Dorsiflexion ($90^\circ = \text{neutral}$) for Each Subject at Each Level of Weight Bearing Removed

<table>
<thead>
<tr>
<th>Percentage Weight Bearing Removed</th>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>95.40</td>
<td>97.10</td>
<td>95.70</td>
<td>94.60</td>
</tr>
<tr>
<td>3-6%</td>
<td>94.70</td>
<td>94.80</td>
<td>98.10</td>
<td>91.30</td>
</tr>
<tr>
<td>15%</td>
<td>94.50</td>
<td>95.40</td>
<td>96.90</td>
<td>91.00</td>
</tr>
<tr>
<td>30%</td>
<td>93.90</td>
<td>94.40</td>
<td>96.30</td>
<td>90.00</td>
</tr>
</tbody>
</table>
CHAPTER V
DISCUSSION

Previous literature has shown the effectiveness of partial body weight support treadmill training (PBWSTT) for individuals after cerebrovascular accidents (CVA), traumatic brain injuries (TBI), spinal cord injuries (SCI), and other neurological and musculoskeletal pathologies. Positive benefits include improved cadence and stride length for individuals after CVA, improved gait kinematics at increased speeds and improved joint motion and EMG activity for individuals after a SCI. Visintin and Barbeau have shown PBWSTT facilitates a more normal gait pattern both in EMG activity and joint motion.

As discussed in Chapter II, Field-Fote has stated the maximum body weight support to use for gait training is 30%. This allows for ambulation that most closely resembles gait kinematics at 0% BWS. Hesse, Konrad, and Uhlenbrock also supported the use of 30% BWS because their research had shown that BWS over this amount significantly reduced the muscle activation of the essential lower extremity weight-bearing muscles. According to the results from our study, there was a significant difference between the electromyography (EMG) results of the gluteus medius when 0% weight support was compared to both 3-6% BWS and 15% BWS. We found no significant difference between 0% and 30% BWS, thus supporting the aforementioned researchers.
We believe that the increases in EMG activity during both 3-6% and 15% may be the result of the ability of individuals without impairments to adjust to the varying BWS levels. At 3-6% and 15% BWS, the subjects may have altered their muscle activity to compensate for the increase in support. At 30% BWS, the harness provided the most stabilizing support for the pelvis; therefore, the gluteus medius was not required to stabilize the pelvis as much. As discussed earlier, one of the determinants of gait is pelvic tilt. The pelvis tilts downward on the stance leg in order to lower the center of mass during ambulation. PBWSTT at 30% BWS does not allow the center of mass to lower; therefore, the gluteus medius does not be to be engaged to the same degree to maintain the pelvic tilt.

There was no significant difference found between the firing of the erector spinae, biceps femoris, gastrocnemius, rectus femoris, and anterior tibialis at all levels of body weight support (Appendix E). Hesse, Konrad, and Uhlenbrock\textsuperscript{17} conducted a study using PBWSTT, and they also found EMG activity between 0%, 15%, and 30% BWS at the anterior tibialis, vastus lateralis, biceps femoris, and erector spinae was not significantly different. Trends showed decreases in the EMG activity of the vastus lateralis and anterior tibialis. Our current study does not support that trend. At 30% BWS, vastus lateralis and tibialis anterior showed the greatest amount of EMG activity.

In addition to EMG data, video motion analysis (VMA) was used to analyze both step length and ankle dorsiflexion between subjects at the various body weight support levels. The results of our study showed a significant difference in step length between amounts of body weight support of all four subjects. The greatest significance was found between 0% (0.5025 +/- 0.01 meters) and 30% (0.48 +/- 0.01 meters) BWS. Data gathered
to determine step length (in meters) was measured from the moment of initial contact to the moment of terminal stance. This time frame was determined by the stepping on and off of the heel switch that was placed in the subject's right shoe. Individuals without impairments have a longer stride length compared to those with impairments. When our subjects were lifted by the increasing body weight support, they took shorter steps because the heel lifted earlier. Previous studies that have looked at people with impairments showed step length increases with increased body weight support. This is a result of the person's ability to take larger, more normal steps due to the fact that they can support themselves on his/her involved extremity/extremities. For example, Hesse and company\textsuperscript{21} studied seven subjects with hemiparesis using PBWSTT. These subjects had a 42% increase in stride length after PBWSTT therapy.

Ankle dorsiflexion was not found to be significantly different between subjects at the various body weight support levels which is in contrast with the study done by Threlkeld et al\textsuperscript{10} who found that with increasing body weight support, ankle dorsiflexion increased at initial contact. Our study's results showed an overall decrease in average ankle dorsiflexion as body weight support increased; however, our average ankle dorsiflexion was based on the entire stance phase, not just initial contact. With increased body weight support, the tibia does not advance as far over the ankle at terminal stance. At terminal stance, you would expect the average person to have 10° of dorsiflexion. We hypothesize our subjects were not able to reach this point because of their shortened terminal stance which was shown in the area of step length.
Limitations

We feel there are a number of limitations that played into the final results of this study. First of all, due to the limited number of studies using PBWSTT on subjects without impairments, it is difficult to compare the results from this study to other studies previously performed. With only four subjects, our statistical power was extremely low (less than or equal to 0.316). Second of all, during data collection the foot switch did not function appropriately and had to be replaced twice. This may have affected step length measurements which were based on the proper workings of the foot switch. Thirdly, while digitizing, the computer program was unable to recognize data point consistently. This required a great deal of manual data point placement by the researchers. Human error could play a factor in the placement of these data points; however, the Butterworth filter was used to smooth out the data points. The fourth limitation noted was seen when subject number four appeared to be uncomfortable in the harness during greater body weight support levels (15% and 30%). Subject four was unable to ambulate in a "normal" manner, which may have altered his EMG and VMA results. The fifth limitation found is the matter of within subject variability. All people walk differently; therefore, you would not expect their EMG and VMA results to be identical.

Recommendations

We would recommend that future studies perform this same study again but with a larger sample size. This would allow for increased power, reliability, and validity of the results. In addition, using larger motion analysis reflectors would enable the researchers to have more accurate VMA results. We also recommend performing this study on patients with neurological or musculoskeletal insults to compare muscle activation and
gait kinematics between normal and impaired individuals (motor planning vs. motor learning).

In conclusion, we found that PBWSTT did not significantly alter the gait pattern of normal individuals. This in turn will allow future studies to be performed on individuals who have impairments and limitations knowing that further compensation patterns will not be elicited from the use of PBWSTT.
Appendix A
The ASIA Impairment Scale

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Complete: No sensory or motor function is preserved in S4-S5.</td>
</tr>
<tr>
<td>B</td>
<td>Incomplete: Sensory function is preserved below the neurological level and includes S4-S5</td>
</tr>
<tr>
<td>C</td>
<td>Incomplete: Motor function is preserved below the neurological level. More than half of the key muscles below the neurological level are &lt;3/5 strength.</td>
</tr>
<tr>
<td>D</td>
<td>Incomplete: Motor function is preserved below the neurological level. At least half of the key muscles below the neurological level are ≥3/5 strength.</td>
</tr>
<tr>
<td>E</td>
<td>Normal. Sensory and motor function is normal.</td>
</tr>
</tbody>
</table>

Figure 2: ASIA Impairment Scale (Adapted from Goodman and Boissonnault)
Appendix B
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

Date: 4/8/2004 Project Number: IRB-200404-323

Principal Investigator: Flom-Meland, Cindy; Silbernagel, Jenny; Klempel, Amanda; Hanson, Melanie; Kingzett, Cherron

Department: Physical Therapy

Project Title: The Effects of Partial Body Weight Support Treadmill Training on Muscle Activation and Gait Kinematics with Normal Subjects

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on April 22, 2004 and the following action was taken:

☑ Project approved. Expedited Review Category No. 46
☑ Next scheduled review must be before: April 22, 2005
☐ Copies of the attached consent form with the IRB approval stamp dated April 22, 2004 must be used in obtaining consent for this study.

☑ Project approved. Exempt Review Category No.
☐ This approval is valid until ________________ as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.
☐ Copies of the attached consent form with the IRB approval stamp dated ________________ must be used in obtaining consent for this study.

☐ Minor modifications required. The required corrections/additions must be submitted to ORPD for review and approval. This study may NOT be started UNTIL final IRB approval has been received.
(See Remarks Section for further information.)

☐ Project approval deferred. This study may not be started until final IRB approval has been received.
(See Remarks Section for further information.)

REMARKS: Any adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

Any changes in protocol or Consent Forms must receive IRB approval prior to being implemented. You must submit a memo with a copy of the Consent Form and a revised Human Subjects Review Form, with the appropriate signatures, to the Office of Research and Program Development for review and approval.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.

☒ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)
University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and the Office of Research and Program Development (ORPD), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below:

Principal Investigator: Cindy Flom-Meland, Jenny Silbermangel, Amanda Klemmel, Melanie Hanson, Cherron Kingzett

Telephone: 777-4130  E-mail Address: cfmeland@medicine.nodak.edu

Complete Mailing Address: PO Box 9037 PT

School/College: School of Medicine and Health Sciences  Department: Physical Therapy

Student Adviser (if applicable): Cindy Flom-Meland

Telephone: 777-4130  E-mail Address: cfmeland@medicine.nodak.edu

Address or Box #: PO Box 9037 PT

School/College: School of Medicine and Health Sciences  Department: Physical Therapy

Project Title: The effects of partial body weight support treadmill training on muscle activation and gait kinematics with normal subjects

Proposed Project Dates: Beginning Date: 05/01/04  Completion Date: 05/01/05

(Including data analysis)

Funding agencies supporting this research: NA

(A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)

Does the Principal Investigator or any researcher associated with this project have a financial interest in the results of this project? If yes, please submit, on a separate piece of paper, an additional explanation of the financial interest (other than receipt of a grant)

YES or X NO

If your project has been or will be submitted to other IRB's, list those Boards below, along with the status of each proposal.

________________________________________  Date submitted:  Status: Approved Pending

________________________________________  Date submitted:  Status: Approved Pending

Type of Project: Check “Yes” or “No” for each of the following.

X  YES or  NO  New Project  X  YES or  NO  Dissertation/Thesis

YES or  X NO  Continuation/Renewal  X  YES or  NO  Student Research Project

YES or  X NO  Is this a Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.

YES or  X NO  Does your project involve medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

YES or  X NO  Does your project include Genetic Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

YES or  X NO  Does your project include Internet Research? If yes, refer to Chapter 3 of the Researcher Handbook for additional guidelines regarding your topic.

YES or  X NO  Will subjects or data be provided by Altru Health Systems? If yes, submit two copies of the proposal. A copy of the proposal will be provided to Altru.

YES or  X NO  Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?
If yes, list all institutions:

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands
their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the
individual signing the letter and, if possible, should be printed on letterhead.

Subject Classification: This study will involve subjects who are in the following special populations: Check all that apply.

- Minors (< 18 years)
- Prisoners
- Persons with impaired ability to understand their involvement and/or consequences of participation in this research
- Other

For information about protections for each of the special populations, refer to Chapter 5 of the Researcher Handbook.

This study will involve: Check all that apply.

- Deception
- Radiation
- New Drugs (IND)
- Non-approved Use of Drug(s)
- Recombinant DNA
- None of the above will be involved in this study

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any
sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such
as minors, prisoners, pregnant women/fetuses).

Gait dysfunction is a common result of stroke, traumatic brain injury, spinal cord injury and other neurological insults. Many
individuals who suffer from these insults are non-ambulatory for some length of time. Therefore, gait training is key to the
rehabilitation process. Traditionally, physical therapists focus on approaches of strengthening and single-movement practices.
These approaches include NDT techniques. Current approaches in the rehabilitation process concentrate on task-specific gait
training, which includes partial body weight support treadmill training (PBWSTT).

PBWSTT allows a patient to perform multiple, complex ambulatory movements through the use of a supportive harness. This is
done by decreasing the patient’s body weight by a given percentage while providing trunk and equilibrium stabilization. Current
literature states the use of 40% or less body weight support for rehabilitation provides appropriate support without alteration of
normal gait kinematics. Through the use of EMG and motion analysis, we will analyze normal individuals’ gait patterns and
muscle activity at a constant speed and varying body weight support. We believe that there will not be a significant deviation in
EMG measurements or gait kinematics as compared to normal, full weight-bearing ambulation.

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following
categories. Individuals conducting clinical research please refer to the “Guidelines for Clinical-Research Protocols” on the Office
of Research and Program Development website.

1. Subject Selection.

   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will
be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects.

   Subjects will be recruited from the School of Medicine and Health Sciences Physical Therapy Department by the
researchers. This will be done by placing a sign-up sheet on the physical therapy students’ bulletin board. Each subject
will be recruited for a one-time, 2-hour commitment. A total of 20 subjects will be recruited.

   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from
any of the categories listed in the “Subject Classification” section above.

   All subjects must be 18 years of age or older and will be asked to fulfill a 2-hour commitment of time. Subjects
must be able to ambulate without the use of an assistive device and have prior treadmill experience of greater than a one-
time use for 5 minutes.
c) Describe your exclusionary criteria and provide a rationale for excluding subject categories.

Participants will be excluded from the study if they have a history of lower extremity orthopedic surgeries, injuries, or use of orthotics. They will also be excluded if they have a prior or present history of cardiovascular conditions. Subjects will be asked the Par-Q questionnaire to rule out existing cardiovascular conditions (see attached form). No written documentation will be kept regarding this form for each individual subject.

d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects.

This study will include 20 subjects due to the fact this is a pilot study.

e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

Research has shown that EMG and motion analysis are valid, objective tools. A power analysis was not performed. Due to the fact that this is a pilot study to standardize the treatment protocol for future studies.

2. Description of Methodology.

a) Describe the procedures used to obtain informed consent.

Prior to participation in the study, each subject will be given a copy of an information and consent form. They will be asked to read and sign the consent form indicating they understand the study and its objectives. They will be provided with the consent form to take with them in case further questions/concerns arise. The researcher or subject has the right to terminate participation at any time during the study without penalty.

b) Describe where the research will be conducted.

Research will be conducted in the Physical Therapy Department at the University of North Dakota.

c) Indicate who will carry out the research procedures.

The four student researchers, along with the student advisor and 2 faculty members from the Department of Physical Therapy at UND will conduct the research procedures.

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

After obtaining informed consent, each participant will be prepared for both EMG and motion analysis. In order to perform EMG, self-adhesive electrodes will be placed on the subject’s skin after the area has been shaved using clippers and cleaned with rubbing alcohol. The electrodes will be placed on the following muscles according to EMG standards: right anterior tibialis, gastrocnemius, rectus femoris, vastus lateralis, biceps femoris, gluteus medius and erector spinae. Each electrode will be placed over motor points of the above muscles. Pressure switches will be located on the plantar surface of the right calcaneous to determine when initial contact occurs and on the planter surface of the first metatarsal head to determine toe off phase of the gait cycle. A ground electrode will be placed on the subject’s right fibular head. The EMG signals will be transmitted to the Noracon Telemyo8 Receiver and then fed into a computer for display and recording of data. Maximum voluntary contractions of the previously mentioned muscles will be measured during manual muscle testing techniques administered by the testers to determine baseline. This muscle activity will be recorded and considered to be the 100% activity level. This is used to normalize the EMG data for analysis.

Video analysis will be used to measure lower extremity range of motion during the activity. Motion analysis reflective markers will be placed on the following bony landmarks: right greater trochanter, lateral femoral condyle, lateral malleolus, sacrum, ASIS, and two small markers will be placed on the subjects’ shoes at the lateral calcaneous and head of the fifth metatarsal (these two markers will be level with each other). The reflective markers will be attached to the individual using double-stick tape. Four video cameras will be placed around the subject and will film lower extremity movements. This will be recorded on videotapes and be transferred to a computer for analysis. Before performing the activity, all subjects will be weighed on a standard scale in order to determine the appropriate level of body weight support used during the activity.

Once the subject has been prepared, he/she will begin to walk on a treadmill at 3 miles per hour (1.34 meters per second). EMG and motion analysis measurements will be taken at this time to determine the subject’s baseline numbers. After the subject has walked 3 minutes, the harness will then be donned. After the harness is donned, the subject will randomly select
the order of treatments received: slack in the support straps removed (3-6% body weight support), 15% or 30% of body weight support. With each treatment, the subjects will ambulate 3 minutes, rest for 1 minute, and then ambulate for another 3 minutes. Data collection will be performed during the 1-2 minute span and 2-3 minute span of this final ambulatory session. The randomization will be determined by drawing the percentages out of a hat. After all subjects complete the study, the EMG and motion analysis recordings will be analyzed.

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

Motion analysis will be performed using four video cameras and will be recorded on video tape. These tapes will be secured in a locked cabinet in the Physical Therapy Department at the University of North Dakota. Participant consent forms will also be kept in a locked cabinet separate from the videos. Records will be destroyed using a paper shredder three years after conclusion of the study. The four student researchers, student advisor, and two faculty members will be the only individuals who have access to this information.

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

The four student researchers are students in the UND physical therapy program and have experience with all tools utilized in the study. The student advisor and faculty members that are assisting with this project are trained in the use of Lite-Gait, EMG, and motion analysis. All researchers are certified in CPR.

g) Describe compensation procedures (payment or class credit, etc.).

N/A

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

See attached: Subject information and consent form.


a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.

When using any type of exercise equipment, there is always a slight risk for minor injury (i.e. muscle strain, fatigue, falls, etc.). This study consists of low-level exercise. The level of exertion from participating in this study is comparable to the subjects' daily routines (walking to a car, walking to class, etc.). The subjects may have mild skin irritation from application of the EMG electrodes due to the adhesive.

c) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.

Subject and result information will not be linked to the consent form in order to protect the confidentiality of participants.

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).

Participants will be informed of possible skin irritation from the self-adhesive electrodes, rubbing alcohol, and/or double-stick tape. They will also be educated on the use of treadmills and the safety features of the treadmill.

b) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.).

Subject and result information will not be linked to the consent form in order to protect the confidentiality of participants. Names will not be included on subject research data forms. Rather, Subject numbers 1-20 will be used to identify the participants.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
Prior to participation in the study, subjects will be given a copy of an information and consent form (see attached) to read and sign. Participants will be able to read and understand the document and will be competent and independent in their decision-making. Participants will be provided with a copy of the consent form for their records.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe: 1) the storage location of the research data (separate from consent forms and subject personal data) 
2) who will have access to the data 
3) how the data will be destroyed 
4) the storage location of consent forms and personal data (separate from research data) 
5) how the consent forms will be destroyed

Results from the study will be secured in a locked cabinet in the Physical Therapy Department at the University of North Dakota. Participant consent forms will be kept separate from the research data forms. Records will be destroyed using a paper shredder three years after conclusion of the study. The four student researchers, student advisor, and two faculty members will be the only individuals who have access to this information.

c) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.).

If injury occurs during the study, medical treatment will be available as it would be to any individual in the community. The participant and his/her third party payer will be responsible for paying for such treatment.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

If injury occurs during the study, medical treatment will be available as it would be to any individual in the community. The participant and his/her third party payer will be responsible for paying for such treatment.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: payment is not a benefit and should be listed in the Protocol Description section under Methodology.

The purpose of this study is to evaluate gait kinematics of PBWSTT with normal individuals to determine if there are any gait deviations as a result. According to our hypothesis, we hope to find no significant gait deviations (kinematics and muscle activation) with the use of PBWSTT. With these results, future studies can be conducted to apply the findings to populations who will benefit from such task-specific gait training. In conclusion, the positive benefits from PBWSTT can carryover to functional over-ground gait activities.

IV. Consent Form
A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects. Refer to the ORPD website for further information regarding consent form regulations.

Please note: Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if subject does not continue participation. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. It is recommended that the consent form be written in the third person (please see the examples on the ORPD website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp. The consent form must include the following elements:

a) An introduction of the principal investigator 
b) An explanation of the purposes of the research 
c) The expected duration of subject participation 
d) A brief summary of the project procedures 
e) A description of the benefits to the subject/others anticipated from this study 
f) A paragraph describing any reasonably foreseeable risks or discomforts to the subject 
g) Disclosure of any alternative procedures/treatments that are advantageous to the subject
h) An explanation of compensation/medical treatment available if injury occurs.

i) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who will have access. The following statement must be included in all consent forms and informational letters: "Only the researcher, the adviser, [if applicable] and people who audit IRB procedures will have access to the data." Please make appropriate additions to the persons that may have access to your research data. Indicate how the data will be disposed of. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.

j) The names, telephone numbers and addresses of two individuals to contact for information (generally the student and student adviser). This information should be included in the following statement: "If you have questions about the research, please call (insert Principal Investigator’s name) at (insert phone number of Principal Investigator) or (insert Adviser’s name) at (insert Adviser’s phone number). If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279."

k) If applicable: an explanation of who to contact in the event of a research-related injury to the subject.

l) If applicable: an explanation of financial interest must be included.

m) Regarding participation in the study:

1) An indication that participation is voluntary and that no penalties or loss of benefits will result from refusal to participate.

2) An indication that the subject may discontinue participation at any time without penalty, with an explanation of how they can discontinue participation.

3) An explanation of circumstances which may result in the termination of a subject’s participation in the study.

4) A description of any anticipated costs to the subject.

5) A statement indicating whether the subject will be informed of the findings of the study.

6) A statement indicating that the subject will receive a copy of the consent form.

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

(Principal Investigator) Date:

(Student Adviser) Date:

Requirements for submitting proposals:
Additional information can be found at the ORPD website at www.und.nodak.edu/dept/orpd

Original Proposals and all attachments should be submitted to the Office of Research and Program Development, P.O. Box 7134, Grand Forks, ND 58202-7134, or brought to Room 105, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects’ education. Please go to http://www.und.nodak.edu/dept/orpd/regucomirb/Default.htm for more information.

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the ORPD website regarding required copies and IRB review categories, or you may call the ORPD office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company’s protocol must be provided.

Please Note: Student Researchers must complete the “Student Consent to Release of Educational Record".”
INFORMATION AND CONSENT FORM

The Effect of Partial Body Weight Support Treadmill Training on Muscle Activation and Gait Kinematics within Normal Subjects

You are invited to participate in a research study conducted by Cindy Flom-Meland, physical therapy professor at the University of North Dakota, and Jenny Silbernagel, Amanda Klempel, Melanie Hanson and Cherron Kingzett, students of physical therapy at the University of North Dakota. The purpose of our study is to analyze the effects of partial body weight support treadmill training (PBWSTT) on individuals without problems with walking.

You will be excluded from this study if you are under the age of 18, have a history of serious injuries and/or surgeries involving the legs, have a history of cardiovascular conditions, use prescription orthotics in your shoes or need the use of a cane, walker, crutches, etc. to walk.

In order to participate in this study, you will need to be able to commit to a one-time, 2-hour time period. During this time, you will be expected to walk on a treadmill at 3 miles per hour for approximately 30 minutes. The rest of the time commitment will occur prior to the treadmill walking and includes having electrodes placed on various muscles of the right leg and reflectors markers placed on various bony landmarks on both legs and shoes. Your participation in this study will allow us to determine if PBWSTT changes muscle and body movements when compared to walking without any support. Your results will benefit future researchers when they are applying the PBWSTT to patients with walking disabilities.

This form of exercise is considered to be a low-risk activity; however, with any type of exercise, there is some risk for injury. These risks will be minimized with proper training on the treadmill as well as guidance by the researchers. The electrodes used in this study may possibly cause mild skin irritation. If injury occurs while this study is being conducted, medical treatment will be available as it is to a member of the general public in similar circumstances. Payment for any medical treatment will be covered by you and your third party payer. By signing this document, you are not giving up any legal rights you may have in the case of negligence or other legal fault of anyone that is involved in the study.

The information obtained in this study will be kept confidential. Your name and identifying information linking you to this study will not be revealed at any time. The results from this study will be securely kept in the Physical Therapy Department at the University of North Dakota. The only individuals who will have access to these results

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include the researchers named above and the individuals at the University of North Dakota who audit research projects on campus. They will be destroyed three years after the conclusion of the study. There will be no financial compensation awarded to either you or the researchers associated with involvement in this study.

Participation in this study is entirely voluntary. Your decision whether or not to participate will not change your future relations with the University of North Dakota. If you decide to participate, you or the investigators can choose to discontinue participation at any time during this study without penalty.

If you have any questions or concerns regarding this study at any time, please feel free to contact Cindy Flom-Meland at the University of North Dakota at 777-2831 or 775-2476. You can also reach any of the student researchers through the Department of Physical Therapy at the University of North Dakota between the office hours of 8:00AM-4:30PM at 777-2831. If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279.

I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND WILLINGLY AGREE TO PARTICIPATE IN THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. A COPY OF THIS CONSENT FORM HAS BEEN GIVEN TO ME.

Participant’s Signature

Date

Investigator’s Signature

Date
Appendix C
Par-Q and You

Y/N 1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?

Y/N 2. Do you feel pain in your chest when you do physical activity?

Y/N 3. In the past month, have you had chest pain when you were not doing physical activity?

Y/N 4. Do you lose your balance because of dizziness or do you ever lose consciousness?

Y/N 5. Do you have a bone or joint problem that could be made worse by a change in your physical activity?

Y/N 6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart?

Y/N 7. Do you know of any other reason why you should not do physical activity?

Figure 3: Par-Q Questionnaire (Adapted from the Canadian Society for Exercise Physiology^28)
Appendix D
Figure 4: Set-up of Lite-Gait, treadmill, EMG, and VMA with subject.
Figure 5: Erector Spinae Mean EMG Activation Per Subject

Figure 6: Biceps Femoris Mean EMG Activation Per Subject
Figure 7: Gastrocnemius Mean EMG Activation Per Subject

Figure 8: Vastus Lateralis Mean EMG Activation Per Subject
Figure 9: Rectus Femoris Mean EMG Activity Per Subject

Figure 10: Anterior Tibialis Mean EMG Activity Per Subject
REFERENCES


