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Official Title: Reducing Asymmetry During Gait Using the TPAD (Tethered Pelvic Assist Device) for Stroke Patients

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TITLE: The Integration of Principles of Motor Learning to Reduce Load Asymmetry Using a Novel Robotic Device in Individuals Chronically Post-Stroke

Standard Operating Procedure - Study Protocol Manual

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I. Project summary / Abstract

BACKGROUND: Hemiparesis, spasticity and reduced motor control are typical impairments after stroke and commonly contribute to motor deficits that affect gait. These deficits manifest as reduced velocity, decreased cadence and asymmetries in temporal, spatial and force parameters during ambulation. Robotic-based therapies have been used to increase gait velocity and reduce asymmetry in a population of individuals after stroke, however these therapies have demonstrated results similar to that of conventional training. This is possibly due to guided-assist control strategies used to deliver robotic training, which strategies limit participant involvement and thus constrain motor learning.

The TPAD is a robotic device that employs actuated tethers at the user's pelvis to guide the user's pelvis along a pre-set movement trajectory. The TPAD tethers can be configured in an infinite array of possibilities, and most recently have been used to increase loading onto the paretic limb in a population of individuals after stroke. While other robotic devices guide the limb through the motor trajectory, and constrict the participants ability to participate in the motor planning and movement execution, the TPAD promotes weight shifting, but allows an individual to freely move the limb and to navigate spatiotemporal aspects of training independently. Further, if coupled with overground to focus on addressing a specific task goal, this device may prove useful to improve symmetry in individuals after stroke.

OBJECTIVES: The purpose of this study is to evaluate the overall feasibility in terms of safety, treatment tolerance and adherence as well as address preliminary efficacy of implementing a treatment paradigm using the TPAD with visual feedback and overground training to reduce load asymmetry on the treadmill and promote increased stance symmetry on the paretic limb during overground gait.

PARTICIPANTS: To account for 20% attrition, a total of 12 individuals in the chronic (>6 months) stages post stroke will be recruited from a voluntary stroke research registry with anticipation that 10 individuals will complete participation.

DESIGN: A non-randomized pilot study of feasibility will be used to establish the preliminary efficacy of using the TPAD in combination with overground training to reduce load force asymmetry in this population.

METHODS: Participants will undergo a series of three assessments within a one week time frame prior to initiating intervention. Intervention using the TPAD and overground training will occur the following week for five consecutive visits. On completion of the final training visit, participants will be re-assessed, and return for a single follow up visit the next week for the final assessment. Each study visit will be approximately 1-1.5 hours in duration, and total participation should be completed within three weeks.

EXPECTED OUTCOMES: We anticipate this training paradigm will prove feasible in reducing both load and stance asymmetry in a population of individuals with chronic stroke.

II. Research Questions:

- 1) Is a five day gait training program using the TPAD and incorporating augmented visual feedback and an overground walking component feasible in terms of safety, treatment tolerance, and adherence in individuals with chronic stroke who present with gait asymmetry?
- 2) Is this training program effective at improving load force symmetry after five sessions?
- 3) Is this training program effective at improving stance time symmetry in overground gait?

III. Study Design/Methodology

This is a single arm, non-randomized pilot study of feasibility. The study population and details of study procedures are specified below.

IV. Outcome Measures

A. Primary Outcomes

- Measures of Feasibility
 - Safety
 - Adverse Events / Serious Adverse Events
 - Adherence
 - Attendance Rates of Study Visits
 - Tolerance
 - Ratings of Perceived Exertion (RPE)
 - Heart Rate (HR)
- Efficacy
 - Overall Load Force Symmetry (over the course of training)
 - Stance Time Symmetry

B. Secondary Outcomes

- Daily Load Force Symmetry (intraday changes in load force)
- Time in Double Support
- Swing Time Symmetry
- Stride Length Symmetry
- Stride Velocity Symmetry
- Gait Velocity
- Balance (as per the Berg Balance Scale)

V. Study Population

A total of 12 adults (ages 18-75) will be recruited for participation from a voluntary stroke registry, anticipating 20% attrition, or that at least 10 participants will meet criteria and complete study participation.

Inclusion Criteria:

- Chronic (>6 months) stages post stroke
- History of a single stroke event (either ischemic or hemorrhagic by origin)
- Minimal score of 22 or higher on the MoCA
- Must be independent community ambulator (with/without AFO)
- May use a unilateral assistive device (cane, quad cane)
- Must have a notable asymmetry in stance time (defined by a symmetry ratio of 0.90 or lower)

Exclusion Criteria:

- History of multiple strokes
- History of other neurological disease (e.g. Parkinson's Disease, Multiple Sclerosis)
- Uncontrolled medical conditions that would limit exercise tolerance (e.g. hypertension)
- Excessive spasticity in the paretic lower limb (score >3 on Modified Ashworth Scale)
- Contractures of the lower limb that prevent the ankle and knee from achieving a neutral position (sc

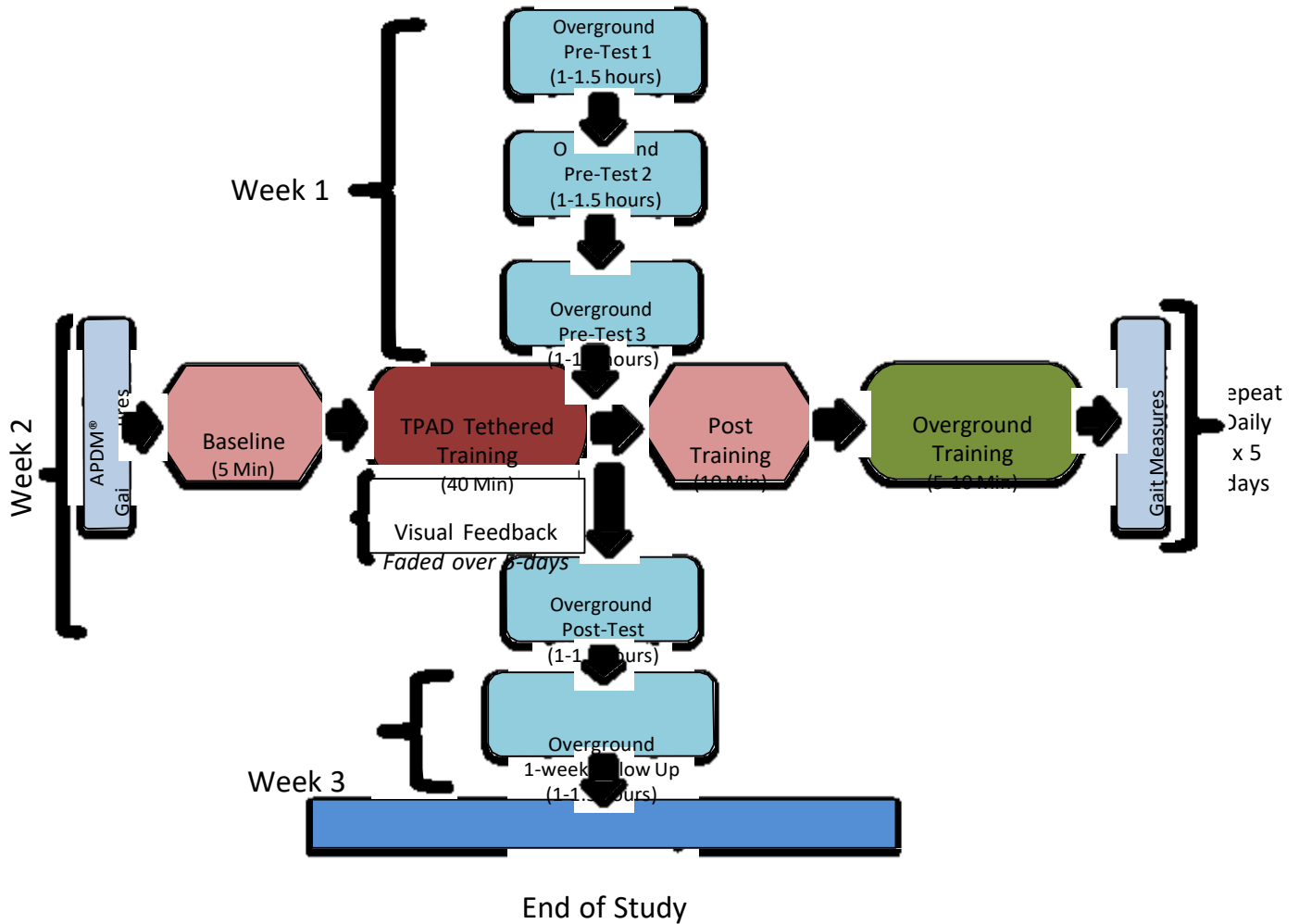
VI. Procedures

A. Informed Consent Process

Written consent forms with associated HIPAA forms will be prepared, approved by the institutional review board, and reviewed with each participant by a member of the research team prior to initiating study procedures. All participants will have the opportunity to ask any questions they may have, and a member of the research team will answer any questions posed. All participants will sign written informed consent and HIPAA forms prior to participating in any study related procedures. Participants will be given a copy of these signed forms for their personal record.

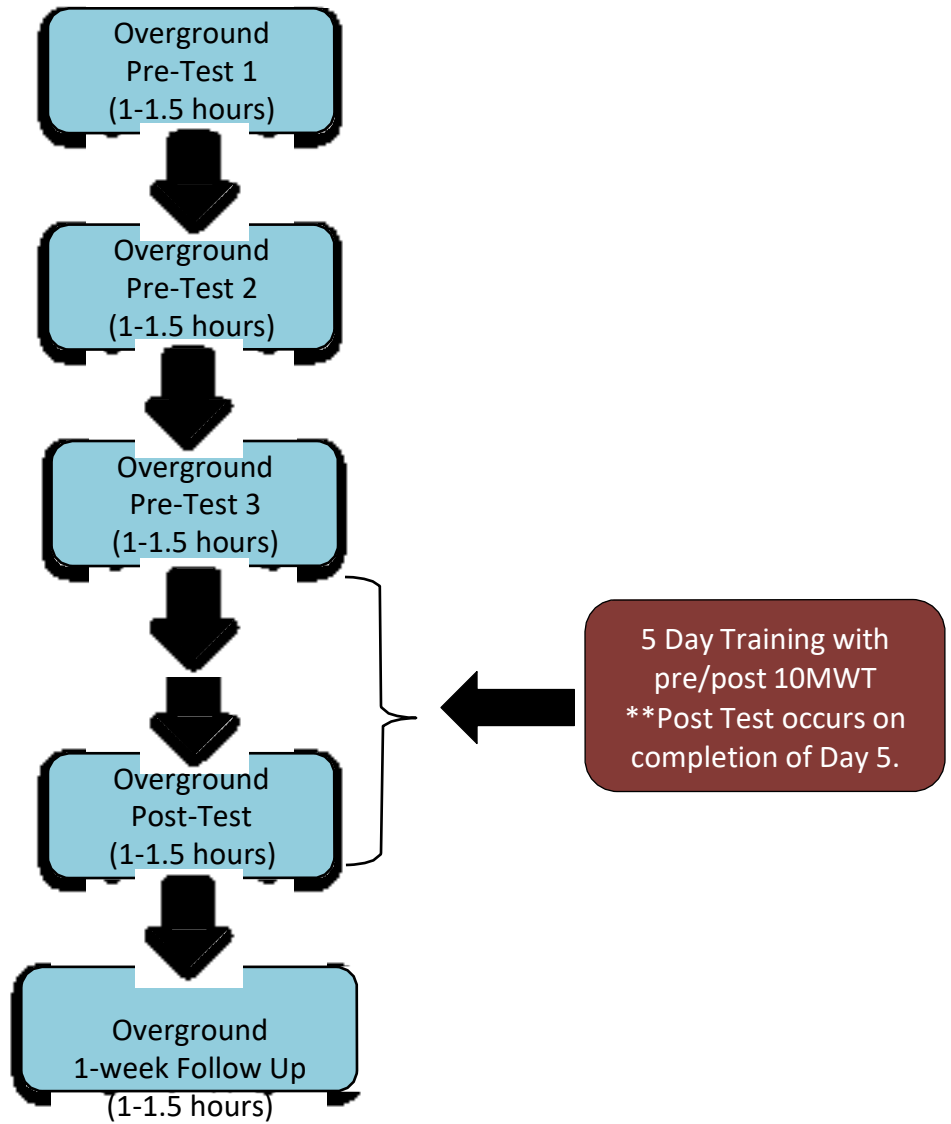
- Prior to initiating study procedures, participants will also complete a demographic form (Case Report Form (CRF_TPAD_Form_01)– See attached) and will be asked about use of an Ankle Foot Orthosis (AFO) – specifically if s/he typically ambulates inside the home with or without an AFO.
 - **IF** the participant typically **DOES NOT** wear the AFO for household ambulation, then the AFO **WILL NOT** be worn during the study procedures.
 - **IF** the participant typically **DOES** wear the AFO during household ambulation, then the AFO **WILL** be worn during the study procedures.

B. Overall Study Schema



Week 1 - PRE TEST (3 visits)	Week 2 - TRAINING (Daily visits)	Week 3 - FOLLOW UP (1 visit)
Consent **Day 1 only	10MWT with APDM® before and after training daily	10MWT with APDM®
Info Sheets **Day 1 only	Treadmill (TM) Training with Feedback	BBS
MoCA **Day 1 only	Overground Training	SIS
Stroke Impact Scale (SIS) **Day 1 only	Treadmill Assessments (Force Measures in tandem with baseline and post training gait on TM)	
10MWT with APDM®	BBS **Day 5 only	
Berg Balance Scale (BBS)	SIS **Day 5 only	

C. Assessments



i. Overground Assessments

Overground assessments will include:

- ✓ Gait Assessments
 - 10MWT as measured with APDM® sensors
- ✓ Balance Assessments
 - Berg Balance Scale (BBS)
- ✓ Self Assessments
 - Stroke Impact Scale (SIS)

Overground assessments will be taken during week one (Pre Testing), week two (Gait Assessments before/after Intervention and Post Testing on Day 5) and week three (Follow Up) of study procedures.

The **Overground Assessment** will occur as per the following schedule:

- ✓ **Week 1:** (Pre Test) Participant sessions will include ***gait assessments, balance assessments and self-assessment*** (Day 1 only) for each of three visits during the first week of study participation.
- ✓ **Week 2:** (Intervention) Participants will repeat ***gait*** assessments before and after each daily intervention session. On day 5 after study intervention, participants will be given a 10-15 minute seated rest break, and ***all (gait, balance, and self assessment)*** assessments will be repeated. These will be recorded as Post Test.
- ✓ **Week 3:** (Follow Up) Participants will complete ***all (gait, balance and self assessment)*** assessments.

** Denotes primary outcome measure.

- Participant will complete the 'Informed Consent' process prior to initiating any assessment or study related procedures.
- A physical therapist and at least one other member of the research team will be present to perform all assessment procedures.
- Participants' height and weight will be measured and recorded on CRF_TPAD_Form_03a (See attached).
- Any incidents with patient safety** during assessment sessions will be reported on CRF_TPAD_Form_03/03a/03b.
- Any missing visits** of the assessment sessions will also be noted on CRF_TPAD_Form_03/03a/03b.

1. *Gait Assessments*

Gait variables recorded include:

- Percentage of time in Stance phase of gait cycle (for each limb individually)**
- Percentage of time in Swing phase of gait cycle (for each limb individually)
- Percentage of time in Double Support phase of gait (net for both limbs)
- Stride Length (for each limb individually)
- Stride Velocity (for each limb individually)

A 14-meter course will be measured along a quiet hallway. The middle 10-meter segment of this course will be marked. Gait measures will be recorded during a series of three, 10 meter walk tests (10MWT) using the APDM® inertial based sensors.

A. **Set up:**

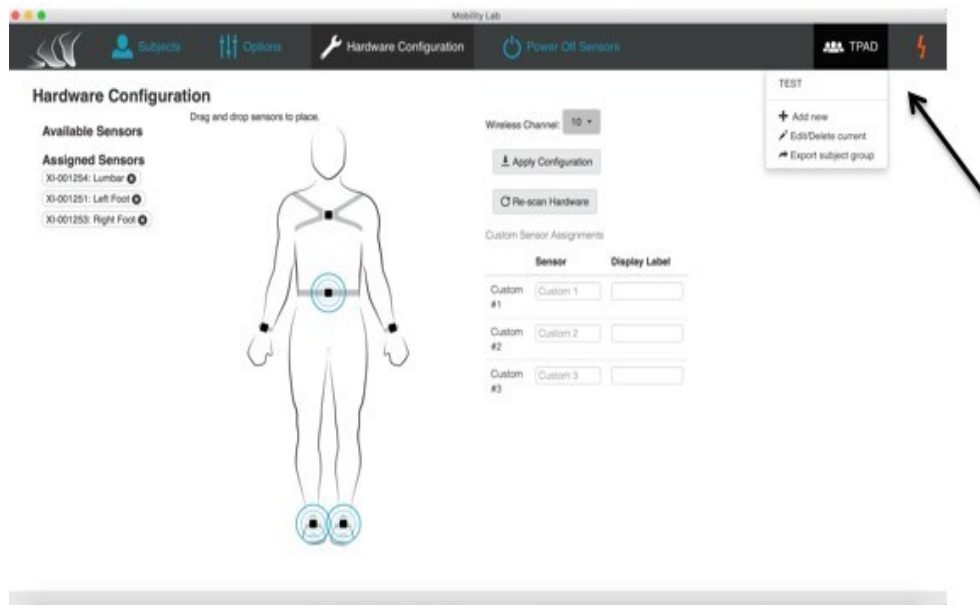
- a. Turn on MacBook Pro (Mid 2015, Apple®, Inc.) laptop and login with the User Name “*NRR_Lab*” and Password “*anngentile1*”.
- b. Secure the Access Point in the accompanying stand, and attach to the MacBook Pro laptop via the (18 inch) Micro USB cable provided.
- c. Attach Opal Sensors (Sensor Numbers: 1251, 1253, 1254) to the Docking Station using 3 of the (6 inch) Micro USB cables provided.
- d. Attach the Docking Station to the MacBook Pro laptop with the attached USB cable.



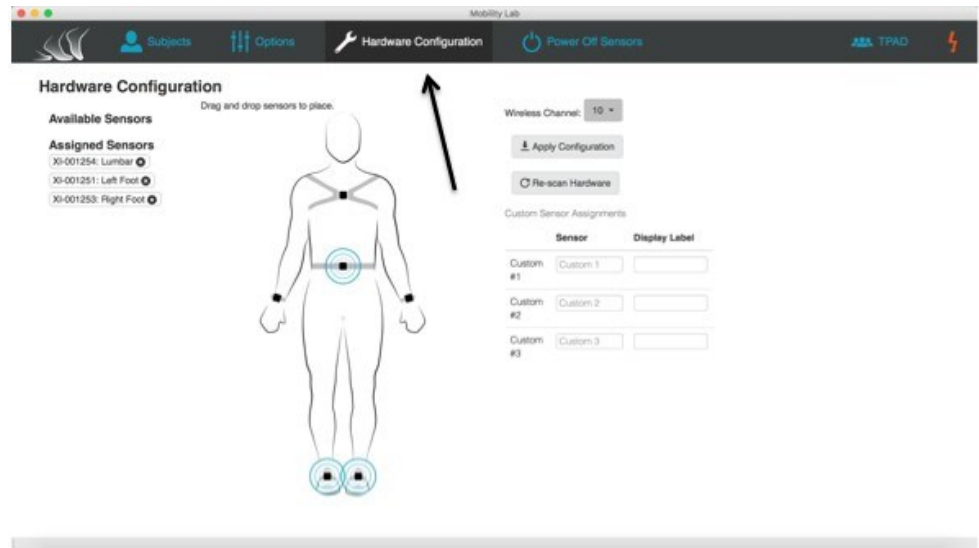
e. Initiate Mobility Lab© 2015 (Version 2.0, APDM, Inc.) software.



f. Ensure that Project Group “TPAD” is selected.

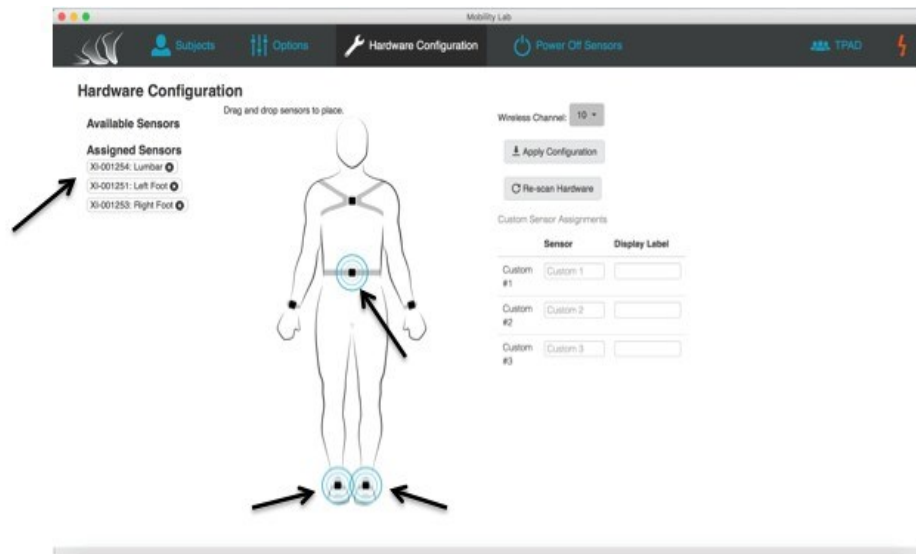


g. From tabs (at top of page), select “Hardware Configuration”.

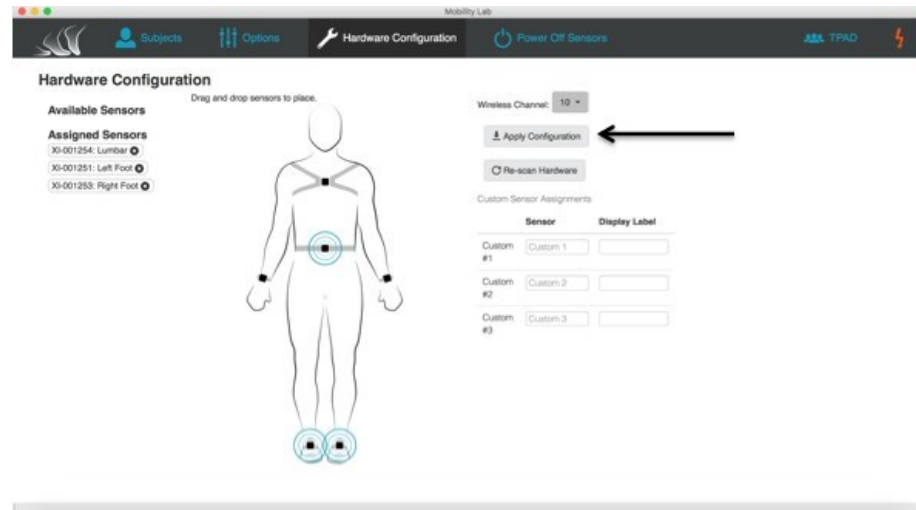


h. Ensure and/or assign sensors by dragging ‘Available Sensor’ to associated position at figure. Sensor assignment is:

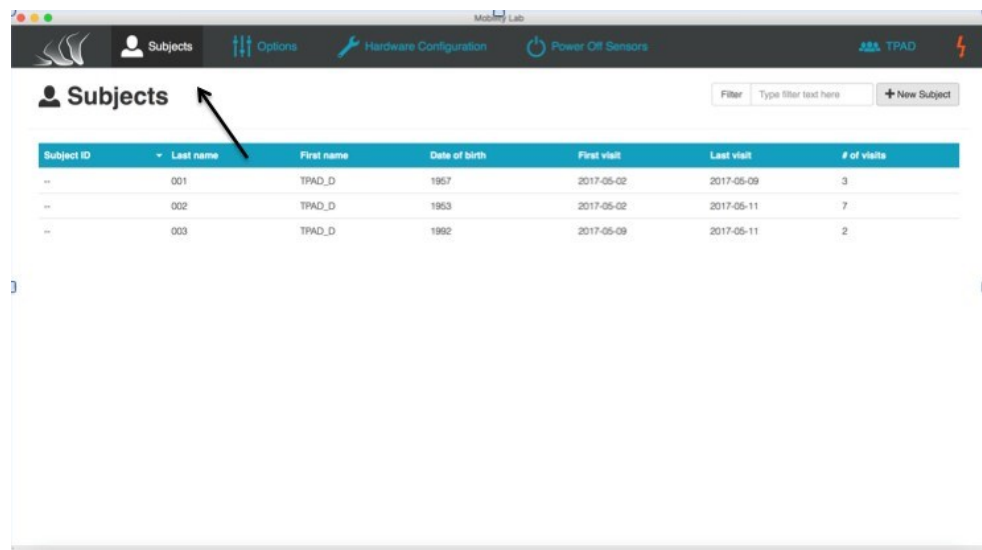
- ✓ **XI-001254: Lumbar**
- ✓ **XI-001251: Left Foot**
- ✓ **XI-001253: Right Foot**



- i. Select “Apply Configuration”.

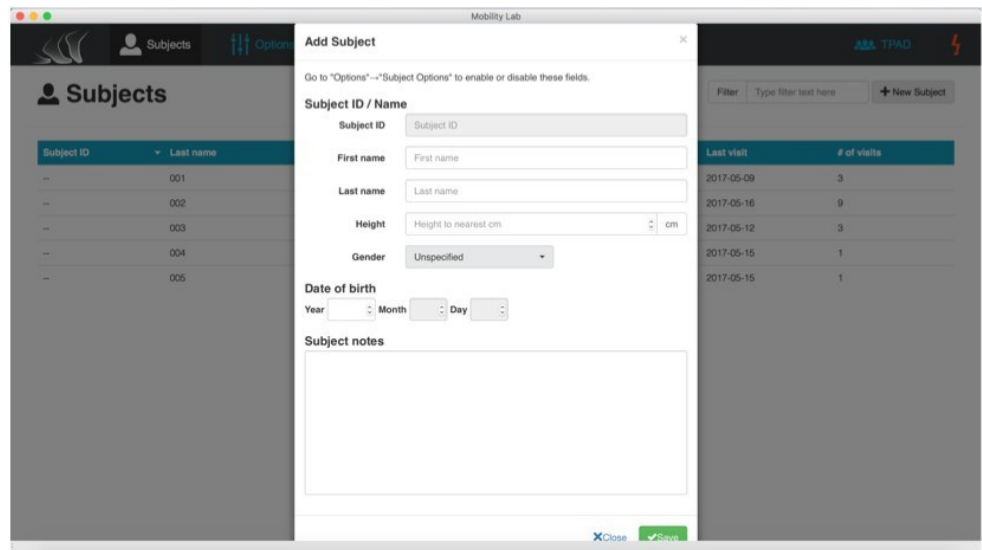
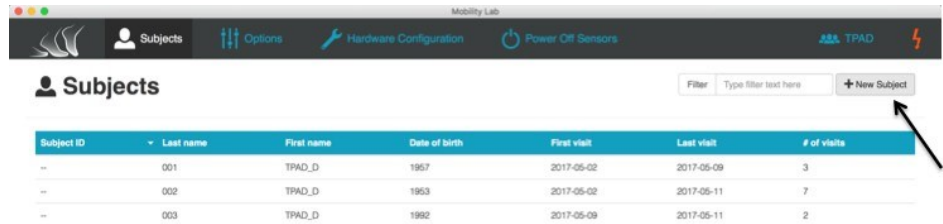


- j. From tabs (at top of page), select “Subjects”.



1. For New participants (**DAY 1 Pre Test ONLY**):

- a. Select “+ New Subject” (at top right of screen).
- b. Add First Name = “TPAD_D” (for ALL participants).
- c. Add Last Name = Enter Participant’s Study ID number.
- d. Enter participant height.
- e. Select ‘gender’.
- f. Enter year of birth.



2. For **Returning** participants:
 - a. Select participant from list by clicking on “Last Name” / Participant Study ID number.

Subject ID	Last name	First name	Date of birth	First visit	Last visit	# of visits
--	001	TPAD_D	1957	2017-05-02	2017-05-09	3
--	002	TPAD_D	1953	2017-05-02	2017-05-11	7
--	003	TPAD_D	1992	2017-05-09	2017-05-11	2

- k. From tabs (below Project Group), select “New Test”.
- l. At Pop Up Test Selection prompt, select ‘Open Ended’ from the ‘Walk’ parameter (top of list).

Test Selection

Single tests:

Walk	<input checked="" type="checkbox"/> 2-minute <input type="checkbox"/> Open Ended	+
TUG	3m Walkway	+
360 Degree Turn	1x	+
SAW	7m Walkway	+
Sit to Stand	5x	+
Sway	Feet Apart, Eyes C	+

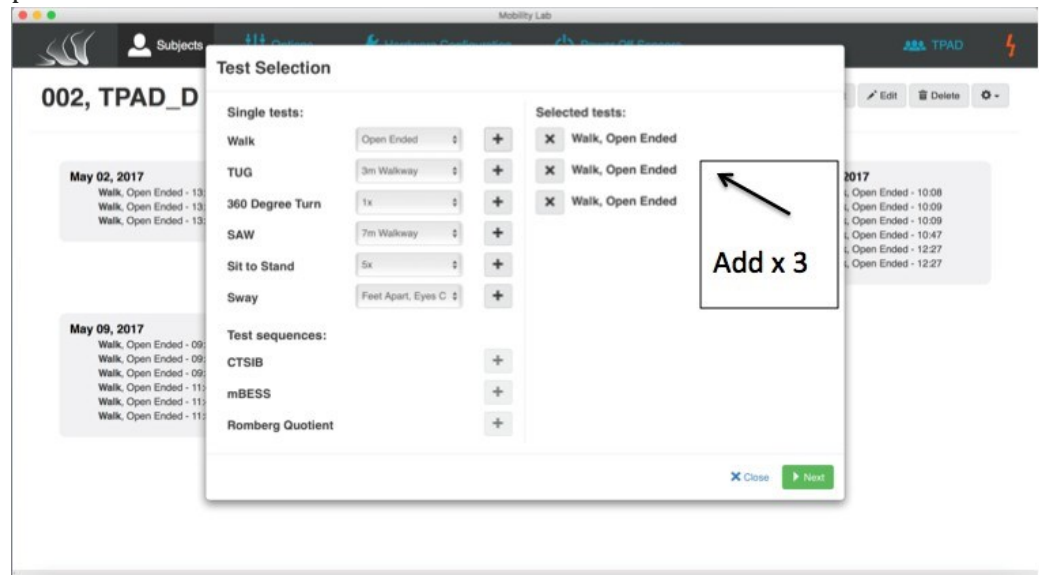
Test sequences:

CTSIB	+
mBESS	+
Romberg Quotient	+

Selected tests:
No tests. Select tests to add.

Close Next

- m. Select the “ + ” button 3 times to add a total of 3 walks to the participant profile.



- n. Select 'Next'.
- o. Ensure participant is seated for sensor placement.
- p. Remove Opal sensors from Docking Station and place on participant at L2, and at the dorsal surface of bilateral feet as shown. (Port faces down for lumbar sensor and towards the toes for feet sensors.)



- q. Participant is asked to stand and is assisted (if needed) to one end of the 14-meter walkway.
- r. Turn on Sony 6300 camera.

B. Procedures: Conducting the Assessment

- a. Instruct the participant to walk from their current position to the opposing end of the 14-meter path at a 'comfortable pace' on your "GO" signal.
- b. Activate Opal sensors by selecting "Start Recording".
- c. At the sound of the tone, instruct the participant to begin walking.
- d. A stopwatch will be used to capture the 10MWT portion of the pathway.
- e. Times will be recorded on CRF_TPAD_Form 03/03a/03b (See attached).
- f. A member of the study team will walk alongside the participant to ensure safety.
- g. A second member of the study team will video record the participant's gait during performance of the walk using the Sony 6300 camera.
- h. Repeat procedures for all 3 walk trials.
- i. On completion of all 3 trials, the participant will be seated, Opal sensors removed and reattached to the Docking Station.
- j. From tabs (at top of page) select "Power Off Sensors".
- k. Remove sensors from docking station after 'Power Off' sequence is complete.
- l. Ensure Opal sensors go blank.
- m. Detach Docking Station and Access Point from MacBook Pro laptop and replace into APDM® suitcase.
- n. Close Mobility Lab software and shutdown MacBook Pro laptop.

☐ This will complete the gait assessment portion.

2. Balance Assessments

A standardized Berg Balance Scale is performed with each of the participants (CRF_TPAD_Form_04 – See attached).

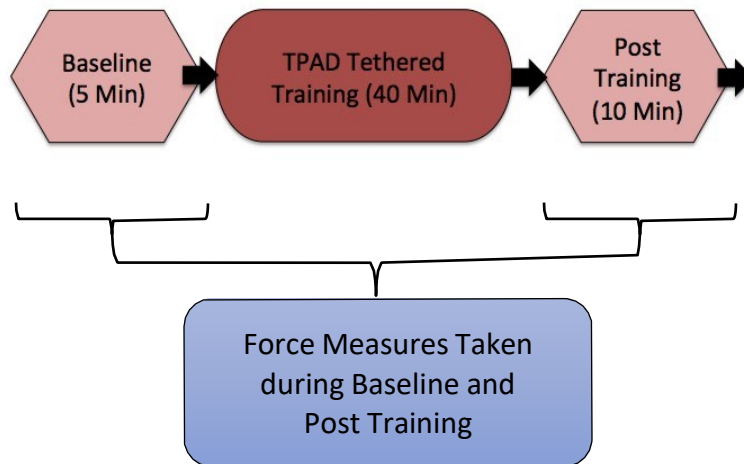
- Assessments will be video recorded, and independent reviewers will score each item of the assessment.
- Total scores will be recorded on CRF_TPAD_Form_03/03a/03b (See attached).

3. Self Assessment

- A Stroke Impact Scale (SIS) will be given to participants to complete on Pre Testing, Day 1, on Post Testing, and on Follow up. Total scores of these assessments will be recorded.

□ This will complete the overground assessment portion.

ii. Treadmill Assessments



- Force Assessments will be recorded on the treadmill in an effort to calculate force symmetry between the affected/less affected limb.

Treadmill assessments will occur simultaneously within the interventional sessions. These assessments will be completed daily during week two of study participation. As they will occur within the intervention, no additional time is needed for data collection during these procedures.

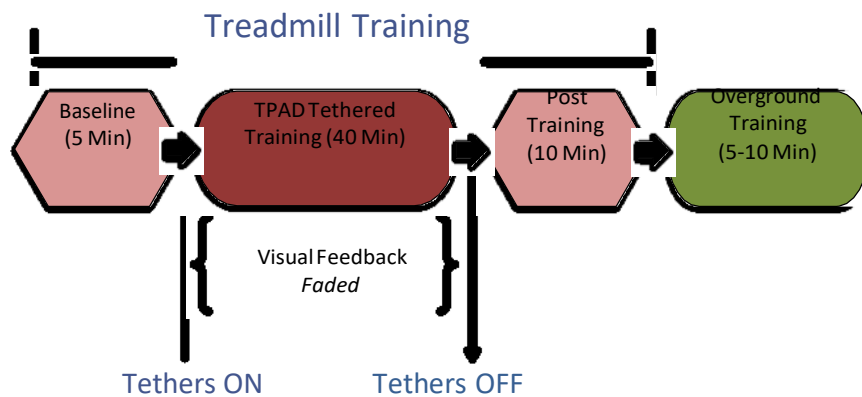
An engineer trained in the use of the TPAD will be present and record data while the physical therapist is supervising the participant during the treadmill portion of the intervention.

Data collected from baseline (Intervention Day 1) and post training (Intervention Day 5) will be used as a primary outcome of vertical Ground Reaction Force (GRF)**. Daily measures (Baseline to Post Training within day) will be used as secondary measures of GRF over the course of training.

Procedures are as follows:

- Reflective markers, safety harness, pelvic belt and arm sling will be placed as described in 'Intervention' section above.
 - The participant will be assisted onto the dual belt treadmill and confirmed gait speed established as described in 'Intervention' section above.
 - Force plates embedded under the dual belts of the treadmill will be activated for data recording of Forces in the vertical direction (F_z) as a measure of GRF. These recordings will occur during minute 1, 3 and 5 during 'Baseline' gait procedures as described in the 'Intervention' section above.
 - RPE** and HR** will be recorded before (at resting) and after 'Baseline' gait, at 10-minute intervals during TPAD force intervention, on completion of 'Post Training' gait, and lastly on completion of overground gait. These measures will be recorded on CRF_TPAD_Form_02.
 - Force plates will also be activated for data collection of F_z as a measure of GRF during minutes 1, 3, 5, 7, 9 of 'Post Training' gait procedures as outlined in the 'Intervention' section above.
 - These procedures will be repeated during daily intervention sessions.
- This will complete the Treadmill Assessment portion.**

D. Intervention



All interventional procedures are to be performed during week two of study participation. These sessions will occur daily for five consecutive days. The duration of each interventional session will be approximately one and one half hours (90 minutes).

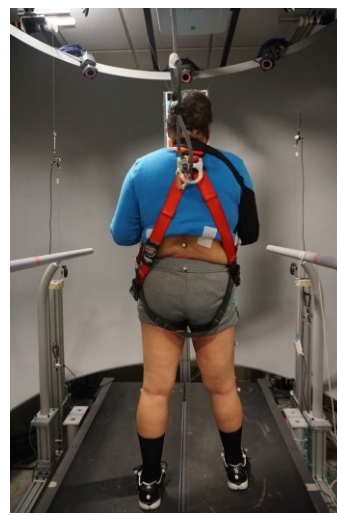
Participants will be asked to wear gym shorts and comfortable walking shoes for each training session. If participants wear other clothing to the session (e.g. in winter months), they will be given the opportunity to change clothes prior to initiating any study procedures.

A licensed physical therapist will supervise all training sessions. Engineers experienced in operating the TPAD will be primarily responsible for the operating and running of the TPAD and treadmill during the training session.

1. Set up

Prior to initiating the training, a member of the research team will complete the Treatment Checklist, including:

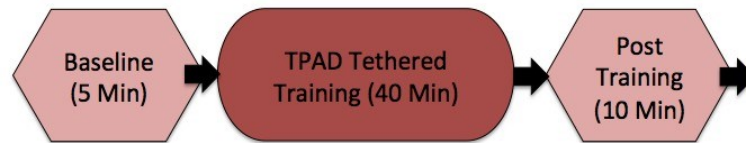
- a. Participants will stand while reflective markers are placed bilaterally at:
 - ✓ R/L Medial & Lateral metatarsal heads
 - ✓ Superior surface of first distal toe
 - ✓ R/L Med & Lateral malleoli
 - ✓ R/L Heel
 - ✓ R/L Tibial Plateau
 - ✓ R/L Fibula Head
 - ✓ R/L Med & Lateral distal Femur
 - ✓ R/L anterior shaft of the Femur (at midpoint)
 - ✓ R/L lateral shaft of the Femur (at midpoint)
 - ✓ Anterior Superior Iliac Spine (ASIS)
 - ✓ Superior (on abdomen) to ASIS for ASIS Recreation
 - ✓ L3



- b.** Patient clothing will be taped in place to ensure marker visibility throughout treatment.
- c.** Participants will then don:
 - ✓ A safety harness that will connect to an overhead metal brace/beam during gait tasks on the treadmill.
 - ✓ A sling to support the paretic arm during gait. This is done to prevent the blocking of reflective markers during gait that are needed for the application of forces.
 - ✓ A pelvic belt that has been altered to allow the attachment of force tethers.
- d.** Heart Rate (HR) monitor and Borg Scale will be in place to allow recordings throughout treatment session.

- e. Participants will then be assisted onto the dual belt treadmill.
- f. A still image will be recorded using a Vicon® infrared recording system and evaluated to ensure all markers are in place and are visible.
- g. During the still image, recordings will be made of vertical forces (Fz) during quiet stance for both the paretic and non-paretic limb.
- h. Measures of resting heart rate (HR) and Ratings of Perceived Exertion (RPE) will be taken and recorded on CRF_TPAD_Form_02 (See attached).

2. Treadmill Training



- a. The treadmill will be initiated and speed gradually increased by 0.1 m/s intervals. The participant will be asked when s/he feels this will be a challenging, yet tolerable speed to sustain for one hour (60 minutes). A supervising Physical Therapist will confirm the speed and this will be recorded on CRF_TPAD_Form_02 (See attached). The confirmed speed will be used for all subsequent treatment sessions. *This will occur during Day 1 treatment ONLY.
- b. The participant will continue walking at the self-selected gait speed for five minutes.
- c. During this time the participant will gain familiarity with treadmill walking (Baseline), and vertical force measures (Fz) will be recorded. This is explained in detail in the 'Assessments' section.
- d. Video recordings will be taken from a posterior view during minutes 3-4 of baseline gait.
- e. On completion of the five minutes of baseline gait, the supervising therapist will verbally tell the patient to hold on to the side hand rails, and the treadmill will be stopped.
- f. HR and RPE will be recorded on CRF_TPAD_Form_02 (See attached).
- g. Tethers will be attached to the pelvic belt.
- h. Participants will be offered a seated rest break. Time of rest break will be recorded.
- i. Reflective markers will be placed on the tethers at the point of attachment to the pelvic belt and at the level of the pulley/frame.

- j. A force of resting magnitude will be applied during static standing (enough force to keep tethers taut during gait, but this resting magnitude will be evenly distributed among the four force tethers along a horizontal plane at left/right anterior/posterior positions).
- k. A still image will be taken to ensure tethers are appropriately in place, and markers attached to tether attachment points will be removed.
- l. Once forces tethers are taut, the visual feedback monitor will be turned on and the supervising therapist will explain the role of feedback during the training.
 - Verbiage to be used:
 - “Do you see the 2 bars in front of you? The right/left (side of the paretic limb) represents your weaker leg. This bar moves depending on how much weight you put into your leg. Go ahead and lift your leg so you can see the bar move.”*** [Participant lifts leg and bar representing paretic limb lessens].
 - “Do you see the other bar? It is your target. On each step, I want you to try and get your right/left (paretic) bar up to the top of that target and keep it there as long as possible while you are walking. Do you have any questions?”*** [Participant is given an opportunity to ask questions for which a member of the research team will respond appropriately.]
 - “There will be points during training where this screen isn’t on. I still want you to think about the screen and put as much weight on your weaker leg and keep it there as long as possible – even when you do not see the screen. Do you understand?”***
- m. The treadmill will be re-initiated at the self-selected speed, and a force of 10% of the participants’ body weight will be applied along the horizontal plan in the anterolateral direction, ramping up/down in a trapezoidal fashion on the side of the paretic limb. This will occur at the point of heel strike and be completed by mid-stance during each step. This will be sustained for 40 minutes.
- n. At the midpoint of training participants will be offered a seated rest break, after which training will immediately be re-initiated.
 - If participants decline rest at midpoint (20 minutes), they will be offered another rest break at minute 30 of training.
 - Duration of rest break(s) will be recorded.

- o. Visual feedback will be given as indicated by Table 1:

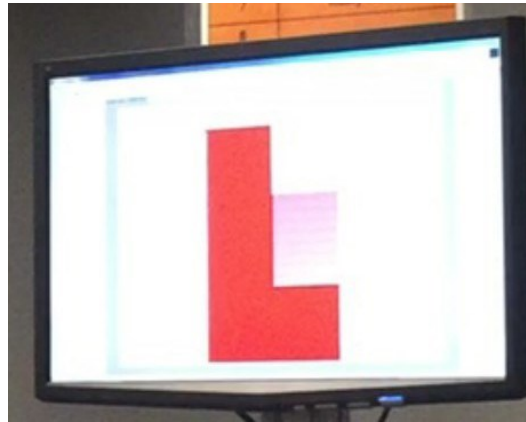


Table 1: Visual Feedback Schedule per Training Day Visit

	Day 1	Day 2	Day 3	Day 4	Day 5
Minute 1-10	9 minutes on/ 1 minute off	7 minutes on/ 3 minutes off	5 minutes on/ 5 minutes off	3 minutes on/ 7 minutes off	1 minute on/ 9 minutes off
Minute 11-20	9 minutes on/ 1 minute off	7 minutes on/ 3 minutes off	5 minutes on/ 5 minutes off	3 minutes on/ 7 minutes off	1 minute on/ 9 minutes off
Minute 21-30	9 minutes on/ 1 minute off	7 minutes on/ 3 minutes off	5 minutes on/ 5 minutes off	3 minutes on/ 7 minutes off	1 minute on/ 9 minutes off
Minute 31-40	9 minutes on/ 1 minute off	7 minutes on/ 3 minutes off	5 minutes on/ 5 minutes off	3 minutes on/ 7 minutes off	1 minute on/ 9 minutes off
Total	90% on (36 min)/ 10% off (4 min)	70% on (28 min)/ 30% off (12 min)	50% on (20 min)/ 50% off (20 min)	30% on (12 min)/ 70% off (28 min)	10% on (4 min)/ 90% off (36 min)

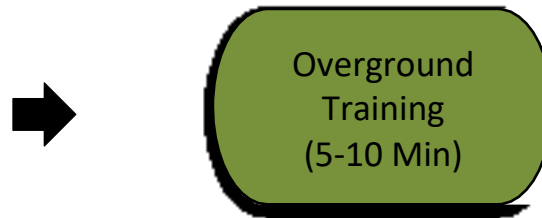
***** Video Recordings using a posterior view will be made during minutes 5, 15, 25, and 35 of training.

- p. On completion of the 40 minute training with the force tethers and visual feedback, the participant will be cautioned to hold onto the hand rails and the treadmill will be stopped.
- q. HR and RPE will be taken and recorded at every 10 minute interval (at minute 10, 20, 30 & on completion) throughout the treatment session using CRF_TPAD_Form_02 (See attached).
- r. Participants will be offered a seated rest break and water at completion of training.
- s. Immediately on completion of the rest break, participants will stand, and continue to walk for an additional 10 minutes on the treadmill with no force tethers attached (Post Training). This will allow the participant to 'cool down' from the training.

During this time vertical forces (F_z) will be taken for each the paretic and non paretic limb.

- t.** Video recordings will be made from a posterior view during minutes 5 of post training.
- u.** On completion of post training, participants will be assisted off of the treadmill and reflective markers, safety harness, pelvic belt and arm sling will be removed.
- v.** HR and RPE will be taken and recorded on CRF_TPAD_Form_02 (See attached).

3. Overground Training



- a. Participants will then initiate overground training for which they will ambulate in a quiet corridor and will receive verbal and gentle tactile cues to reinforce TPAD training. Overground training will be between 5-10 minutes. Duration of overground training period will be recorded.
 - Verbal cues will include:
 - “Remember to walk and put as much weight on your right/left (paretic) limb as possible and keep it there as long as possible.”
 - “Can you put more weight on your right/left (paretic) side?”
 - “A little more”
 - “More weight over here”
 - “Keep it/your weight there a little longer with each step.”
 - Tactile cues will include:
 - Gentle tapping at right/left (paretic) side.
 - Gentle tapping at right/left (paretic) quadriceps.
 - Light hand hold around pelvis with gentle weight shift onto paretic side.
- b. On completion of overground training, HR and RPE will be taken and recorded one additional time on CRF_TPAD_Form_02 (See attached).
- c. CRF_TPAD_Form_02 will be completed daily for each intervention session.
- d. Any incidents with patient safety during interventional procedures will be reported on CRF_TPAD_Form_02.
- e. Any missing visits** occurring during intervention will also be noted on CRF_TPAD_Form_02.
- f. This will conclude the training portion of the session.

VII. Participant Withdrawal

Participation in this study is voluntary. Participants will be allowed to withdraw from the study at any point. Withdrawal of participation from this study will not preclude individuals from participating in any future studies relating to stroke or for which the individual would be a potential candidate.

The participant may be withdrawn by a member of the research team if:

- The participant does not complete all Pre-Test Assessments.
- The participant completes < 4/5 training visits
- The participant does not complete Post-Test Assessment
- The participant sustains an injury while participating that would prevent s/he from completing study procedures

VIII. Risk / Benefit

No invasive interventional procedures will be used during these study procedures. Thus, this is a low risk study. General risks of exercise are expected during study participation, including but not limited to muscle fatigue, muscle stiffness, and muscle soreness. In an effort to minimize risk to participants, a licensed physical therapist will be present for all study related activities. Additionally, a MD will be available in the event of an injury or the occurrence of an adverse event. Any medical injuries sustained during participation in this study will be recorded (CRF_TPAD_Form_02), and the Principle Investigator and the Institutional Review Board will be notified within 24 hours of event. The study participant will be responsible for any incurred cost from a study related injury.

We anticipate that participants who complete study procedures may receive improvement in gait symmetry by participating in this trial. However, we cannot guarantee physical benefit from study participation. Additionally, it is likely that any benefit in gait performance seen from participating in this trial will be temporary and not long-lasting due to the short duration (one week) of the intervention.

IX. Data Management/ Storage

Hard copies of CRF and study documents will be stored in files coded by patient identification numbers assigned at the onset of study participation. These files will be stored in a locked file cabinet in the office of a member of the study team. Only team members will have access to these files.

Electronic data will also be coded using the same patient identification numbers. A code key will be located in the hard copy files. All electronic data will be stored either in a REDCap Database (feasibility results of safety, adherence, treatment tolerance, gait velocity and balance scores) or on a CUMC encrypted end point device (gait data from embedded force plates and APDM inertial sensors) that is backed up regularly. Patient data sheets will be input into the REDCap database and each member of the study team will have access via an individualized login/password combination. Coded copies of electronic data will be shared between members of the research team via Columbia University email

system. To ensure data security, all electronic data will be coded, and the code key will not be included with data files.

X. Adverse Event Reporting

Adverse events include study related injuries including, but not limited to:

- Falls
- Ankle sprains/strains
- Fractures
- Orthopedic related injuries
- Dizziness
- Severe fatigue that requires a ceasing of study procedures

In the case of an adverse event (AE), the participant will be evaluated immediately by the physical therapist present for all study procedures. If the AE persists, study procedures will be stopped, and the study MD notified to evaluate the participant. In such cases where applicable (e.g. fracture, ankle injury) the participant will be referred and assisted to the Emergency Room for immediate attention.

All AEs will be recorded and reported to the PI and IRB within 24 hours.

XI. Statistical Analysis

Please see attached Statistical Analysis Plan.

XII. Dissemination of Results and Publications

Results of this work will be analyzed and a manuscript prepared for publication. Full details of this work including prior work using the TPAD, background, study procedures, statistical analysis procedures and detailed results will be written and stored on file as a part of the final dissertation report.

Lauri Bishop, PT, DPT will serve as primary author on the dissertation with Lori Quinn, EdD providing sponsorship. Ms. Bishop will also serve as a primary author for manuscripts prepared discussing the feasibility and preliminary efficacy of the TPAD to reduce asymmetry in a population of individuals after stroke. Moiz Khan, MS will serve as primary author for any manuscripts detailing technical specifics of implementing TPAD treatment in a population of individuals after stroke. Other participating members of the research team will be recognized in authorship in all manuscripts submitted for publication.