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

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Multiple Baseline TPAD and Over Ground Training

Statistical Analysis Plan

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Introduction to the study:

Stroke is the leading cause of disability worldwide, and predictions indicate that the prevalence of stroke will continue to rise[1]. Impairments resulting from stroke lead to mobility deficits in the lower limb, affecting gait [2]. Symmetry is a critical component to describe the characteristics and overall skilled quality of gait, specifically in respect to reductions in walking speed[3–6] and limitations in endurance and the flexibility to adapt to different environmental contexts[4–8]. Asymmetries between the paretic and non-paretic limb exist in spatial and temporal parameters of gait as well as in load force production of the limbs [8–11]. Increases in load force of the paretic limb (improved symmetry) have been correlated with gains in temporal gait parameters as well as improved modulation of gait speed [3,6,7,12].

Traditional care models have focused on improving gait velocity and reducing asymmetry in a post stroke population, however despite efforts, there is questionable carry over into community participation activities[13–15] and individuals are left with residual deficits[16]. Body-weight supported treadmill training (BWSTT) has been used to increase gait velocity and remediate asymmetries in this population [3,17–20]. BWSTT can provide training at a higher intensity (number of steps per therapy session) than can be achieved in traditional overground care models[21], with a greater reproducibility of step kinematics[22]. Further, the task-specific nature of this training makes BWSTT appealing [18,21–27]. However, despite these benefits, BWSTT has not proven to be more efficacious than traditional training [17,21,23].

Robotic devices have also been used to improve gait velocity and symmetry. These devices share many of the same promising design features as BWSTT including providing a higher intensity training[26,28–30] with a greater kinematic reproducibility of stepping parameters[31] than do traditional care models. Also, similar to BWSTT, these devices do provide training that

is task-specific in nature[26,28–30]. However, despite best efforts, robotic-based gait training devices have been shown to have effects similar to conventional care models[28–32]. This is likely due to employing guided assist control models[33] that render robotic treatments more passive than active on the part of the user[34]. These training paradigms can be beneficial in the early stages of learning, as they provide the learner with information about an 'ideal' or desired pattern that can be used as a reference for future movements in the development of the motor program [34–37]. However, a drawback of guided assist control is that if the guidance is not reduced over the course of training, users can become dependent on the guided feedback they receive from the system, which improves performance, but can lead to reduced retention[35–37].

The tethered pelvic assist device (TPAD) is a novel robotic device that uses an arrangement of force tethers attached to a pelvic belt to manipulate load forces on the pelvis[38,39]. In contrast to other robotic devices, the TPAD does not move or guide the limb to a target position during gait tasks, but maintains a prescribed force or guided assist at the level of the pelvis to increase loading onto the paretic limb while the user freely controls the spatiotemporal aspects of limb movement. This allows the user to play an active role during training, rendering the TPAD an ideal device to explore various training paradigms while promoting a sufficient training intensity to drive motor learning and maximize the effects of gait training.

Rationale for current trial:

A detailed description of the TPAD can be found in the Standard Operating Procedures Manual. Prior experiments have used the TPAD to improve loading onto the paretic limb in a post-stroke population[39]. Initial studies using the TPAD in this population delivered a short duration of TPAD training that provided guided loading directly onto the paretic limb during a single training session. Measures of perceived exertion using the Borg Scale were recorded, as

was the number of falls sustained during study participant. Results showed no falls and Borg Scale measures indicated this was a feasible training paradigm for individuals post-stroke. Further, results also demonstrated that participants were able to increase loading onto the paretic limb during training, and these gains were maintained even when TPAD forces were removed during a post-training interval on the treadmill. However, gains made on the treadmill did not transfer to improvements in overground spatiotemporal gait measures.

A follow up experiment looked at the effects of TPAD training in two different training paradigms over the course of a five-day training. For this study, the TPAD tethers were arranged to apply a horizontal force in the anterolateral direction to induce a weight shift onto the limb during the stance phase of gait without downward forces that passively increase loading onto the limb. Similar to the previous study, the goal of the TPAD training was to improve load symmetry between the two limbs. In addition to the application of TPAD forces, augmented visual feedback was supplied during the course of the training period. This feedback reflected the amount of loading onto the paretic limb in real time and provided a visual representation of the task goal. While the details of the two training paradigms will not be discussed here, results were equivocal between the two paradigms. Both training paradigms showed improvements in load forces on the paretic limb, and thus improved load symmetry between the two limbs. Further, in both training paradigms these improvements were retained after force tethers were removed on the treadmill. However, neither of these training models proved effective at promoting transfer of increased load force symmetry from treadmill training to gains in overground spatiotemporal gait parameters.

Results from these prior studies suggest that TPAD training in a post-stroke population is feasible in regards to safety and tolerance to treatment. Further, TPAD based training has

demonstrated limited preliminary efficacy in improving loading onto the paretic limb and reducing load force asymmetry. However in both studies, participants were not able to transfer gains in load symmetry to overground spatiotemporal measures. In the initial study using the TPAD device, the haptic guidance received specifically directed limb loading onto the paretic side minimizing the active engagement from the user in the training process. Further, this training was provided over the course of single, short duration training session. In the following study, modifications were made to configure TPAD tethers in a way that provided guidance to weight shift over the affected limb, while still enabling the user to play an active role in the training process. Further, visual feedback was also provided to further engage the user during training. However, this visual feedback was not faded over the course of the five-day training. It is plausible that the gains seen on the treadmill were mitigated by the lack of fading, limiting transfer to overground measures.

Other studies have incorporated a short bout (5-10 minutes) of over ground training to reinforce the goals of the treadmill based intervention[4,40]. It is plausible that the task-specific nature of over ground training is critical to promote transfer of treadmill training to overground. For the current experiment, visual guidance will be faded over the course of training to promote symmetry during a retention period in which tethered forces are removed. Further, we will also integrate an overground training component reinforcing weight shift onto the paretic limb in an effort to promote transfer of improved load symmetry to overground spatiotemporal gait parameters.

Study Objectives:

The chief purpose of this study is to evaluate the overall feasibility of implementing a five-day, treadmill-based TPAD training with faded visual feedback and an additional task

specific over ground training component to reduce asymmetry in individuals with chronic stroke (> six months after incident).

SPECIFIC OBJECTIVES:

1) Is this five-day intervention using the TPAD and incorporating faded visual feedback and overground walking feasible in terms of safety, treatment tolerance and adherence in individuals with chronic stroke who present with gait asymmetry?

As a measure of treatment efficacy, this study will specifically address the following questions:

2) Is this treatment paradigm effective at improving load force symmetry over the course of five training sessions as measured from Baseline Day one to Post Training Day five?

3) Is this training paradigm effective to promote transfer and improve stance time symmetry in over ground gait as measured from a mean of the three days in Pre Testing to Post Testing?

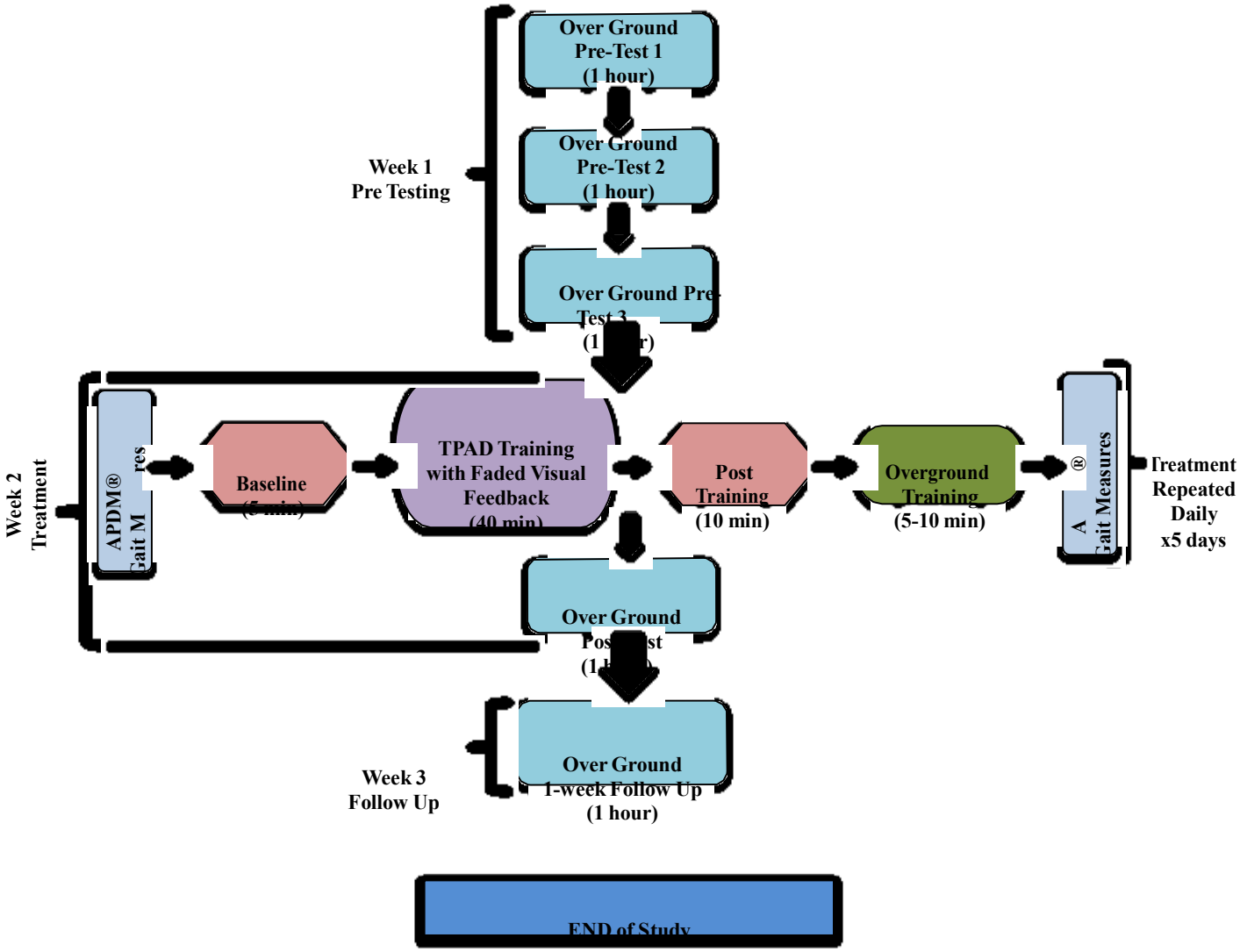
The presence of preliminary efficacy in the prior two questions, coupled with measures of safety, treatment tolerance and adherence will be used to answer the over arching question of feasibility and preliminary efficacy.

Study Design

We will conduct a single arm, pre / post study with a series of three baseline (Pre-Test) measures, a single post assessment (Post-Test) and a one-week follow up assessment (Follow up). Feasibility measures (in terms of adherence, tolerance and safety) will also be recorded. The availability of feasibility measures is critical for planning future, long-term, randomized controlled trials. Based on prior work, force symmetry can be improved with TPAD training. However, we offer that the integration of a task specific overground training component will

allow individuals to improve transfer of force symmetry into spatiotemporal gait parameters that may ultimately impact gait speed, gait function and quality of life. See Figure 1 for a detailed study schema.

Figure 1: Trial Schema



A total of 12 participants will be enrolled to participate. Participants will be assessed over a series of three over ground Pre-Tests by a member of the study team. On completion of over ground Pre Tests, symmetry ratios (paretic/non-paretic limb) will be calculated for percentage of time in stance phase. The mean value of these ratios will be calculated. As the minimal detectable change (MDC) for time in stance has been identified as 0.09[5], participants will be required to have a mean symmetry ratio of 0.90 or less of time in stance after Day one of Pre Testing to be considered eligible for participation in the trial. Details of other

inclusion/exclusion criteria can be found in the Standard Operating Procedure Manual for this study. The details of data collection are outlined here with an associated plan for statistical analysis.

Following these three visits of Pre-Test assessments, participants will return to complete five consecutive days of the training intervention. The intervention will consist of five consecutive days of TPAD training plus visual feedback training with a short over ground training (5-10 minutes) each day immediately following completion of treadmill based activities. After participants are readied for intervention, they will be assisted onto the treadmill and the treadmill will be initiated. Individuals will self-select gait speed with a physical therapist confirming speed is safe for the duration of training. Once gait speed is set, individuals will initiate five minutes of Baseline gait on the treadmill during which load force measures are recorded at minute 0-1 (BL1), minute 2-3 (BL2) and minute 4-5 (BL3). This Baseline gait will be followed by 40 minutes of tethered TPAD training with visual feedback provided. The amount visual feedback will be faded over the course of the five-day training. On completion of the tethered portion of training, participants will continue to ambulate on the treadmill for an additional 10 minutes during a Post-Training period. Measures of load force will be recorded during minute 0-1 (PT1), minute 3-4 (PT2), minute 6-7 (PT3) and minute 9-10 (PT4) of Post Training. Participants will then be assisted off the treadmill and an additional 5-10 minutes of over ground training will be conducted reinforcing weight shifting onto the paretic limb. Participants will be required to complete at least four days of training for data to be considered in the final analysis. Training sessions will last approximately 60 minutes (one hour) in duration.

On the fifth day of training, immediately following the final training session, participants will be allowed a 10-15 min seated rest break and over ground measures will be reassessed (Post

Test). All participants will be asked to return one week after completion of the intervention to undergo one final over ground assessment (Follow Up).

Sample size justification

This is a pre/post pilot with a one week follow up using multiple baseline (Pre-Test) measures to establish a baseline level of function and variability of gait. Results from this study will be used to calculate sample size for future, larger trials in this population.

Study Outcomes

1. **Feasibility**

The primary feasibility outcomes will include an evaluation of safety, tolerance to treatment, and adherence over the course of the trial.

1.1. Safety of the intervention will be assessed by recording the number of adverse events (AE) and/or serious adverse events (SAE) that occur throughout the duration of the trial and will be reported as summary data.

1.2 Treatment tolerance will be measured primarily by rates of perceived exertion (RPE) and secondarily by the percentage of maximum heart rate (HRmax) throughout daily training sessions.

1.3 Rates of adherence will be presented as a proportion of visits attended out of the total study visits. Participants who are not able to complete at minimum four out of the five training visits (80% adherence) will not be included in the final data analysis.

2. **Efficacy**

There will be two primary measures of preliminary efficacy. First, we aim to establish treatment efficacy on the treadmill. Additionally, we aim to determine whether individuals will

be able to transfer gains to improve symmetry in over ground parameters. Specific outcomes are as follows:

2.1 The primary outcome measure for efficacy of training on the treadmill will be the calculated load force symmetry ratio as measured load force recorded during Baseline and Post Training on the treadmill with embedded force plates.

2.2 The primary outcome measure for efficacy of transferability will be the stance symmetry ratio calculated from percentage of time in spent in stance phase of the gait cycle. This will be extracted from data provided by APDM® inertial sensors and measured by the mean of the Pre Test visits to Post Testing.

2.3 Secondary measures of preliminary force efficacy will include within day changes in load force symmetry as taken on the treadmill. As secondary outcomes to evaluate for transfer of the intervention to overground gait, APDM® inertial sensors will be used to record the percentage of time spent in double support, time in swing phase, stride length, and stride velocity. Symmetry ratios will be calculated for percentage of time in swing phase of the gait cycle, and stride length. Gait velocity as a measure of time performing the 10MWT will also be recorded. Lastly, as an additional balance measure, we will also use the total score of the Berg Balance Scale (BBS).

See Table 1 for a detailed list of measures recorded.

Table 1. All outcome variables and time points at which they will be measured.

Table 1 key for time points when variables are measured.
1=Pre-Testing; **2**=Prior to daily treadmill intervention; **3**=Baseline on treadmill; **4**=Tethered TPAD Treatment; **5**=Post Treatment on treadmill; **6**=Post Overground Training; **7**= Post Testing; **8**=1-Week Follow Up Testing

Domain to be Measured	Outcome Measure	Variable Name	Time Required	When
Measures of Participation and Overall Health				
1. Adherence	Attended Visits	ADHER	1 minute	1,2,7,8
Measures of Activity				
2. Perceived Tolerance	Perceived Exertion	RPE	1 minute	2,3,4,5,6
3. Physiological Tolerance	Heart Rate	HR	1 minute	2,3,4,5,6
Measures of Body Functions				
4. Load Symmetry	Load Force	Fz	1 minute	3,5
Overground Spatiotemporal Measures of Gait				
5. Stance Symmetry	Symmetry Ratio - Stance Time	STANCE	15 minutes	Measured Simultaneously 1,2,6,7,8
6. Swing Symmetry	Symmetry Ratio – Swing Time	SWING		
7. Time in Double Support	Double Limb Support Time	DS		
8. Stride Length Symmetry	Symmetry Ratio – Stride Length	StrLENSYM		
9. Stride Length	Mean right/left -Stride Length	StrLENGTH		
10. Stride Velocity	Mean right/left -Stride Velocity	StrVEL		
11. Gait Velocity	Time of 10MWT	10WTIME		
12. Balance	Berg Balance Scale	BBS	20 minutes	1,7,8

3. Data collection and handling

Pre-Testing, Post-Testing and Follow Up gait assessments (percentage of time in stance, swing, double support, stride length, and stride velocity) will be recorded using APDM® inertial sensors as participants complete a series of three, 10 meter walk tests (10MWT). Gait velocity and Berg Balance Scale (BBS) results will be recorded on paper forms at the time of assessment. Baseline, Training and Post-Training measures of load force will be recorded via force plates embedded in the treadmill. Safety issues/injuries/falls and adherence will be noted on paper forms at day of visit. Measures of perceived exertion will be verbally taken and recorded on paper forms. Heart rate will be taken using a Polar H10 heart rate monitor and recorded on paper forms.

All assessment and intervention data will be coded by a participant identification code and entered into a Microsoft Excel Spreadsheet. This spreadsheet will be stored on a CUMC password secured and encrypted end point device. Hard copies of paper forms will be filed by participant identification code number, and kept in a locked file cabinet in the locked office of a member of the research team at CUMC. Only members of the research team will have access to the electronic and hard copy data. The code key for each participant will be stored in the hard copy of each file. No electronic code key will be made.

4. Definitions/Calculations

The following section describes each measure used in the study. Calculated values will be noted in *RED*.

4.1 Feasibility Measures

4.1.1 *Safety*

Assessed at each study visit

All falls, injuries, and any safety concerns that arise will be recorded on paper forms and reported summarily.

4.1.2 *Adherence*

Variable = **ADHER**

Assessed at each study visit

Attendance will be recorded on paper forms at each study visit.

4.1.3 *Tolerance*

4.1.3.1. Ratings of Perceived Exertion

Variable = **RPE**

Assessed at each training visit at time points 2,3,4,5, and 6.

Perceived exertion will be measured by the Borg Scale. The Borg Scale is displayed for participants throughout each training session. Individuals are read a script explaining the use of the scale (See script in Standard Operating Procedures Manual) and asked for a numeric value that represents their overall level of exertion. Responses will be recorded on paper forms.

4.1.3.2 Heart Rate

Variable = **HRmax**

Assessed at each training visit at time points 2,3,4,5, and 6.

Measures of heart rate will be taken via Polar H10 monitor and recorded on paper forms. The maximum heart rate reached by each participant will be reported as a percentage of the participant's heart rate maximum.

HRmax = 220 – participant's age

Individual Percentage of HRmax = (Measured HR/(220 – age)) *100

4.2 Efficacy Measures

4.2.1***Force Measures***
Variable = **Fz**

Assessed at each training visit at time points 3 and 5.

Measures of load force will be taken while the participant is ambulating on the treadmill during both Baseline gait (at minute 0-1 (BL1), minute 2-3 (BL2) and minute 4-5 (BL3)) and Post Training (during minute 0-1 (PT1), minute 3-4 (PT2), minute 6-7 (PT3) and minute 9-10 (PT4)). This will be recorded via force plates embedded under the treadmill belts. The magnitude of force in the downward, vertical direction (z) and time the force was exerted on each force plate (for each the paretic and non paretic limb) will be extracted and used for analysis. These forces and times will be multiplied to yield an impulse force, and symmetry ratios will be calculated from the impulse of the load force.

Impulse Force = Fmagnitude * Ftime

Force Symmetry = FzParetic/FzNon-paretic)

4.2.2***Spatiotemporal Measures***
Variables = **STANCE**
SWING
DS
StrLENSYM

StrLENGTH
StrVEL
10MWTIME

Assessed at time points 1,2,6,7, and 8 during a series of 3 instrumented 10-meter walk tests.

Participants will be instrumented with APDM® inertial sensors and perform a series of three, 10-meter walk tests (10MWT). Once sensors are placed, individuals will begin the test in a standing position at one end of a marked 14-meter path. They will be asked to walk to a line at the end of the marked path using the instructions, "***Please walk at a comfortable pace to the line at the other end of the hallway. Do you see the line?***". A member of the research team will tell the participant when to begin. A 10-meter section at the middle of the path will be labeled. A stopwatch will be used to time the participant during ambulation of the middle 10-meters. Time of ambulation for 10MWT (10MWTIME) will be recorded on paper forms. Other variable data (STANCE, SWING, DS, StrLENSYM, StrLENGTH, StrVEL) will be downloaded in .csv file format from APDM® Mobility Lab software.

Mean values of the three trials will be calculated:

$$\text{Mean} = (10\text{MWT}_{\text{Trial1}} + 10\text{MWT}_{\text{Trial2}} + 10\text{MWT}_{\text{Trial3}})/3$$

Mean values will be reported directly (10MWTIME, DS, StrLENGTH, StrVEL), or used to calculate symmetry ratios.

Symmetry ratios will be calculated from the mean values as follows:

STANCE Symmetry Ratio = (% of time in Stance Paretic/Non-Paretic Limb)

SWING Symmetry Ratio = (% of time in Swing Paretic/Non-Paretic Limb)
StrLENSYM Symmetry Ratio = (Stride Length Paretic/Non-Paretic Limb)

4.2.3***Balance Measure***

Berg Balance Scale
Variable = **BBS**

Assessed at time points 1,7, and 8.

This assessment is a 14-item test that has been validated in various populations (including individuals post stroke) to measure balance[41]. The items are performed in either seated or standing postures, and the total score reflects a quantitative measure of balance.

Scoring

Each of the 14 items is scored individually based on a numeric scale of 0 (unable to perform) to 4 (able to maximally perform task). The total score reflects a summation of each of the individually scored items (maximum score = 56). All BBS examinations were video recorded, and an external rater, blind to the study protocol and to testing order, scored the test based on the video recording.

5. Missing Data

Missing data will be identified as soon as possible after data collection and an attempt made to get as much information as possible about the data point in question. Missing data will be excluded from the final analysis. If a single variable has more than 15% of data missing, this variable will not be included for interpretation in the final results.

6. Outliers

Any unusual data points or measures will be reviewed for authenticity both during and after the trial. The influence of any outliers on the primary analyses will be checked. If any outliers are removed from the dataset, this will be reported along with the rationale for exclusion.

7. Study/Analysis Time Frame

The total time for individual participation in the study is three weeks. The participant will complete three initial (pre-test) assessments within one week. The following week s/he will receive the five-day training and the post-test assessment. The individual will return the third week for a single follow up assessment.

Statistical Analyses

Statistical assumptions and normality will be tested prior to running statistical analysis for measures of treatment tolerance, force symmetry, spatiotemporal gait parameters including stance symmetry and balance. A *p value* of 0.05 or lower will be considered statistically significant for all analyses.

1. Descriptive Analysis

We will report descriptive statistics (age, gender, side of impairment, time since stroke event, baseline functional ambulation scoring, and stroke impact scale scores) summarily. Graphs and/or tables will be used to represent descriptive data.

2. Analysis of Primary Outcomes

2.1 Primary Outcomes of Feasibility

2.1.1 Safety

All adverse events (related to participation) including any injuries or falls will be reported summarily in the final report.

2.1.2 Treatment Tolerance

Group means (SD) of Rate of Perceived Exertion (RPE) over the course of the intervention will be reported summarily for the group. A repeated measures analysis of variance (ANOVA) will be used to determine effect, or change of RPE over the course of the intervention (by day). The percentage of maximum heart rate (HRmax) will also be reported using descriptive measures (mean, standard deviation) for the group, and a repeated measures ANOVA used to assess for change over the course of the intervention.

2.1.3 Adherence

The proportion of adherence to the intervention will be reported descriptively as a percentage of total visits.

2.2 Primary Outcomes of Preliminary Efficacy

Prior to statistical analysis, a visual inspection of the data will be completed. Celeration lines with additional 2 standard deviation bands will be added to graphical representations of the data to aid in statistical analyses.

2.2.1 Load Force (Fz)

Mean values of Fz Symmetry Ratios will be compared over the course of the five-day training. Specifically, after normality is tested, either a Wilcoxan Signed Ranks test or a paired t test will be used to examine ratio values from the mean of Baseline Day one

to Post Training Day 5. These values will be reported with the associated level of significance. Effect sizes and 95% confidence intervals will also be calculated and reported in the final report. Results will also be presented graphically.

2.2.2 Stance Time Symmetry Ratio

Descriptive values (mean (SD)) of stance symmetry will be included in the final report. Mean values of Stance symmetry ratios will be analyzed using repeated measures ANOVA to first compare the relationship of the multiple pre-test measures. If there is no significant difference between the multiple pre-test measures, then the mean of the pre-test measures will be compared to measures at post-test and follow up also using a repeated measures ANOVA. Bonferonni corrections will be used to control for multiple comparisons. The F value and statistical significance will be reported with 95% confidence intervals and effect sizes. A graphical representation of the data will also be reported.

Secondarily, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3. Analysis of Secondary Outcomes

3.1 *Load force within session*

Descriptive statistics (Mean (SD)) of daily load symmetry will be reported. Within day comparisons of load force symmetry (mean of Baseline to same day Post

Training at each PT1, PT2, PT3, PT4) will be made using paired t tests (or Wilcoxan Signed Ranks tests) and reported with the appropriate t/Z statistic and p value. Effect sizes and 95% confidence intervals will also be calculated and reported in the final report. Results will also be presented graphically.

3.2 *Swing Symmetry Ratio*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of swing symmetry will be analyzed using repeated measures analysis of variance (ANOVA) to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance symmetry, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3.3 *Percentage of Time in Double Support*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of time in Double Support during the gait cycle will be analyzed using repeated measures analysis of variance (ANOVA) to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple

comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance and swing symmetry, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3.4 *Stride Length Symmetry Ratio*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of Stride Length Symmetry ratios will be analyzed using repeated measures analysis of variance (ANOVA) to compare to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance and swing symmetry and double limb support, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will

be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3.5 *Stride Length*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of Stride Length will be analyzed using repeated measures analysis of variance (ANOVA) to compare to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance and swing symmetry and double limb support, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3.6 *Stride Velocity*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of Stride Velocity will be analyzed using repeated measures analysis of variance (ANOVA) to compare to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported

with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance and swing symmetry and double limb support, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3.7 *Gait Velocity*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of Stride Length Symmetry ratios will be analyzed using repeated measures analysis of variance (ANOVA) to compare to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance and swing symmetry and double limb support, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

3.8 *Balance*

Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of raw scores on the BBS will be analyzed using repeated measures analysis of variance (ANOVA) to compare the mean of Pre-Test measures to measures at Post Test and Follow Up also using a repeated measures ANOVA. The F value and statistical significance will be reported. A graphical representation of the data will also be reported. Effect sizes and 95% confidence intervals will also be calculated and included in the final report. Descriptive statistics (Mean (SD)) will be calculated and reported. Mean values of Stride Length Symmetry ratios will be analyzed using repeated measures analysis of variance (ANOVA) to compare to compare the mean of the pre-test measures to measures at post-test and follow up. Bonferonni corrections will be used to control for multiple comparisons. Effect sizes, and 95% confidence intervals will be calculated and reported with the F/Z statistic and p value. A graphical representation of the data will also be reported. Similar to stance and swing symmetry and double limb support, a linear regression model of daily change over time will be created using change scores from the mean of the three Pre Test measures to Day 1 of training. Within day changes for each of the five training days and changes from daily Pre Testing and from daily Post Testing will also be examined with a regression over time. Results of the regression models will be used to determine the presence of a significant change over the course of the intervention and will be reported with the corresponding slope.

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