

PROTOCOL: MACHINES ASSISTING RECOVERY FROM STROKE

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**Study Title:** “Machines Assisting Recovery from Stroke: Robotic Activity Mobility Center in a Fitness Center for People with Neurologic Disability”

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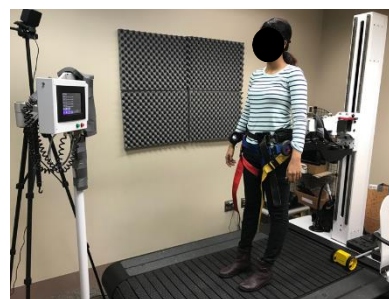
**OBJECTIVE:** We discuss our study protocol, which involved the use of five targeted training domains in the KineAssist®-MX robotic treadmill device aimed to challenge participants, who were at least four months post-stroke, in various walking conditions. The training domains were to provide similarities to real life walking challenges they may encounter during community-ambulation.

**Study Center:** All study meetings, participant assessments and training sessions were conducted at the UAB Locomotor Control and Rehabilitation Robotics Laboratory.

### METHODS/DESIGN: DEVICE

#### KineAssist®-MX

The KineAssist®-MX (KA-MX) is a self-driven treadmill that allows users to control the speed and direction (forward or backward) of the belt. Pelvic forces are detected by force transducers in the pelvic mechanism, and an embedded computer sets the velocity of the belt based on the amount and direction of the forces applied. It offers a body weight support mechanism, which allows individuals to freely practice a variety of exercises and skills that simulate real world activities while also catching the user in the event of an unintended fall or loss of balance.



**Figure 1.** User in KineAssist-MX device wearing the attached pelvic harness

### METHODS/DESIGN: PARTICIPANTS AND TRAINING

#### Inclusion Criteria:

1. Community dwelling unilateral stroke survivors
2. 19 years of age or older
3. 4 months or more post incident with residual hemiplegia
4. Able to ambulate at least 14 m with an assistive device or the assistance of one person
5. Have receptive and expressive communication capability
6. Approval of treating physician and voluntarily provided informed consent
7. Modified Mini-Mental State Exam score  $\geq 24$

#### Exclusion Criteria:

1. Significant and acute medical conditions or amputations
2. Spasticity management that included phenol block injections within 12 months or botulinum toxin injections within 4 months of the study
3. Any cognition involvement that impairs the ability to follow directions
4. Plans to move out of the area within the next year or no transportation to the study area

**Pre-Post Participant Evaluations**

Participants were evaluated by a licensed physical therapist (PT) at baseline, post-intervention and at six months post-study intervention to determine if the effects of the trainings were sustained. The PT was blinded to the biweekly trainings received by participants. The evaluations consisted of a Six-Minute Walk Test (Pohl et al., 2002) as a measurement of walking capacity, 10-Meter walk test (Bohannon, 1997) as an assessment of the participant’s slow and fast comfortable walking speeds, the lower extremity Fugl Meyer to quantify hemiparetic motor impairments (Mehrholz, et al., 2007), the Berg Balance Scale (Blum, 2008) as a measure of balance and fall risk, Geriatric Depression Scale (Yesavage, et al., 1982) as a measure of emotional state, Activities-Specific Balance Confidence Scale (Powell & Myers, 1995) as a measure of participants’ confidence in performing ambulatory tasks without loss of balance, Dynamic Gait Index (An, et al., 2016) as a measure of participants’ ability to modify balance demands during walking, Modified Mini-Mental State Exam (Folstein et al., 1975) as a measure of cognitive impairment (score  $\geq 24$ ), and the Stroke Impact Scale (Michaelsen, 2014) as a measure of health status post-stroke. Time points for when these evaluations were used throughout the study are seen in Table 1.

**Table 1. Participant Evaluations at Study Time Points**

| <b>Evaluation</b>                                  | <b>Baseline</b> | <b>Post-Intervention</b> | <b>6-Month Follow Up</b> |
|--|-----------------|--------------------------|--------------------------|
| 6-Minute Walk test                                 | X               | X                        | X                        |
| 10-Meter Walk Test                                 | X               | X                        | X                        |
| Activities-Specific Balance Confidence Scale       | X               | X                        | X                        |
| Berg Balance Scale                                 | X               | X                        | X                        |
| Geriatric Depression Scale                         | X               | X                        | X                        |
| Dynamic Gait Index                                 | X               | X                        | X                        |
| Lower Extremity FUGL-MEYER-Motor Function (Part 5) | X               |                          |                          |
| Modified Mini Mental State Exam                    | X               |                          |                          |
| Stroke Impact Scale                                | X               | X                        | X                        |

**Training Paradigms**

Participants had targeted biweekly trainings based on assessments (differs from PT pre-post evaluations). There were five training domains: hyperspeed, aerobic, strength, locomotor challenge, and balance (Table 2). Each biweekly training focus was selected based on the scoring of all domains assessed during biweekly assessments. Training sessions were three times a week and designed to last 30 minutes excluding time for setup and dismount (heart rate monitor, transition in and out of KA-MX device) and calculations (heart rate and blood pressure); however, it could also be longer depending on the number of rest breaks taken by participants allowing for individuation based on ability and comfort. Each session consisted of multiple bouts

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(5 minutes each) depending on the training domain. Participants were encouraged to aggregate bouts with training progression (i.e., minimize rest breaks). Manual assistance by research assistance was not provided during training except in the case of aiding participants training in the stepping domain.

**Participant Body Weight Support Determination:** The participant’s body weight support (BWS) was attained by use of a 10-meter walk test at 0%, 10%, 20%, and 30% BWS in the KineAssist-MX device. The lowest BWS that generated the highest comfortable walking speed (CWS)( $\geq 0.08$  m/s, FWS) was used for the training to allow for individualization of the training session. It was calculated for each training session.

**Heart Rate and Blood Pressure:** Heart rate (HR) and blood pressure (BP) was monitored throughout the training and during respective challenges/activities. Prior to training, the target heart rate was determined according to the Karvonen formula (Karvonen & Vuorimaa, 1988) and adjusted based on whether participants were on beta blockers. Participants targeted 60-80% of their heart rate reserve during the 30-minute training sessions. If they exceeded 80% of their heart rate reserve, participants were given a seated or standing rest break to allow their HR to fall below 60% of their target before continuing with training. Pre and post session training, BP was monitored. If it was too low or too high, participants were allowed to rest for approximately 10 minutes before their BP was rechecked. If it remained the same, they were dismissed to go home or to visit their primary care physician before returning for another visit. In some cases, participants were placed in the KA device and carefully monitored to see if their BP would remain the same (still low or still high) or improve. If it improved with exercise, then they were cleared to begin training; otherwise, they were allowed to go home.

**Table 2: The Five Targeted Training Domains**

| Training   | Purpose  | Bout Characteristics  | Performance measure(s)   |
|------------|--|---|--|
| Hyperspeed | To continually challenge participants to walk at their fastest successful speed without losing balance | Each bout consists of alternation between 40 s at CWS and 20 s at FSS<br><br>3 bouts of approximately 5 minutes each        | # of successes (i.e. no loss of balance) for FSS                                 |
| Aerobic    | To challenge participants to reach 60-80% of target HR reserve and build aerobic capacity              | Each bout consists of walking at 60-80% target HR reserve<br><br>6 bouts of approximately 5 minutes each                    | HR/min<br>RPE<br>Distance per bout<br>Total distance<br># of rests<br># of falls |
| Strength   | To challenge participants to walk against increasing horizontal resistance                             | Each bout consists of walking at a 12-step maximum force level for both legs<br><br>6 bouts of approximately 5 minutes each | Distance per bout<br>Total distance<br>HR  |

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|                     |   |  |   |
|---------------------|---|--|---|
| Locomotor Challenge | To provide nine locomotor challenges that simulate what an individual typically encounters while walking in the real world. | Each bout consists of one challenge<br><br>2 bouts per challenge of approximately 5 minutes each<br><br>3 challenges per day | HR/min<br>RPE every 2 min<br>Distance per bout<br># of rests<br># of falls  |
|                     | Long stepping (LS)  |  | LS - Max step length  |
|                     | Speeding up and slowing down (SU/SD)  |  | SU/SD – FSS   |
|                     | Head turns (HT)   |  | HT – success of head turns (i.e. no loss of balance)  |
|                     | Hurdles (H)   |  | H – successful max height clearance (i.e. no collision with hurdle)   |
|                     | Backward perturbation during forward walking (BP/FW)  |  | BP/FW – highest successful perturbation distance and velocity without loss of balance   |
|                     | Backward walking (BW)   |  | HR/min<br>RPE every 2 min<br>Distance per bout<br># of rests<br># of falls  |
|                     | Foam shoes (FS)   |  | FS – height of foam successfully used while walking   |
|                     | Narrow stepping (NS)  |  | NS - narrowest successful step width distance   |
|                     | Sideways walking (SW)   | HR/min<br>RPE every 2 min<br>Distance per bout<br># of rests<br># of falls   |   |
| Dynamic Balance     | To provide nine balance challenges to simulate what an individual might encounter in their day to day lives                 | Each bout consists of one challenge  | # of attempts<br><br># of successes (i.e. no loss of balance)<br><br>HR after each 5 min bout, when necessary<br><br>BP after each 5 min bout, when necessary |
|                     | Step onto Step (SOS)  |  | SOS - Highest step height without losing balance  |
|                     | Forward Step Length (FSL)   |  | FSL - Longest step without losing balance   |
|                     | Slippery Surface (SS)   |  | SS - Largest tilt angle held without losing balance   |

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|  |                                |   |   |
|--|--------------------------------|---|---|
|  | Stepping onto Foam (SF)        | 2 bouts (one per leg) per challenge of 5 minutes each<br><br>3 challenges per day<br><br>3 successful attempts (doesn't have to be consecutive) before moving on to next level within each 5 min challenge bout | SF - Highest foam height without losing balance   |
|  | Forward Perturbation (FP)      |   | FP - Greatest distance and velocity at which participant held their balance without taking a step due to perturbation     |
|  | Backwards Perturbation (BP/FW) |   | BP/FW - Greatest distance and velocity at which participant held their balance without taking a step due to perturbation  |
|  | Forward Reach (FR)             |   | FR - Farthest target distance participant is able to reach with their hand without losing balance                         |
|  | Sit to Stand (SST)             |   | SST - Lowest height participant is able to stand up from without losing balance and without using their hands for support |
|  | Hurdle (H)                     |   | H - Highest hurdle clearance without loss of balance or collision with hurdle   |

\*FSS = fastest successful speed, CWS – comfortable walking speed, HR = heart rate, RPE – rating of perceived exertion

**Training Domains:**

**Hyperspeed Domain**

The goal of the training was to challenge the participants to walk at their fastest successful speed (FSS) without loss of balance. The participant trained at their ideal BWS according to the BWS level determination (see above).

**Determination of FSS:** The participant targeted walking at a maximum of their CWS + 0.2m/s. The speed of the treadmill belt was gradually increased until reaching CWS + 0.2m/s. The participant was instructed to maintain that speed for 10 steps at a maximum of 20 seconds. Success or loss of balance was recorded, and the participant was asked whether they were willing to try a faster speed. If so, they were instructed to target the previously recorded FSS + 0.2m/s, and again to maintain the speed for 10 steps at a maximum of 20 seconds. This continued until five 20-second attempts at FSS were completed with incremental increases based on the previously successful FSS or the participant could no longer walk at the targeted speed or declined to go faster. Between FSS attempts, the participant gradually walked up to their CWS and maintained that speed for 40 seconds before targeting 10 steps at the FSS. This was repeated until the 5 rounds are completed whereby the participant walked for 40 seconds at their CWS. The bout lasted approximately five minutes.

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The participant was allowed to rest for 2-3 minutes (seated or standing based on preference) and their heart rate was checked to ensure that it fell below their 60% target before continuation with the next five-minute bout. The training process was repeated until three total bouts were completed. The next training session used the FSS from the previous session as the initial target of the first bout.

### **Aerobic Domain**

This domain allowed the participant to walk for six 5-minute bouts on the treadmill without stopping unless the participant requested to do so as a rest break or their target heart rate exceeded 80% of their heart rate reserve target. BWS support was selected based on the BWS level determination. Heart rate was recorded every minute and the participant was asked to rate how hard they perceived themselves to be working after every two minutes according to the Borg Scale (rating of 6 – 20; Noble et al., 1983; Borg et al., 1987). This was done to have both a physiological and subjective measure of exertion. We were interested to know if both measures were correlated.

After completion of each 5-minute bout, the participant was given the option to continue for another five minutes or rest. The process was repeated until a full 30 minutes of training was completed. Distance was recorded using a Stanley wheel placed at the front of the treadmill belt to measure the distance of the moving belt during each 5-minute bout yielding total distance traveled by the participant.

### **Strength Domain**

BWS was selected according to the BWS determination level. The participant was instructed to walk at their CWS for 30 seconds then for 12 steps (with both legs) with the addition of the appropriate amount of horizontal resistance.

***Resistance Determination:*** Resistance was applied by selecting a deadband level of force (i.e. amount of force required to initiate belt movement using the self-drive mechanism of the KineAssist-MX). For the first bout of the session, the participant targeted  $\pm 20\%$  of their CWS and an initial deadband of 5N. Additional 5N was added if the initial +5N was insufficient to reduce speed by 20%. For every 12-step interval, 5N was added to increase the challenge level. The task was considered “too hard” only when there was a 20% drop in walking speed. Following the 12 steps, deadband was returned to a default of 2N and the participant was allowed to walk again for 30 seconds at CWS. If training was not the first bout of the first session, the bout began with the highest level of deadband from the past session. Deadband was then added or removed throughout the bout as tolerated by the participant.

Each session consisted of six bouts of approximately five minutes totaling 30 minutes. It was therefore formatted as five intervals comprising of the 1<sup>st</sup> 30 seconds at CWS, 1<sup>st</sup> 12 steps at resistance, 2<sup>nd</sup> 30 seconds at CWS, 2<sup>nd</sup> 12 steps at resistance up until the 5<sup>th</sup> interval. Heart rate was recording between intervals (i.e., directly after completion of 12 steps at respective deadbands).

### **Locomotor Challenge Domain**

Tasks were demonstrated prior to starting. BWS was selected according to BWS determination level.

**Long stepping:** This test was designed to train the participants to take long steps in order to simulate common challenges posed in the real world of stepping over environmental hazards, such as puddles of water or potholes. The participant was instructed to walk at their CWS and take the longest step he/she can with the non-paretic leg. After examination of the participant's heel strike position (point 0), an infrared laser was aligned with that position and the participant was instructed to step over the laser line while walking. Successful completion of a trial constituted 5 consecutive strides (5 steps each leg) taken with heel strike at or past the laser line. Three tries are given to pass each trial. Passing resulted in the increase of laser position by one inch.

**Speeding up and slowing down:** This task was used to simulate and help improve the speed up and slow down one does throughout ambulation. Using the speed up/slow down setting in the KA-MX device, "nominal speed" was set to the participant's CWS, "hold time" was set to 10 seconds, "plus/minus" was set to  $\pm 0.2$  m/s and "trials" was set to 30 and thus constituting five minutes for a bout. The participant was encouraged to walk whereby the green trace on the KA device screen matched the yellow goal line. The device essentially sped up and slowed down, and the participant was instructed to keep up with it as best as they could.

**Head turns:** This task was designed to simulate the need to turn and observe different directions during ambulation without losing balance. The participant began by walking at their CWS. At 10 second intervals, they were instructed to turn their head either up, down, left or right and to maintain the position for 10 seconds. If this task was too easy, then we added shaking the head left and right, and up and down. Successful maintenance of CWS with their head turned resulted in slow-fast combinations of the sequences such as "look up and down, close your eyes, open your eyes and look forward." This cycle continued per each minute of training.

**Hurdles:** This task simulated and trained for stepping over objects in the environment. The participant was instructed to step over a hurdle positioned at a 2-inch height in front of their non-paretic leg while walking at their CWS. The height was lowered if the participant could not step over the given height. If there was consistent clearance of the hurdle, however, there was an increase in one inch of the hurdle height, until the person was just barely able to clear the hurdle. This was practiced for 5 minutes per foot (i.e., one bout per foot).

**Backward perturbation during forward walking:** This task was designed to simulate the interruptions (other people or objects) encountered during walking and improve the individual's reactionary balance control. The perturbation push program on the KA device was set to a default of 0.48 peak velocity and 0.40 distance. The participant was allowed to walk at their CWS and once reaching steady state, backward perturbation was introduced approximately every 10 seconds. If the perturbation was tolerated well by the participant (i.e. no loss of balance), the distance and peak velocity was increased by intervals of 0.1 on the device. This continued until the perturbation posed a challenge to participants and was repeated for the second bout after a 2-3-minute rest break.



***Backward walking:*** This task simulated the act of walking backwards without the loss of balance. The participant was instructed to walk backwards in the KA device for 5 minutes (one bout) at a speed that attained their target HR. In any event that the participant fell with the KA safety catch was engaged, the task was reset on the device and the 5-minute period continued uninterrupted.

***Walking with foam shoes:*** This task simulated walking on uneven surfaces and surfaces of varying height, and also intended to improve the participant's proprioceptive ability. Foam blocks were attached to the participant's shoes while seated in the device. We had two heights, 2" and 4" and initially began with the thin foam. The participant was instructed to put their weight into the shoes to avoid slack and walk at their CWS to attain target HR. If the foam size did not pose a struggle for the participant (i.e., successful maintenance of CWS), it was changed to thicker foam (4 inches) until reaching the 5-minute stopping point for the bout before continuing to the next bout.

***Narrow stepping:*** This task was designed to simulate narrow steps one has to take in an environment with a narrow walking path (e.g. hallway). The participants were instructed to take the narrowest step that they could. A laser beam was fitted to this narrowest step. The goal was to challenge the participant rather than induce a loss of balance. Once the step width distance was determined, the participant was instructed to walk at their CWS within that width for 5 minutes (one bout). The trial was repeated for the second bout.

***Sideways walking:*** This task was designed to simulate sideways walking in the environment when one is required to turn to maneuver a path. The participants were instructed to walk sideways towards their affected or weaker limb at their CWS for 5 minutes. The goal was to walk without a loss of balance and attain target HR with appropriate speed increases. For the second 5-minute bout, they were instructed to walk sideways towards their non-affected or stronger leg.

### **Balance Domain**

This domain challenged participants by introducing various balance tasks that simulate real life activities participants may encounter. The goal was to determine the highest level of each activity they could perform, successfully repeating it three times within 5 minutes of training nonconsecutively per bout before moving on to the next level of difficulty within the 5-minute timeframe. For all nine challenges, one challenge bout trained with one leg leading and the next bout trained with the opposing leg leading. The tasks were demonstrated prior to starting.

***Step onto Step:*** This simulated the act of walking up and down stairs in an environment. The participants were instructed to first step up with their right or left leg and the other leg following, and then back down leading with leg they stepped up with first. It was repeated as many times as needed within the 5-minute bout timeframe until 3 successful attempts were completed. The steps were progressively increased by 1-inch intervals following successful completion of the task without a loss of balance until 5 minutes was up.

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**Forward Step Length:** To determine the participants' longest step, they were instructed to take the longest step they could leading with their right or left leg without losing their balance. It was repeated two more times. The longest step out of the three was used as the initial training goal. A laser beam was aligned with that distance and participants were instructed to use their right or left heel to pass the laser beam then bring the other leg to meet it ensuring that both heels pass the laser beam. Once the task was successfully completed 3x, the step length was increased by 1 inch. If the participant failed to successfully complete the task, they continued to train at the longest step length until 5 minutes were up.

**Slippery Surface:** Participants were instructed to step onto a slippery surface plate leading with their right or left foot then followed by the other foot to determine what level they were able to stay on the surface without sliding/slipping off. They were to attempt to hold the step for three seconds before stepping backwards off the surface leading with their right/left foot. Starting off, the slippery surface was set to an angle of 0°. The level of slipperiness was increased by 1° until the task was successfully completed three times. Participants were trained at the level of slipperiness at which they could not hold on for three seconds three times.

**Stepping onto Foam:** Similar to stepping onto step, participants stepped onto the foam leading with their right/left leg followed by the other leg and then stepped back down with the leading leg. The foam was progressively increased by two inches as long as participants successfully completed the task three times.

**Forward Perturbation:** Participants stood comfortably in the KA device with their eyes facing forward and walked at CWS. Forward perturbation was introduced (default of 0.48 peak velocity and 0.40 distance) by the device so that participants were pushed at the waist and instructed to hold their balance without taking a step. If a step was needed, it was done with the designated foot used for the bout training (right or left). After taking the step, they returned their foot back to the starting position. The perturbation was gradually increased (0.1 increments) after three successful attempts to push the participants harder until they were forced to take one and then two steps. The goal was to train participants at the level at which they needed to take two steps to recover their balance until they were able to take only one step.

**Backwards Perturbation:** Similar to forward perturbation, participants stood comfortably in the device with their eyes forward and walked at CWS. They were pulled backward at the waist and instructed to try to hold their balance without taking a step. Only one step was required if a step was needed to catch their balance. It was to be taken with the designated foot used during bout training and returned to the starting position. The level was increased after the defined successful attempts. Training was conducted at the level at which they took more than one step until they were able to take only one step.

**Forward Reach:** Participants stood straight and tall in the device with eyes facing forward and one foot behind the other (feet are foot length apart with front foot ahead of back foot). They were instructed to ball their non-paretic hand into a fist and use it to reach forward as far as they could without losing their balance. They were to touch a target located in front of them with their fist. Upon touching the target, they were to stand up as quickly as they could without losing their balance. The distance of reach was determined, and the forward reach was repeated two more

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times. With three successful attempts, the target was moved an inch out for the next level, and participants were trained at the farthest distance reached. It was repeated with both feet in front of them.

***Sit to Stand:*** The goal for this challenge was to have the participant stand up from the lowest seat level possible without a loss of balance or the aid of their hands for support. They were to sit down on a step with their right/left foot in front of the other and stand without using their hands for support or changing their feet position. Three successful repetitions resulted in lowering the seating distance by 1-inch increments until failure until the participant fails to complete 3 repetitions. Participants were then trained at that level.

***Hurdle:*** Participants' step height was first determined. They were instructed to step over the hurdle with their right/left leg then bring the other leg over to meet it. Step height was increased by increments of one inch until participants were unable to clear the hurdle height. Training was conducted at the highest height reached until three successful clearance attempts were attained before increasing the height by 1-inch for the next level.

### **Stepping Domain**

Participants were trained on stepping if they came into the study with a very low level of walking ability whereby they were unable to complete the assessments. They were trained on taking steps in the KA device during the training sessions. After two weeks of training, an assessment will be attempted. If they were not able to complete the assessment, then they returned to step training; otherwise, they moved forward with the appropriate training domain as dependent on the assessment scores. Notice the expected progression of standing levels within the standing category as indicated in Fig 1. Because taking steps were often a challenge for participants, they may require the assistance of the research assistant to give them a push forward to initiate or increase steps taken using the KA force sensor or joystick mode as well as to help participants get into their target HR zone.

### **Assessments**

Participants were assessed at biweekly intervals during the 10-week training period by a graduate research assistant to determine what training was to be conducted for a two-week period (Table . The first assessment was conducted on the second visit (after PT initial evaluation) to determine what training domain to begin with. There were six assessments in total (initial, end of week 2, end of week 4, end of week 6, end of week 8, and final – end of week 10). The following assessments after the first, evaluated participants beginning with the highest level achieved in the previous assessment for each domain.

**Table 3. Biweekly Targeted Assessment Domains**

| <b>Assessment Domain</b>        | <b>Instruction</b>  | <b>Performance Measure</b>                     |
|---------------------------------|---|--|
| Comfortable walking speed (CWS) | “Walk at your comfortable walk speed.” Participants walk a total of 10m while achieving steady state speed. | Average meters/sec                             |
| Strength                        | “Walk as fast as you can against the resistance.” Participants  | Max resistance calculated by extrapolating the |

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|                                   |   |  |
|-----------------------------------|---|--|
|                                   | first walk against 5 lbs resistance and then researcher adds 1 lb per each 0.1 m/s attained until the participant cannot achieve 0.2 m/s. | predicted resistance value at which the participant would not be able to move the treadmill belt.                              |
| Dynamic Balance:                  |   |  |
| 1. Forward Reach                  | 1. "Reach with non-paretic hand balled into a fist towards target while facing forward and bending at the waist"                          | 1. Initial position of outstretched fist of self-determined reach; final successful position (i.e., farthest distance reached) |
| 2. Forward Step with Perturbation | 2. Forward perturbation during forward walking at CWS without losing balance and steadying oneself with only one step                     | 2. Max perturbation treadmill belt displacement; Max speed at max step length  |
| 3. Step Up Test                   | 3. Using involved limb to step up on a step with progressive height increases without loss of balance                                     | 3. Max height when leading with the involved limb  |

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|   |   |  |
|---|---|--|
| <p>Locomotor Challenge:</p> <ol style="list-style-type: none"> <li>1. Max Step Length</li> <li>2. Narrow Stepping</li> <li>3. Walking with Backward Perturbation</li> </ol> | <ol style="list-style-type: none"> <li>1. Participants were to take long steps towards a laser beam target (heel strike past laser beam) at their CWS; Progressive increase in distance by 1 inch</li> <li>2. Participants were to walk at their CWS within a laser beam target of certain widths, which progressively narrowed if successful at the previous width target</li> <li>3. Participants walked at CWS. With introduction of perturbation, they were to catch themselves without a loss of balance. If successful, perturbation was successfully increased until failure; Initial assessment setting of perturbation was 0.48 m/s initial speed and 0.4 m as distance</li> </ol> | <ol style="list-style-type: none"> <li>1. Position of final successful attempt; Total step length (final-initial)</li> <li>2. Width between feet (right light guide position and left light guide position)</li> <li>3. Max step length; Max speed at max step length</li> </ol> |
| <p>Maximum Walking Speed</p>  | <p>Participants started walked at the fastest speed attained during the 10-meter walk test done within the device + 0.2 m (if first assessment)</p> <p>Progressive increase in speed of 0.2 m until failure</p>   | <p>Speed of failure; Final successful walking speed (speed of failure – 0.2)</p>   |
| <p>Aerobic Endurance</p>  | <p>Stages 1 – 10 (1 min/stage)</p> <p>Participants were to walk at targeted deadband magnitudes of resistance (lbs.) per stage</p>  | <p>Test termination time; stage of test at termination</p>   |

**Scoring the Assessments**

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Scoring for each domain of the assessment categorized performance as levels 0 to 3 (0 – basic, 1 – developing, 2 – competent, and 3 – expert). The participant’s lowest scored domain was their targeted training for the following two weeks. Within domain where multiple activities were assessed, the scores of were averaged to obtain an overall score. In the event of a tie of scores between domains, the domain not previously trained was targeted. It was also possible for participants to remain training at the same domain after each round of assessment based on scoring. Figure 2 shows detailed scoring breakdown for the assessments.

**Figure 2. Assessment Scoring Sheet**

| Level         | Sit-stand                                       | Standing  | Stepping   | Walking  | Strength                 | Speed                       | Endurance                     | Balance  | Locomotor Challenge  |
|---------------|---|---|--|--|--------------------------|-----------------------------|-------------------------------|--|--|
| 0: Basic      | Pt requires >50% BW assistance (standard ht)    | Pt requires >50% BW assistance (standing mode)        | suspended stepping mode (assistance with advancing one or more legs) | Pt requires BW assistance (walking mode)                           | max force value <10 lbs  | top speed of <0.5 m/s       | unable to complete 1st 2 mins | FR=not > than initial reach; PUSH<.40 m AND 0.48 m/s; STEP UP=1 in or less                                     | STEP LENGTH 2 in or less; PULL<.40m AND .48 m/s; NARROW >3 shoe widths   |
| 1: Developing | Pt requires 1% –50% BW assistance (standard ht) | Pt requires 1% –50% BW assistance (standing mode)     | suspended stepping < 0.5 m/s (no assistance with leg advancement)    | Pt requires does not require BW assistance <0.5 m/s (walking mode) | max force value <14 lbs  | top speed of <1.0 m/s       | 2 mins -4 mins                | FR=2 in or less beyond initial reach; PUSH between .40 - .59 m AND >0.48 - .74 m/s; STEP UP between 2 - 5 in.  | STEP LENGTH between 3 and 6 inches; PULL between .40 - .59 m AND >0.48 - .74 m/s; NARROW between =2 shoe widths to 3 shoe widths |
| 2: Competent  | Pt does not require BW assistance (standard ht) | Pt does not require BW assistance (standing mode)     | suspended stepping < 1.0 m/s (no assistance with leg advancement)    | Pt requires does not require BW assistance <1.0 m/s (walking mode) | max force value <26 lbs  | top speed of <2.0 m/s       | 4+ mins - 8 mins              | FR between 3 -6 in beyond initial reach; PUSH between .60 - .80 m AND 0.74 - .90 m/s; STEP UP between 6-10 in. | STEP LENGTH between 7 and 10; PULL between .60 - .80 m AND .74-.90 m/s; NARROW between <2 shoe widths to >1 shoe widths          |
| 3: Expert     | Pt does not require assistance (>4 in. ht)      | Pt does not require assistance (>6 with walking mode) | suspended stepping > 1.0 m/s (no assistance with leg advancement)    | Pt does not require assistance > 1.0 m/s                           | max force value >=26 lbs | top speed of > or = 2.0 m/s | 8 mins+                       | FR > 6 in. beyond initial reach; PUSH > .80 m AND .90 m/s; STEP UP >10 in.                                     | STEP LENGTH >10 in.; PULL > .80 m AND .90 m/s; NARROW =1 shoe width  |

Pt - participant, FR - forward reach, BW - body weight, PUSH – forward perturbation, PULL - backward perturbation

**Statistical Analysis Plan:**

Statistical analysis will be performed using Repeated measures ANOVA (subject x pre/post). Primary outcome measures will be pre vs post changes in BBS (primary balance measure), in the 10m walk test speed, and 6 minute walk test distance. Secondary measures will be pre vs post changes in the Stroke Impact Scale (SIS) – Mobility Score, and the ABC. A significance level of p<0.05 will be used to determine statistical significance.

References

- Billinger S, A.R., Bernhardt Julie, Eng Janice,, Physical Activity and Exercise Recommendation for Stroke Survivors: A statement for health care professionals from the American Heart Association/American Stroke Association. Stroke American Heart Association, 2014. PMID: 24846875, DOI: 10.1161/STR.0000000000000022
- Karvonen, J. and T. Vuorimaa, Heart rate and exercise intensity during sports activities. Practical application. Sports Med, 1988. 5(5): p. 303-11. PMID: 3387734
- Tabet, J.-Y., et al., Determination of exercise training heart rate in patients on  $\beta$ -blockers after myocardial infarction. European Journal of Cardiovascular Prevention & Rehabilitation, 2006. 13(4): p. 538-543. PMID: 16874142 DOI: 10.1097/01.hjr.0000209813.05573.4d
- Noble, B.J., et al., A category-ratio perceived exertion scale: relationship to blood and muscle lactates and heart rate. Medicine and science in sports and exercise, 1983. 15(6): p. 523-528. PMID: 6656563
- Borg, G., P. Hassmén, and M. Lagerström, Perceived exertion related to heart rate and blood lactate during arm and leg exercise. European journal of applied physiology and occupational physiology, 1987. 56(6): p. 679-685. PMID: 3678222
- Pohl, P.S., et al., *Influence of stroke-related impairments on performance in 6-minute walk test.* Journal of rehabilitation research and development, 2002. 39(4): p. 439. **PMID:** 17638141
- Bohannon, R.W., *Comfortable and maximum walking speed of adults aged 20—79 years: reference values and determinants.* Age and ageing, 1997. 26(1): p. 15-19. **PMID:** 9143432
- Mehrholtz, J., et al., *Predictive validity and responsiveness of the functional ambulation category in hemiparetic patients after stroke.* Archives of physical medicine and rehabilitation, 2007. 88(10): p. 1314-1319. **PMID:** 17908575 DOI: [10.1016/j.apmr.2007.06.764](https://doi.org/10.1016/j.apmr.2007.06.764)
- Folstein, M.F., S.E. Folstein, and P.R. McHugh, "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res, 1975. 12(3): p. 189-98. **PMID:** 1202204
- Blum, L. and N. Korner-Bitensky, *Usefulness of the Berg Balance Scale in Stroke Rehabilitation: A Systematic Review.* Physical Therapy, 2008. 88(5): p. 559-566. **PMID:** 18292215
- An, S., et al., *Validity of the Original and Short Versions of the Dynamic Gait Index in Predicting Falls in Stroke Survivors.* Rehabilitation Nursing, 2016: p. n/a-n/a. **PMID:**

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Powell, L.E. and A.M. Myers, *The activities-specific balance confidence (ABC) scale*. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 1995. **50**(1): p. M28-M34. **PMID:** 27278685

Yesavage, J.A., et al., *Development and validation of a geriatric depression screening scale: a preliminary report*. J Psychiatr Res, 1982. **17**(1): p. 37-49. **PMID:** 7183759

Michaelsen, S., *Stroke Impact Scale*, in *Encyclopedia of Quality of Life and Well-Being Research*, A.C. Michalos, Editor. 2014, Springer Netherlands: Dordrecht. p. 6365-6368.