Gait Training Combined With Behavioral Strategies for People With Stroke

Study Protocol & Statistical Analysis Plan

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1. Study Protocol

Although a variety of strategies to improve motor function of the paretic lower extremity after stroke have been developed in the past two decades, there is still no consensus on the best intervention to improve walking and mobility impairments. One of the most common interventions to address walking after stroke is treadmill training with and without body weight support (BWS). These modalities have produced significant improvements in walking speed and endurance during and immediately after the intervention. Yet, motor function improvements are not maintained on follow-up assessments and there is no clear evidence of how well improvements transfer to everyday situations.

While the above strategies focus on step repetition and increased exercise intensity, strategies focusing on behavior management in rehabilitation protocols could promote long-term recovery of function by encouraging participation in activities outside clinical settings or research protocols. In fact, the combination of motor training with behavior management strategies has been shown to be an effective mechanism to produce long-lasting improvements in motor function in real life situations in people with stroke. However, few studies using behavior management strategies for lower extremity (LE) function for people with stroke have been published. Preliminary studies on the effectiveness of motor training combined with behavior management strategies showed significant improvement in real-world use of the paretic LE. In these studies, the systematic and structured application of a group of strategies called the Transfer Package (TP) was associated with the lasting effects.

This study aimed to investigate the effect of BWS gait training in a robotic treadmill with the TP on (1) changes on walking speed, endurance, motor function and use of the affected LE, and (2) long-term retention of improvement on these outcomes.

This study was approved by the Institution Review Board (IRB) at the University of Alabama at Birmingham (IRB-300005407-006). All participants signed an informed consent form prior to their inclusion in this study. Nineteen individuals in the chronic phase of recovery after stroke were included in this parallel pilot randomized trial of a robotic treadmill gait protocol combined with behavior management strategies.

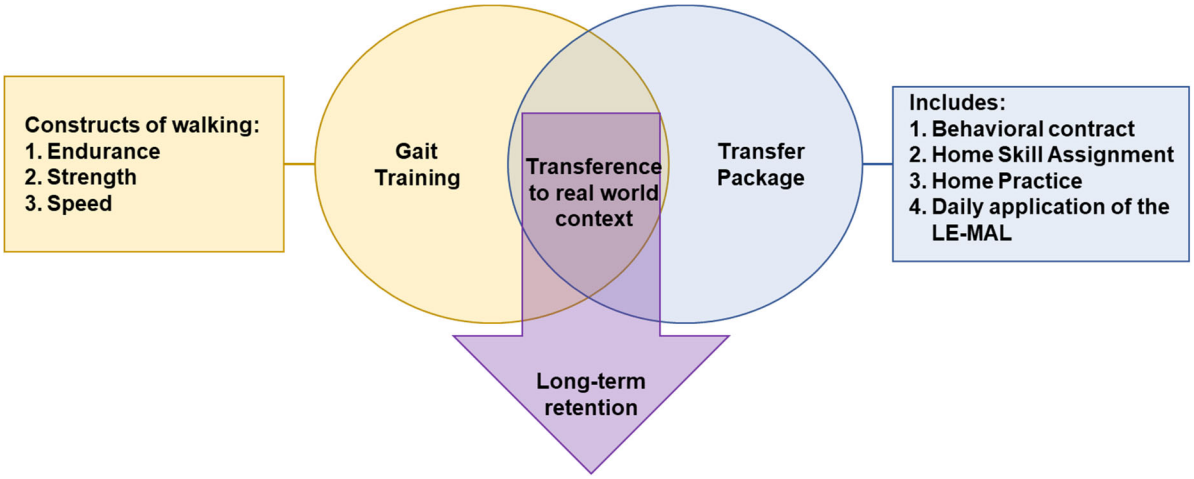
All participants received a 6-week intervention that consists of 30–60 minutes of Treadmill Training (TT) sessions, depending on the individual`s endurance. The experimental group also received a group of behavioral strategies called the “transfer package” (TP) for 30 minutes after each training session. On the first day of the intervention, the control group (TT) received a handbook with exercises and stretching techniques suggested by the American Stroke Association (ASA). Participants were assessed immediately before and after the intervention, as well as 3 and 6 months after the intervention. All participants received the same TT, which consisted of 18 sessions distributed over 6 weeks (Figure 1). The TT sessions were divided into endurance, strength, and walking speed training, with six sessions for each of these modalities (Figure 1).

Figure 1. Modalities of Treadmill Training

The intervention group (TT+TP) received the TT combined with the TP (Figure 2). The original TP is an element of the well-established Constraint-induced Movement Therapy. Participants were asked to sign the behavioral contract (BC). The purpose of the BC is to

ensure that participants: (1) perform tasks with the affected LE in a safe manner, (2) increase use of the more-affected LE in daily tasks, and (3) increase coordination between both LEs. Additionally, the behavioral contract formally engages the patient in actively exploring more ways to use their more-affected LE outside the clinical setting and in adopting a problem-solving approach to accomplish that end.

Figure 2. Combined intervention model



During the 6-week intervention and after every TT session, a new HSA was developed. Each list included up to 10 tasks or exercises to be performed daily between the TT sessions. The list was reviewed at the next session by the therapist, to check: 1) if all activities were performed and 2) if there was any challenge in the participant's performance that should be addressed (e.g., level of difficulty of the task and safety).

The use of the affected limb was assessed in all treatment sessions through the administration of the LE-MAL. A full description of the LE-MAL is provided in the outcomes section.

The last component of the TP is the Home Practice (HP), which is a list of exercises that the participant should do daily after the end of the treatment period. This list was given to the participant at the end of the last day of the intervention. The purpose of the HP is to assure continued progress with LE use after the intervention program is completed. The expectation was that engagement in home practice would help individuals maintain the changes observed due to the intervention.

The control group (TT) received the same treadmill training described above and also received a list of exercises at the beginning of the intervention (i.e., session 1). The handouts were based on videos provided by the American Stroke Association (available at https://www.stroke.org/en/life-after-stroke/stroke-rehab/post-stroke-exercise-videos). All participants received the same list of exercises.

2. Statistical Analysis Plan

An initial sample of 24 individuals would be selected for this pilot trial. However, due to time and recruitment constraints faced by the PI during the SARS-COVID pandemic, this sample size dropped. A total of 19 people with chronic stroke were selected and were randomly allocated using a 2:1 ratio to either TT+TP (N = 12) or TT group (N=7). Individuals were allocated using an online randomization tool (randomization.com, first generator).

The primary outcomes were the Lower Extremity Motor Activity Log (LE-MAL), Berg Balance Scale (BBS), 10 Meter Walking Test (10MWT), and 6-minute walking test (6MWT). The secondary outcomes were: 5 times sit to stand (5TSTS), and the Fear of Falling Avoidance Behavior Questionnaire (FFABQ).

Assessments were administered pre- and post-treatment, and at follow-up visits (3 and 6 months after the end of the intervention protocol). Each assessment visit lasted approximately 60 minutes and was conducted by a physical therapist blinded to group assignment.

Demographic characteristics including age, gender assigned at birth, chronicity, ethnicity, race, and NeuroQoL score were reported by frequency (%) mean and standard deviation, or range. Due to the small sample size, a descriptive analysis was conducted, and results are shown in mean scores and standard deviation in each time point. The average scores at post-treatment, 3 months follow up and 6 month follow up visit were compared to the average scores obtained at pre-treatment. The differences were compared to the Minimal Clinically Importance Difference (MCID), or Minimal Detectable Change (MDC) of each outcome, if reported in the literature, to identify

significant changes since statistical analysis was not conducted due to the small sample size.