Combined Functional Electrical and Transcranial Direct Current Stimulation for Foot Drop

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No NCT # yet

Study Protocol and Statistical Analysis Plan

This study will employ a randomized controlled design. The control group will receive functional electrical stimulation (FES) combined with walking therapy, which previous meta-analyses have shown to be more effective than walking therapy alone, along with sham transcranial direct current stimulation (tDCS), where the machine is set up but not activated. The intervention group will be treated with FES combined with walking therapy and active tDCS. This study is single-blinded, meaning that only the participants will be unaware of their group assignment, with sham tDCS facilitating this blinding. A random number generator will assign each participant to either the treatment or control group at baseline. The treatment will occur twice a week for a total of 8 weeks. Evaluations will be conducted at 3 time points: at baseline (time zero), after 4 weeks, and following the completion of the 8-week treatment.

Intervention

The tDCS will be applied using electrodes placed on specific cranial locations to target the motor areas associated with the impaired lower extremity. These motor areas will be determined using the cortical homunculus model. This model shows the motor and sensory distribution to the parts of the body along the cerebral cortex. The exact locations for the electrode placements will be determined based on a 20-point electrode system, in which we chose two points that targeted the motor cortex region corresponding to the left lower limb. As for the dosage of the tDCS device,

the subject will undergo a 40 mA-min for 60 minutes. This procedure was developed with Dr. Gregory Thielman, who had special training in the tDCS modality.

The second intervention will be FES. Functional Electrical Stimulation will be administered to the tibialis anterior muscle of the impaired lower extremity. Electrodes will be placed on the muscle belly and the common peroneal nerve to stimulate contraction, enhancing dorsiflexion. We first find the motor point on the muscle belly, and stimulation is done with one electrode over the motor point and the other over the common peroneal nerve at its most superficial location around the fibular head. The FES parameters will be set to achieve a visible and functional muscle contraction appropriate for each subject for 60 minutes. We will set the current to be continuous, using a heel strike pad to control the on and off times. The exact role of the heel strike pad is to switch off the stimulation when standing to allow for the appropriate plantar flexion required during the gait cycle. When the heel strike pad is no longer pressed, the stimulation will be turned back on, enhancing dorsiflexion.

Procedure

During each session, participants will be equipped with the appropriate stimulation device(s) based on their specific treatment group. The walking therapy treatments will consist of functional exercises to improve dorsiflexion and overall control of foot drop. Before and after each session, the participant's vital signs will be recorded to monitor the effects of the treatment and to assess any contraindications based on their blood pressure readings.

The exercises involved in each session will primarily focus on walking tasks. These tasks will include treadmill walking (both forward and backward), ramp walking (both forward and backward), stair climbing (both upward and downward), walking over obstacles, and actively assisted dorsiflexion while using the FES device. The intensity of the exercises will be monitored

using the participant's heart rate, measured with a pulse oximeter, along with the Rating of Perceived Exertion (RPE) scale, which ranges from 6 to 20, to determine how hard the participant is working.

We will utilize training sheets to track the exercises performed during each session. These sheets will enable researchers to observe improvements and determine appropriate modifications to ensure safe and effective treatment in subsequent sessions. All treatment sessions are anticipated to last 60 minutes.

Data Collection

Three-time points of outcome measure data collection:

1. Baseline (pre-intervention): Before the beginning of phase one, 2-3 hours
2. Mid-intervention (week 4): 2-3 hours
3. Post-intervention (week 8): End of study within two weeks of completing the exercise intervention 2-3 hours

Outcome measures included Kinematic Motion Capture, Functional Gait Assessment (FGA), Activity-specific Based Confidence scale (ABC scale), Walk-12, Lower extremity Fugl-Meyer Assessment, and the Stroke Impact scale. A Kinematic Motion Capture system (Vicon) was used to evaluate the toe clearance, ankle joint angles, and walking speed. Motion capture methods include:

Participants will be fitted with a modified Cleveland Clinic marker set where 4 clusters of 4 markers were attached to the thighs and shanks, and wand-mounted markers will also be attached bilaterally to the anterior superior iliac spines (ASIS) and sacrum. Additionally, six 14 mm reflective markers will be attached to the shoe at the upper ridge of the posterior surface of the

calcaneus, sustentaculum tali, and lateral aspect of the calcaneus (peroneal tubercle), and the heads of the first, second, and fifth metatarsal (MET). In Visual 3D (C-Motion, Maryland, USA), a single-segment foot will be built with the 1st and 5th MET head markers and a virtual ankle joint (constructed from virtual markers of the lateral and medial malleoli) using the calibrated anatomical system technique (CAST) described by Cappozzo et al.[24,25]

During each testing session, all participants will complete 25 walking trials, each at a self-selected normal walking speed. Eight infrared cameras (Bonita 10 cameras, VICON Nexus software v.2.15.0, Oxford, UK) recording at 100 Hz will capture the maker trajectories in the central 7 m of a 20 m walkway. Participants will begin walking a minimum of 2.5 m before the cameras' collection volume to achieve steady-state walking.

Lastly, we will monitor the patient's walking activity throughout the study's timeframe with activity monitors that the participants will wear on their wrists. Data will be collected during a 1-week window before and throughout the training and then a 1week window post-training. Weekly averages will be gathered to analyze this data.

Data analysis: The marker data will initially be processed in Vicon Nexus 15 software (Oxford, UK), where marker labeling and gap filling are performed. In Visual 3D (C-Motion, Maryland, USA), marker trajectories will be first interpolated for gaps less than 10 frames (0.1s) if present using a 3rd-order polynomial and then filtered. The filter was a zero-phase shift, low-pass, 4th-order Butterworth filter with a cut-off frequency of 6 Hz. To determine the joint angles, 3D marker trajectories will be processed with Visual 3D pipelines using the Cardan rotation sequence X-Y-Z to derive joint angle data. For flexion-extension movements in the sagittal plane, rotations were characterized around the mediolateral (X) axis. The gait events, heel strike, and toe-off were identified using kinematic data with an automated program in Visual 3D.[26] All

events were verified by visual inspection. Next, Visual 3D's metric compute temporal distance command will be used to calculate temporal distance gait parameters from the gait events. Visual 3D's (C-Motion, Maryland, USA) Landmark function will be used to define the virtual points. A digitizing pointer will be used during the static calibration trial to create the virtual markers (Landmarks) and establish the relationship with the local coordinate system of the tracking cluster (1st and 5th MET and great toe markers),[27-30] then a transformation matrix will be used to convert the virtual points' location into the global coordinate system for gait trials using Visual 3D (C-Motion, Maryland, USA). The virtual points will comprise the point on the tip of the shoe and 5 other virtual points on the shoe's medial, anterior, and lateral aspects. These points are positioned to characterize the front of the shoe because this is the part that may contact the floor in the mid-swing phase of the gait cycle and result in a trip-related fall. [31]