Enhancing Locomotor Learning with Motor Imagery and Transcranial Direct Current Stimulation: A Pilot Randomized Controlled Trial in Young Adults.

NCT06414213

09-20-2022

Study protocol

Study Design

The primary goal of this study is to investigate an novel intervention on improvements in walking and balance. The design of this study is a randomized, double-blinded clinical trial. The study will use a pilot intervention that will utilize a dual strategy combining MI with tDCS (a non-invasive brain stimulation) to activate the frontal/executive networks of the brain to enhance motor learning to increase retention and transfer of locomotor learning. Participants, separated by age by age 18-35 and 50 and older, will be randomly allocated to experimental (active tDCS) or sham groups and will be assessed at baseline, immediately following the intervention, and at 1-week. Outcome measures include cortical activation (oxygenated Hemoglobin, HbO2), assessed through functional near-infrared spectroscopy (fNIRS), cognitive assessments, and gait and balance assessments. Complete participation will consist of 2 visits to the Neuromechanics laboratory at Leon Levine Hall.

Outcome Measures

Assessments will be conducted by the experienced examiner(s) blinded to group tDCS assignment and will occur at three time points: baseline, post-Intervention, and follow-up (1 week after the baseline assessment). Prefrontal cortical activity will be assessed during walking to investigate intervention-induced prefrontal/executive activity changes. Using a commercially available Functional near infrared spectroscopy (fNIRS) monitor (OctaMon by Artinis Medical Systems), changes in oxygenated hemoglobin concentration (O2Hb) relative to a baseline task will be measured for the orbitofrontal and dorsolateral prefrontal cortex. During walking assessments, we will use fNIRS to measure frontal cortical activity. Changes in O2Hb will be assessed at baseline and after the intervention week. All manufacturer guidelines will be followed in the collection of fNIRS.

Time to completion: Participants will walk over a 4-m instrumented walkway mat during the assessments. The walkway system is a clinical instrument that allows for objective gait assessment. Spatial and temporal gait variables calculated from the walkway system have strong concurrent validity and test-retest reliability (intra-class coefficients >0.8 for most variables). These measures will allow us to determine time to completion and changes in gait quality (stepping characteristics) during pre/post/ and follow-up testing.

Kinesthetic and Visual Imagery Questionnaire (KVIQ): The ability to imagine movements was assessed with the KVIQ. This test evaluates the subject's ability to see (visual imagery) and feel (kinesthetic imagery) movements. TheKVIQ consists of 10 items, (5 movements for each scale), each item being a separate movement followed by rating the ease or difficulty of generating those self-images on a 5-point Likert scale (where 1 = no image or sensation and 5 = Image as clear as seeing or as intense as executing the action). Higher scores reflected higher imagery abilities.

Baseline visit and Intervention

We will enroll 40 adults age 18 to 35 (n=20) and 50 and older (n=20) without neurological conditions. Participants will be randomized to one of the two groups: 1) MI with sham tDCS ('MI /sham') and 2) MI with active tDCS ('MI/ active').

For Visit One, All participants will undergo fNIRS, Gait assessment, and KVIQ. Additionally, all participants will perform the locomotor learning task.

Locomotor Learning

Participants will begin in a quiet, standing position with the fNIRS attached to themselves and after a period of 30 secs of quiet rest, participants will stand for a period of 30 secs and then begin walking over the course. The course is a 10-meter obstacle course containing foam obstacles of various heights and widths at their fastest safe pace. Participants will repeat this process 10 times. Participants will be asked not to speak and only engage in thinking about the walking course. Rest periods of a minimum of 1 min will be permitted to prevent fatigue and standardize the procedures. Time to complete the course will be recorded and the change in time to complete the course will be used as an outcome.

Following the baseline testing and locomotor learning assessment, the participants will engage MI with active or sham tDCS intervention. Participants enrolled will receive standardized instructions explaining the protocol and undergo the assessment using a 24-in computer to watch video clips. Instructions, "Please watch the following video. You will see someone walking over the course you did for the baseline visit, which will be repeated several times. Place your focus on each foot as it approaches each obstacle and imagine performing the task yourself during the entire period of the video. At the end of the video you will be asked to close your eyes and to continue performing

mentally the task until you hear the stop sign. From time to time, I will encourage you to perform the task. Now try to relax and press the spacebar to start the video while concentrating as much as possible on the task when you are ready." This will be implemented to cue participants' visual attention to the obstacles and anatomical regions that are fundamental for correctly and safely walking the course, as consistently emphasized by physical therapists and gait rehabilitation experts. This method has been utilized in previous investigations and used during the intervention, The anodal electrode will be placed over the frontal cortex (F3/4 10:20 location) contralateral to the test side, and the cathode will be placed over the supraorbital region ipsilateral to the test leg (opposite side as the anode). Prior to placement of the electrodes, the area will be inspected for signs of scalp irritation and the scalp will be cleared with an alcohol pad. Electrodes will be secured with an elastic strap around the forehead and top of head (EasyStrap, Soterix). A Soterix clinical transcranial electrical stimulator will be placed within a clear backpack to be worn by the subject. The investigator will explain the stimulus to the patient (a tingling or itching sensation) and provide a pre-stimulus tickle to ensure proper electrode impedance (measured by stimulator) and familiarize the subject. The investigator will enter a specific subject code that will initiate either a sham current (2-minutes ramp on followed by no stimulation), or a constant 2.0mA current for the sham or tDCS groups, respectively. The current (or sham current) will go on for 18-minutes as participants perform a movement intervention. tDCS will be performed using a Soterix Clinical Trial stimulator and Soterix sponges. All manufacturer guidelines will be followed in its usage.

The groups will watch a standardized video sequence consisting of five walking trials (5 video clips—each trial representing 1 clip) over the 10m complex walking course containing the intermittent soft surfaces (foam mats). Participants will watch the video first at normal play speed and then in slow motion after a short break (30 secs to 1 min). Total training time will be approximately 20 mins, consistent with the locomotor intervention's duration and stimulation. Literature dictates that 15 to 30 mins of observation

is an appropriate duration for observational learning protocols to observe improvements. The model video sequence will show a typical pass through the complex walking course by a gender matched model.

Follow up

All participants will then return after one week and repeat the baseline assessments. Including the fNIRS, Gait assessment, and KVIQ and the locomotor learning task.

Statistical Design

Times of the three trials at each test will be averaged to observe any learning effects during the obstacle course. ΔO2Hb at each of the 3 trials during each test were averaged. A 2-way factorial ANOVA with a between-subjects factor of group (3 levels) and a within-subjects factor of time (3 levels) will be used. In the case of significant interactions of main effects, pairwise comparisons using Fisher's LSD will be used post-hoc. Effect sizes will be interpreted from partial eta squared as small=0.01, medium=0.06, and large=0.14. Independent samples t-tests will e used to analyze any differences in the MIQ-3, and the tDCS sensitivity between groups.