Combined Functional Electrical and Transcranial Direct Current Stimulation for Foot Drop

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No NCT # yet

Confidential

CONSENT TO PARTICIPATE IN RESEARCH

Feasibility investigation of transcranial direct current stimulation (tDCS) paired with functional electrical stimulation of the lower extremity in chronic stroke

Conducted by
Gregory Thielman, PT, MSPT, ATC, EdD
Saint Joseph's University School of Health Professions,
600 S. 43rd Street, Philadelphia, PA 19104. Ph: (215)-596-8680

You received this consent form because you expressed interest in participating in this research project. The choice to participate in this project is voluntary. You may withdraw at any time with no penalty. Please review this consent form in its entirety before agreeing to participate. Should you have any questions or concerns, contact the Principal Investigator at (215)-596-8680 or the Research Compliance Coordinator at (610)-660-1298 or irbadministrator@sju.edu.

Purpose:
This study aims to determine if combining the treatments of transcranial direct current stimulation (tDCS) and functional electrical stimulation (FES) will better help persons with stroke who have difficulty lifting their toes. In this study, you will be asked to attend an exercise program 2 times per week for 8 weeks and complete one baseline and 2 testing reviews.

Procedures:
By participating in this research project, you will be asked to give basic information, including your age, time of stroke, and your opinion on the impact of your stroke on your life. Then you will come to the lab to perform measures of your leg's strength and ability to walk. Then you will be given activity monitors that are placed on your arm to monitor your activity over 3 days. **Twelve** people are being asked to participate in this study.

Treatment and testing will occur at **the Patricia Leahy Research Lab on the 1st floor of 4500 Woodland Ave, Philadelphia, PA 19104**. Participants are asked to wear their shorts and sneakers or bring them to the department to change into. During the initial visit, a screening tool will be used to collect data about age, height, thinking, weight, gender, limb dominance, leg strength, and medicines. This **will** help to decide if you are eligible for the study. Once eligible, reflective markers will be attached to your pelvis, thighs, shanks, and feet with velcro straps and tape. Next, you will be asked to walk 25 times without your AFO over a level surface at your normal speed while infrared cameras capture your walking. We anticipate the initial visit and the 2 follow-up sessions to last 90 minutes each. Following all tests, markers will be removed.

As part of the treatment, you will receive electrical stimulation through pads on your scalp (similar to what you may have received in physical therapy previously to your arm or leg). This protocol is called transcranial direct current stimulation (tDCS). You will also receive electrical stimulation through pads on your leg. This is called functional electrical stimulation (FES). **You will have FES during all training sessions at the full does to lift your foot. The tDCS will either be given at one dose or another throughout the training periods. This will be decided randomly.** During treatment sessions, you will also perform leg activity/strengthening exercises. You will be allowed to sit down whenever you want to rest. The

exercise/treatment classes will meet 2 times per week for 8 weeks for 60 minutes each. After 4 weeks and at the end of 8 weeks, you will return to complete follow-up testing.

Duration:
All 8 treatment sessions are expected to last one hour and occur twice weekly for 8 weeks.

Location:
The procedures for this study will take place at the Patricia Leahy Research Laboratory University City campus on the 1st floor of 4500 Woodland Ave, Philadelphia, PA 19104, located in Woodland Hall at Saint Joseph's University.

Inclusion and Exclusion Criteria:
To participate, you must be:

- 18 years or older
- Have had 1 or more strokes (> 6 months) affecting ankle dorsiflexion.
- Discharged from all rehabilitative services.
- Can walk independently with/without using an assistive device such as a cane without an ankle-foot orthosis (AFO) for 15 minutes.

You must not have:

- An inability to repeat and understand 2 step commands.
- Peripheral neuropathy
- Damage to the skull or scalp, such as a fracture
- History of seizures or epilepsy
- Extremely high or low blood pressure or heart rate **(i.e. 160/90 or below 90/60 and resting HR over 85)**
- Chest pain or shortness of breath when you are resting
- Botox injections to your leg or foot in the last 4 months

Risks & Benefits:

This study's potential risks and discomforts include minor skin irritation from the electrical stimulation. tDCS may produce difficulty concentrating, moderate fatigue, and/or headaches. **Participants will be questioned about these with each visit at check in (including any reports of these in the past 24 hours after the session, since effects are reported to occur up to 24 hours) and at check out for each visit. Specific questions will be: "Are you experiencing any difficulty concentrating? Are you experiencing any fatigue?" Are you experiencing any headaches? Are you experiencing any difficulty sleeping?" If subjects experience any of these traditional effects from therapy the sessions will be paused until the symptoms have been resolved for a period of 24 hours.**
There is also potential for muscle/joint soreness and fatigue. If you become injured during testing or exercise sessions, you will receive first aid. If you require additional medical treatment, a caregiver will transport you to medical services, and you will be responsible for the cost. If your caregiver cannot transport you and they are on University grounds, a call will be placed to 911.

Evidence from a narrative review suggests that Anodal Transcranial Direct Current Stimulation (tDCS) can improve lower extremity function in healthy young and older adults and, hence, gait.[1] In persons with stroke, tDCS has also been shown to improve functional measures such as the Barthel Index, which includes lower extremity/gait metrics.[2]

There is also evidence that functional electrical stimulation (FES) improves lower limb/gait metrics.[3] This is particularly important as much as 30% of people with stroke are thought to have ankle dorsiflexion weakness.[4] These improvements appear to also come from sensory level stimulation and not only motor level stimulation.[5]

There is evidence that combining tDCS and FES produces benefits above the individual interventions alone at improving balance.[6] There is also evidence that the combination of tDCS and electrical stimulation (Sensory) may better "prime" (or increase the excitability) the motor cortex.[7] In this study, we are exploring whether adding a FES program for the ankle dorsiflexor to a program with tDCS or

adding tDCS to a program of FES for the ankle dorsiflexor will improve gait metrics in persons with chronic stroke that have dorsiflexion impairments.

We hypothesize that the combination will have better results because the will better "prime" the motor cortex for the specific act of dorsiflexion. tDCS alone does not produce a stimulation that is specific to any area of the motor cortex. It is hoped that the sensory and motor inputs from FES will produce more specific results in improved motor functioning of the ankle dorsiflexor.

We, the investigators, believe that the risk is no greater than that experienced in a clinical setting and that potential benefits outweigh the risks. In addition, to reduce the risk of harm, the tDCS technique will only be performed by Dr. Theilman, who has specific training in this technique. Further, Dr. Carter, who teaches this technique, will supervise the FES. Additionally, during training participants will be supported with a bodyweight support system or are supervised by two investigators at all times to mitigate fall risk.

The risk of a significant electrical shock from an adequately used Transcranial Direct Current Stimulation (tDCS) device is considered very low, as the current delivered is minimal and designed not to harm brain tissue. Additionally, tDCS uses very low electrical currents (typically below 2 milliamps), which are not strong enough to produce a noticeable shock sensation in most individuals. Similarly, functional electrical stimulation (FES), while it does deliver electrical currents to activate muscles, the risk of a significant electrical shock is generally considered very low due to the low voltage and carefully controlled current used in clinical settings. Additionally, although they are to be delivered simultaneously, one is delivered to the scalp and the other to the leg. The current is so small, and the sites are so distant that an additive effect is impossible.

The potential benefits of this project include increased leg strength and control, which may improve your ability to walk and do activities at home and potentially reduce your fall risk.

As with any study, you should be aware that unforeseen problems may occur. However, the likelihood of any serious problem is believed to be low. Your participation is voluntary, and you may refuse to participate or stop your participation at any time for any reason without penalty. You may choose to skip a question or terminate participation at any time.

Participation Costs and Participant Compensation

There will be no cost to you to participate in this study. **However, there is a cost if someone needs to seek medical care**. **You will be compensated 150$ for participating in this study. If a subject drops out near the ½ way point, they will receive 50$, otherwise there will be no compensation for any dropouts.**

Refusal or Withdrawal of Participation

Participation in this study is voluntary, and you may withdraw at any time with no consequences. If, at any time during the study, the investigator decides that you should not continue due to concerns for your well-being, your participation in the study will end. All data collected until your withdrawal from the study will be stored and potentially used for analysis.

Available Resources:

Further information regarding this study may be obtained from (215) 596-8680. If you have questions concerning your rights as a research participant, you may contact the IRB administrator at irbadministrator@sju.edu or (610) 660-1298. If you are interested in the findings **fr**om this research study, we will provide them to you at study completion.

Use of Research Results:

Data may be used in publications, presentations, and/or for teaching purposes.

The research data we will be collecting during your participation in this study may be useful in other research studies in the future. Your choice about the future use of your data will not impact your participation in this research study. Do we have your permission to use data collected from you in future studies? Please write your initials next to your preferred choice.

_____ YES _____ NO

Confidentiality

All participant information will be de-identified, and participants will be identified using participant numbers. All information gathered throughout the study will be used for research purposes only and made available only to people involved in this study unless participants permit in writing to do otherwise. Any computer files containing information that could identify you will be password protected. All data collection sheets will be stored indefinitely in a locked cabinet in a locked office and may be used in future research studies. Neither your name nor identifying information will be used in any publication or presentation resulting from this study.

Institutional Review Board Approval:
This research study has been approved by the Saint Joseph's University Institutional Review Board (IRB) for the Protection of Human Subjects in Research. If you believe that there is an infringement upon your rights as a participant in this research you may contact the Research Compliance Coordinator at irbadministrator@sju.edu.

Subject's Agreement
I have read the information provided above and voluntarily agree to participate in this research study. I understand that I will be given a copy of this consent form.

_____	_____
Name of Research Participant (Print)	Signature of Investigator
_____	_____
Signature of Research Participant	Date