H-52200- TRANSCRANIAL DIRECT CURRENT STIMULATION (TDCS) FOR IMPROVEMENT OF COGNITIVE FUNCTIONING, BRAIN FOG, AND WORKING MEMORY

Concise and Focused Presentation

You are being asked to participate in a voluntary research study. The purpose of this study is to see if wireless, transcranial direct current stimulation (tDCS) benefits people with cognitive issues such as poor memory or difficulty concentrating. In this study we will place a device on your forehead that will deliver a low and safe level of electrical stimulation. No research procedures will take place before signing the consent form. You may benefit from this study by experiencing improvement in certain functions such as working memory, learning, and task performance. You do not have to participate in this study.

We propose the daily use of tDCS for 4 weeks to address cognitive issues. During the first visit, the research team will show you how to use the transcranial direct current stimulation device and may provide you some stimulation at the visit. You will have the opportunity to practice using the device during this visit. During this visit you will also be asked to answer sixteen questionnaires which will assess your quality of life, symptoms frequency, cognitive status, among other things. You will then be asked to take the device home and use it for 20 minutes per day for the study period (4-weeks). At the end of the 4-weeks, you will return to the clinic, conduct the same questionnaires as those completed in the first visit, and return the device. The potential risks in this study involve possible device malfunction or discomfort from the sponges; should you experience any risks or discomfort, notify study staff immediately. Each study visit will take 1-2 hours. There will be no cost to you to participate and you will not be paid for in person visits or phone calls.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Cognitive issues occurs when an individual struggles with learning new information, concentrating, remembering, or making decisions. This can be due to underlying neurological diseases (i.e. Alzheimer's disease, dementia, etc.), caused by viral illness (i.e. brain fog experienced by COVID-19 survivors) or physical trauma (i.e. concussion). Recent reports indicate that two out of three Americans experience some amount of cognitive issues in their lifetime. To address this issue, we suggest the daily use of transcranial direct current stimulation (tDCS) therapy provided your frontal part of the head. We think that tDCS may improve your improve working memory, learning and task performance.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this pilot study is to examine effectiveness of daily use of transcranial direct current stimulation (tDCS) therapy to improve working memory, learning and task performance.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine.

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We will prospectively recruit 10 patients with cognitive issues such as poor working memory, brain fog, or impairments due to dementia, Alzheimer's, or concussions.

Over the course of 4 weeks, you will receive of daily use of transcranial direct current stimulation (tDCS). It will consist of home-based therapy, meaning you will take the device home for 4 weeks and attend the clinic for final assessment at the end of that time period.

This study will consist of up to 2 visits total (Baseline [BL] and Visit 1 [V1]) and possible follow up phone calls. You will not be compensated for this study but your parking will be validated.

Device: The device will come in a packet which includes the following; LIFTiD device headband, 1 mirror, 1 plastic spoon, 6 white sponges, 1 USB charging cable, and 1 plastic bottle. Research staff may also provide you a user guide and additional instructions.

Each study visit may last between 1-2 hours. If you need to stop the study visit at any time, you are permitted to do so.

During the baseline visit (BL):
1. The research staff will demo to you the LIFTiD neurostimulation device which uses transcranial direct current stimulation (tDCS). This may include teaching you how to set it up, dampen the sponges, and position the device.
This also may include up to 20 minutes of stimulation.
2. Research staff may also perform questionnaires to assess your ability to carry out daily living activities (IADL, KATZ), symptoms of depression (CES-D), symptoms of fatigue (FACIT, MAF), cognitive functioning (MOCA), cognitive functioning (MOCA), attention(Number Span forward) working memory (Number Span backward), processing speed and executive functioning (Trail Making Test Part A and Part B), and memory encoding, recall, and recognition (Hopkins Verbal Learning Test) pain pain and mobility (VAS), perception of your general health (PROMIS), sleep quality (PSQI), frailty status (TSFI, FRIED FRAILTY), symptoms of anxiety (BAI), level of community engagement (Life-Space), and user acceptability (TAM).
3. You will take the device home and be instructed to wear it for up to 20 minutes daily. Stimulation frequency: maximum of 20 minutes daily. During the Stimulation you should perform an activity, such as read, answer emails, homework, etc.

During V1 (4 weeks after initial visit):
1. Research staff may provide you with up to 20 minutes of stimulation using this device.
2. Research staff may also perform questionnaires to assess your ability to carry out daily living activities (IADL, KATZ), symptoms of depression (CES-D), symptoms of fatigue (FACIT, MAF), cognitive functioning (MOCA), attention(Number Span forward) working memory (Number Span backward), processing speed and executive functioning (Trail Making Test Part A and Part B), and memory encoding, recall, and recognition (Hopkins Verbal Learning Test) pain and mobility (VAS), perception of your general health (PROMIS), sleep quality (PSQI), frailty status (TSFI), symptoms of

anxiety (BAI), and user acceptability (TAM).
3. You will return the device to the research staff.

Study staff may collect additional information from you or your electronic health record such as:
1. Demographics and medical history: age, body-mass-index, history of fall/s, health status, chronic disease history, history of surgery, type of cancer, type of cancer treatment, number of medication prescription as well as over counter medication use, history of vein insufficiency, thick blood, previous and possible in-trial blood clotting, protein levels, surgery time, and walking ability
2. Social factors: marital status, years of education, type of work, tobacco history (pack years, current smoker,
current use of chewing tobacco, previous smoker, no tobacco history), drug history (current, previous history, no drug history), and alcohol history.

Phone calls between study visits will occur at an as-needed basis. You may contact study staff or study staff may contact you to review any logistics such as: address any questions/concerns, discuss feedback, schedule a weekly in-person visit, etc. You will not be compensated for study-related phone calls.

All study visits will occur at the Baylor College of Medicine McNair Campus.

The researchers will take digital photographs /videos of both of you throughout the study. ** We will blur your face out in the photographs/videos. While we do all our efforts to mask your face in some cases (for example journal policy) this may not be practical. We will only use videos and photos of you for scientific presentations or scientific publications.

Initial your decision below.
____I agree to have my photographs/videotape presented in scientific presentation or scientific publication.

____I do NOT agree to have my photographs/videotape presented in scientific presentation or scientific publication.

If you are eligible, the research personnel would like to contact you in the future for participation in other research studies. You are not required to participate in these studies and your medical care or involvement with the current research study will in no way be affected if you choose not to participate. You may ask us to stop contacting you at any time.

_____I agree to be contacted for future research studies

_____I do not agree to be contacted for future research studies.

Please provide below your Emergency contact information:
Contact name:_____

Relationship: _____
Phone number:_____
Please note that the research staff may contact you for any study related questions or concerns during your participation of the study.

If you are a student or employee, note that your participation will NOT affect your academic position or employment. You may also refuse to participate without any penalty.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine is required by law to protect your health information. By signing this

document, you authorize Baylor College of Medicine to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: To revoke this Authorization, you must write to: Bijan Najafi, PhD 7200 Cambridge Street, Room B01.529

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

The potential risks to you are minimal. However, like any battery powered systems, there is a minimal risk of sensor malfunctioning. In addition, the study devices are not waterproof, and although they use a low powered battery (similar to a cellphone battery), in order to avoid any risk of shock the monitor should not be submerged or saturated with fluids during operations or cleaning. It does not emit any radiation to the human body and does not offer any significant risk to the subject.

Subjects may experience mild discomfort or irritation from the band or sponges on their forehead or mild headaches during period of adaptation after initiation of therapy. We will inform the subject to please notify the investigators if the band or sponges are uncomfortable.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand There is potential benefit of improvement of working memory, concentration, or task performance. In addition, the participation in this study may help the investigators better understand how electrical stimulation affects cognitive functioning..

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose to not participate in this study..

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact

the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: BIJAN NAJAFI at 713 7987536 during the day and MARIA NOUN at 713-798-7538 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date