Official Title:	A Teleheath tDCS Approach to Decrease Cannabis Use: Towards Reducing Multiple Sclerosis Disability
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Research Subject Informed Consent Form

Title of Study:	A Telehealth tDCS Approach to Decrease Cannabis Use: Towards Reducing Multiple Sclerosis Disability s21-01028
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to determine if transcranial direct current stimulation, or tDCS, can be used to treat cannabis use disorder (CUD) in patients living with multiple sclerosis (MS). There are currently no established standard-of-care treatments for cannabis use reduction, including for the MS patient. This study will evaluate whether tDCS combined with mindfulness meditation results in decreased distress and, in turn, decreased cannabis use.

tDCS is a safe, noninvasive (does not enter your body) brain stimulation that uses a small handheld tDCS device to deliver a mild electrical current through a headset to the brain to help improve brain activity.

The tDCS device used in this study is the 1 x 1 Mini-CT (Soterix Medical Inc.). It is an investigational device because it is not approved by the US Food and Drug Administration (FDA) for commercial use. However, it is used in research studies such as this one. It also has received regulatory approval for clinical use (routine care) to treat mood disorders in the EU, UK, Australia and Brazil.

3. How long will I be in the study? How many other people will be in the study?

Your participation will take place over the course of 4.5 months and will involve about 24 virtual visits (can be completed from your home). All visits will take place remotely using Zoom or Webex.

- Consent *(20 minutes)*
- Telehealth research screening *(1 hour)*
- Baseline & tDCS Session 1 *(approximately 2 hours)*
    - tDCS training *(20 minutes)*
    - Cannabis urine test *(5 minutes)*
    - Questionnaires and measures *(1 hour)*
    - tDCS + mindfulness meditation session 1 *(20 minutes)*
- tDCS + mindfulness meditation sessions 2-20 (*20 minutes per session over 4-6 weeks)*
- 3 follow-up visits *(once a month for 3 months after the last tDCS session,1 hour per visit)*

We expect to enroll 52 female patients with MS into this study at NYU Langone Health.

4. What will I be asked to do in the study?

After signing this informed consent form the following research procedures will take place over approximately 4.5 months. All visits will be completed remotely through Zoom or Webex which can be downloaded from the App Store (iOS) or Google Play (android).

- *Telehealth Research Screening (1 hour):*

  You will meet with a study clinician who will review your medical history and conduct a screening assessment to determine if you are eligible for this study. If eligible, you will be randomly assigned (like flipping a coin) to receive either active 2.0mA tDCS or placebo tDCS (mimics tDCS but is not active). The study equipment (tDCS device, tDCS headset, sponges, laptop computer, and cannabis urine test kit) will be shipped to you. You have a 2 to 1 chance of getting the active tDCS. This study is called “double blind” because neither you nor the study staff knows which group you’re in. However, we keep records of which group you’re in. The study staff can get this information if needed.

  We will ask you to do the following in this study:
    - Take care in the proper handling and safekeeping of the study equipment.
    - Use the laptop computer for the study only
    - Return the equipment within 5 business days of your last tDCS session
    - Follow the instructions we give you on the care and maintenance of the equipment.

  Upon signing this consent form, you will be loaned a laptop computer and a tDCS unit.

- *Baseline Visit & tDCS session 1 (2 hours):*

    - First, a trained study technician will orient you to the tDCS device, headset, pre-soaked saline sponges, and show you how to use the device, including proper headset placement and safety features.

    - Next, a **tDCS tolerability test** will be performed to ensure you are comfortable receiving 2.0mA stimulation. This involves a 90-second stimulation in which the device will ramp up to the target intensity of 2.0mA and then is aborted by pressing “0” on the device. The test can be aborted at any time prior to the 90 seconds if it is uncomfortable.

- You will be asked to collect a **urine sample** using a test kit that will be provided to you. You will obtain the sample in a cup in privacy, then in view of the study technician you will place a test strip into the cup and show the results. You will then dispose of the cup and test kit, wash your hands, and sanitize the area.

- You will complete a series of **self-report questionnaires** about your physical and mental health, and cannabis use.

- Lastly, you will have your **first tDCS + mindfulness meditation** session. Mindfulness meditation is the practice of non-judgmental acceptance and awareness of your current state, including your body sensations, thoughts, mood, and surroundings. Mindfulness meditation practice has been shown to reduce distress and anxiety.

  Once the study technician visually confirms correct headset placement and you confirm there is adequate contact quality (moderate or good), the study technician will provide you with a one-time use unlock code to enter into the tDCS device and initiate the stimulation. During each stimulation session you will listen to a guided mindfulness meditation audio track on the study provided laptop computer. The study technician will remain connected with you for the duration of every session.

- *Remotely-supervised tDCS sessions 2-20*

  - Over the next 4-6 weeks, you will complete the remaining daily tDCS sessions (20 minutes each day) just as you did for session 1.

  - At sessions 5, 10, and 15, you will be asked to complete self-report questionnaires. These sessions will take approximately 45 minutes (20 minutes for tDCS session and 25 minutes to complete questionnaires).

  - After session 20, you will be asked to complete treatment end assessments which will be the same questionnaires, measures, and urine test that you completed at your baseline. We will also provide you with a prepaid shipping label to return the equipment.

- *3 Follow-up Visits (1 hour)*

  You will be asked to repeat the questionnaires at 1 month, 2 months, and 3 months after your last treatment session. After the 3-month follow-up you will also repeat the cognitive measures and urine test and your treatment group (active or placebo) will be told to you.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Risk of tDCS: More than 1200 research studies involving thousands of participants have been published using tDCS. No serious or long-lasting effects have been reported. The most common side effects are tingling, itchy sensations, and warming sensations on the scalp, and mild skin irritation under the area of the electrodes. These side effects are infrequent, mild, and typically resolve when the stimulation stops.

Guided mindfulness meditation: Mindfulness meditation is not associated with any known risk. To minimize possible frustrating feelings, each session will be monitored in real-time via HIPAA-compliant videoconference with a trained study technician.

Self-report questionnaires: Completing questionnaires about one's physical and mental health and cannabis use may produce some discomfort and/or emotional distress in some patients, especially questions that are sensitive in nature, like drug use and self-harm. If you indicate you want to hurt yourself, we will ask you follow up questions and may refer you for additional care, as would be done outside of this study. You will be allowed to take breaks as needed and may skip questions you do not feel comfortable answering. Please note, there are some assessments that must be completed in order for us to conduct this study. If you do not wish to complete those assessments you may withdraw from the study without any negative effects to your future care.

Single panel urine test: Completing the procedure for urine strip testing in the context of video visit may cause some emotional discomfort. Participants may become upset if the results of the strip test are not consistent with their self-reported use

Risks to Confidentiality
While your information will be kept strictly confidential there is a small possibility that a breach of confidentiality can occur. Your research documents will be stored in locked cabinets behind locked doors only accessible to the research staff. Data from the self-reported questionnaires will be printed and stored in locked cabinets only accessible to the research staff.

The results of your drug tests will NOT be included in your medical record. Your data will only contain a unique code and will not have your private identifying information (e.g. name, date of birth, address etc.). A link between your name and unique code will be stored separately from the data and will be deleted as soon as possible after data collection.

Unforeseeable Risks
While it is not expected, there may be risks associated with tDCS that we currently do not know.

6. What if new information becomes available?
During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?
Some study subjects may benefit from the mindfulness meditation practice as there is robust research on the health benefits of meditation (e.g. reduced distress and anxiety). There is also a chance reducing your stress will reduce your cannabis use. However, we don't know for sure this is the case. You may not benefit from taking part.

Other patients may benefit in the future from what we learn in this study regarding whether tDCS can help treat CUD in patients with MS.

8. What other choices do I have if I do not participate?
Your participation in this study is voluntary. You may choose not to participate and if you decide to participate you may withdraw at any time without negatively affecting your routine clinical care. In addition, you may choose to use tDCS even if you do not participate in this study.

9. Will I be paid for being in this study?

You will be paid a total of $250 for completing this study ($50 after your baseline, $100 at treatment-end, and $100 after the last follow-up). If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will not be compensated for research visits that were not completed.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (check or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Leigh Charvet, PhD at leigh.charvet@nyulangone.org.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

10. Will I have to pay for anything?

You will not be responsible for the costs associated with participating in this study.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYU Grossman School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data and documents) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, MRIs, information about the investigational device used in this study, may be included in your NYU Langone Health electronic medical record.

HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study.
- The study sponsor: National Institute of Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

14. Electronic Medical Record and Release of Study-Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?
The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

In this study, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because the information is specific to this research and is not part of your medical history and clinical care.

Results that will not be placed in the medical record: self-report questionnaire responses, cannabis drug test, and research measures will not be placed in your medical record.

The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date