Title: Home-based tDCS for Prevention of Suicidal Ideation

Informed Consent Form

NCT05280756

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CONSENT FORM

Home-based transcranial direct-current stimulation (tDCS) for prevention of suicidal ideation relapse after inpatient treatment

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This consent form describes the research study, what to expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. Staff from the University of Rochester Medical Center (URMC) will explain this consent form to you. Please ask questions about anything that is not clear. You may take this consent form home to think about and discuss this consent form with family or friends.

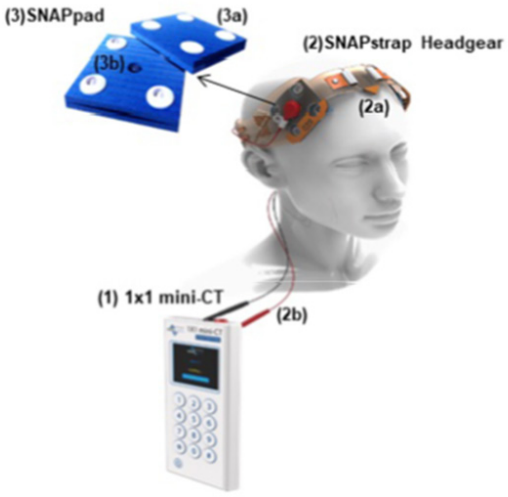
Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you reported suicidal thoughts or suicide attempt.
- The purpose of this study is to determine if you can perform home sessions of a non-invasive brain stimulation called transcranial direct current stimulation (tDCS) in addition to your regular outpatient mental health treatment for preventing suicidal ideation after hospital discharge.
- If you choose to participate in this study, you will be asked to use the home-based tDCS at your home for 30 minutes per day, for 10 consecutive days, except on Saturdays and Sundays, totalizing 10 (ten) home-based tDCS sessions. All sessions will be monitored via telehealth by our research staff.
- Your participation in this study will last about 2 months.
- Participation includes completing research questionnaires when you join the study, and again at day 14, day 30, and day 60 after the first home-based tDCS session. These assessments will be done via telehealth.
- There are risks from participating:
    - The most common risk is discomfort in discussing past difficult events.
    - Another risk is the possibility of breaking confidentiality if there is concern you may attempt suicide. See the "Risks of Participation" section for more information. You should discuss these risks in detail with the study team.

    - Some known risks associated with tDCS include itching, burning, headache, fatigue, nervousness, dizziness, and difficulty concentrating.
- You might not benefit from being in this research study. The potential benefits include learning more about yourself through research assessments and decreasing depressive symptoms, as tDCS sessions have been associated with improving depression.
- If you choose to participate in this study, you allow the research team to speak with the treatment team if there are reasons for concern during or at the end of the research assessment at the hospital.

This study is led by Dr. Yeates Conwell and Dr. Alexandre Paim Diaz, University of Rochester Medical Center Department of Psychiatry.

Purpose of Study
The purpose of this study is to determine if you can perform home sessions of a non-invasive brain stimulation called transcranial direct current stimulation (tDCS) in addition to your regular outpatient mental health treatment for preventing suicidal ideation after hospital discharge. This tDCS has not been approved by the Food and Drug Administration (FDA); therefore, it is called an investigational device. The transcranial direct current stimulation (tDCS) looks like this:



Description of Study Procedures
If you decide to take part in this study, you must consent that you will be in standard clinical outpatient psychiatric care during the study. In addition, if you decide to take part in this study, you will be asked to complete the following study procedures:

- Contact Information: You will provide personal contact information as well as contact information for up to two others for emergencies or in the event we cannot reach you.

- Baseline Assessment: You will be asked to complete a series of questionnaires. The questions will be about your general health, mental health, suicidal thoughts and behaviors, and depressive symptoms. This visit will take about 30 minutes. After you answer the questionnaires, we will do an orientation session with the device you will use at home, which includes a test session with the device. This session will help to determine if you tolerate the electric current delivered by the device. This orientation session will take about 20 minutes.

- Randomization: After your baseline assessment, you will be assigned by chance (like flipping a coin) to one of two groups.
    - **Group 1** – **active home-based tDCS**: If you are assigned to this group, you will receive 10 consecutive sessions, once daily, of active dose (a weak electric current) from a home-based tDCS device. Each session lasts 30 minutes. There will be no sessions on Saturdays and Sundays. In addition, you will receive the usual care following discharge that is prescribed by your treatment team.
    - **Group 2** – **sham home-based tDCS**: If you are assigned to this group, you will receive the same 10 consecutive sessions of 30 minutes duration each, once daily, with no sessions on Saturdays and Sundays, but with a sham device. The sham home-based tDCS delivers a much smaller electric current. In addition, you will receive the usual care following discharge that is prescribed by your treatment team.

  There is a 50% chance you will receive the active home-based tDCS and a 50% chance that you will receive sham home-based tDCS. Neither you nor your doctor will know if you are receiving active home-based tDCS or sham home-based tDCS.

- Remote supervision: all home-based tDCS sessions, for both active and sham groups, will be supervised remotely by one person from our research staff via HIPAA-compliant videoconference. This is why we will also refer to the home-based tDCS as remotely supervised tDCS (RS-tDCS).

- After each RS-tDCS session you will be asked to answer a clinical questionnaire, questions related to potential side effects associated with the stimulation, and let us know of any other health problems that have come up since you last met with the study staff. Each session will take about 50 minutes (5 minutes to set up the device, 30 minutes for the tDCS session and 15 minutes for the answering the questionnaires). After the last RS-tDCS session (the tenth session) we will also apply a questionnaire to assess the acceptability of the intervention (this will last more 5 to 10 minutes).

- You will be asked to sign an IRB-approved device loan agreement. This agreement has the following statements: “You are responsible for the proper handling and safekeeping of all study equipment provided to you during this study, including the tDCS device and the headset, for the duration of the study”; “You agree to return equipment within 5 business days of your last tDCS session”; “You agree to return all equipment in working order and without damage”; “You agree to follow all instructions for care, maintenance and storage of the equipment in order to keep it safe and in working order throughout the period of the equipment loan”. The RS-tDCS device will be sent to you by mail in a pre-paid FedEx package to send it back.

- Follow-up Assessments: A research assistant will administer a series of questionnaires to you by telephone or via HIPAA-compliant videoconference 14, 30, and 60 days after the first RS-tDCS session. This assessment will take about 30 minutes.

- The clinical questionnaires include the Columbia Suicide Severity Rating Scale (C-SSRS) (for the follow-up assessments at days 14, 30, and 60 from the first RS-tDCS session) and a short version of the C-SSRS that will be applied after each RS-tDCS session. Depending on the risk evaluation, the research staff may contact a licensed clinician from our research team to determine if emergency evaluation is required.

- Maintaining Contact with You: We will use the contact information you provide to us for the follow-up assessments. We primarily use text messages, but may use email, letters, and/or calls as needed to contact you. We will also ask you to provide names and contact information of up to two individuals who are likely to know your whereabouts and whom we can call if we need to find you.

- Chart Review: We will also collect information from your hospital medical records related to the inpatient treatment you receive. This data will include admission and discharge dates, characteristics of the suicidal ideation and method and circumstance of eventual self-harming behavior, psychiatric diagnoses, and medication.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects
Approximately 20 subjects will take part in this study.

Risks of Participation
The following potential risks might result from your participation in this study:

- Discomfort During Clinical Assessments: During the research clinical assessments, it is possible that you may feel uncomfortable about the topics being discussed. You will not have to answer questions that you do not wish to. We will provide breaks at your request or if we determine that you could use one. The research staff will stop a clinical assessment at your request or if it's determined that stopping is needed.

- There is a risk that you could have side effects from the RS-tDCS. Some of the most common side effects reported in the research literature are: itching, burning, headache, and fatigue. Some of the less common side effects that have been reported are: nervousness, dizziness, and difficulty concentrating. If at any time you want to stop a RS-tDCS session, the research staff will instruct you in how to remove the device from your head and turn the device off.

- If you are an individual able to become pregnant, it is important to know that the tDCS used in this study could be harmful to an unborn baby in ways we do not currently know. If you are sexually active, you must agree to use a medically acceptable form of birth control while receiving the treatment. It is very important that you check with your doctor about what types of birth control or pregnancy prevention to use. If you become pregnant while taking part in this study or if you have unprotected sex, you must inform the study research staff immediately.

- Loss of Confidentiality and Addressing Safety Concerns: If it is determined that you are at risk of harming yourself or others, we are required by law to break confidentiality to ensure safety. Also, if we witness or you disclose to us information regarding potential child abuse or neglect, abuse of a disabled adult, or elder abuse, we will contact the appropriate authorities.

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 website for information related to this study by using this study's identification number NCT05280756.

Use of E-mail and Text Messaging in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. This research study involves sending you text messages that are relevant to your participation and are limited to communications regarding scheduling, reminders of your study visits, and payment.

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the research team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email or texting.

Email communications between you and the research team may be filed in your research record.

You are responsible for any fees charged by your carrier's service plan for text messaging. You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "Stop Research Text". Your consent, and any request to stop email or text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

Benefits of Participation

You might not benefit from being in this research study. The potential benefits include learning more about yourself through research assessments as well as a decreased in depressive symptoms.

Costs

There will be no cost to you to participate in this study. The clinical services where you receive treatment may bill you or your insurance, as they normally would.

Payments
You will receive an Amazon gift code for the baseline and follow-up assessments. Amazon gift codes will be sent to you via mail, text, or email. You will receive up to $160 for taking part in this study: $40 following completion of the baseline assessment, $30 for telephone assessments at days 14, 30, and 60 from the first RS-tDCS session, and $30 for your time when sending the device back in a pre-paid package by mail.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, all research files will be coded using a study identification number. Subject identifying information and protected health information will be stored with additional access restrictions on top of the protections for all other data collected for this study and will only be accessible by those investigators, clinicians, or staff with a need to know this information for the purpose of conducting the study. All identifying data will be stored in password-encrypted files. Access to these files is limited to investigators and support personnel with the need to enter or analyze data. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. While others normally protect the privacy of the information, they may not be required to do so by law.

Your permission to use your health information for this study will not expire unless you tell us you want to cancel it. We will keep the information we collect about you indefinitely. If you cancel your permission, you will be removed from the study. Results of the research may be presented at meetings or in publications, but your name will not be used.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Research records
- Records about phone calls made as part of this research
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Records about your study visits (your testing results from your baseline research assessment with your consent)

Who may use and give out information about you?
- The study doctor and study staff
- University of Rochester Medical Center and Affiliates

Your information may be given to the following organizations according to regulations:
- The Department of Health and Human Services

- The National Institute of Mental Health
- The University of Rochester
- The Brain & Behavior Research Foundation

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last for seven years during which your data will be held.

May I cancel my permission to use and disclose information?
Yes, you may cancel your permission at any time by sending written notice to the study doctor. Upon receiving this, the study team will no longer use or disclose your health information, but you will not be able to stay in the study. Information that has already been gathered may still be used for research purposes.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

Certificate of Confidentiality
The National Institutes of Health (NIH) issued a Certificate of Confidentiality (CoC) for this study. A Certificate of Confidentiality provides extra protection for you and any information and/or samples (blood, tissue, etc.) collected from you as part of this study because it prevents us from disclosing this information in a lawsuit or legal proceeding. We cannot release your study information in a lawsuit or legal proceeding unless you provide your consent for us to do so. This is an extra layer of protection above the already existing protections in place for you and any information and/or samples (blood, tissue, etc.) collected from you as part of this study. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency funding this study requests the information, or if the FDA tells us to release this information. You should visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

Future Use of Information
Your information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information is used or distributed.

Early Termination
You may be terminated from the study if:

- You appear to be harmed by participating
- If you not tolerate the tDCS stimulation at the orientation session
- If you become pregnant or planning to become pregnant during the time of the study comprehending the RS-tDCS sessions
- If you initiate treatment with electroconvulsive therapy or transcranial magnetic stimulation at any time during the trial

Sponsor Support
University of Rochester is receiving payment from the Brain & Behavior Research Foundation and the National Institute of Health to conduct this study.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any emotional or physical discomfort please contact: Dr. Alexandre Paim Diaz at 585-690-6989.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., Rochester, NY 14642, Telephone 585-276-0005 or 877-449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject
- To voice concerns about the research
- To provide input concerning the research process
- In the event the study staff could not be reached

Voluntary Participation
Taking part in research is voluntary. You are free to not take part or to withdraw at any time, for whatever reason. No matter the decision you make, there will be no penalty or loss of benefits to which you are entitled. If you do withdraw from this study, the information you have already provided will be kept confidential.

Optional Research Activities:

Place your initials in the YES **OR** NO box, based upon your decision to take part.

Communication with the Study Team

YES *(initial)*	NO *(initial)*	
		*I consent to the use of **email** in this study. If yes, enter email address:* _____
YES *(initial)*	**NO** *(initial)*	*I consent to the use of **text messaging** in this study. If yes, enter phone number:* _____

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done
- What will happen during the study
- Any possible risks and benefits to you
- Other options you may have instead of being in the study
- What to do if you have problems or questions about this study

Subject Consent

I have reviewed the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. If I choose to, I will receive a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have reviewed this form with the subject. I will provide a copy of this consent form if the subject would like one. An explanation of the research was given and questions from the subject was solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date