Transcranial Direct Current Stimulation Treatment for Warriors Experiencing Chronic Pain

NCT05254379

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 100 people who are being studied, at Emory.

Why is this study being done?

This study is being done to examine how useful a device may be in pain management. The device, called a transcranial direct current stimulation (tDCS) is a non-opioid, self-administered device that has showed effectiveness in pain reduction in other populations and we will look at whether it is effective in Servicemembers and Veterans within the Emory Healthcare Veterans Program's intensive outpatient program (EHVP-IOP). You are being asked to be in this research study because you are seeking treatment at EHVP-IOP and have reported a history of chronic pain.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate during your 2-week treatment program (10 study visits). You will be asked to complete 5 series of surveys and a single phone interview, remotely, after your treatment is completed. You will not need to return to the study site after treatment completion to participate in the surveys. The researchers will ask you to do the following: participate in tDCS sessions, donate blood and saliva ,and complete a series of assessments and surveys. ALL these procedures will be paid for by the study

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question and you will receive tDCS as a treatment that has shown benefit for pain management in other populations and may reduce your pain.

What are the risks or discomforts you should know about before deciding?

This study will take time. The device that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Light tingling or itching
- Mild discomfort at the area of stimulation
- Dizziness and/or nausea
- Loss of privacy
- Breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

If you choose not to participate in this study, you can continue your current pain management treatment and discuss referral for alternative pain management outside of EHVP after completion of the program.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the "Costs" section further below.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time is required to participate in the study, make sure that you get clarity on any words you do not understand, and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Transcranial Direct Current Stimulation treatment for Warriors Experiencing Chronic Pain

IRB #: 00003899

Principal Investigator: [redacted]

Study-Supporter: Wounded Warrior Project, Inc (WWP)

Introduction

You are being asked to be in a research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to examine the effectiveness of tDCS in reducing pain in military Servicemembers and Veterans with chronic pain. We are interested in observing the changes in biological markers, blood and saliva, as it relates to treatment processes. tDCS, transcranial direct current stimulation, is a non-invasive, painless brain stimulation treatment that uses electrical currents, at a low-intensity level, to excite specific parts of the brain. This device is not approved by the FDA for the use of pain reduction in participants with PTSD or other mental health conditions. However, it is a non-significant risk device. You are being invited to participate in this study because you have reported chronic pain and are seeking treatment from EHVP-IOP for an invisible wound such as PTSD or other mental health conditions.

If you agree to be in this study, you are granting researchers access to your clinical information. This includes the information gathered during your regular visits and the information saved in your medical record. Your records may be used for an indefinite period. You will be one of 100 participants in this research study.

What will you be asked to do?

Standard of Care Procedures

Standard of Care Procedures are appointments or assessments that are a part of your treatment and intended for your care. They are designed specifically for you and will be scheduled as a part of the treatment program whether you choose to join or not join the study. If you decide not to join the study, the standard of care procedures will remain as a part of your treatment plan. The following activities are scheduled for standard of care:

- Individual and group therapy sessions
- Group wellness sessions
- Treatment surveys
- Clinical labs (blood and urine collection)

Later in this document, we will explain the difference between blood drawn for research and blood drawn for treatment and is a part of your clinical care. If you have any questions during the program, please contact any member of the research team. There will be contact information available to you via email and towards the end document.

Screening Pregnancy Test

If you are NOT of child-bearing potential, no pregnancy test will be performed.

If you are of child-bearing potential, you will be asked to provide a urine sample to determine the current pregnancy status. Whenever possible, the test will be combined with clinical labs to reduce the number of samples collected. If the test comes back positive, you will be withdrawn from this study and will continue your treatment program. If the test comes back negative, we will continue with the study visits as planned.

Transcranial Direct Current Stimulation (tDCS) Administration

Figure 1:
Soterix 1x1 tDCS mini-CT Stimulator (Soterix Medical Inc , NY)

Figure 2:
Head Strap and Sponges

You are being asked to use a handheld device, called a tDCS stimulator, in which you will set up and administer yourself while being monitored by a study team member. tDCS is a non-invasive technique that has been used in treating pain management and depression. All equipment will be provided and loaned to you for the duration of your treatment at EHVP. You may transport these items between the clinic (12 Executive Park) and your place of lodging (home/hotel) as some sessions may occur off campus.

Snappads are damp, saline-soaked sponges, that snap into the head strap and will be discarded after each use. For the best results, the sponges must be as close to your scalp as possible. This may require you to alter the styling of your hair, remove any head coverings, or press the sponge onto your scalp to improve the connectivity. Please communicate any scalp conditions or other concerns you have that may hinder the application of the head strap to the study coordinator.

During the first visit, a study coordinator will instruct and help you to setup and apply the equipment. For all other visits, you will complete the setup of the device for each session and the study coordinator will be monitoring via Zoom. Once the system is setup, you will receive a unique one-time code in order to begin the stimulation. A timer will countdown the minutes until the end of the session starting at 20. Then, a constant flow of low intensity electrical

currents (electric charges that flow between two points) will travel from one electrode to the next. You may experience a tingling sensation during the session, which is normal and expected. The sensation will become less noticeable but should not be intolerable. If it is intolerable or you do not wish to continue after experiencing the stimulation, inform the research staff and the coordinator will instruct you on how to stop the session. Your participation is voluntary and at any time, you may withdraw from the research study. At the end of the session, the device will make a beeping sound and automatically turn off. Then, remove the headset, discard the sponges, and store all materials safely for the next session.

Up to 10 tDCS sessions will occur, over Zoom, with a study coordinator who will be monitoring each visit. The study coordinator will be available for questions, concerns, or to assist with any troubleshooting needs. Each session will last for 20 minutes and will occur during your 2-week treatment period. Three of these sessions will include the collection of blood and saliva. More details can be found in the Blood Sample and Saliva Sample sections below. You will need to report to the Veterans Program site for all blood and saliva collection activities. See next page, 'Table 1', for an overview of each visit and its locations.

Your participation in this study is voluntary. You do not have to receive the tDCS pain treatment, though, by not completing the tDCS session you may not participate in this study. Your medical treatment will not change, and you will continue to receive care from the Emory Healthcare Veterans Program.

Blood Sample

A nurse or medical staff member will draw your blood at 3 different study visits (days):

1) before the start of treatment,
2) mid-point of treatment, and
3) at the end of treatment.

Within each of these visits (days), up to 3 tubes of blood and saliva in total:

1) before session x 1,
2) after session x 1, and
3) after therapy session x 1.

About 3-4 tablespoons of blood is collected per visit, up to 3 days throughout treatment. This will be drawn from a peripheral IV, which is a small, plastic catheter placed into a vein, usually in the hand or elbow. The IV catheter would remain inserted for the duration of the study visit and blood will be drawn to reduce the number of sticks. The IV will be removed at the end of the visit and before returning to your regular programming.

Alternative option: blood may be collected using a single stick for each draw, by trained personnel.

Your samples will be processed and stored using a code number instead of your name or any information that can be used to identify you.

Saliva Sample

A saliva (spit) sample will be collected alongside the blood samples at the same time points described above. You will gently chew on a sterile swab and place it into a tube provided to you. Do not to smoke, eat, or drink anything, except water, 30 minutes before providing this sample. Your samples will be processed and stored using a study code instead of your name or any other information that can be used to identify you.

Questionnaires (Surveys)

Study visits will include responding to questionnaires and interviews for the purpose of assessing your chronic pain and analyzing usefulness of the tDCS device. These will be completed via REDCap, a confidential electronic database. A link will be emailed to you by the study coordinator each day they are scheduled to be completed, including follow-ups, explained on the next page. Completing the research surveys will take up to 20 minutes, at each visit.

Table 1 - Schedule of Treatment Study Events

	Day/Visit	Study Activities	Location
Week 1	1	▪ *Pregnancy test, if applicable* ▪ Initial tDCS Session ▪ Survey	12 Executive Park
	2	▪ tDCS Session ▪ Research Blood/Saliva Collection	12 Executive Park
	3	▪ tDCS Session ▪ Survey	Remote Optional
	4	▪ tDCS Session	Remote Optional
	5	▪ tDCS Session ▪ Research Blood/Saliva Collection ▪ Survey	12 Executive Park
Week 2	8	▪ tDCS Session ▪ Survey	Remote Optional
	9	▪ tDCS Session	Remote Optional
	10	▪ tDCS Session ▪ Survey	Remote Optional
	11	▪ tDCS Session ▪ Blood/Saliva Collection	12 Executive Park
	12	▪ tDCS Session ▪ Survey ▪ Compensation	12 Executive Park

Long-term Follow-up

Additional data will be collected for up to 12 months following your treatment at the Veterans Program. These will be conducted remotely and will not require any travel to the study site. A survey link will be emailed to you at scheduled times. Be sure to check your email's inbox and spam folders for all follow-up communications from the research team.

The research team will collect available days and times from you to schedule the 3-month phone interview. This follow-up will be conducted no later than your 6-month assessment. The interview will review current pain and symptoms of any mental health condition reported during your initial treatment program. The phone interview may take up to 1 hour of your time.

In addition to these, your clinician or the study investigator may choose to offer you a boost of tDCS administration. If this is not suggested by the study team or clinician, only questionnaires will continue to be collected. For participants with child-bearing potential, a pregnancy test will be required to continue with booster sessions. Booster sessions will occur daily for an added two weeks, not including weekend days. The device would be shipped to you with shipping materials and instructions for its return. After the two-week booster period is completed, the device will be returned to the study site and no further tDCS sessions will be performed for the rest of the study.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. All samples will be stored in a Department of Psychiatry laboratory. A code will be used to link your samples to the other research information you provide. At any time, you may ask to have your samples or data destroyed so that no future research can be collected from them. If you leave the study, the data and samples that were already collected may still be used for this study.

The data collected for this study will be kept in a secure manner. Samples/data may be shared with other researchers and used in future research. The goal of the study is to learn more about PTSD and other related mental health issues, their response to treatment and the effectiveness of tDCS in the reduction of reported pain.

What are the possible risks and discomforts?

There may be side effects from the study device or procedures that are not known at this time.

The **most common** risks and discomforts expected in this study are:

- Loss of privacy or confidentiality
- Blood draw:
  - discomfort at the needle site
  - possible bruising and swelling around the needle site

The **less common** risks and discomforts expected in this study are:

- Light tingling or burning sensation at the area of stimulation
- itching at the area of stimulation
- mild discomfort at the area of stimulation
- Dizziness
- Nausea

Rare but possible risks include:

- Blood draw:
  - Infection
  - Fainting

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study device, people who are pregnant may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant participants will be taken out of the study immediately.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. Your condition may improve while you are in this study, or it may get worse. This study is designed to learn more about the effectiveness of the tDCS device in reducing reported pain

symptoms in Servicemembers and Veterans receiving treatment. The study results may be used to help others in the future.

Will you be paid for your time and effort?

There will be no costs to you for participating in this study. If you agree and complete the research study, you will receive a reloadable gift card (Clincard) for compensation. The card will be loaded if the study visits and follow-up visits are completed in full:

Table 2. Compensation Schedule

Compensation Schedule			
Payment #	Time Point(s)	Amount	Requirements
1	Initial Study Completion	$100	If you complete all initial study visits
2	**1-month** Follow-up	$10	If you complete all follow-up questionnaires
3	**3-month** Follow-up	$15	If you complete all follow-up questionnaires
4	**6-month** Follow-up	$10	If you complete all follow-up questionnaires
5	**9-month** Follow-up	$10	If you complete all follow-up questionnaires
6	**12-month** Follow-up	$10	If you complete all follow-up questionnaires
	TOTAL	**$155**	***If all study visits and follow-up visits are completed***

You will get $155 total if you complete all study visits. If you do not finish the study, we will prorate your compensation according to the study visits you have completed. Withdrawals within the first week will be prorated to no more than $10 for each study visit completed.

What are your other options?

This study is completely voluntary. If you choose not to join this study, you can still get treatment through the Emory Healthcare Veterans Program (EHVP). You do not have to be in this study to be treated for PTSD or any other mental health condition.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request to produce documents.

Storing and Sharing your Information

We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.
Your individual health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you.

Returning Results to Participants/Incidental Findings

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

The results of all your study tests and procedures will be used only for research purposes and will not be placed in your medical record. Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for taking part in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to properly exit the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- Early dismissal or termination from clinical program
- Failure to follow instructions of study procedures
- Failure to complete study activities

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

Research-Related Treatment
This study involves research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. We will use and share your IIHI to provide you with study related treatment and for payment for such treatment. We may share your IIHI with others if we feel you are a danger to yourself or someone else in the interest of protecting you or another person from harm. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- Wounded Warrior Project, Inc. is the supporter of the study. The supporter may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The study supporter may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at:

[redacted] Veterans Program
Atlanta, Ga 30329
[redacted]

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people

who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To keep the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns, or complaints about the research

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke**.

Consent and HIPPA Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**