Consent to Participate in Research

Study Title: Toward personalized treatment of Chronic pain using transcranial direct current stimulation paired with deep learning

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Sponsor and/or Funder
This study is funded through a career development award from The University of Arizona Health Sciences.

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.

Summary of the Research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

The purpose of this study is to determine the impact on chronic pain using tDCS, a non-invasive brain stimulation treatment that uses low-amplitude direct electrical currents to stimulate specific parts of the brain. This study will use an investigational device called the tKIWI to deliver tDCS to participants experiencing chronic pain. The tKIWI is a product of ni2o, Inc. tDCS is recognized to be a safe, non-invasive brain stimulation treatment. This treatment has been widely studied for a number of neurodegenerative brain disorders, and literature reports minimal side effects, which may include tingling at the site of the electrode, slight burning upon treatment, itching at the site during the treatment, redness at the site of the electrode, headache, and discomfort. All of the potential side effects have been reported to be temporary and transient. For example, when tingling and itching occurs, it has been reported to last approximately ten minutes after treatment ends. If there is any redness at the site the electrode is placed, it has been reported to last up to a couple of days due to the increased blood flow to that area during treatment of tDCS.

Participants in this study are required to experience chronic pain symptoms for at least three months that may be associated with a medical diagnosis or have a documented history of chronic pain. The overarching goal of this study is to evaluate the use of tDCS to reduce chronic pain and reduce the self-reported need or desire to use opioids.

By agreeing to participate in this study, you are agreeing to attend 7 study sessions over an 11-day period. During the first visit, you will be asked to complete a demographic survey, a pain

medication survey, and a screening survey. You will be asked to indicate your current pain level using the FACES Pain Scale and the Visual Analog Pain Scale (VAS), and you will take a short cognitive survey called the Mini Mental State Examination (MMSE). You will also receive an electroencephalogram (EEG). An EEG is a test that measures electrical activity in the brain using small electrodes resting on the top of the scalp. Your brain cells communicate via electrical impulses and are active all the time, even during sleep. This activity shows up as wavy lines on an EEG recording. We will also measure your vital signs, such as pulse, blood pressure, pulse, and temperature. This first session may take up to 1.5 hours.

Visits 2-6 of this study will consist of a pre-session survey to ensure nothing has changed in your study profile, pre-treatment EEG, a twenty-minute tDCS session broken into three different sessions, and a post-treatment session EEG. You will also report any side effects during each visit by filling out a brief survey. Vitals (heart rate, pulse, blood pressure, and temperature) will also be taken at the beginning and end of each session, as will self-reporting your level of pain using the pain surveys. Visits 2-6 could take between 1-1.5 hours.

The final visit will consist of a final EEG and completion of a Pain Medication Use Survey, self-report surveys FACES, VAS, and MMSE. This visit will take approximately 1 hour.

Why is this study being done?

The purpose of this study is to determine the impact of tDCS, a non-invasive brain stimulation treatment that uses low amplitude direct electrical currents to stimulate specific parts of the brain. This study will use an investigational device called the tKIWI to deliver tDCS to participants experiencing chronic pain.

What will happen if I take part in this study?

Once recruited, you will be randomly placed in one of two groups. One group will receive the tDCS treatment and the other group will receive a placebo tDCS treatment. Each participant has a 50% chance to be in either the treatment group or the nontreatment group.

Participants in this study are required to experience chronic pain, but not currently be using illicit substances. The overarching goal of this study is to provide personalized treatment for reducing chronic pain.

How long will I be in this study?

By agreeing to participate in this study, you are agreeing to attend 7 study sessions over an 11-day period.

How many people will take part in this study?

We are recruiting 40 participants for this single blind clinical trial. A single blind clinical trial means that participants will be randomly selected to be in one of two groups.

What benefits can I expect from being in this study?

You may or may not feel a reduction in pain by participating in this study. Your participation will be contributing to an innovative, non-invasive, non-habit forming, and safe supplemental treatment for chronic pain.

What risks, side effects or discomforts can I expect from being in the study?

The risk is minimal and any discomfort you may feel should be minor and temporary, as outlined in the Procedures and Protocols section. As in any research study, there is always a small chance of a breach of confidentiality. While we do not anticipate this occurring, if it does, we will notify you via email of a breach.

What other choices do I have if I do not take part in this study?

Your participation in this study is voluntary, and you may withdraw at any time without any negative consequences to you or without penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw, we will use the data we have collected from you up until your date of withdrawal. If you do not want us to use data we have collected from you, please notify us upon your withdrawal. There are no alternative procedures related to this study other than to not participate.

When may participation in the study be stopped?

If, at any time and for any reason, you elect to leave the study, you may do so without any repercussions to you. Our preference is for you to notify our research staff via email or telephone if possible so we can appropriately debrief you. We will use the data we have collected up until the point of your study departure unless you request in writing otherwise.

What happens if I am injured because I took part in this study?

If you should experience any of the possible side effects indicated above that require attention, please notify the research team immediately or email the PI, Dr. Allison J. Huff. Because the possible risks to you are minimal and if they occur are expected to be temporary, we do not offer compensation for experiencing one of the more commonly reported side-effects listed under the Procedures and Protocols section. However, general first aid will be available to address any superficial side effects. We do not provide compensation for the unlikely event of a more serious side effect/injury. Medical care is not available on site or covered through this grant. However, if you suffer an injury from participating in this study, you should seek treatment.

What are the costs of taking part in this study?

There is no cost to you for participating in this study other than your time. The transcranial direct current stimulation (tKIWI device) and services performed for research only will be provided at no charge to you or your insurance company.

Will I be paid for taking part in this study?

You will be compensated a total of $175 upon completion of the study. You will receive the payments in cash in the amounts outlined herein: $25 at visit 0; $50 at visit 3; and $100 at visit 6 Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. Please note, if you are an employee of UArizona, any compensation from a research study is considerable taxable income.

For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes. Identifiable information collected for financial compliance purposes will not be linked to your research data. If you do not want us to collect this information, you can still participate in this study, but you will not be able to receive any payment for your participation.

Will my data be stored for future research?

Deidentified raw EEG and tDCS data may be stored for future research and may possibly be used to identify different biomarkers and further train algorithms. The deidentified EEG and tDCS data will be shared with industry partner, ni20, Inc., as per our data sharing agreement.

Will my data be sold for commercial profits?

Your data will not be sold for commercial profit.

Will I hear back on any results that directly impact me?

The results of this trial will be submitted for publication in peer reviewed journals, but you will not be notified of results that directly impact you.

Will my study-related information be shared, disclosed, and kept confidential?

It is anticipated there will be circumstances where your study related information and data will be released to persons and organizations described in this form. If you sign this form, you are giving permission to the research team to use and/or disclose your data and demographics for this study. Your information may be shared or disclosed with others to conduct the study, to comply with regulations, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- The University of Arizona (UA) and the UA Institutional Review Board
- The sponsor and/or funder supporting the study, their agents or study monitors

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study, you may contact **Allison J. Huff, DHEd (Principal Investigator)**.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program.

Signing the Consent Form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	Signature of subject	Date

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date

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