Neurofeedback-EEG-VR System for Non-opioid Pain Therapy

NCT04551092

Document dated March 6, 2021

University of California, San Diego
Consent to Act as a Research Subject

Neurofeedback-EEG-VR (NEVR) System for Non-opioid Pain Therapy

Introduction

Dr Krishnan Chakravarthy is conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

We are trying to find out more about a non-invasive, non-medication alternative that could treat pain by combining virtual reality (VR) and brain waves. You have been asked to participate in this study because you have chronic back pain. Participation in the study may or may not benefit you directly and may result in new knowledge that may help others.

You will first be screened to determine if you are eligible for the study. If you are eligible, you will be asked to come in 3 times a week, every other day, for 7 weeks (20 sessions total). At these visits, you will wear a VR head set and asked to follow the directions for 30 minutes. Afterwards, you will fill out a series of questionnaires. Each visit will last an hour.

The potential risks of the study are eye strain, headache and nausea, which are not very common.

We do not expect any serious risks. If you experience discomfort, the headset will be removed immediately.

The alternatives to participation in this study is not to participate. You can discuss with your pain physician alternatives such as physical therapy, manual manipulation, regularly prescribed analgesic medications, and standard interventional therapies including steroid injection and radiofrequency ablation.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why is this study being done?

The purpose of this study is to see if the Neurofeedback-EEG-VR (NEVR) system can reduce pain in chronic back pain patients. The data collected will then be used to further develop and

design the system. There will be approximately 25 participants in this study. This is the only site for the study.

What will happen to you in this study and which procedures are standard of care and which are experimental?

In addition to the information at the beginning of this form, here are some additional details about will happen to you if you agree to be in this study,

You will be asked to read and sign this consent form before any study-related procedures are performed.

Visit 1, 1 hour, Altman Clinical and Translational Research Institute (ACTRI):

To participate in this study, you must be screened to see if you qualify for the study.

- A full medical history, including a listing of the previous treatments you have undergone for your chronic back pain. You will be asked several questionnaires regarding your chronic back pain

Once you are eligible to be in the study, you will be asked to do the following after eligibility and at all subsequent visits:

- You will sit in a comfortable seat and the NEVR headset will be placed on you. There will not be any gel applied. Each contact point will be worked through your hair to ensure good contact with the scalp in order to provide adequate signal quality.
- The NEVR headset is a combination of a virtual reality (VR) headset with a dry electrode brain activity (EEG) monitoringheadset. The VR headset is a consumer product similar to most that are commonly on the market today; the EEG headset consists of a plastic cap that is donned lie a bicycle helmet and holds the dry electrode EEG sensors. These sensors have spring-loaded pins that go through the hair to make contact with the scalp and earclip sensors. The headset weighs approximately 1.5 lbs and is typically found to be very comfortable to wear. Neither device is FDA approved, however they are both commercially sold and considered minimal risk.

- The headset will be calibrated by having you sit quietly and open your eyes for 2 minutes and close your eyes for 2 minutes while EEG is being monitored and recorded.

- After calibration, you will complete 6 blocks of 5 minutes each. During each 5 minute block you will be asked to either watch a VR movie or play a VR game, and follow the instructions. The parameters of the movie or game will change based upon your brain activity. For instance, when your brain activity reaches the desired threshold, the screen may change in brightness or clarity, the audio may become louder or more clear, the video playback or gaming speed may increase, or the game may progress to higher levels in order to create a more rewarding experience. On the other hand, when your brain activity falls below the threshold, the screen may become dimmer or less clear, audio may become softer or less clear, video playback or gaming speed may slow, or the game may not progress to the next level in order to create a less rewarding experience.
- You will have the opportunity to rest between the 5-minute blocks.
- You will answer a series of questionnaires regarding your pain, anxiety, depression, disability, sleep and improvement in treatment.

At the 10th session and at the last study session, you will be asked to answer additional questionnaires about your pain, disability and improvement in treatment.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form, these include the following:

- **Loss of Confidentiality Risk:** Absolute confidentiality cannot be promised because information needs to be shared as described below. However, information will be collected and shared following standards of confidentiality. Your identity as a participant in this study will remain strictly confidential. You will be identified in the study under a study-specific code. Should results of this study be published, you will not be identified through your name or personal information.
- **Questionnaires:** You may be uncomfortable answering certain questions. You may also experience boredom, fatigue, or embarrassment.
- **Device:** This device is for research only and does not have a FDA status. The risk is considered minimal.
    - **Electrical Safety:** During the set-up of the headset, contact between the electrodes and the skin is assessed via a measurement of the contact impedance. To accomplish this, a very small current is applied to the skin. This system uses a current far below the safety standard. For comparison, holding a 1.5V AAA battery would result in a current of 0.75 μA, or 700 times that of our system
    - **Materials:** The materials coming in contact with you are compatible and minimal risk. The electrode tips are coated with a material that is commonly used in FDA-approved EEG and ECG electrodes. The other material that may come in contact with you is the foam padding which is made from a neoprene material commonly used for underwater garments.
    - **Comfort:** The headset been designed for comfort and feedback from users indicates high tolerability and comfort in extended continuous wear for periods up to 8 hours. However, should you report discomfort from wear of the headset that normal adjustments cannot resolve, the headset will be promptly removed, and the data collection will be terminated.

- **VR headset:** The HTC Vive is a commercial consumer device that is believed to be minimal risk, though VR usage may pose risks of eyestrain and headache and nausea from the visual experience.
- **Neurofeedback:** Negative side effects from neurofeedback rarely occur, when neurofeedback protocols are well controlled. When present, they have been primarily associated with mild anxiety, fatigue, or frustration during the session itself. In general, there is a risk that sitting still might make your pain worse. We will try to ensure that you are in a comfortable position for the duration of the session, including offering the option of doing the sessions while standing up or laying on the floor. If there is significant concern for intolerability, we will ask you to stop the treatment.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you from these procedures. It is possible that you may benefit from pain relief during these sessions. In addition to the benefits listed at the beginning of this form, you may gain some benefit from the neurofeedback portion of these sessions

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, please inform study staff.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

- If it is in your best interest or for any other reason deemed appropriate by the primary investigator or the sponsor
- You do not consent to continue in the study after being told of changes in the research that may affect you
- You have an adverse event that prevents further participation
- The study is terminated
- You no longer fit the inclusion criteria
- Or for any other reason deemed appropriate by the primary investigator or the sponsor

You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?

In compensation for your time and travel, you will receive $200 for participating in this research. You will be paid $10 per visit for a total of 20 visits. Gift cards will be paid in increments of $30. You will receive additional $100 bonus upon for completion of all the 20 study visits
If you stop the study, you will be paid for all completed visits.

Are there any costs associated with participating in this study?
You will be responsible for the cost of parking ($5 for 4 hours of parking). All study procedures will be provided at no cost.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. Any identifying information will be kept separate from research files and will be only accessible to study staff. All research records will be stored in a locked cabinet in a locked office which is only accessible by study staff. A copy of this informed consent form will be scanned into your medical records at UCSD. Research records may be reviewed by the UCSD Institutional Review Board and other regulatory authorities like the FDA.

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.

Who can you call if you have questions?
Dr. Krishnan Chakravarthy and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Chakravarthy at 858-822-0787.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____
Subject's signature Date