Consent to be a Research Subject

Introduction

Professor David D. Busath, M.D. at Brigham Young University is conducting a research study at the BYU MRI Research Facility (MRIRF) about what happens to brain activity when people who experience chronic pain use Trans-Epidermal Nerve Stimulation (TENS) or the Calmare® Pain Therapy Medical Device. Both are treatments used to reduce chronic pain by electrically stimulating the skin in safe doses near affected areas. You are invited to participate in this study because you are chronically suffering from pain due to peripheral neuropathy.

Procedures

If you agree to participate in this research study, the following will occur:

- You will answer several questions about your general health and chronic pain that will determine your eligibility to participate in this research.
- If you meet the eligibility criteria, you will be randomly assigned to one of the two treatment groups.
- The research will take place each day over 2 consecutive business weeks.
- Before the 2-week treatment period, you will receive an MRI scan at the MRIRF. You will be informed about necessary safety measures to prepare you for the scan. During the scan, you will be asked to lay motionless and watch a video. The scan will take about 30 minutes. You will also take surveys about your pain level and your emotional well-being, which will take about 30 minutes.
- During the 2-week treatment period, you will come to the MRIRF at the same time each day. You will be seated in a comfortable treatment room to receive a 30-40 minute session of therapy from a qualified professional. Treatments will consist of electrical stimulation of the skin near the pain site using electrodes similar to EKG electrodes. The treatment will feel like a tingling, mild prickling or pins-and-needles sensation, and may also include mild muscle contraction. While the sensation may be somewhat uncomfortable, the therapist will strive to make sure that the treatment is not painful or distressful.
- Before and after each treatment session during the 2-week treatment period, you will also take the surveys about your pain level. The therapy sessions and surveys will take approximately one hour.
- If you choose to stop the treatment sessions before the completion of the 10-session set, you will be asked whether this is because the treatment is ineffective, totally effective, or some other reason. Whatever the reason, you will be invited to finish the remaining part of the study (initial and 6-week MRIs and the 3-month phone survey) at the originally scheduled times. These final steps will be very valuable for the statistical validity of the study.
- After the 2-week treatment period you will receive two more MRI scans and surveys: one within a few days and one six weeks later.
- Three months after the initial study, you will take a final survey about your pain level by telephone. At this time, you will be informed which group you were in and given information about how to get additional therapy at your own cost.

Risks/Discomforts

Risks to participants in this study:

- *TREATMENT:* When administered properly, the risks of TENS and Calmare® therapy are mild. Electrical currents from the electrodes may cause some physical discomfort or pain due to muscle contraction or skin irritation. You may experience some emotional discomfort or embarrassment before, during, or after the placement of electrodes on your body. The therapy will be conducted by a trained professional who will be attentive to your needs. Before performing any procedures, he will explain the process and allow for you to ask questions, so that you can be as comfortable as possible during the therapy.
- *MRI SCAN:* When proper safety procedures are followed, the MRI scan will also present minimal risks. You may experience some physical or emotional discomfort during the MRI scan due to restricted movement and being in an enclosed space. If you have any metal medical devices or implants in your body, you will need clearance before participating in this study, and there may be some risk of the MRI magnet affecting the proper function of the

device/implant. The MRI scans will be administered by trained researchers who will ensure that the safety guidelines are followed and that the risks are minimized.

- In the event of a significant emotional or physical injury, the researcher will refer you to appropriate counseling or medical services for treatment at your own expense.

Benefits

There are no direct benefits to you. However, you may receive information about a non-invasive way to manage chronic pain. You may experience a temporary or long-term alleviation of pain. More broadly, this study may be very helpful to the clinical community and subjects involved with questions of chronic pain by adding to the body of related research and stimulating further research.

Confidentiality

The research data will be stored both on password protected computers and in a locked file cabinet, and only the researcher will have access to the data. During the study, you will be assigned a unique ID number which will be used to label your surveys and MRI scan data. Information connecting the ID numbers to your identity will be used only to contact you for scheduling purposes. At the conclusion of the study, any publications or presentations resulting from this research will not disclose information that could identify you.

Compensation

No compensation will be awarded for completion of the study.

Participation

Participation in this research study is voluntary. You have the right to withdraw or refuse to participate at any time.

Questions about the Research

If you have questions regarding this study, you may contact David Busath, M.D. at (801) 422-8753; david_busath@byu.edu for further information.

Questions about Your Rights as Research Participants

If you have questions regarding your rights as a research participant contact an IRB Administrator at (801) 422-1461; irb@byu.edu.

Statement of Consent

I have read, understood, and received a copy of the above consent and desire of my own free will to participate in this study.

Name (Printed): _____ Signature_____ Date:_____