Official Study Title: Addressing Opioid Use Disorder with an External Multimodal Neuromodulation Device: Clinical Evaluation for Opioid-Sparing in Acute Low Back Pain

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INFORMED CONSENT FORM

Addressing Opioid Use Disorder with an External Multimodal Neuromodulation Device: Clinical Evaluation for Opioid-Sparing in Acute Low Back Pain

You have been invited to take part in this study. It is important that you read and understand the info below before you agree to participate. Your relationship with the clinic will not change if you decide not to be in the study. Please ask questions about what you do not understand before agreeing to take part.

Purpose of the Study

The purpose of this study is to determine whether providing a stimulation device to patients with acute low back pain (LBP) reduces pain and opioid use.

Procedures

If you agree to be in this study, we will ask you to do the following things: After completing the initial paperwork, you will rate your pain and complete background paperwork. Next, the computer program will determine your group assignment to one of two neuromodulation devices designed for daily home use using either mechanical or electrical stimulation both with multiple therapy cycles.

After your group assignment, you will receive a standard pain management regimen typically used for low back pain. Regardless of group assignment, you will be instructed on how to use the data collection system via an online instruction video. We are collecting information on opioid use. Therefore, we will ask you to complete the surveys on how much medication you are taking, including if there are different kinds that may be from different sources and medication you have taken prior to getting a prescription. You will be prompted by the **text message with a link** to record the following information on the website:

- Daily for one month – use of pain medication and pain relief (Device, exercise, stretching, bath, hot tub, therapy, massage, etc.).
- Weekly – how pain interferes with movement and how intense it is
- Months 1, 2, 3– changes in function and your mood

Your participation will consist of an hour for paperwork/instruction today and then a quick 2-minutes survey daily for a month. Each week there will be a 15-minute questionnaire for the full three months of the study.

	Initial	Week 1,2	Week 3,4	2nd Month	3rd Month
Enrollment Paperwork	X				
Watch appropriate video	X				
Back pain & background info	X				
Multiple Pain Impact Rating Scales	X	Weekly	Weekly	Weekly	Weekly
Pain after 30 minutes of use	X				
Pain, device & pain medicine use	X	Daily	Daily	Weekly	Weekly

Risks and *Benefits* of being in the study

Possible Risks: The risks of the device should be no greater than the risks of a hand-held massager, electrical stimulator, or hot or cold pack depending on which group you're in. The possibility exists that the focus on pain assessment will draw attention to the LBP and could increase your pain. You will be given your own device so risk of transmitting infection will be minimal. In previous research, patients with LBP supported that the use of the device is helpful; no patient has stated that it increases pain or causes other problems. The risk of receiving no intervention is the same risk which is standard of care for patients being treated for LBP throughout the country. Electrical stimulation is already a standard of care and found safe for LBP. Cold and heat are already a standard of care in home remedies for LBP – the possibility of increased sensitivity to cold exists, but you choose whether or not to use the cold portion if you're in this group. Patients receiving cold therapy will not be exposed to enough cold to result in frostbite. Likewise, if you do not want heat, you do not have to use heat with your device, or if you do not want electricity you don't need to use it.

Benefits: This study will determine whether different kinds of low back stimulation for patients with LBP will reduce opioid use. Achieving our aims implies, you may reduce your use of pain medication or not need to start opioids. The results of the study may also be translated to other musculoskeletal complaints where inflammation, pain and stiffness are concerns that decrease quality of life. If the stimulation device increases compliance with medical care, it may diminish pain, stress and reduce opioid use, which provides a significant benefit to you. Conceptually it will challenge the pharmaceutical focus of current pain strategies, changing practice in the field of pain relief and rehabilitation. If there are lower unused opioids in circulation, this is also an important addition to combatting opioid use disorder.

Confidentiality

All info you reveal in this study will be kept confidential. Your records will be assigned a random number instead of using your name. Documents will be stored in a locked cabinet and electronic files will be kept on a secure computer. Only members of the research team will have access to these records. Three years after the study, we will shred all papers. When the study is published your name will not be included. Your records may be looked at by the Kaizo Clinical Research Institute IRB, Department of Health and Human Development, the Food and Drug Administration, and state and federal agencies.

Compensation

You will be compensated for each of the questionnaires you complete according to the following schedule.

- Weeks 1 and 2: $1 a day for every time you complete the daily form. If you complete 7 days in a row you will earn a $3 bonus for hitting the streak.
- Weeks 3 and 4: $2 a day for every time you complete the daily form. If you complete 7 days in a row you will earn a $6 bonus for hitting the streak.
- Months 2 and 3: $10 every time you complete a weekly survey. If you complete four weekly surveys in a row you will earn a $10 bonus for hitting the streak.

This will total a maximum of $160 you can earn. You will be paid with an Amazon gift card at the end of each month. You must complete 80% of the data in weeks 1 and 2 to continue to weeks 3 and 4. If you complete 80% of the data in the first month you get to keep the assigned device. If you do not, we will ask for you to return the device and you will forfeit the money earned during this first month.

Injury or Illness

If you say YES to participate, then your consent in this document does not waive any of your legal rights. However, in the event you are injured or become ill as a result of participating in this study, neither Kaizo Health, Kaizo Clinical Research Institute, Kaizo Clinical Research Institute IRB, or any other researchers are able to give you any money, insurance coverage, free medical care, or any other compensation from such injury. In the event that you suffer injury as a result of participation in any research project, you may contact Dr. Jay Greenstein at (301) 518-1006 or Dr. Barton Bishop the current IRB chair at (240) 766-0300 x835 at Kaizo Clinical Research Institute, who will be glad to review the matter with you.

Voluntary Nature of the Study:

Taking part in this study is completely voluntary. You may withdraw and stop participating at any time. If at any time, you wish to withdraw from the study please let any member of the research staff know.

Contacts and Questions

If you have any questions, you can call Jena Slaski (240) 766-0300x838. If you have concerns about your rights as a research participant, you can contact Kaizo Clinical Research Institute IRB Chair, Barton Bishop at (240) 766-0300x835.

Statement of Consent

I have read the info above. I have had the chance to ask questions and have them answered. I agree to participate in the study and have been given a copy of the consent form.

_____ _____

Participant's Signature Date

_____ _____

Researcher's Signature Date