Official Study Title: Usability of a Multimodal External Neuromodulatory Device to Relieve Acute Low Back Pain

NCT #: NCT04494841

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INFORMED CONSENT FORM

Feasibility of the DuoTherm in Acute and Chronic 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 evaluate the feasibility of the DuoTherm device in reducing low back pain (LBP).

Procedures

If you agree to be in this study, we would ask you to do the following things: After completing the informed consent, you will rate your pain and complete background paperwork. Next you will be instructed on how to use the DuoTherm device. This will be by reading a piece of paper and watching a video. After you understand how to use it, you will try out the device for twenty minutes. While you are using the device, you will answer questions related to the features of the device and how it relieves your back pain. After you use the device, the skin temperature will be measured and you will complete one more questionnaire. Your participation will consist of one 30-minute session at Kaizo Health.

***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 or hot or cold pack. 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. Cold and heat are already a standard of care in home remedies for LBP – the possibility of increased sensitivity to cold exists, but you can remove the cold portion, and the amount of gel in packs does not have thermal energy enough to result in frostbite. Likewise, if you do not want heat you do not have to use heat with your device.

Possible Benefits: Participating in this study may not benefit you directly, but it will help us improve the DuoTherm product design. Achieving our aims implies, you may reduce your pain. It may also be translated to other musculoskeletal complaints where inflammation, pain and stiffness are concerns that decrease quality of life. If this vibratory device increases compliance with medical care, it may diminish pain, stress and reduce opioid use, which provides a significant benefit to you.

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 and delete electronic files. When the study is published your name will not be included. Your records may be looked at by the Kaizo Clinical Research Institute IRB, the Food and Drug Administration, and state and federal agencies.

Compensation
You will be given a $25 gift card for your participation in the study.

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 Sport & Spine Rehab 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 Sport & Spine Rehab Clinical Research Foundation, 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.
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_____	_____
Participant's Signature	Date
_____	_____
Signature of Parent/Guardian	Date
_____	_____
Researcher's Signature	Date