Duotherm Usability Study

IRB Approved: 6/11/2020

The purpose of this focus group is to evaluate the feasibility of the DuoTherm device in treating low back pain.

Methods: A convenient sample of up to 20 patients with acute or chronic low back pain (LBP) will be recruited in two tronches for this study. Exclusionary criteria will include: less than 18 years of age; pregnancy; cancer; radicular pain likely reflecting a surgical or mechanical problem; BMI greater than 30 (device won't fit); sensitivity to cold or vibration (e.g. Raynaud's or Sickle Cell Disease); diabetic neuropathy rendering a patient unable to determine if the device is too hot; new neurologic deficits, skin lesions over the low back area; the inability to apply DuoTherm device. Up to 10 participants will be recruited to provide feedback on the device at the conclusion of their treatment. Upon agreement, consent will be obtained, and participants will complete all study paperwork and rate their current low back pain on a 0 – 10 Visual Analog Scale. Participants will be given instructions on how to use the DuoTherm. They will then be given up to 20 minutes to use the device on the setting of their choosing.

Study personnel will give enrolled patients a choice of heat, cold, or no thermal intervention. A frozen solid ice pack (VibraCool®, Pain Care Labs, Atlanta Georgia) with 4-22g sections or a microwaved single chamber 150g clay pack will be inserted behind the metal plate, and the device attached to the patient over a single layer of thin clothing. Patients will be instructed how to toggle between 12 different vibration frequency patterns, with 5 different intensity settings for each pattern. Patients will rate their pain again using a 10cm 0-10 Visual Analog Scale and chose the mechanical stimulation pattern they preferred. In addition, participants will comment on usability, mechanical stimulation pattern preference, comfort, suggested improvements, whether they would recommend the device, pain relief on an additional 1-7 Likert scale ranging from "No relief" to "Complete relief".

After using the device, they will complete a device specific questionnaire. All participants who complete the questionnaires will be given a $25 gift card for participating. After 10 participants have completed the study, the results will be discussed with the manufacturer and any issues will be addressed by revising the prototype. Additionally, investigators will evaluate the device instructions and revise as needed. The new prototype and instructions would then be evaluated on an 2nd cohort of up to 10 participants using the same protocol.

Data Collection:

Background Information: The background information questionnaires will be administered at the beginning of the focus group. Data collected by self-report with this instrument will include of age, gender, current pain medication usage, history of low back pain, and experience with pain modalities.

Statistical Analysis Plan:

Sample Size: 32 Patients have already tried the early version of the device. In addition to pain relief, we anticipate the revisions will improve the device, and are primarily interested in collecting information about comfort, usability, and choice of thermal interventions device. Prior studies with the device showed a reduction in pain of 3 +/-1 on a ten point scale. The VibraCool device with only cold and a single vibration frequency had an effect size of 0.56.

The study number will be powered by pain ratings. We anticipate the device will reduce pain by 2 after 20 minutes of use in patients with a pain score of 4 or more. If the initial pain is 5 +/- 2, with an alpha of .05 a sample size of 8 will have 80% power to detect a difference of 2. A sample size of 11 will have 90% chance.

Analysis:

Averages and standard deviations will be reported for age (<40 years and ≥40 years), cold/hot treatment preference, sex, device plate configuration, and pain chronicity. Pain scores in cm on VAS will be reported with standard deviations and t-test p values before and after device, and total percent pain relief will be reported.