Institutional Review Board
nCap Pain Modulator

Abstract
Pain is the most common reason humans go to their doctors. At any given time it is estimated that 20% of the population will be suffering some degree of pain. Pain is often associated with inflammation, trauma and disease and can be disabling and destroy lives. In clinical settings pain is described quantitatively through a numeric description. The human subject suffering pain is frequently asked to "rate their pain". The subject will then give an estimate of the pain by rating it on a one to ten scale where one represents no pain and ten represents the most pain possible. This is a very common way to diagnose the level of pain. The current solutions for Pain include prescription drugs, over the counter drugs, electromagnetic stimulation, chiropractic manipulation, physical therapy, heat, cold, herbal tinctures and trans-cutaneous electrical nerve stimulation (TENS) many of which have serious side effects. There are numerous alternative therapies that help with pain relief and novel ideas that have great promise. The need for pain management with prescription free products is paramount to this study.

Materials

The device is a Nano-capacitor film material encased in plastic. It is 5 inches wide by 5 inches long and the thickness of a penny. As a Nano-capacitor that interfaces with the body's electrical field it influences neuromuscular junctions resulting in pain modulation. All active pain modulators and placebo devices will be randomly numbered and entered into spreadsheet to track which devices are active or placebos.

Methods

The active Pain Modulator has shown great promise at modulating pain, and is the focus of this study. The purpose of this study is to determine if in fact the pain modulator product has the ability to modulate pain. The design of the study includes 10-15 randomly selected human subjects that will give base line evaluation of their initial pain and updates throughout the time they wear the modulator (through the use of a pain questionnaire/rating system).

Each of the subjects will be exposed to two modulators one active and one placebo; the subjects will alternate between the two. The modulator will be held in a holster that positions it in the center of the subjects lower back near the waistline. The holster is constructed of fabric and will provide a barrier between the device and the subject's skin. To ensure the credibility of this study the subjects and screeners will be blinded from the knowledge of which modulator is the placebo and which is the active pain modulator.

Experimental Design

After the evaluation of base line pain, each of the subjects will receive two modulators, they will be asked to wear one at a time for 23 hours a day. They will wear their first selection for two days, then the switch to the second for 2 days, then they will be allowed to choose the one they believe works best for 2 days and then return both modulators and reports to the screening location. There will be a 3-hour break without wearing a modulator between switching to allow pain to return. Each subject will rate his or her pain before each use, one hour after pain modulator is applied, then 24 and 48 hours after pain modulator is worn. To ensure the credibility of this study the subjects and doctors will be blinded from the knowledge of which modulator is the placebo and which is the active pain modulator.

Results

Results will be determined through APA approved pain questionnaires (that rate pain) and the statistical review of each creating a matrix of data that tests before, after, placebo, and active. The results determine whether the active product reduces pain as compared to placebo modulators.

Human Subjects

Human subjects will be obtained through advertising in social media. Human subjects that respond to the phone number or e-mail will be reviewed for possible inclusion in the study. All subjects will have a diagnosis of low back pain that has been ongoing for at least one month. Subjects will be invited to join a study and informed they will be paid 50 US dollars for their participation.

All human subjects will receive the pain modulator and placebo modulator for application at the time they are instructed by a screener. Each subject will sign a release form indicating they have been notified of the potential problems, hazards and giving full acceptance of the risk. The risk is little or none due the fact that the modulator is not placed on the surface of the skin and consists of inert plastic held in place by a fabric holster.

Human subjects will not be put at risk from any product, environmental toxin nor any hazardous material. The pain modulator is simply a plastic coated card like structure that will be enclosed and held in place by a fabric holster that is in contact with the mid back.

The mission of this study is to determine the safety and pain modulating potential of the pain modulator in human subjects.

Instructions to Study Participants

You have received two pain modulators; each one has a unique identification number marked upon them. You will use this identifier when filling out the surveys.

To get started you will choose one of the modulators and place it in the holster and arrange it around your waist so that it rests in the center of your back near your waistline. You can adjust the strap for a comfortable fit. The modulator should be worn underneath your shirt.

We ask that you wear the modulator 23 hours a day, please remove it for bathing. If this becomes uncomfortable during sleeping or throughout the day please fill out a survey at the time you removed it and another survey prior to putting it back on, and one hour after putting it back on. We have provided you with 25 survey sheets. Also please comment on the back of the survey the reason for early removal.

Study Schedule:

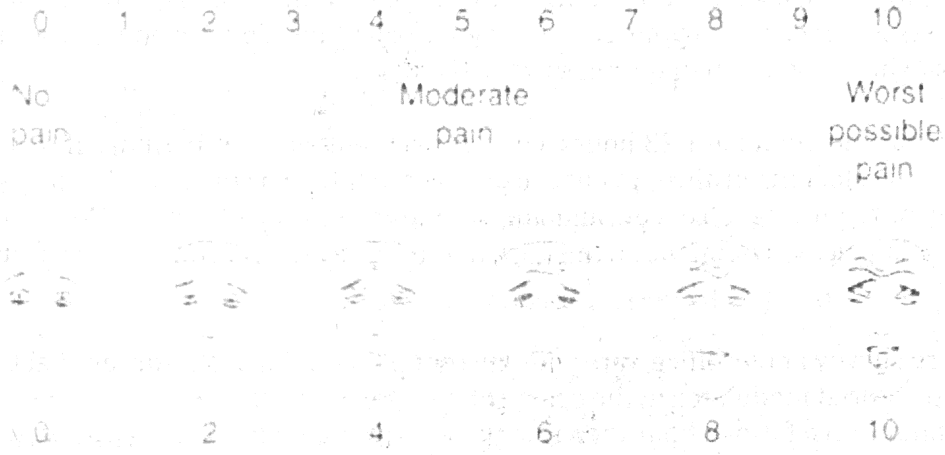
1. Day one pre survey at our office, rate your current pain level using a survey sheet.
2. Place the holstered modulator in the center of your lower back.
3. Remain at our office for one hour then rate your current pain level using a survey sheet.
4. If you have questions please ask the survey staff prior to leaving, if you have questions during the study period you may call 801-623-7182.
5. Continue wearing the modulator 23 hours a day.
6. After 24 hours rate your current pain level using a survey sheet.
7. After 45 hours rate your current pain level using a survey sheet then remove modulator.
8. After a 3-hour break, rate your current pain level using a survey sheet.
9. Swap the first modulator with the SECOND unused modulator in your holster.
10. Place used modulator back into envelope.
11. Place the holstered modulator in the center of your lower back.
12. One hour later rate your current pain level using a survey sheet.
13. Continue wearing the second modulator 23 hours a day.
14. After 24 hours rate your current pain level using a survey sheet.
15. After 45 hours rate your current pain level using a survey sheet then remove modulator.
16. After a 3-hour break, rate your current pain level using a survey sheet.
17. It's now your choice of which modulator you want to wear.
18. Continue wearing the second modulator 23 hours a day.
19. After 24 hours rate your current pain level using a survey sheet.
20. After 45 hours rate your current pain level using a survey sheet then remove modulator.
21. After a 3-hour break, rate your current pain level using a survey sheet.
22. Place all study materials into the envelope and return them to where you picked them up. Upon review and inspection of the modulators and survey materials you will be mailed a check for $50.00

You may take additional surveys throughout the study if you have information you want to share.

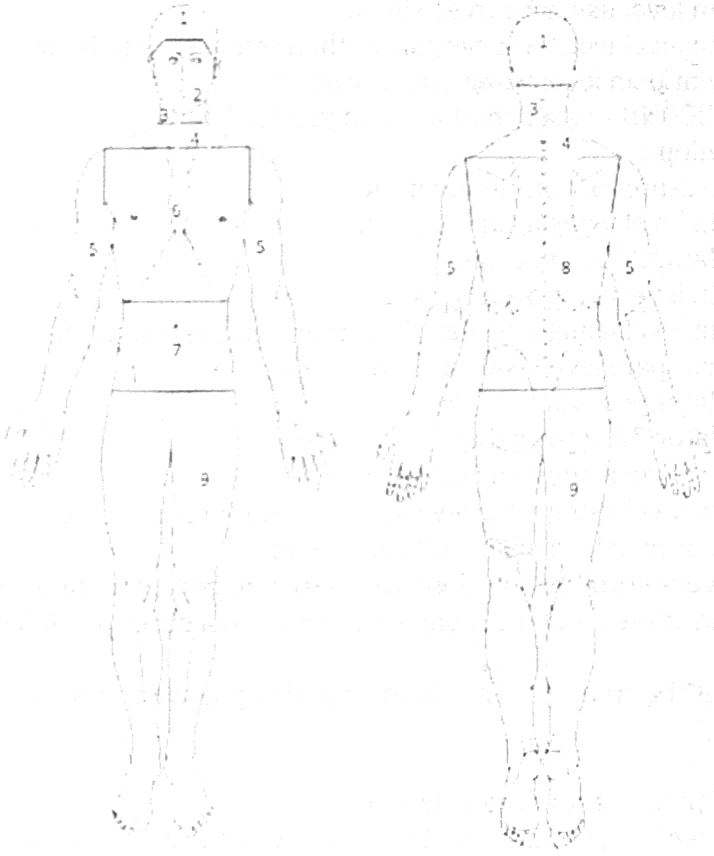
Please:
Do not communicate with other study participants about the study.
Do not fiddle with the modulator or try to take it apart, they will be inspected at the end of the study.
Do not let others play with or test the modulators during the study period.

Participant# _____ Modulator#: _____ Date: _____ Time: _____

Rate your overall pain level



Mark pain location and pain level number



Frequency of Pain

A. Constant
B. Intermittent
C. Occasionally
D. Infrequent
E. Variable

What time of day is your pain the worst?

T. Morning
U. Afternoon
V. Evening
W. Night

nCap NanoRelief IRB Study Summary

	Active			Placebo			-70	4
Study	Start	End		Start	End		Active	Placebo
11				5	5		0	0
11				2	2		0	0
11				1	1		0	0
11	1	0					-1	0
11	0	0					0	0
11	5	3					-2	0
5				4	3		0	-1
5				4	4		0	0
5	3	2					-1	0
5	2	1					-1	0
5	1	0					-1	0
8				6	6		0	0
8				5	5		0	0
8	6	1					-5	0
8	4	1					-3	0
8	5	1					-4	0
8	5	1					-4	0
12	5	3					-2	0
12	2	1					-1	0
12				2	4		0	2
12				2	2		0	0
12	2	1					-1	0
7	7	4					-3	0
7	7	4					-3	0
7				5	5		0	0
7				5	5		0	0
7	7	5					-2	0
7	7	5					-2	0
14	1	1					0	0
14	5	0					-5	0
14				2	1		0	-1
14				2	3		0	1
14	1	0					-1	0
14	2	1					-1	0
14	3	5					2	0
1				4	7		0	3
1	7	3					-4	0
1	5	2					-3	0
13	6	2					-4	0
13	4	2					-2	0
13	6	2					-4	0
13				6	6		0	0
13				6	6		0	0

13		
4	5	5
4	5	5
4	5	5
4		
4	5	5
2	4	0
2	4	0
2	4	0
2		
2		

6	6
5	5
5	5
4	4
4	4

0	0
0	0
0	0
0	0
0	0
0	0
-4	0
-4	0
-4	0
0	0
0	0
0	0
0	0
0	0
0	0