The effects of a single session of chiropractic treatment on pain processing

We will ask if you want to participate in a health research project initiated and conducted by the research group Mech -Sense (for further information see www.mech-sense.com) . The research group is part of the Gastroenterology Department at Aalborg University Hospital. The trial will be conducted in research laboratory at Aalborg University Hospital.

Before you decide whether to participate in the trial, you must fully understand what the study is about and why we are implementing it. We would therefore ask you to read this participant information carefully. If you are interested in participating, you will be invited for an interview about the experiment where this participant information will be explained in detail, and where you can get answers to any questions. You are welcome to bring a family member, friend or acquaintance to the conversation.

It is voluntary and if you decide to participate, you will be asked to sign a consent form. You can at any time withdraw from the trial without further justification, even after signing the consent form.

The experiments will be conducted in:

Mech -Sense Research Laboratory
Medical Gastroenterology
Medicinerhuset , Aalborg University
Mølleparkvej 4
9000 Aalborg

Purpose of the study
The purpose of this study is to examine how the movement of the joints (chiropractic treatment or placebo) can alter your pain ratings, the activity in your brain and muscle tissue.

Inclusion criteria
- You must be between 18 and 50 years old.
- You must have had recurring discrete back pain in the past.
- You must not have previously received treatment for this pain.
- You must be able to read and understand English.
- You must not have had complications associated with chiropractic treatment.

We are looking for 25 volunteers to be included in the trial.

If you choose to participate in the experiment, you will need to attend two experimental days. The experiment is designed so that one day you will receive chiropractic treatment and one day you will receive the control treatment. The treatment days will be randomized.

Test description

For pain rating assessment, the following will be done:

- Nociceptive reflex threshold will be found by stimulating electrically at the sole of the foot. This will be done by slowly increasing the intensity until your leg automatically withdraws as if you stepped on a needle or something hot.
    - Pain and unpleasantness ratings of this threshold, threshold * 1.3, and threshold * 1.6 will be taken on scales 0 -10
- Heat pain threshold will be found by placing the heat probe on the right arm and continuously increasing the temperature until you say your pain tolerance threshold is reached.
    - You will be asked to rate 5 seconds of heat at this threshold on pain and unpleasantness scales
    - You will then asked to insert left hand in cold water (2 degrees) for two minutes
    - After the hand has been in the cold water for one minute, you will be asked to rate the cold water on pain and unpleasantness scales
    - After the hand has been in the cold water for 90 seconds, you will again be asked to rate the 5 seconds of heat on pain and unpleasantness scales
    - After the hand has been in the cold water for two minutes, you will be asked to rate the cold water on pain and unpleasantness scales and take the hand out
    - 30 seconds after the hand has been out, you will be asked to rate 5 seconds of heat again.

All the ratings will be taken before and after the treatment.

For neurophysiologic assessment of spinal manipulation, the EEG will be recorded from 62-scalp electrodes using the extended 10-20 system montage (Quick-Cap International). By fitting cap on the head, which contains 62 electrodes, we can, using high-tech equipment, record the electrical signals sent from the stimulated nerves via the spinal cord to the brain. It does not hurt to get the cap fitted, and you cannot feel the electrodes. However, there may be some time involved in getting all electrodes to function optimally.

Part one of neurophysiologic assessment will involve nociceptive withdrawal reflexes where 18 stimuli at randomized intensities (nociceptive reflex threshold, 1.3 * the threshold, and 1.6 * the threshold) will be delivered. There will be 8-12 seconds between the stimulations. EEG will be recorded simultaneously.

Part two of neurophysiologic assessment will involve recording the EEG signals while the hand is in the cold water for two minutes. The EEG recording will start one minute before the hand is inserted in the cold water to have a baseline and be stopped once the hand is out of the cold water.

For EMG assessment of spinal manipulation, surface EMG electrodes will be placed over tibialis anterior and biceps femoris muscles. We will need to scratch your skin with sandpaper in order to get good contact with electrodes and this may cause minor discomfort. The EMG will be recorded (simultaneously with EEG) at these sites while 18 nociceptive withdrawal reflex stimulations are given as described above.

After the initial session of stimulation and EEG recordings, your joints will be moved around by a chiropractor (either actual chiropractic treatment or control treatment) and immediately following this, another session of the above recordings will be done.

The treating chiropractor will for each visit interview you to evaluate the effect of treatment. Each evaluation session will take about two hours.

After completion of the Trial

After completion of the trial, results will be compiled and published as articles in various international journals. You have the ability to get information on the overall results obtained from the investigator. The contact information of the investigator is at the end of this participant information.

Usefulness of the Trial

By participating in the trial, it is our hope that you can help to build a general model of pain, which may benefit future patients and better understanding of pain mechanisms. There are no immediate benefits by participating in this trial for you as a healthy volunteer.

Side effects, Risks, Complications and Drawbacks

You will not receive medication during the investigation. However, there may be unforeseen impacts and risks associated with participation in the trial. In the various studies, the following complications or difficulties occur.

Pain Studies: In connection with these investigations, you will naturally experience a short-lasting discomfort or pain. However, it disappears immediately after the experiment. Pain studies have been used for more than twenty years in our laboratory, and during this period, we have never seen complications.

Measurement of brain activity and muscle activity: There are no previously described side effects associated with the measurement of brain activity and surface muscle activity.

Chiropractic Treatment: Only approved techniques in the context of the chiropractic treatment will be used. These techniques have been used by a research group in New Zealand in several studies without any complications of this treatment.

Exclusions and disruption of trial

There may be special circumstances that may require you to be excluded from the study, if the investigator considers it necessary. It could be, for example, if you are experiencing significant discomfort associated with experimental pain. The trial will be interrupted for technical reasons, for example if equipment breaks down. This also may lead to termination of the trial as a whole.

Insurance and redress

If you become ill or injured because of the study, you will receive the necessary medical treatment in the public sector. You have exactly the same rights as those who do not participate in clinical trials, and you have the opportunity to seek redress and compensation for damages under the law on complaints and

compensation within the healthcare system. If you plan to travel while participating in the study, you must ensure that your private insurance applies. Therefore, you should contact your insurance company if you plan to travel.

Quality Control and Quality Assurance
If you would like to participate, please fill out a consent form. Besides making sure that you understand what the study involves, by signing the consent form, you also allow access to the necessary information about health, other purely private matters and other confidential information as part of quality control and monitoring. This is to ensure that trials are conducted in a responsible manner and in accordance with applicable law.

Information on economic conditions
This study is economically supported by a local grant at Aalborg University Hospital comprising kr 15.000, the New Zealand College of Chiropractic (NZCC) comprising kr 75,000 and the NZCC Research Supporters Programme comprising kr 45,000.

You will receive 150.00 DKR per hour as compensation for participation in the trial. Costs for transportation to and from Aalborg University Hospital will be held in accordance with government tariffs. Current rates can be found on www.statenstakster.dk .

Additional Information
Research Group Mech -Sense is composed of many different professions, i.e. doctors , nurses , pharmacists, engineers, veterinarians and different students.

All involved information will remain confidential.

If you would like to participate, please fill out a consent form.

We hope that this information has been sufficient insight into what it means to participate in the trial, and that you feel equipped to make the decision about your possible participation. We also ask you to read the accompanying literature: “Your Rights as a test subject in a health science research."

This participant information is designed to help you decide.

If you have any questions or want to know more , please feel free to contact Dina Lelic , 97 66 35 20/97 66 35 24, E- mail: dile@rn.dk

Annex
• " Your Rights as a test subject in a health science research . "

Sincerely,

Practical responsible:
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