**Participant Information for Healthy Volunteers**

**The effects of a single session of chiropractic treatment on brain activation and single motor unit recruitment patterns**

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 laboratories at Aalborg University Hospital and Aalborg University.

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 studies will be conducted in:

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

Center for Sensory-Motor Interaction (SMI)
Aalborg University
Room: E1 -202
Fredrik Bajers Road 7
9220 Aalborg East

**Purpose of the study**
The purpose of this study is to examine how the movement of the joints can alter the activity in your brain and spinal cord.

**Inclusion criteria**
- You consent to participation in the study.
- You must be between 18 and 50 years of age.
- No history of back/neck pain.
- You must be able to read and understand English.

We are looking for 10 volunteers to participate in the study.

If you choose to participate in the experiment, you have to choose whether to participate in Part A or Part B, or both Parts A and B. It is optional if you want to be part of one trial or both trials. Each part requires that you meet on one test day, so if you choose to participate in both parts of the experiment, you will need to meet on two test days.

**Test description**

**Part A**
In part A, you will receive electrical stimulation on the wrist to elicit the twitch of a thumb. When the skin is stimulated by electrical stimulation, it is done only with approved equipment. While receiving these electrical stimulations, we will measure brain activity also called electroencephalogram (EEG). By fitting a cap on the head, which contains 62 electrodes, we can, using high-tech equipment record the electrical signals sent from the body via the spinal cord to the brain. It does not hurt to get the cap fitted, and you can not feel the electrodes. However, there may be some time involved in getting all electrodes to function optimally. In order to achieve good electrode contact, we will ask you to wash your hair in the morning before meeting for the study, and ask that you refrain from using any type of hair products after shampooing.

After the initial session of electric stimulations and EEG recordings, you will receive placebo chiropractic treatment (your joints will be moved around by a chiropractor as if you are receiving chiropractic treatment). Immediately following this, another session of EEG recordings to electric stimulations at the wrist will be recorded.

**Part B**
Part B will measure muscle activity, also called electromyography (EMG).

For recording of muscle activity, we will place a few needles in the muscles. The recording of muscle activity can cause a mild tingling sensation on the skin over the muscle. This is not painful but can be uncomfortable. The stimulation will cause the muscles to contract.
This will be done before and after the placebo chiropractic treatment as in Part A.

**Common to Parts A and B**
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**
After completion of the experiment, 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. For the measurement of muscle activity, there may occur slight bleeding and superficial infection at the injection site. To avoid this, everything is done by the use of sterile one-time use needles.

**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 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 and Aalborg University 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 is confidential.

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

We hope that with 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 :
Dina Lelic
M.Sc. , Ph.D.
Mech-Sense, Department of Gastroenterology and Hepatology
Mølleparkvej 4, Aalborg University Hospital
DK-9000 Aalborg, Denmark
Tel . 97 66 35 20 / 97 66 35 24

Clinical responsible :
Asbjørn Mohr Drewes
Professor, Chief Physician, MD . , PhD
Mech-Sense, Department of Gastroenterology and Hepatology

Mølleparkvej 4, Aalborg University Hospital
DK-9000 Aalborg, Denmark