

PATIENT INFORMATION SHEET

Project title: Distraction from pain in Fibromyalgia, Arthritis and healthy volunteers.

You have been invited to participate in the above research project because you have been diagnosed with Fibromyalgia, Osteoarthritis or Rheumatoid Arthritis. Your results will be compared with those from healthy people with no pain. The purpose of the study is to investigate how well you can be distracted from a painful feeling, and how your brain responds to this. The results of the study will help us to determine the cause of pain in patients with Fibromyalgia, and in the future may help to develop more effective pain treatments.

The painful feelings will be produced by a laser stimulator, which delivers very brief (less than a second) pulses of heat pain to your skin. The strength of the pulses will be tailored to each individual person, and you will never be asked to endure levels of pain that you cannot tolerate. We will deliver the pain pulses to your forearm, and will ask you to do one of two things: sometimes you will be asked to rate the intensity of the pain on a 0-10 scale; on other occasions you will be asked to perform a simple calculation task whilst you receive the laser pulses, and give us your answer after each pulse. You will also be asked to give an average pain intensity rating at the end of each block of pulses.

Whilst you are feeling the painful pulses we will record the electrical activity of your brain by a procedure known as electroencephalography (EEG). It will involve wearing a stretchy elastic cap containing a number of electrodes that make contact with your scalp. This is a totally safe, non-invasive procedure. In order to make good contact with your scalp, each electrode will be filled with a type of gel and we will use a blunt needle to gently scratch your scalp, although this can sometimes be a bit uncomfortable. The gel will be in your hair throughout the study, but we have the facilities for you to wash and dry your hair before you leave. We may also ask if we can measure the positions of the EEG electrodes on your head. This will be done after the EEG recording using an instrument called a digitiser, and only involves you sitting still with the electrode cap on for a few minutes.

After the study you may experience some reddening of the skin on your arm due to the laser, but this should disappear within a few hours to days. There is a very small risk that you may have some superficial soreness of the skin, in which case advice will be given to you about this before you leave. There is also a risk that this area of skin may have a change in pigmentation, which should return to normal within 4-6 weeks. However in the 10 years that our group has been using this technique, one case has been brought to our attention where this pigmentation has persisted.

The study will be carried out in our research laboratory at Hope Hospital, Salford. You will also be asked to come to the lab. for about an hour on a separate day before the EEG recording. During this visit you will become familiar with how the laser pulses feel and be trained on the specific tasks you will be asked to do during the EEG recording. You will be reimbursed for your time and travel expenses for both visits.

In order to take part in these studies you must be right-handed and aged 18-65, without high blood pressure, previous heart attack or angina, previous stroke, fits, and previous brain tumours. At the time of the study we require that you are not taking any medication. Therefore if you agree to take part, we will gradually reduce your medication before the study. You will be able to begin taking your medication again after the study. With your permission, your GP will be informed of your participation in this research study, and will receive a copy of this information sheet.

Your participation in the trial is entirely voluntary. You are free to decline to enter or to withdraw from the study at any time without having to give a reason. If you choose not to enter the trial, or to withdraw once entered, this will in no way affect your future medical care. All information regarding your medical records will be treated as strictly confidential and will only be used for medical purposes. Your medical records may be inspected by competent authorities and properly authorised persons, but if any information is released this will be done so in coded form so that confidentiality is strictly maintained. Participation in this study will in no way affect your statutory legal rights.

Thank you for considering taking part in our research.

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