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## PATIENT INFORMATION SHEET

### **Project title: The Expectancy of Pain in Fibromyalgia, Osteoarthritis and Healthy Volunteers**

You have been invited to participate in the above research project because you have been diagnosed with Fibromyalgia or Osteoarthritis. Your results will be compared with those from healthy people with no pain. The purpose of the study is to investigate how you respond to anticipating pain, 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 rate the strength of the pain on a 0-10 scale, giving us your answer a short time after each pulse. Prior to each pulse we will tell you on half the occasions what the strength of the pulse will be, either 'high', 'medium' or 'low'. The 'low' pulses are likely not to be painful at all. On the other half of the occasions, we will not tell you what the strength of the pulses will be, and will just inform you that the strength is 'unknown'. So that you know exactly when each pulse is going to happen, there will be a series of three brief sounds that take place once per second until the laser pulse happens. The timing will be as if you were counting up to four, with the laser pulse at number 'four'.

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 be reimbursed for your time and travel expenses. The study will take place over one afternoon. However, if you have not volunteered for one of our studies using the laser before, and have not had any previous experience of the laser heat pulses, it will be necessary for you to make a brief visit to our laboratory on a day prior to the day of the experiment in order to familiarise you with the laser. You will be reimbursed for your time and travel expenses for this visit also.

In order to take part in these studies you must be right-handed and aged over 18, without 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 certain types of 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.

**Prof Anthony Jones, Consultant**

**Dr Christopher Brown, Research Scientist**