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Participant Information Sheet

Project Title: Understanding persistent low back pain where it resides, in the brain.

You are invited to participate in a study conducted by Dr Siobhan Schabrun, NHMRC Clinical Research Fellow, School of Science and Health, University of Western Sydney.

What is the study about?
The purpose is to investigate the mechanisms underlying the development and persistence of chronic low back pain. We hope to explain why some people get better after hurting their back while others do not.

How is the study being paid for?
This study is funded by a project grant from the National Health and Medical Research Council of Australia. There are no commercialization or intellectual property implications of the funding/support arrangement and no conflicts of interest.

What will I be asked to do?
If you agree to participate in this study the following procedures will be performed:

Electromyography - To measure the activity of the limb muscles sensors will be placed on the skin overlying the back muscles. The specific muscles to be recorded will be explained to you prior to the study. There are no risks associated with this procedure.

Electroencephalography - Small sensors will be positioned on your scalp using a small amount of gel. These are recording electrodes only thus, you will not feel anything as a result of their placement. There are no risks associated with this procedure.

Electrical stimulation of nerves and muscles - To evaluate brain activity in the sensory cortex, a brief train of electrical stimuli will be applied to your back muscles. The intensity should not be uncomfortable or painful but will cause a mild tingling or pins and needles sensation. We will also apply an electrical stimulus to the nerve at your ankle in order to measure spinal activity. The intensity will be adjusted until we see a reflex in your leg muscles. This intensity will be strong and potentially uncomfortable for a very brief period (1-2 seconds). You will be asked to rate how uncomfortable you find the stimulation. Electrical stimulation will be applied to your skin using re-usable electrodes. Electrical stimulation is used commonly in physiotherapy practice and provides very few risks. The main risk is skin irritation. However, we will clean your skin to lessen this risk. If the skin under the electrodes starts to get itchy and red, please let us know and we can reduce or stop the electrical stimulation.

Transcranial magnetic stimulation (TMS) - TMS will be used to evaluate the activity of cells of your brain that control your back muscles. The technique involves a brief magnetic field that induces changes in the

electrical activity of the brain directly under the stimulator. The stimulator is placed over the region of the brain responsible for control of movement. When stimulated, an electrical signal is delivered to the muscle to make it contract. We detect this muscle activity via sensors placed on the skin as described above. We will use a computer system to ensure accurate location of the magnetic stimulation. A loud click accompanies the stimulus and sound and feels like flicking a bike helmet while it is on your head. Ear plugs may be worn if desired.

Blood sample - A blood sample will be taken by a trained investigator using normal procedures. Collection of blood may involve minor discomfort due to the needle insertion. There is a small risk of minor bruising after the procedure. Although all necessary hygiene standards will be met, there is also a remote risk of infection. You will be asked to lie down while blood is taken, however, if you feel dizzy at any time please let the investigator know.

Salivary sample using a cheek swab - You will be asked to take a salivary sample using a cheek swab. There are no risks associated with this procedure.

Pressure and thermal pain thresholds - A test will be performed to identify the point at which a pressure sensation and a hot/cold sensation placed on your back or hand changes from that of pressure/heat/cold to pain. You will be asked to indicate this point and the sensation will be relieved immediately. This is a threshold test and as such you are to indicate when the sensation *first* becomes painful. This procedure will be repeated 3 times.

Central pain mechanisms - Thermal and electrical stimuli (as described above) will be applied repeatedly just above your threshold to pain. The number of stimuli will be kept to a minimum and you can request to stop at any time.

Questionnaires - You will be asked to complete a series of questionnaires that provide details about your beliefs and attitudes about pain, depression and distress, details about you (e.g. age, gender) and your pain history.

How much of my time will I need to give?
Your participation in this study will involve three sessions of approximately 3 hours. The sessions will occur within four weeks of a back pain episode and again 3 and 6 months later. You will be asked to answer the questionnaire measures either online or in a telephone interview 9 and 12 months after your first lab session. You will be reimbursed for your participation after each session.

What benefits will I, and / or the broader community, receive for participating?
This is a research project and not a treatment program, thus there may not be any direct benefit to you from your involvement. On completion of this study we hope to better understand why some people recover after hurting their back whilst others do not.

Will the study involve any discomfort or risk for me? If so, what will you do to rectify it?
The study is designed to address our aims in such a manner that you are exposed to the minimum possible degree of risk, inconvenience and discomfort. The specific risks are detailed in the explanations above. You are able to withdraw from these procedures at any time should you wish to do so, without penalty or affecting the ongoing management of your condition in any way.

Will anyone else know the results? How will the results be disseminated?

All aspects of the study, including results, will be confidential and only the researchers will have access to information on participants (except as required by law). A report of the study may be submitted for publication (in a journal or conference or thesis), but individual participants will not be identifiable. Feedback on individual assessment results will be provided on request and a summary of the overall outcomes of the study will be available at the completion of the research project.

Can I withdraw from the study?
Participation is entirely voluntary: you are not obliged to be involved and, if you do participate, you can withdraw at any time without giving any reason and without any consequences. If you withdraw from the study, any collected data will be de-identified, potentially analysed and included in publications unless you indicate otherwise.

Can I tell other people about the study?
Yes, you can tell other people about the study by providing them with the chief investigator's contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

Provide a description of the financial benefits that might arise from the conduct of the research
Your clinician will receive a contribution to cover costs from Western Sydney University for referring you into this study. This fee is to reimburse the time taken to explain the study to you, provide this information sheet and forward your details to the research team.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Data storage
There are a number of government initiatives in place to centrally store research data and to make it available for further research. For more information, see **http://www.ands.org.au/** and **http://www.rdsi.uq.edu.au/about**. Regardless of whether the information you supply or about you is stored centrally or not, it will be stored securely and it will be de-identified before it is made available to any other researcher.

What if I require further information?
When you have read this information, Dr Schabrun will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Dr Schabrun, NHMRC Clinical Research Fellow (02 4620 3497).

What if I have a complaint?
This study has been approved by the University of Western Sydney Human Research Ethics Committee. The Approval number is H10465

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Research, Engagement, Development and Innovation office on Tel +61 2 4736 0229 Fax +61 2 4736 0905 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form.