**PARTICIPANT INFORMATION STATEMENT**

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| **HREC Project Number:** | HRE2021-0150 |
| **Project Title:** | Why does pain spread? An investigation of inhibition in the human brain. |
| **Chief Investigator:** | Dr Flavia Di Pietro, Lecturer  |
| **Version Number:** | 7 |
| **Version Date:** | 02.03.2023 |

**What is the Project About?**

Our research group investigates chronic pain. One of the major problems of chronic pain (i.e. persistent pain) is that is can spread from its initial body area to other areas. Chronic pain is also known to be associated with interesting deficits in the function of touch. People with low back pain and limb pain, for instance, have been found to perform worse than people in no pain when it comes to simple tests of touch perception on the skin.

The basic mechanisms of pain spread and deficits in touch are not fully understood. It is thought that inhibition in the brain and spinal cord may be affected, but this is not known. This study uses a safe and novel way of treating pain using touch, and involves an investigation of brain function before and after the touch training program.

We aim to determine if a tactile (touch) training program has positive effects on low back pain, and we hope the brain investigations before and after the training will help us understand how the training might have its effect. This work is important because at the moment there are very few effective and safe treatment options for people in long-term pain. We are looking to recruit up to 40 volunteers for this research project.

**Who is doing the Research**?

The project is being conducted by Flavia Di Pietro from Curtin Medical School. This research project is funded by a grant from The Raine Medical Research Foundation. There will be no costs to you; you will be reimbursed for participating in this project.

**Why am I being asked to take part and what will I have to do?**

We are looking for volunteers who are aged 18-70 and experiencing chronic low back pain, i.e. pain of a duration of 3 months or more. If you decide to take part in this investigation we will ask you to attend several sessions. The first and last session may involve a magnetic resonance imaging (MRI) scan and an electroencephalography (EEG) scan (session approximately two and a half hours in total). The other sessions (up to 8) will involve the tactile training program and we anticipate that these sessions will be less than an hour in duration. You will also be asked questions about your pain and we will ask you to complete some brief questionnaires. We may expose your lower back and draw minor markings on your skin and take a digital photo of you. This is so that you can then mark your areas of pain on this photo.

At the first session we will put you in to one of 2 tactile training groups. The two groups will receive different tactile stimulation and different instructions from the researcher. This will be done by chance, like tossing a coin. Neither you nor the researcher can choose which group you go in.

An MRI is a safe and non-invasive procedure, which involves you lying inside the scanner. MRI has been in routine clinical use for over two decades and is approved by the Australian Therapeutic Goods Administration, the European Union and the USA Food and Drug Administration for this purpose. You will lie on a motorised bed which is then moved into an open chamber which generates the magnetic field. The chamber is small. Some people find it claustrophobic. You will be screened by questionnaire for contraindications to scanning, such as presence of a pacemaker, metal shards or other metal implants. You will be required to remain still in the chamber for up to sixty minutes until the scanning is complete. The scanner makes loud banging noises during this procedure, but you will be given ear-plugs to minimize disturbance.

An EEG is an electrode cap we use to record brain activity. This cap is not painful in anyway. You may have some water-soluble gel placed on your hair in a number of places. This gel can be easily removed with a cloth. Using this EEG cap, we will record the activity of your brain at rest.

The first and last study sessions will take place at the MRI facility; all other sessions will take place at Curtin University or at a mutually convenient location. There will be no cost to you for taking part in this research. We will give you up to $220 in voucher form (if you attend the maximum number of sessions). This reimbursement is intended to cover your car parking and/or transport to attend the study sessions. The payment voucher for the first session (including the scans) will be given to you at the end of the first session. The remainder of the payment vouchers (depending on how many training sessions you are able to attend) will be given to you as a lump at the final session.

**Optional Consent**

We would like you to consider allowing us to send you information about future research projects. Once you receive the information it is your choice if you decide to take part or not. We would also like you to consider letting us share the information we collect during this research with other researchers working in this area. All data shared will be re-identifiable (which means your name will not be shared, rather you will be identified with a code).

**Are there any benefits to being in the research project?**

Although you are not expected to receive any direct benefit from taking part in this research project there is a potential that one or both forms of tactile training can improve your pain. The findings from this research project will contribute to our understanding of pain, pain spread and deficits in touch in chronic pain. This work will help to develop safe and effective treatment options for chronic pain. When the research project ends you can speak with the researchers about the possibility of continued access to the tactile training for your pain, if you wish.

**Are there any risks, side-effects, discomforts or inconveniences from being in the research project?**

Being involved in a research project like this one can pose risk. You may be asked questions (e.g. about pain) that make you uncomfortable. You do not need to answer any questions that you do not wish to answer. The touch stimuli are gentle and they do not cause pain on healthy parts of the body. However, when they are placed onto body regions where you have pain, they may hurt or make your pain worse for a short time (e.g. similar to when clothing touches that part of your body). You can stop the testing at any time, or we can skip the regions where you have pain until you feel ready. There is a risk of discomfort with MRI scanning, due to the small space and the loud noises associated with scanning. If you feel discomfort in the MRI scanner please let us know and the scanning can be stopped at any time. Apart from giving up your time, we do not expect that there will be any further risks or inconveniences associated with taking part in this study.

We will ensure that we closely adhere to the latest available advice from the Government and the University regarding COVID-19. At present this includes: strict hand hygiene practices for researcher and participants; thorough cleaning of the testing space and equipment between participants; observing the current limitations on number of people per space; ensuring all involved have 'signed in' to campus using the Safe WA app; and ensuring that no one involved in our research attends the university campus if feeling unwell or awaiting the results of a COVID-19 test.

**Who will have access to my information?**

The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify you, but will then remove identifying information on any data and replace it with a code when we analyse the data. Only the research team have access to the code to match your name if it is necessary to do so. Any information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development. Electronic data will be password-protected and hard copy data will be in locked storage.

The information we collect in this study will be kept under secure conditions at Curtin University for 25 years after the research is published and then it will be destroyed. The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented.

**Will you tell me the results of the research?**

We will send out a summary of the project’s overall results to participants. The results we send will be group results – not results on an individual level. It is anticipated that these results will be available by approximately the middle of 2023. If you are interested in obtaining a summary of the results please contact the researchers after February 2023.

Since brain MRI is most commonly used in diagnosing neurological diseases, there is a chance we may find unexpected pathology in your brain scan. A radiologist will look at all images obtained during your scanning session and will provide a report. It is standard policy to release the report to the researcher in charge of this study (Dr Flavia Di Pietro) or the medical doctor on our team (Dr Gillian Cowen) who would then be responsible for any follow up. If abnormalities should be found, Dr Gillian Cowen would be responsible for liaising with you or your primary health care provider to ensure the appropriate care/action is taken.

**Do I have to take part in the research project?**

Taking part in a research project is voluntary. It is your choice to take part or not. You do not have to agree if you do not want to. If you decide to take part and then change your mind, you can withdraw from the project at any time.

With your permission, if you choose to leave the study we will use any information collected unless you tell us not to (in which case the data collected from you will be destroyed). Please let us know if you want to stop participating so we can make sure you are aware of any thing that needs to be done so you can withdraw safely.

**What happens next and who can I contact about the research?**

If you need further information or have any questions about this research project then please contact Flavia Di Pietro on 08 9266 7516.

If you decide to take part in this research we will ask you to sign the consent form. By signing it, you are telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number 2021-0150). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.