PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participant

Plain Language Statement

Full Project Title: Pain systems analysis and machine learning for specificity in non-specific chronic low back pain

Project Number: 2020-124

Principal Researcher: A/Prof Daniel L Belavy

Student Researcher: Mr Scott Tagliaferri

Associate Researcher(s): Prof Guy Trudel, Prof Maia Angelova, A/Prof Tim Wilkin, Dr Bernadette Fitzgibbon, Prof Jessica van Oosterwijck, A/Prof Hugo Masse-Alarie, A/Prof David Connell, Dr Clint Miller, Dr Patrick Owen

---

This Plan Language Statement and Consent Form is 7 pages long. Please make sure you have all the pages.

You are invited to take part in this research project.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project so that you can make a fully informed decision whether you are going to participate.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the document. Please also feel free to discuss the project with a relative or friend or your local health worker.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

Participation in this study is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to participate will not affect your relationship with Deakin University.

The research question

Can data science be used to improve the understanding of how different body systems contribute to non-specific persisting low back pain?

Purpose

Back pain is the greatest cause of disability around the world. In Australia, back pain is predicted to cost around $9.2billion per year. Low back pain remaining for longer than 12 weeks is classed as 'persistent' low back pain and affects around 20% of the global population. A certain diagnosis for the pain cannot be made in up to 95% of cases of low back pain and is deemed 'non-specific'. When a clear cause of the pain in the spine cannot be established, it is difficult for health care practitioners to know how to best treat the condition. Psychological and social health, as well as changes to our nervous system, can also play a role in how we experience pain. There could be many underlying factors that relate to pain, meaning generic treatments may not be sufficient in treating the condition. To better understand this, we will assess the health of the spine, psychological and social health, as well as changes in the nervous system, to see if there are different sub-groups of individuals with persisting low back pain. This research will lead to more individualised treatment approaches for people with persisting low back pain.

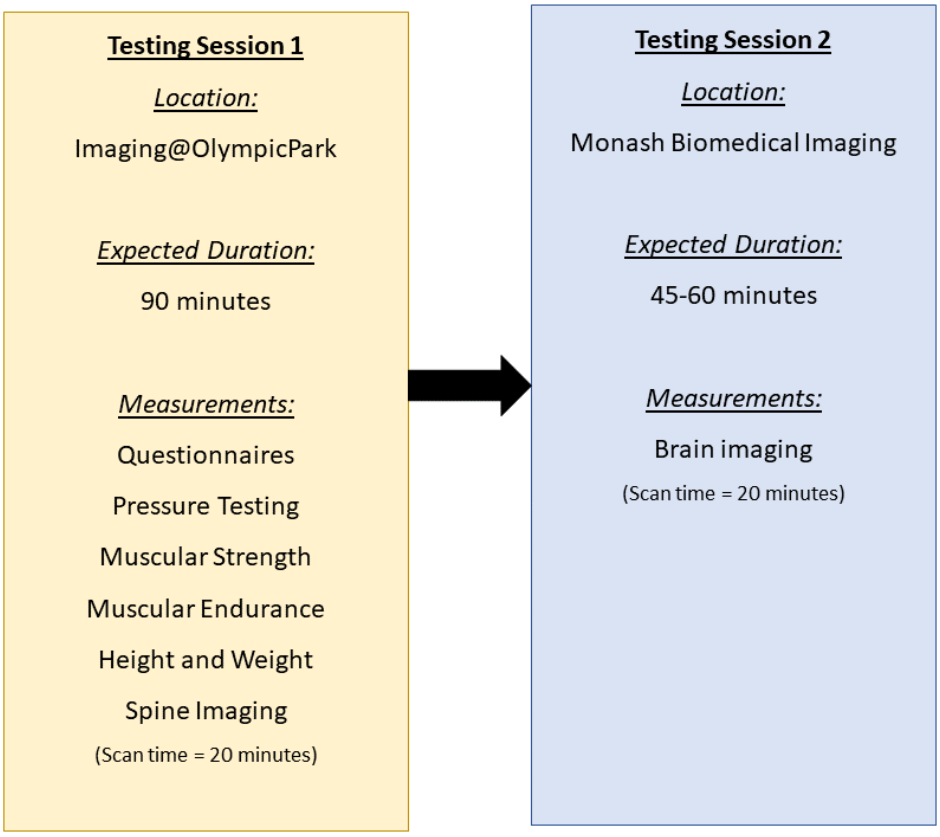
Methods

We are recruiting people that have persisting (>12 weeks) low back pain to participate in several tests to help us get a better understanding of how different body systems contribute to the condition. We are also recruiting individuals that have never experienced low back pain (never had to take days off work or see a health care professional due to low back pain) to act as the control group. Participating in this research will consist of attending two testing sessions.

What the participation will involve

Two testing sessions at Imaging@OlympicPark and Monash Biomedical Imaging are required, ideally within a 1-week period. A 1-week period between testing sessions is preferred but not required. The first session is expected to take 90-minutes, while the brain imaging visit is expected to take 30-45 minutes. The following measurements will be completed across testing sessions:

- Questionnaires: these will assess your physical, mental, and social health, current back pain, disability, other musculoskeletal pain, and nervous system sensitivity.
- Trunk endurance and strength: these will assess the ability of your trunk muscles to produce (strength) and sustain (endurance) a contraction.
- Pressure testing: this will assess your sensitivity to pressure and how your nervous system responds to multiple pressure stimuli.
- Anthropometry: your height and weight will be measured using standard techniques.
- Spinal imaging: this will assess the health of your spine.
- Brain imaging: images will be taken of your brain to determine how pain processing areas are activated during rest.



For magnetic resonance imaging (MRI) testing sessions please ensure you have comfortable clothing and ensure there are no metallic objects on your clothes or underwear, otherwise we may need to give you a gown to wear for the scans. Please refrain from wearing jewellery where possible, especially earrings, most other piercings will not affect the images. When you arrive, you will complete a form for the scanning centre and then you will be instructed on the scanning procedure. You will then enter the MRI scanner and a series of scans will be performed to measure different parameters of different structures. MRI is a way of getting images of various parts of your body without the use of radiation. It is estimated that the scanning protocol will be over within 20 minutes. Overall, you should budget on 60 minutes in total at the scanning centre.

Potential risk for participants

Given the current environment with COVID-19, we plan to implement the following as part of our data collection protocol to ensure your safety: (a) testing will be rescheduled if yourself or the assessor are unwell, (b) the assessor will wear a disposable facemask and gloves for physical testing, (c) a disposable facemask and gloves will also be offered to you to wear during testing, (d) hands will be washed with hand sanitiser between protocol steps where required and (e) maintenance of physical distancing of 1.5m unless required for testing.

MRI has no known risks when standard screening procedures are implemented and does NOT expose you to radiation. You will be asked specific questions regarding things that might preclude you from having a MRI scan (e.g. becoming nervous in enclosed spaces, any metal implants or fragments, any electronic implants such as a pacemaker, piercings that cannot be removed, possible pregnancy). If you have a tattoo, there is a slight risk you may get skin irritation (like a sunburn) due to the magnetic

fields in the scanner. Some older tattoos and black inks may contain iron in the colours used. In the MRI, the magnetic field can cause heating of the iron compounds. As part of screening for this study, the MRI operator will clarify what kind of tattoo you may have, if any. As part of normal MRI routine, if the radiologist, in reviewing your images, see any abnormal findings requiring medical follow-up, your general practitioner will be contracted by the imaging centre to organise subsequent medical follow-up.

Muscular endurance and strength tests may result in minor muscle soreness that resolves within 48h hours.

The pressure pain threshold test will cause some temporary discomfort; however, the test is over quickly and is not expected to cause any pain once completed.

There may be additional unforeseen or unknown risks.

Potential benefits for participants

For completing the study, participants will receive pre-paid credit card to the value of $70. We cannot guarantee or promise that you will receive any other benefits from this project. By participating in this project, you could gain access to information on your own body, via the outcome measures, that you would otherwise not have.

Expected benefits for the wider community

This study aims to improve the understanding of how different body systems contribute to persisting low back pain to improve the way it is diagnosed and managed in the future.

If applicable, provision of services to participants adversely affected by the research

Whilst the research team considers the study to be of low risk, should you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

How privacy and confidentiality will be protected

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, subject to legal requirements. Forms with identifying information will be stored in a locked filing cabinet in the researcher's office or in a password protected electronic file. A unique code will be used on all forms and data collected from you, and not with your name or any other identifying information. This data will be stored on a password protected Deakin University server. Only the investigators will have access to the data. Sharing of data between investigators will occur only in a coded, de-identified way and no identifying or personal information will be shared. None of the information provided will be made public in any

form that would reveal a participant's identity to an outside party, thus all participants will remain anonymous. As part of good scientific practice and research transparency, we intend to publish the anonymised data collected from participants in this research project in an online repository. Publishing research data helps to ensure maximum potential benefit is gained from data collected from research participants, as the data can be used in future research to answer related or new research questions. All information that could reasonably be used to identify you will be removed from the data before it is published, so that only anonymous data is published and you will not be able to be identified from the published data. Paper copies of data will be stored for a period of seven years after publication after which they will be destroyed as per Deakin University guidelines. Electronic copies of all data will be retained indefinitely. In accordance with the Freedom of Information Act 1982 (VIC), you have the right to access and to request correction of information held about you by Deakin University.

Dissemination of the research results

On request, a summary of the project will be emailed to you at the completion of the study. If you wish, you will also be able to obtain a copy of your spine and brain MRI after the completion of the study. The results of this study will be presented at research conferences and communicated in scientific journals.

Researcher contact details

Scott Tagliaferri (PhD Candidate)
Email: spine@deakin.edu.au
Deakin University
Institute for Physical Activity and Nutrition
School of Exercise and Nutrition Sciences
221 Burwood Highway
Burwood, Victoria 3125
Phone: 03 5227 8054

Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number 2020-124.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participant

Consent Form

Full Project Title: Pain systems analysis and machine learning for specificity in non-specific chronic low back pain

Project Number: 2020-124

I have read and I understand the attached Plain Language Statement.

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

Please indicate below whether you agree to have your contact details stored to be invited to participate in future research.

☐ Yes, I agree to be invited to participate in future research.

Please tick the box below if you would like to receive a copy of the study results, via email, at the end of the study.

☐ Yes ☐ No

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

Participant's Name (printed) ……

Signature …… Date …….

Please scan and email this form to spine@deakin.edu.au and keep the original to bring with you to your first testing appointment at Deakin.

Scott Tagliaferri (PhD Candidate)
Deakin University
School of Exercise and Nutrition Sciences
221 Burwood Highway
Burwood, Victoria 3125
Phone: 03 5227 8054

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participant

Withdrawal of Consent Form

(To be used for participants who wish to withdraw from the project)

Full Project Title: Pain systems analysis and machine learning for specificity in non-specific chronic low back pain

Project Number: 2020-124

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University.

Participant's Name (printed) …….

Signature ……. Date …….

Please scan and email this form to spine@deakin.edu.au.

Scott Tagliaferri (PhD Candidate)
Deakin University
School of Exercise and Nutrition Sciences
221 Burwood Highway
Burwood, Victoria 3125
Phone: 03 5227 8054