

INFORMATION SHEET

Project title: The Nature of Neck Pain in Migraine

Chief Investigators:

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Emeritus Professor Gwendolen Jull, PhD: The University of Queensland, School of Health and Rehabilitation Sciences, St Lucia QLD Australia.

You are being invited to take part in a research study

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take as much time as you need to read the following information carefully and discuss it with friends or relatives if you wish. Ask us if there is anything that is not clear or if you would like more information.

We appreciate you taking the time to read, inquire about, and understand the following information.

What is the purpose of the study?

The purpose of this research study is to investigate the nature of neck pain in people with migraine. Although neck pain is commonly experienced by people with migraine, the underlying mechanisms are uncertain. It is possible that musculoskeletal disorders of the neck or pain processing mechanisms are implicated in neck pain associated with migraine. If we can clarify the characteristics of neck pain in migraine, this may in the future improve the management of people with migraine. For this study, you will be asked to complete some questionnaires about the symptoms you experience and undergo some clinical tests of your neck and balance systems.

Why have I been chosen?

You are being asked to consider participating in this study because you have migraine. We want to investigate the behaviour of symptoms in people with migraine, and find out if there are any associated impairments, so the study will help provide data on migraine.

Do I have to take part?

Your participation in this study is completely voluntary. You are free to withdraw from the project at any time, without giving a reason. If you decide you want to take part in the research project, you will be asked to sign the consent form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

What will happen to me if I take part?

During this study, you will be asked to complete some questionnaires (about 15-20 minutes) about your general wellbeing, headache characteristics, neck pain characteristics if you have any, or other symptoms you experience as well as the impact of your migraine on your daily life. You will also be asked to complete a short

questionnaire of your pain symptoms when you are experiencing migraine. You will then attend the university clinic to undergo some clinical testing of your neck, sensation and balance systems. The clinical testing will include an examination of the joints and muscles in your neck, eye movements, visual tests, sensation tests and balance. All testing will be completed in a single session of about 90 minutes, with adequate time allowed for you to have breaks between testing. During this session, you will be asked questions about your symptoms, and your responses may be recorded on audio for transcribing purposes.

What do I have to do?

Complete the questionnaires and undergo physical assessments to the best of your ability whilst providing any experiences of adverse effects to researchers.

What are the side effects or risks of taking part?

There may be slight discomfort or dizziness from some of the tests. We will be keeping your head turned for part of the study, but this movement is well within normal limits. During sensation tests, you will experience slight discomfort from heat, cold and pressure on the skin in your neck and leg. These tests are to assess when the sensation of heat, cold and pressure starts to become uncomfortable and will stop immediately when you press the control button. In our experience people can usually tolerate these tests without any aggravation of symptoms. We will be monitoring you throughout and will cease testing if there is any symptom exacerbation. If this was to occur we would stop testing immediately and not continue until all symptoms were completely settled, and only if you were happy to continue. This should eliminate the rare possibility of these tests triggering a migraine.

What are the possible benefits of taking part?

There is no direct health or financial benefit to you from agreeing to participate in this study. However, your participation will allow us to better understand the involvement of the neck in migraine.

Do I receive my results?

A summary of the study findings will be sent to you if you would like, otherwise you will be directed to any publications arising from the study. We can advise you of your individual results on the day of testing.

Will my taking part in this study be kept confidential?

All information recorded for the purposes of this study will be coded and identified only by a study number. No personal identifying information will be kept in the data recording. Your records obtained while you are in this study will remain strictly confidential at all times.

What will happen to the results of the research study?

The results of the research will be collated during the study and analysed following the end of the study. It is anticipated that the results will be published within 12 months following that analysis. You will not be specifically identified in any report/publication. Data will be stored for up to 15 years and then destroyed in accordance with current regulations at that time.

Who has reviewed the study?

The Ethics Committee of The University of Queensland has reviewed and approved this study in accordance with the National Health and Medical Research Council's guidelines. Reference number 2018001128.

Data Protection: What use will be made of data collected from this study?

Personal data, which may be sensitive, (e.g. date of birth, gender, height, and weight) will be collected and processed, but only for research purposes in connection with this study. Only anonymous and generalised data will be reported. No individual data will be reported.

What happens to data already collected if I withdraw from this study?

If you give us permission to use data already collected, we will retain the data for our research. Otherwise, we will destroy the relevant data when you withdraw from this study.

Contact for further information

Thank you for taking the time to read the information about this study. If you have any questions or concerns now or at any time about the study, your safety or your rights please ask Zhiqi Liang, any of the co-investigators

or study staff, or the contact person(s) indicated below. If you want to take part, you will be asked to sign the Consent Form.

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the *National Statement on Ethical Conduct in Human Research*. Whilst you are free to discuss your participation in this study with project staff (contactable on 07 3365 1644), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinator on 3365 3924.

Thank you for considering this invitation.

Zhiqi Liang Dr Lucy Thomas Dr Julia Treleaven Emeritus Prof Gwendolen Jull