PARTICIPANT INFORMATION LETTER

PROJECT TITLE: Sensory, musculoskeletal and psychological factors in persistent post-traumatic headache.

Lay title: The role of the pain system, the neck and psychological factors in those with headache after a traumatic brain injury

PRINCIPAL INVESTIGATORS:

- Julie Hides, PhD, Deputy Head of School, School of Allied Health Sciences, Griffith University.
- Dilani Mendis, PhD, Research Fellow and Lecturer, Physiotherapy, School of Allied Health Sciences, Griffith University.
- Andrew Gardner, PhD, Clinical Neuropsychologist, Priority Research Centre for Stroke and Brain Injury, School of Medicine and Public Health, University of Newcastle; Hunter New England Local Health District Sports Concussion Clinic, Newcastle.
- Leanne Bisset, PhD, Senior Lecturer, Menzies Health Institute Queensland, School of Allied Health Sciences, Griffith University.

STUDENT RESEARCHER:

- Margot Sexton, BPhty (Hons I), Grad.Cert Pain Management, Physiotherapy, School of Allied Health Sciences, Griffith University (Nathan Campus, Brisbane).

STUDENT'S DEGREE: Doctor of Philosophy

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

Headache is the most common and often longest lasting symptom following mild traumatic brain injury (TBI) or concussion. What causes headaches to persist after a mild TBI or concussion remains largely unknown. It has been suggested that persistent headaches may

be the result of a combination of an 'up-regulation' of the pain system, a change in the way the body modulates pain, injury to joints and muscles of the neck and psychosocial factors. This study aims to identify changes in the pain processing system that may contribute to the development of persistent headache after a mild TBI or concussion, compared with an age and gender matched pain-free control group, with no history of mild TBI or concussion. This study will also investigate the contribution the neck may have in the headache presentation. Finally, psychological and sleep factors will be investigated, including thoughts and opinions about pain and quality of sleep. This research will add to the current knowledge regarding persistent headaches after a mild TBI or concussion.

Who is undertaking the project?

This project is being conducted by a student researcher, a team of senior physiotherapists and a clinical neuropsychologist. This study is part of a Doctor of Philosophy degree, being undertaken by a student researcher (Margot Sexton), at Griffith University (Nathan Campus, Brisbane), under the principal supervision of Professor Julie Hides.

Are there any risks associated with participating in this project?

The risks involved in this study are minimal. All techniques involved in this research are non-invasive. Previously published procedures and protocols, used in physiotherapy and clinical pain research studies, will be followed. All testing will be supervised by a trained physiotherapist. Testing will require pressure to be applied to your skin until the first point of discomfort or pain. At this point, the test will be stopped immediately by pressing a patient operated pause button. For one test (conditioned pain modulation), a cold stimulus will also be applied via immersion of your hand in a cold water bath set at a constant temperature of 8°C, for up to 2 minutes maximum. This may cause some short-lasting moderate pain in your hand during the testing, however, this should be no worse than the pain you experience when you apply an icepack to your body, and the pain disappears quickly on removal of your hand from the water. In addition, the cold water testing may cause a temporary increase in your blood pressure. For this reason, exclusion criteria will be applied to this specific test, and you will be excluded from this one test if you: 1) have uncontrolled high blood pressure or high cholesterol, 2) are currently using medication for depression, 3) have a known cardiovascular condition (hypertension/fainting), 4) have Reynaud's Syndrome, 5) have had a previous reaction to ice or cold water (fainting or skin reaction), 6) have any current injury

to your dominant hand (the hand you write with), 7) your blood pressure reads high on the day of testing. Your blood pressure will be measured using a digital blood pressure cuff around your upper arm, at the beginning and end of testing, to check it has returned to normal levels at the end of the testing session. Finally, standard physiotherapy assessments will be used to examine the joints and muscles in your neck. These tests are unlikely to cause any discomfort and will only be performed to the first onset of tissue resistance or first onset of discomfort. These tests will be carried out by a physiotherapist.

What will I be asked to do?

Participants will be allocated to either a 'headache' group or 'control' group depending on your history of mild traumatic brain injury/concussion and headache. All participants will be asked to attend one (1) testing session, of approximately 90-minutes duration, at the School of Allied Health Science's Research Laboratory, N55, Griffith University, Nathan Campus, 170 Kessels Road, Nathan QLD 4111. Free visitor parking will be provided on campus, while attending the testing session.

The testing session will involve the following:

1. Questionnaires

All participants will complete the following questionnaires:

a) General information: age, height, weight.
b) Injury and medical history: head injury details, other injury/pain history, headache history, neck pain history, medical history and current use of medications. A body chart for pain location and a 100mm visual analogue scale (VAS: 0 = no pain; 100 = worst pain imaginable) will be used to record pain location and intensity.
c) Central Sensitization Inventory (CSI): a self-report questionnaire to help identify sensory changes.
d) Pain Catastrophizing Scale (PCS): a 13-item questionnaire, where you will be asked to rate each item on a five-point scale from zero (never) to four (always) regarding your thoughts on pain.
e) Pain Vigilance and Awareness Questionnaire (PVAQ): a 16-item questionnaire, where you will be asked to indicate how frequently, on a six-point scale from zero (never) to five (always), each item is a true description of your awareness to pain.

f) Depression, Anxiety and Stress Scale (DASS-21): a 21-item questionnaire reflecting emotional symptoms of depression, anxiety or stress.
g) Pittsburgh Sleep Quality Index (PSQI): a self-report questionnaire that assesses your sleep quality over a 1-month time interval.

Participants in the 'headache' group will also complete:

h) Headache characteristics questionnaire: headache location, intensity, type of pain, aggravating and easing factors, use of medications, treatment to date.
i) 3-Question Migraine ID: to indicate presence of migraine headache.
j) Migraine Disability Assessment (MIDAS): to measure the impact your headaches have had on function over the past 3 months.
k) Headache Impact Test (HIT-6): to measure the impact your headaches have had on daily function in the past 4 weeks.

Time taken: approximately 30 minutes

2. Sensory Testing

a) Pressure Pain Thresholds (PPTs)

Pressure pain thresholds are a measure of your response to pressure, applied to the skin using a digital algometer. The algometer consists of a plastic handle with a built in pressure gauge, attached to a rubber tipped probe measuring $1cm^2$. The probe will be placed in contact with your skin and pressure applied at a gradual controlled rate, until you first feel a sensation of pain, at which point you will press a button and the test will stop.

Testing will be performed in a lying position and performed over your forehead, temples, back of your neck, shoulders (deltoid muscle) and shins (tibialis anterior muscle). All testing will be performed on both the left and right side and repeated three (3) times. These areas will be marked with a water-based pen prior to testing. A demonstration over the palm of your hand will be done prior to testing.

Time taken: approximately 15 minutes

b) Static pressure allodynia

This test is a measure of your response to light touch. A Von Frey filament (this is like a single paint brush filament) will be pressed against your skin to replicate the sensation of light touch. The filament will be applied for 1 second to your forehead, back of your neck and inner forearm on both sides, three (3) times. If you feel pain during this test, you will be asked to rank its intensity on a numerical rating scale (0 = no pain, 100 = worst pain imaginable).

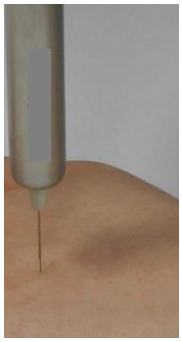
Time taken: approximately 5 minutes

3. Dynamic Pain Modulation Testing

Both tests are a method of testing your body's ability to modulate (increase or decrease) pain:

a) Temporal Summation

A single blunt pinprick will be applied over your elbow, on your dominant side, and you will be asked to rate the intensity of pain you feel (0 = no pain, 100 = worst pain imaginable). Ten (10) repeated blunt pinpricks of the same force and at the same rate will then be applied to your elbow. You will again be asked to rate the intensity of pain you feel (out of 100) at the end of the 10 pinpricks. The process will be repeated five (5) times at five (5) different skin sites over your elbow. The skin sites will be marked on your body with a water-based pen prior to testing. At no point in testing will the blunt pinprick pierce the skin, but will only be placed against the skin.

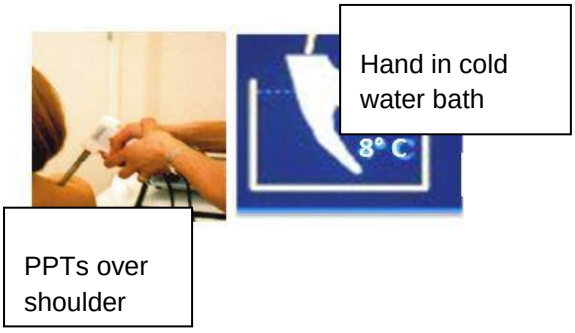


Time taken: approximately 5 minutes

b) Conditioned Pain Modulation

This test will involve assessing pressure pain thresholds (PPTs) over your non dominant shoulder, using the same procedure as detailed in section 2a, before, during and after placing your dominant hand in a cold water bath.

PPTs will be tested first over your shoulder (deltoid muscle) in sitting, on your non-dominant side. PPTs will be measured using a digital algometer, until the first sensation of pain is felt. Your hand (up to the wrist) will then be fully immersed into a cold water bath set at 8°C, for up to 2 minutes. During immersion of your hand, PPTs will be measured over your shoulder every 30 seconds, and 30 and 60 seconds after your hand is taken out from the cold water bath. You will also be instructed to verbally report the moment the first sensation of pain is felt, once your hand has entered the water, and to rate its intensity (out of 100). At 30, 60 and 90 seconds you will be asked to rate pain intensity again (out of 100). You will be free to withdraw your hand from the water bath at any point in time if required. The total time of water immersion will be recorded and any PPTs recorded during this time shall be used.



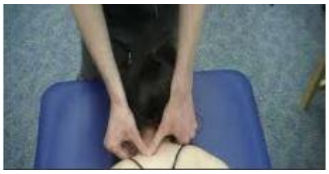
Time taken: approximately 10 minutes

4. Neck Muscle and Joint Tests

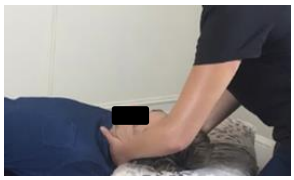
All testing will use standard physiotherapy assessment techniques:

a) Neck joint mobility

The mobility (amount of movement) of your neck joints will first be assessed by the tester applying gentle oscillating pressure (using thumb tips), to each joint in the back of your neck, whilst lying on your stomach. The tester will note the amount of movement in each of your joints and you will be asked to report any discomfort experienced (out of 100).



You will then be asked to roll onto your back, with your head supported in the tester's hands. Your head will be held by the tester and gently moved from side to side, whilst the tester feels for movement in each of your neck joints. Again, the tester will note the amount of movement in each of your joints and you will be asked to report any discomfort experienced (out of 100).



Time taken: approximately 10 minutes

b) Neck Range of Motion

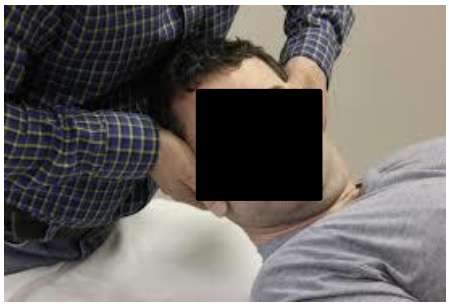
The amount of movement available in your neck will be tested, while in sitting, and using a Cervical Range of Motion (CROM) device, worn on your head. The CROM device measures neck range of movement using 3 separate inclinometers attached to a frame similar to eyeglasses. The CROM device will be placed on your head, and a magnetic collar, also part of the CROM device, will be placed on your shoulders to take into account any twisting of the trunk.

You will then be asked to perform the movements: flexion (forward bend of the head), extension (backwards bend of the head), rotation (look over each shoulder), lateral flexion (sideways bend of the head), protraction (poke chin forward) and retraction (retract chin backwards) to the left and right sides, as far as comfortably possible. Each movement will be first demonstrated to you, then you will perform each movement twice. The CROM device inclinometers will then be read and degrees of movement recorded.

Time taken: approximately 5 minutes.

c) Flexion/rotation test

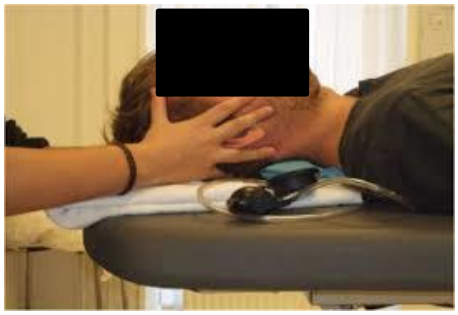
Lying on your back, your head will be supported by the tester, in a forward flexed position. Your head will then be turned left and right, while the tester feels for any restriction in the movement. The amount of movement will be recorded.



Time taken: approximately 5 minutes

d) Neck Muscle control

Neck muscle control and endurance will be assessed by testing your ability to gently nod the chin using neck muscles with control. Lying on your back, with an air cushion under your neck, you will be asked to gently bend the neck by nodding the chin and hold the position for 3-10 seconds, and repeated 3 times. The pressure dial attached to the air cushion will be viewed by the tester and pressure level recorded. The tester will also feel for muscle activation by palpating (feeling for activation) the muscles at the front of your neck.



Time taken: approximately 10 minutes.

How much time will the project take?

The project will require a total time commitment of 90 minutes.

What are the benefits of the research project?

There will be no direct benefit to you as a participant. You will not receive a physiotherapy assessment or treatment session. However, results from this study will add to the current knowledge regarding persistent headache following a mild TBI/concussion.

Can I withdraw from the study?

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can chose to participate in all or some of the above testing procedures and you can withdraw from the study at any time without adverse consequences. If you would prefer to participate in only some of the above testing procedures, please indicate this on the Consent Form, in the table provided. Non-participation or withdrawal will not affect any ongoing treatment you may be having.

Will anyone else know the results of the project?

Participant privacy is maintained at all times throughout the study. All results collected will be de-identified prior to analysis. Data from the study will be kept in a secure location for 10 years. The results of this study may be published in journals and presented at conferences, but individuals will not be identified. Results of this study may be compared with results from further studies or past studies conducted by our research group, but individuals will not be identified. If you withdraw from the study, data already collected will be retained in a de-identified form.

If you would like your individual results to be provided to your treating physiotherapist, please indicate this on the Participant Consent Form. If you do not consent to your information being shared with your regular physiotherapist, this will in no way affect your participation in the study, nor will it affect any ongoing treatment you may be receiving.

Finally, if your blood pressure reading is deemed high at any point this information will be passed onto your local GP or doctor, with your consent.

Will I be able to find out the results of the project?

A summary of the overall outcomes of the study will be available at the completion of the study, but individuals will not be identified in any reports.

Who do I contact if I have questions about the project?

Should you have any questions regarding the nature of the research, please feel free to contact Margot Sexton, who will be happy to provide you with more information.

Tel: 0408 883 099

Email: margot.sexton@griffithuni.edu.au

What if I have a complaint or any concerns?

The study has been reviewed by the Human Research Ethics Committee at Griffith University. If you have any complaints or concerns about the conduct of the project, you may contact the Human Research Ethics Committee, Griffith University:

Tel: (07) 3735 2069

Email: research-ethics@griffith.edu.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

If you agree to participate in this study, you should complete all sections of the consent form (including completion of all yes/no tick boxes on the consent form), and sign both copies of the consent form. Please retain one copy for your records and return the other copy to the Head, Neck and Jaw Clinic staff, who will email the consent form back to the student researcher or email the consent form directly to the student researcher:

Email: margot.sexton@griffithuni.edu.au

Thank you for your interest in this research project.

Yours sincerely,

Margot Sexton (Student Investigator)

Prof Julie Hides (Principal Supervisor)

Dr Dilani Mendis (Principal Supervisor)

Dr Andrew Gardner (Associate Supervisor)

Dr Leanne Bisset (Associate Supervisor)