Participant Information and Consent Form for Research Study

Magnetic Resonance Spectroscopy to Document Alterations to Neurochemistry Associated with Post-Traumatic Stress Disorder (Short Title: MRS of PTSD)

Contacts:

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You are invited to take part in this research study that is being conducted by researchers from the Translational Research Institute, which is based on the Princess Alexandra Hospital campus in Brisbane. This study is being conducted in order to find out if magnetic resonance spectroscopy (MRS) of the brain can be used to provide a better understand of, and assist in the diagnosis of, Post-Traumatic Stress Disorder (PTSD).

For the purposes if this study both people who have been diagnosed as suffering from PTSD and those who have not will be invited to participate.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Your participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide you want to take part in this research study, you will be asked to sign the consent form. You will be given a copy of this information sheet and your signed consent form to keep.

If you decide to participate in this research study, the study team will ask you to provide the contact details of your local doctor

Background

Post-Traumatic Stress Disorder (PTSD) is a complex condition where sufferers are affected by a varying range of symptoms following an exposure to a traumatic situation or event. Sufferers may experience symptoms such as recurrent and intrusive thoughts, nightmares, flashbacks, or distress and avoidance of situations that are similar to the event that first occurred.

It is not yet known why some people experience PTSD following a traumatic event and others do not. This research study aims to try to determine if the chemicals that allow the brain to carry out its normal functions are different in a person who suffers from PTSD when compared to a person who does not.

In this study researchers will use a technique called Magnetic Resonance Spectroscopy (MRS) to look for any changes in the normal chemistry of the brain. The researchers will then compare the images obtained from participants who have PTSD with those who do not.

The researchers conducting this study hope that by using MRS to look for and isolate any abnormalities in the brain chemicals of those with PTSD this may lead to improvements in the diagnosis and treatment for PTSD suffers in the future.

MRS is a non-invasive medical test. It is conducted on the same machine as conventional Magnetic Resonance Imaging (MRI) scans. The MRI scan uses a powerful magnet, radio waves, and a computer to create detailed images. MRS is a series of tests that are added to an MRI scan to measure the chemical properties of molecules in cells and tissues.

In this study MRI will be used to take anatomical images of your brain and MRS will be used to provide detailed information about the nature and chemical environment of the molecules in your brain.

Informed Consent

This Participant Information contains details about the research study and explains all the procedures involved. Knowing what is involved will help you decide if you wish to take part in this research.

Please read this information carefully and ask any questions you may have about this study. Participation is voluntary. If you don't wish to take part, you don't have to.

Once you know what the research study is about and if you agree to take part, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you:

- understand the information;
- consent to take part in the research study;
- consent to have the tests that are described;
- are willing to provide the name and contact information of your local doctor and
- consent to the use of your personal and health information as described.

Study Procedure

Volunteers interested in participating in this study will be sent a copy of this Participant Information and Consent Form. Volunteers who decide to participants will need to sign and return the Consent Form prior to the commencement of the following sequential study procedures:.

Telephone Screen

Upon receipt of a signed Consent Form the participants will be contacted by the research nurse who will conduct a telephone screen to check your initial eligibility for the study. This telephone screen will be carried out at a time convenient to you and will take approximately 30 minutes.

During this telephone screen the research nurse will ask you questions relating to your current medications, previous history of any mental health condition, previous history of injuries to your head or neck and past medical history.

Online Survey

If the research nurse confirms that you meet the initial eligibility to continue in the study you will be asked to complete an online survey. This survey will be sent by email to you for you to complete. Your name will not appear on the survey it will be replaced with a unique participant number. This survey will ask you more in-depth questions about your previous medical history including any history of depression and/or anxiety, any drug and alcohol use, previous head injury and/or pain. You will be asked to complete the survey on your own and it is expected to take you approximately 30 minutes.

The research nurse or study psychologist will contact you soon after you have completed the online survey to discuss any queries or concerns that may have arisen for you as a result.

Psychological Assessment
If you are confirmed to be eligible to continue to participate in the psychological assessment, an appointment will be made for you with the study's clinical psychologist. In this study the researchers prefer this assessment to be carried out face-to-face, However, we recognise that this may not possible for all participants because of the distance they are from the study site. For participants who are unable to attend a face-to-face interview, which will be conducted in the Clinical Research Facility at the Princess Alexandra Hospital, than the clinical psychologist will conduct this assessment via Skype or telephone at an appointed time.

The clinical psychologist will perform the psychological assessment using a structured interview process which includes the completion of questionnaires. The WebNeuro cognitive assessment that will be required to be complete online assesses your motor tapping, choice reaction time, verbal memory-recall and digit span. This assessment takes approximately 30 – 60 minutes to complete.

If you are confirmed to be unsuitable to continue participation in the study during this assessment then the clinical psychologist will inform you of this either during or after your assessment. If you require further clinical follow up or require ongoing psychological support, the study psychologist will provide a written referral to your local doctor or alternatively refer you to the public mental health care system closest to you.

Magnetic Resonance Imaging and Magnetic Resonance Spectroscopy
If you are confirmed to be eligible to proceed on to have the imaging of your brain then the research nurse will arrange an appointment visit for you at one of the following facilities:

- Herston Imaging Research Facility, Royal Brisbane and Women's Hospital campus, Bowen Bridge Road, Herston
- Princess Alexandra Hospital Medical Imaging Department, Ipswich Road, Woolloongabba
- Hunter Medical Research Institute Imaging Centre, John Hunter Hospital campus Newcastle, Lookout Road, Newcastle

During your visit to the imaging facility you will be required to undergo two non-invasive imaging procedures with a clinical scanner used for routine testing. Your two scan procedures will be done in a single visit on the same day with a short break in between.

For the 1st MRS scan you will be require to lie in the scanner for approximately 40 minutes. During this scan images of your brain and information on its chemistry will be obtained.

The 2nd MRI scan is a functional MRI and will assess the blood flow in different areas of your brain. This scan will take approximately 45 minutes. These are additional MR scans which you would not be undergoing unless you were part of the study.

As it is unknown how pregnancy may affect chemical changes in the brain pregnant females cannot participate in this study. So if you are a female participant of child bearing potential and you suspect you may have become pregnant prior to attending for your

imaging appointment you are asked to contact the research nurse who will arrange for you to have a urine pregnancy test.

The major discomforts of an MRI are that the scanner is noisy. You can be giving some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. Should you feel discomfort or become distressed while lying in the MR scanner the healthcare specialist working with you at that time will provide information and advice regarding additional support and/or referral for your particular concerns. You can signal at any time that you wish to be removed from the scanner and the healthcare specialist will remove you.

Possible Benefits

It is not expected that there will be any direct benefit to you as a result of your participation in this research study. However, potential benefits to the wider community include:

- Assisting researchers to better understand what chemical changes occur in the brains of Post-Traumatic Stress Disorder suffers.
- Assisting researchers to develop new objective methods for diagnosing PTSD.

You are able to request an individual summary of your MRI results. This summary might be beneficial to you in terms of your medical history.

Possible Risks

There are no known risks associated with standard MR procedures, unless you have any electrically, magnetically or mechanically activated implants or vascular clips, metallic plates, cardiac stents or metal fragments in your body. If you have any of these types of implants or you suffer from claustrophobia you will not be not be able to participate in this study.

It is possible that during your study participation and assessments you may be identified as suffering from a mental health disorder. If this occurs, the clinical psychologist will recommend that you seek follow up with your local doctor.

It is also possible that reliving distressing experiences and other traumatic events during your participation in this research study may continue to cause distress during and after the assessments. Your will have ability to contact the study's clinical psychologist throughout your participation in the study and if required the psychologist will make contact with your local doctor so that you can be provided with access to ongoing mental health support and private treatment.

There may be some circumstances where the study psychologist will refer individuals to the public mental health system for follow up and treatment. If either of these two scenarios arises, the study psychologist will inform you of their plan of action to further support you.

If you would like to discuss any issues relevant to your participation in the psychological assessments you can contact the clinical psychologist for the study.

Dr Katie Trickey (Clinical Psychologist) – 07 3443 7779

Alternatively if you prefer you can accessing these community based services for support.

Lifeline – 131114.
Beyond Blue – 1300 22 4636

If you would like any further information, or have questions or concerns about participation in this study you can contact these members of the study team.

Professor Peter Malycha (Clinical Principal Investigator) - 07 3443 7813
Lisa Rich (Research Nurse, Clinical Research Facility) – 07 3176 9002

Incidental Findings

If during the study any abnormalities are identified in your scans that require immediate attention or follow up, the clinical principal investigator will make contact with your local doctor to discuss the finding and if required will arrange a referral to an appropriate specialist. Any incidental finding as part of this research study may require you to have repeat imaging tests in a clinical setting.

Privacy and Confidentiality

All personal and health information obtained throughout the study, including information collected during your psychological assessment will remain strictly confidential as required by law. Any information collected in identifiable form will only be accessible to the principal investigator and the relevant research staff assigned to the study.

Data that is collected as part of the WebNeuro assessment will be processed by the owners of the software, the Brain Resource Company. All data collected will be de-identified and your name will be replaced unique participant number. Your de-identified data will be transferred for analysis using the same encryption used by many banks. A report about this data will be generated and given to the study team. All raw data from the cognitive assessment will be destroyed after 15 years.

All information obtained during this research study may be subject to inspection by an authorised representative of the approving ethics institutions. The purpose of these inspections is to verify procedures and the data. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

All data collected during the study will be stored in a secure location in either electronic or paper format. De-identified data will be stored in an encrypted electronic database and stored indefinitely. Paper recorded will be stored securely in accordance with the Australian Regulatory Guidelines and then destroyed 15 years after study completion.

Disclosure of Results

It is anticipated that the results of this research study will be published and/or presented in a variety of forums. No identifiable information will be used in publication of the results. Your information will only be used for the purpose of this research study and will only be disclosed with your permission, except as required by law.

Remuneration

Although the study will not cover travel costs associated with participation in the study, parking vouchers will be supplied to you when you attend for your appointment at either the Herston Imaging Research Facility or the Princess Alexandra Hospital Medical Imaging Department.

Further Information and Complaints

The ethical aspects of this research study have been reviewed and approved by the Metro South Health Human Research Ethics Committee (HREC/15/QPAH/793).

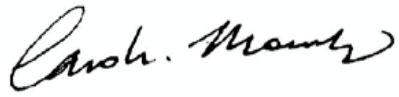
If you have any complaints about any aspect of this study, the way it is being conducted or any questions about your rights as a research participant, then you may contact Metro South Health HREC Coordinator on 07 3443 8047 or ethicsresearch.PAH@health.qld.gov.au

Withdrawing from the Study
You can withdraw from the study at any time by contacting the clinical principal investigator and inform him of your decision. Your decision to withdraw from the study, will not affect your relationship with the Translational Research Institute or the hospitals involved.

Ethical Guidelines
This study is being be carried out in accordance the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you would like to participate, please complete the consent form below and return it directly to the study team. A member of the study team will then contact you directly to arrange an appointment convenient to you, so the assessments can be completed.

Thank you for considering this invitation.



Professor Carolyn Mountford,
Chief Investigator

partnering for better health

Consent Form

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Declaration by the participant:

- I have read the Participant Information or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I authorise assigned study personnel and any authorised representatives of approving institution to access my personal or health information collected for the purposes of this study.
- I understand that all electronic data collected including contact details will remain on an encrypted database.
- I understand that my personal and health information will remain confidential, except as required by law.
- I understand that my local doctor (GP) may be contacted about my participation in the study and that information gathered during the course of the study that is relevant to my ongoing healthcare will be passed on as required.
- I understand I will be given a copy of my signed consent form to keep for my records.

Full Name_____ **Signature** _____

Date and time of Signature _____

Optional Additional Participant Consents

☐ Yes	☐ No	I consent to the use of de-identified images of my brain scans in any publications and presentations relevant to this research .
☐ Yes	☐ No	I would like to receive personal, individual feedback on the results of my MRI imaging
☐ Yes	☐ No	I would like to receive a summary of the overall finding of the study when it has been completed.
☐ Yes	☐ No	I consent to the use of my de-identified data collected during this study to be used in future research of a similar nature
☐ Yes	☐ No	I agree to allow researchers from the Translational Research Institute to contact me to participate in any future components of this research study.
☐ Yes	☐ No	I agree to allow researchers from the Translational Research Institute to contact me to participate in any relevant future studies and I understand I am under no obligation to do so

Full Name_____ **Signature** _____

Date and time of Signature _____