CREST Concussion REcovery STudy

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Participant Information Sheet

A validation study to predict poor outcomes following mild traumatic brain injury

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You are being invited to participate in a research project because you have had a concussion. This information sheet explains the study and describes what will be involved should you decide to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend or your GP.

WHAT IS THE PURPOSE OF THIS STUDY?

Following concussion, the symptoms of most patients resolve within a few days to weeks. However, a small proportion of people's symptoms do not resolve, leaving them with debilitating persisting post-concussion symptoms including altered thinking, headaches, dizziness and fatigue.

Patients that present to the emergency department with concussion are frequently discharged with no specific follow up, and currently it is not possible to determine who will have persisting post-concussion symptoms.

This study aims to identify indicators of whether concussion will develop into persisting post-concussion symptoms. In future, patients showing these indicators would then be identified as likely to benefit from follow-up care and could be targeted for new treatments that are being developed.

This study has two phases and is designed to do two things:

1. **Phase I**: Understand better the nature of concussion injuries, their management, and burden on the health system

2. **Phase II:** Provide a way of identifying patients with concussion at risk of persisting post-concussion symptoms so that they can be monitored appropriately

This study is collaboration between Royal Perth Hospital (RPH), Sir Charles Gairdner Hospital, Curtin University, The Perron Institute, The University of Western Australia (UWA) and the Telethon Kids Institute (TKI), and has been funded in part by The Neurotrauma Research Program. It is expected that 500 participants will be recruited into the **Phase I** study, and 120 participants will be recruited into the **Phase II** study.

WHAT WILL PARTICIPATION IN THIS STUDY INVOLVE?

Phase I

If you agree to participate in this study we will first ask you to complete a series of study activities on the first day of your participation

1. A member of the research team will call you by phone or meet with you to answer any questions you have about the study and record your consent to participate.

2. The researcher will then ***collect information*** on the nature of your injury, your symptoms and some more details about your general health. You may also be invited to participate in Phase II of the study.

Phase II

If you meet the inclusion criteria and are able to attend the research centre at QEII Medical Centre you will be invited to participate in an extended set of study activities.

1. You will undergo a ***neuropsychological test*** that will help researchers understand how severe your concussion is, and more clearly understand your symptoms. These tests will take approximately 40 to 50 minutes and will be conducted under the direction of A/Prof Carmela Pestell (Director, Robin Winkler Clinic, Clinical Psychologist & Neuropsychologist).

2. A nurse or qualified researcher will take a 20mL ***sample of your blood*** (this is about four teaspoons). Researchers will analyse your blood to see if there areany indications of your concussion apparent in your blood sample.

3. You will be asked to complete an ***exercise tolerance test*** to assess your tolerance to exercise. This is a stationary exercise bike test, and you will stop the test if any of your concussion symptoms are worse. This test will take a maximum of 30 minutes to complete. You will also be asked to complete a ***walking and balance test*** which involves ten different types of simple walking tasks. The walking balance tests will take a maximum of 10 minutes to complete.

4. You will also have a brain scan by ***Magnetic Resonance Imaging (MRI).*** MRI does not involve ionising radiation. This test will take approximately 40 minutes and will depend on the availability of the MRI machine at the time of your visit.

Follow-up

For both Phase I and II participants, researchers will contact you by telephone at one-, three-six- and 12-month intervals after your first participation day. You will be asked basic questions about your condition, and any remaining symptoms you may be experiencing.

Although this will end the formal study commitment, if your initial MRI results indicate that your injury is more severe and/or if you are still experiencing symptoms at the three-month follow-up point you may be referred for further medical follow up outside of the study. If the neuropsychological testing indicates that you still are experiencing significant symptoms or emotional distress, you will be offered a referral for further clinical neuropsychological

assessment at the Robin Winkler clinic or the State Head Injury Unit, Sir Charles Gardiner Hospital.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits include clear diagnosis of persistent post-concussion symptoms, access to advanced neuropsychological testing including follow up care if required, and access to an additional MRI scan if the first scan was abnormal and significant symptoms persist at the three-month follow up.

People who receive a concussion in the future may benefit from the study findings due to better prediction of ongoing symptoms. A method to identify patients at risk of developing post-concussion syndrome could also be used to assess the effectiveness of treatment strategies in future clinical trials.

WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES?

Because this study does not involve a treatment, the risks and disadvantages of taking part are low and are no more than experienced with blood collection and undergoing an MRI.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

Any information obtained for the purpose of this research study that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

Your personal information will be stored in re-identifiable (coded) format with a study allocated ID. The study ID will be listed against your identifying details in a separate electronic excel log (the 'master log') which will be password protected and accessible by research staff only. The collection of data will be conducted by persons who normally have access to patient records for clinical care or directly related secondary purposes; namely the clinicians and research staff employed by RPH. Non-Health Department employees have signed a declaration of confidentiality.

Paper copies of your personal information will be stored within a secure filing cabinet in a locked research office designated for research staff only at RPH. These will only be accessed by approved research staff. Information relevant to the study will be entered into an electronic database called RedCap. RedCap is a central database based at Curtin University that is used for collection and secure storage of research information. The information entered into RedCap will be encrypted and protected on a secure network accessible only by authorised research staff. The entries in the database will only be identifiable with a study ID that can be cross referenced with the master log which will be kept separate.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Blood samples, for participants in Phase II, may be used to study many indicators of damage; any future study that links your personal information to data from your blood samples will be restricted to the area of interest covered by this project.

In line with WA Health Guidelines all research data will be retained for seven years. After that time, all hardcopy data will be shredded into confidential waste. All electronic data will be transferred onto CD and subsequently destroyed.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research study.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the approved research staff. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel as noted above.

It is anticipated that the results of this study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this study may be recorded in your health records.

In accordance with the Australia Privacy Act (1998) and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

COMPLAINTS AND COMPENSATION

If you suffer any injuries or complications as a result of your participation in this study please contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

Participation in this project does not alter any right to compensation that you may have under statute or common law.

STUDY COSTS

There are no costs associated with participating in this study. All tests required as part of the study will be provided to you free of charge. You will be reimbursed for reasonable travel and parking expenses associated with the study upon presentation of an expense receipt.

No member of the research team will receive personal financial benefit from your involvement in this study (other than their ordinary wages).

DO I HAVE TO PARTICIPATE IN THIS STUDY?

Participation in any research study is voluntary. If you do not want to participate, you do not have to. If you decide to participate and later change your mind, you are free to withdraw from the study at any stage. *You do not have to participate in this study to receive treatment.*

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or any current or future relationship with the hospital or research staff. If you do withdraw from the study personal information already collected will be retained to ensure that the results of the study can be measured properly and the study data is as complete as possible. If you do not want your data retained, please inform the study team at the time of your withdrawal.

If you are interested in the outcome of the study the researchers can provide you with a copy of the research findings once these have been finalised. Please contact Assoc. Professor Melinda Fitzgerald on (08) 6457 0514 to ask for a copy of the study findings.

FURTHER INFORMATION AND WHO TO CONTACT

If you want further information about this project or if you have any medical problems which may be related to your participation (for example, any side effects), please contact: **Prof Melinda Fitzgerald on (08) 6457 0514, Monday – Friday, 09:00 to 17:00 or at** lindy.fitzgerald@curtin.edu.au

This project has been granted ethical approval by the Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC). If you have any concerns about the conduct of the project or your rights as a research participant, please contact the East Metropolitan Health Service (EMHS) Research Ethics and Governance Unit on (08) 9224 2292 or EMHS.REG@health.wa.gov.au and quote the ethics approval number RGS0000003024

ADDITIONAL INFORMATION FOR PHASE II PARTICIPANTS

WHAT ARE THE POSSIBLE RISKS ASSOCIATED WITH BLOOD AND MRI TESTS?

Blood collection

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

MRI Scans

MRI stands for *Magnetic Resonance Imaging*. A MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.

Before the MRI you will be asked to fill out a questionnaire to ensure you tell us if you have any metal implanted in your body, such as a pacemaker or metal pins, which would exclude you from having an MRI.

We will ask you to lie on a table inside the MRI scanner. The scanner will record information about your brain. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still. The scanner is very noisy and we can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins.

INFORMATION OF RELEVANCE TO YOUR HEALTH AND CLINICAL CARE

- Your initial MRI results may indicate that your injury was more severe than first thought. Your treating doctor will have access to this information and will take it into account when deciding upon your best medical care.

- The MRI scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

- The neuropsychological testing may indicate that you are experiencing significant symptoms or emotional distress. If this happens you will be offered a consultation with a Clinical Psychologist at the Robin Winkler Clinic at UWA. This clinic is staffed experienced Clinical Psychologists registered with the Psychology Board of Australia. During the consultation the Clinical Psychologist will assess your condition, and refer on to appropriate counselling or emergency care.

- If you become upset or distressed as a result of your participation in the study more generally, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified Psychologists at the Robin Winkler Clinic who are not members of the research team. This counselling will be provided free of charge.

WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

Your blood samples will be analysed at the Sarich Neuroscience Research Institute for the presence of 'markers' that may indicate the severity of your concussion and help researchers identify useful ways to predict whether symptoms will persist.

Blood samples will be stored at the Sarich Neuroscience Research Institute for a maximum of 15 years. The samples will be stored in re-identifiable (coded) format against a study allocated ID. The study ID will be listed against your identifying details in a separate electronic excel log (the 'master log') which will be password protected and accessible by research staff only. This means your sample can only be matched to your name by research staff who have access to the master log.

One of the reasons for storing samples in re-identifiable format is that it allows you to withdraw your samples at any time. You can do this by emailing concussionstudy@curtin.edu.au. Samples will be disposed of by incineration in appropriate biohazard containment bags, in accordance with the biohazardous project risk assessment, approved by the UWA Biological Safety Office.

Blood samples may be used to study many indicators of damage; any future study/ies will be restricted to the area of interest covered by this project - concussion and recovery from concussion - as approved by a Human Research Ethics Committee (HREC).