Participant Information Sheet

Date Information Sheet Produced: DD MMMM YYYY

PROJECT TITLE

The use of intermittent short-term selective head-neck cooling for the management of acute concussion and post-concussion syndrome

AN INVITATION

My name is Dr Doug King and I am a Research Associate at Auckland University of Technology (AUT) in Auckland. I am also a senior Clinical Nurse Specialist employed in the Emergency Department of the Hutt Valley District Health Board in Lower Hutt, New Zealand. I have previous experience relating to research on sport-related concussion and the impacts that occur during rugby union and rugby league match activities.

You are invited to take part in the above-mentioned research project. Your participation in this research is voluntary. You are free to withdraw consent and discontinue participation from the study at any time before the completion research without influencing any present and/or future involvement with the Auckland University of Technology.

Your consent to participate in this research will be indicated by your signing and dating the consent form. Signing the consent form indicates that you have freely given your consent to participate, and that there has been no coercion or inducement to participate by the researchers from AUT.

WHAT IS THE PURPOSE OF THIS RESEARCH?

The purpose of the study is to monitor you in terms of your post-concussion syndrome with a series of assessments and intermittent short-term head-neck cooling to ascertain how cooling of the head can assist with your recovery.

HOW WAS I CHOSEN TO BE ASKED TO PARTICIPATE IN THE RESEARCH?

You were chosen to participate in the study as you have been referred to the Post-Concussion clinic.

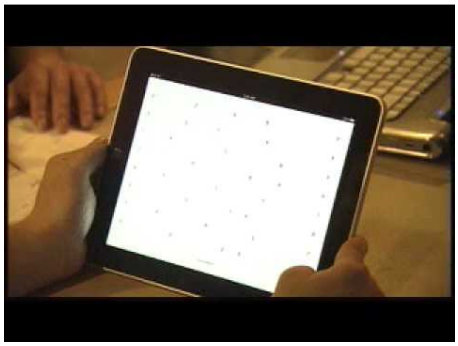
HOW DO I AGREE TO PARTICIPATE IN THIS RESEARCH?

Your participation in this research is voluntary (i.e. it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

WHAT HAPPENS IN THIS RESEARCH?

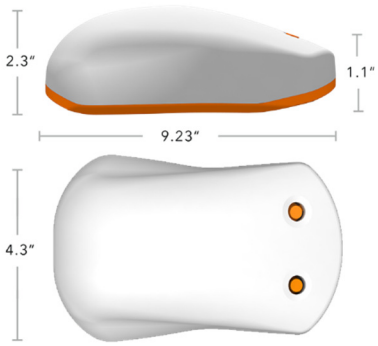
You will be asked to complete a concussion history questionnaire that will be recorded and used as part of the analysis of the data obtained. This history relates to the cause of your concussion, time since your last concussion, your concussion history and any co-modifiers that you may have. This information will be recorded in a database only accessable to the investigators directly involved in the study.

Following the initial consultation you will be asked to complete an assessment with the symptom evaluation of the SCAT5, a balance test, a King-Devick test and the Brain Gauge.



The King-Devick test is a rapid number-naming assessment undertaken on an iPad. There are four screens to the assessment. The first screen is a demonstration screen, the second screen has horizontal lines to guide you, the thrid screen has no horizontal lines and the fourth screen has the numbers compressed. The goal of the test is to read the numbers out in the manner identified without making any mistakes as fast as you can. You will be asked to complete two tests the first time you do the test.

Following the King-Devick test you will be placed in front of a computer and asked to complete an on-line assesment called the Brain Gauge. This test will take approximately 20 minutes to complete.



The 'Brain Gauge' vibro-tactile stimulation hand held device is the same shape and size to that of a standard computer mouse. Sitting at a computer and when your are logged into the Cortical metrics programme you will be guided through a series of tests. The two dots on the top of the mouse will vibrate and the computer program will advise you of what actions to take.

Following the completion of the Brain Gauge you will be asked to wear the Cryohelmet for ten minutes on your head.

The Catalyst Cryohelmet is a neoprene, latex free adjustable headset with eight reusable cold packs inserts that are mouldable to the head. The headset fits over the head and aound the neck to provide cooling to the surface of the skin without any direct cold pack contact to the skin. You will be asked to wear the Cyrohelmet on the sideline for 10 minutes before being assessed with the King-Devick test and the SCAT5. The protocol for the use of the will be discussed if a concussion occurs to you.

Following the ten minutes of wearing the Cryohelmet, you will be asked to repeat the symptom evaluation of the SCAT5, the King-Devick test and the Brain Gauge assessments. You will be provided with the results immediately after completing the Brain Gauge assessment.

You will be provided with information on the use of intermittent short-term selective head-neck cooling for you to complete at home until you return for your subsequent assessment. When you return for your next assesment, you will again be asked to complete the symptom evaluation of the SCAT5, the King-Devick test and the Brain Gauge. Again, your results will be made available immediately after completing the Brain Gauge. This will occur with every subsequent visit to the clinic.

WHAT ARE THE DISCOMFORTS AND RISKS?

The discomforts that may occur are you feeling worn out from the assessments and some people may not like the cooling effects on their head and neck. There is a risk of a cold burn should you apply the cooling packs directly to your skin without the use of a cloth or protective cover.

WHAT ARE THE BENEFITS?

Information gained from this research has potential to help shape management protocols for the treatment of post-concussion syndrome and this may assist with you returning to your normal activities in a shorter time-frame.

WHAT COMPENSATION IS AVAILABLE FOR INJURY OR NEGLIGENCE?

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for any injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

HOW IS MY PRIVACY PROTECTED?

The data from the project will be coded and held anonymously in secure storage at the Sport Performance Research Institute New Zealand (SPRINZ) at Auckland University of Technology under the responsibility of the principal investigator of the study in accordance with the requirements of the New Zealand Privacy Act (1993).

All reference to participants will be by code number only in terms of the research project and publications. Identification information will be stored on a separate file and computer from that containing the actual data.

Only the investigators will have access to computerised data obtained from the participants in study.

In the case of a decrement in the results from your previous assessment, this information will be provided to the facilitator of your rehabilitation to enable adjustment to your treatment regime.

WHAT ARE THE COSTS OF PARTICIPATING?

Participating in this research project will not cost you apart from your time You will be asked to complete the assessments which will take approximately 1 hour at the beginning of the study and approximately 30 minutes at each session throughout your rehabilitation process.

OPPORTUNITY TO CONSIDER INVITATION

Please take the necessary time you need to consider the invitation to participate in this research. The assessments are a routine part of your initial assessment to enable baseline comparisons to be available throughout your rehabilitation program. You can choose to have your baseline data entered into the research at any stage throughout your rehabilitation program and to participate in the research project.

It is reiterated that your participation in this research is completely voluntary.

If you require further information about the research topic, please feel free to contact Dr Doug King (details are at the bottom of this information sheet).

You may withdraw from the study at any time without there being any adverse consequences of any kind.

You may ask for a copy of your results at any time and you have the option of requesting a report of the research outcomes at the completion of the study.

HOW DO I JOIN THE STUDY?

If you are interested in participating in this research, please feel free to contact Dr Doug King (details are at the bottom of this information sheet).

PARTICIPANT CONCERNS

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Professor Patria Hume. Email: phume@aut.ac.nz or phone +64 9 921 9999 ext. 7306.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, ethics@aut.ac.nz, (09) 921 9999 ext. 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researchers Contact Details:

Dr Doug King, Sports Performance Research Institute New Zealand, School of Sport and Recreation, Auckland University of Technology. Email: dking@aut.ac.nz or phone +64 22 034 1580.

Project Supervisor Contact Details

Professor Patria Hume, Sports Performance Research Institute New Zealand, School of Sport and Recreation, Auckland University of Technology. Email: phume@aut.ac.nz or phone +64 9 921 9999 ext. 7306.

Approved by the Auckland University of Technology Ethics Committee on *date of approval*, AUTEC Reference number *reference number*