

# Participant Information Sheet

Date Information Sheet Produced: 12<sup>th</sup> August 2017

## **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 concussion with a series of pre-season baseline and post-match assessments. Should you be identified to have incurred a concussion occurring these assessments will be utilised to assist in your re-evaluation post-match and along the rehabilitation path back for you to participate in your sports code match and training activities.

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

You were chosen to participate in the study as you're a member of either the Hutt Old Boys Marist Rugby Football Club women's team. This process is now standard pre-competition assessment for head injuries and will be included as part of your assessment prior to the season commencing.

### **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 will be recorded in a database only accessible to the investigators directly involved in the study.

During the preseason period of the Wellington women's rugby union competitions you will be asked to complete a baseline King-Devick test, and a baseline Sports Concussion Assessment Tool (v.5) (SCAT5) assessment. These baseline tests will be used to evaluate you against in the event of a suspected concussion occurring during training or matches. This information will be collected at the beginning of your enrolment in the study.

Post-match you will be asked to complete the King-Devick reading test on an iPad. Following the assessment, if there is a suspicion of a concussive injury you will be asked to complete the SCAT5 and will be referred for a full medical evaluation.

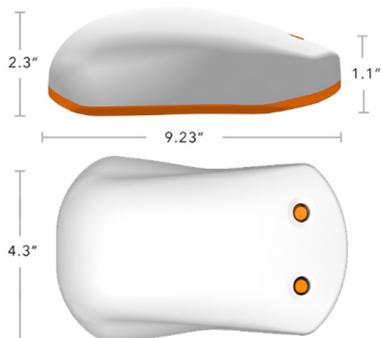
Should you be identified as having incurred a concussive injury, you will be asked to complete the King-Devick reading test and the SCAT5. The results of the SCAT5 will be provided to you to take to your health practitioner for their evaluation as part of their assessment. If, as a result of the health practitioner's assessment, a concussion is diagnosed, then you will be required to complete the sporting code stand-down period and follow the Accident Compensation Corporation National Guideline for Sport Concussion in New Zealand. This includes, but is not limited to a period of cognitive rest, graduated return to activity and, will require a health practitioner assessment and medical clearance before being allowed to return to your sporting activities.

During the first few days following identification of concussion you will be asked to wear a selective head-neck cooling headset. This is similar to an ice-pack for a sprained ankle. You will be asked to wear this for approximately 10 minutes following the identification of the concussion and then to repeat the King-Devick test and the symptom score of the SCAT5.



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 around 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 Cryohelmet 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.

As part of the graduated return to activity, you will be asked to undertake regular assessment with the King-Devick reading test, the SCAT5, and also the Brain Gauge test until you have been medically cleared to return to full sports participation.



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 you 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.

The study duration will be the duration of the women's rugby union domestic competition throughout 2019 and 2020. Match and training activities will be studied over this period.

#### **WHAT ARE THE DISCOMFORTS AND RISKS?**

Only those discomforts and risks that normally occur from participating in Wellington women's rugby union domestic competition match and training activities. This includes the risk of a sports-related concussion. This risk can be increased if you have had a previous concussion.

#### **WHAT ARE THE BENEFITS?**

Information gained from this research has potential to help shape training strategies, and develop prognostic indicators of value to athletes, clinicians, physical conditioners and coaches and in particular to women's rugby union.

#### **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 (outside of those that may be expected by your regular participation in sport), rehabilitation and compensation for 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 the Wellington rugby union, netball, and soccer, domestic competitions.

In the case of you recording a concussion through the course of your sporting activities, the team coach and manager will be advised that you have been injured and you will be medically stood down until cleared by a health practitioner. The nature of the injury will not be passed on to the coach or manager by any of the investigators.

#### **WHAT ARE THE COSTS OF PARTICIPATING?**

Participating in this research project will not cost you apart from your time that you normally provide for participating in the Wellington women's rugby union domestic competitions. In addition, you will be asked to give approximately 5 minutes for a baseline King-Devick test and 15 minutes for a baseline SCAT5 assessment.

If you are identified as having a concussion, or possible concussive injury a repeat King-Devick test taking 5 minutes, a repeat SCAT5 requiring approximately 15 minutes will be undertaken.

You may also be asked to undertake a post-match assessment with the King-Devick test requiring approximately 5 minutes.

As part of your return to participation recovery, you will be asked to routinely undertake a King-Devick reading test, symptom assessment and a Brain Gauge assessment requiring approximately 25 minutes.

### **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 pre-season assessment to enable baseline comparisons to be available in the advent of a concussion occurring. You can choose to have your baseline data entered into the research at any stage throughout the preseason period (January to April) 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 AUPEC, 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*, AUPEC Reference number *reference number*