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PARTICIPANT INFORMATION SHEET

Project Title: Evaluating virtual reality-based eye tracking tests for people with mild traumatic brain injuries.

Researcher(s): Dr Philip Turnbull, Dr Alice Cade, and Ms Jasmine Zoest

Researcher Introduction:

Thank you for taking the time to read this information sheet which you have been given because you have expressed interest in participating in this study. I am Alice Cade, from the School of Optometry and Vision Science (SOVS) at the University of Auckland. I am conducting a project with Dr Philip Turnbull and Jasmine Zoest from the SOVS. This study aims to see if our virtual reality (VR) eye tracking tests are useful in identifying eye tracking symptoms of mild traumatic brain injury (AKA mild concussion)

Project Description:

Eye movements are commonly affected in people who have had a mTBI and computerised eye tests are often used to measure eye movement difficulties. The focus of this study is to see if the VR eye tracking tests can pick up changes in eye movements in people with mild concussions versus healthy people

You are invited to take part in this study as you have indicated you are interested in participating This study is voluntary and your participation will be anonymous. If you do decide to participate you are able to withdraw your participation at any time.

Project Procedures:

If you decide to participate in this study these are the things that will happen:

1. You will have your eye movements tested in virtual reality. This means you will sit, with a VR headset on, and a small camera will record the movements of your eyes while you complete a number of tests. These tests will take around ten to fifteen minutes to complete

Possible benefits

This study is a simple, basic-sciences test of how well we have done creating virtual reality eye movement tests. It is unlikely that these tests will affect you in any way.

How the data will be used

It is anticipated that the results of this study will be written up as part of a PhD project for Ms Jasmine Zoest and may be presented at national and international conferences and submitted for publication in the scientific literature. You will not be individually identifiable in any report from the study. Any data used for this purpose will be entirely de-identified so that your identity cannot be traced from the data.

Participation

Participation in this study is voluntary which means you are under no obligation to take part. Neither your refusal nor agreement to take part will affect the clinical care you receive, from the researchers or any other clinicians, today or in the future. Similarly, if you are a student at the University of Auckland or the New Zealand College of Chiropractic, your decision to participate or not participate will not influence your academic progress in any way. As a student, you may contact your Head of Department (HoD) should you feel that this assurance has not been met.

Eligibility

There are a number of reasons you might not be suitable for this project, these include:

• You have a condition that is known to affect eye-movements, such as attention deficit hyperactivity disorder (ADHD), stroke, or cranial nerve palsy or vision loss in one or both eyes that is not corrected to normal via glasses or contact lenses.

Incidental Findings

It is unlikely this study will result in any incidental findings. However, if any issues arise you will be offered referral consistent with normal clinical care to a registered health practitioner.

Data Storage/Retention/Destruction:

Clinical data (paper copies) will be stored in a secure cabinet at the University of Auckland for six years (for publication purposes) before being securely destroyed. Electronic data will be de-identified immediately following collection and stored indefinitely on password-protected computers to allow comparison to future data sets.

Consent Forms will be held by the Department in a secure location, separate from the research data for a period of six years.

The results of your eye movement tests are used for analysis only and you are not identifiable from them. They will be recorded in a de-identified form for subsequent analysis.

Right to Withdraw from Participation:

If you change your mind about participating, you have the right to withdraw from the study at any time, without providing a reason. You are also at liberty to withdraw any data traceable to you, should you wish to do so.

Anonymity and Confidentiality:

All participants will be assigned a unique alpha-numeric identification code to protect confidentiality. A document linking the code with your name will be stored independently of the clinical data and will be available only to the researchers. All clinical data will be collected, recorded, stored and analysed under your unique code. The linking document will be destroyed along with the raw clinical data after 6 years. If the results of this study are to be published in the scientific literature or presented at a conference, as with the study report, you will not be individually identifiable.

Risk of Harm

The risk of harm during the eye movement assessments is minimal. The investigators are trained to carry out these tests safely. You will be given detailed instructions during the test procedures to minimise risks as far as possible.

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

Contact Details and Approval:

For any queries or concerns about this study please contact one of the following researchers:

Dr Alice Cade Dr Philip Turnbull

Email: a.cade@auckland.ac.nz Email: p.turnbull@auckland.ac.nz

Telephone: 021 400 739 Telephone: 09 923 5499

For any queries regarding ethical concerns, you may contact:

The Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711. Email: ro-ethics@auckland.ac.nz

Cultural support

If you require Māori cultural support talk to your whānau in the first instance. Alternatively, you may contact the administrator for the University of Auckland Māori Ethics Advisor by telephoning 09 373 7513 ext 85005

Health and disability advocate

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

Health and Disability Ethics Committee

You can also contact the Health and Disability Ethics Committee that approved this study:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz