Participant Information Sheet

Home monitoring of age-related macular degeneration

Formal Study title: Home-based monitoring of visual function in age-related macular degeneration

Lead Researcher: Professor Steven Dakin, Head of the School of Optometry and Vision Science

Study Sites: Tony Han Optometrists Tauranga; Milford Eye Clinic Auckland

Contact phone number: (09) 923 8898

Ethics committee ref.: 21/CEN/88

You are invited to take part in a study on a home-based monitoring device, using an 'eReader' app and Apple iPad for age-related macular degeneration. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is nine pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Participation in this project is completely voluntary. Should you wish to withdraw from the study you may do so at any time by notifying Mr Tony Han.

There will not be any penalty or loss of benefits in regard to the services provided to you by Tony Han Optometrists and Milford Eye Clinic, should you decide not to participate in this project.

Your ongoing care will be carried out by Tony Han Optometrists and Milford Eye Clinic as usual, and this care is independent from this project.

There are no direct benefits in taking part in this study.

WHAT IS THE PURPOSE OF THE STUDY?

Age-related macular degeneration (or AMD) is the leading cause of irreversible central vision loss and impairment in Aotearoa New Zealand. The disease affects people over the age of 45 and its prevalence increase sharply with age. AMD has three clinical stages and usually progress from early to late-stage with time and give sight-threatening prognosis.

The challenge for eye doctors is to identify the transition from early to late stage of AMD, so they can promptly intervene and save more sight. Detecting progression currently requires frequent visits to the eye doctors, which is a significant socioeconomic burden to patients and hospitals.

The most common complaint from AMD patients is difficulty with reading. We aim to develop a home-based system to monitor the progression of AMD and alert the eye doctor if there is a change in a patient's reading pattern.

HOW IS THE STUDY DESIGNED?

There will be three groups of participants recruited:

- Group 1, number=100: throughout years one, we will recruit participants to engage in a short (15-30min) reading task in the clinical waiting rooms of the two study sites. This large group will provide "snapshots" of normal reading performance in a mixed control group and will provide feasibility and usability information that will inform the task design going forward.

- Group 2, number=40: from the middle of year one, we will begin recruiting into a control group. The control group consists of patients with healthy eyes.

- Group 3, number=40: from the middle of year two we will begin recruiting into a test group. The test group consists of patients with wet AMD patients undergoing anti-VEGF treatment.

Group 2 and 3 will be age-matched (from 45 to 80 years old).

WHO CAN TAKE PART IN THE STUDY?

For group 1, we are seeking volunteers from all age groups to participate in our study. Participants must be able to speak and read in English fluently.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

As a group 1 participant, you will be given an iPad to read in the waiting room of Tony Han Optometrists for 15-30 minutes. Reading distance, font size, iPad brightness can be changed at a calibration page to suit. The iPad will be held in a normal reading position and can be moved and/or tilted to assist reading. Your eye-tracking data will be collected in eyes/face images then translated into numeric form, and will provide us valuable feedback to refine the 'eReader' app.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The measurements taken in this study are the same ones that are used in ordinary investigations of vision in an eye examination. None of the measures are invasive and none involve contact with your eyes.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

In order to help reducing the socioeconomic burden of AMD management in New Zealand, we aim to develop a simple “eReader” app that leverages the built-in imaging capabilities of modern Apple devices to perform eye-tracking. By having patients read their preferred content on this device, we will obtain an accurate, objective measure of their reading performance, which we hypothesise will be a simple, reliable, cost-effective indicator of the progression of AMD.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative is not to take part.

WILL ANY COSTS BE REIMBURSED?

All of the assessments involved in this study will be provided free of charge. There is no reimbursement for travelling cost.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, Mr Tony Han will record information about you and your study participation. This includes the results of any study assessments.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, address or eyes/face images). The following groups may have access to your identifiable information:

- Mr Tony Han and Professor Steven Dakin, the researchers.

- The ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.
- Rarely, it may be necessary for Mr Tony Han to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- The University of Auckland.
- The ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Regulatory or other governmental agencies worldwide.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

Your coded information may be used for future research related to AMD.

You will not be told when future research is undertaken using your coded information. Your coded information may be shared widely with other researchers or companies. Your coded information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any research that is done using your coded information

Your coded information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your coded information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at Tony Han Optometrists in Tauranga during the study. After the study it is transferred to a secure archiving site at the University of Auckland and stored for at least ten years, then destroyed. Coded study information will be kept by the University of Auckland in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the researcher.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your researcher.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to the University of Auckland. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Use of New Technologies (e.g. Artificial Intelligence, Health Apps.

This study involves the use of Apple iPads, a tablet form of personal computer. This is a mandatory component of this study. There will be no identifiable information collected by the device, such as your name and gender. There will be no video or audio information recorded.

The 'eReader' app pre-loaded on the iPad devices will perform eye tracking and record the results in sets of numbers, these numbers will be transferred to a cloud service to be stored. The app is designed by the University of Auckland, and it will not share information with any third parties.

We will provide all necessary training and equipment for this study, include loaning an iPad to you. There is no cost involved, no credit card information is required.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Should you wish to withdraw from the study, you may do so any time by informing the coordinating researcher, Mr Tony Han. Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

The 'eReader' app will be available on the Apple app store to download once all results are validated and approved by the University of Auckland.

CAN I FIND OUT THE RESULTS OF THE STUDY?

All participants will be provided with a plain English summary of study results, if requested, within one year of completion of data collection and analysis. This is expected to be the end of 2024.

WHO IS FUNDING THE STUDY?

This study is part of the PhD program for Mr Tony Han. He is the recipient of the Senior Medical Research Scholarship at the University of Auckland.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The HDEC has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Mr Tony Han, Optometrist, Coordinating Researcher
Telephone: 07 576 889 or 021 996 555
Email: tony.han@auckland.ac.nz

If you want to talk to someone who isn't 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@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Maori health support please contact:

R2M Team
Maori Responsiveness and Ethics
Email: R2M@auckland.ac.nz
Website: https://www.auckland.ac.nz/en/fmhs/about-the-faculty/tkhm/Responsiveness-to-Maori.html

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Consent Form

Home monitoring of age-related macular degeneration

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	
I consent to the research staff collecting and processing my information, including information about my eyes/face images/positions, and information about my health.	Yes ☐	
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes ☐	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	
I understand the compensation provisions in case of injury during the study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____