PARTICIPANT INFORMATION SHEET

Presbyopia could be avoidable – translating research into a clinical screening trial

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To the Participant,
You are invited to participate in a study investigating the mechanism of presbyopia as you have previously expressed interest in taking part in presbyopia research, or because you responded to our poster/email advertisement. Please take your time to think about the information provided below, and feel free to discuss it with your whanau, family or significant other support people. Taking part is completely voluntary (your choice).

What is the study about?
Presbyopia is the normal loss of near focusing ability, called accommodation, which occurs with age. Most people begin to notice the symptoms of presbyopia at around 40-50 years of age, when they start experiencing difficulty seeing small print clearly. This requires near vision correction, often in the form of reading glasses. Presbyopia is generally believed to be due to a “hardening” of the crystalline lens in the eye that is a result of age-related changes occurring within proteins in the lens. With less elasticity, the lens is unable to change shape and therefore unable to focus up close.

Water transport pathways within the lens are thought to be vital for maintaining protein structure and function. We therefore hypothesise that ageing causes a decline in lens water transport, affecting lens proteins and ultimately resulting in presbyopia. This study uses magnetic resonance imaging (MRI) to visualise and measure lens water transport non-invasively in people with and without presbyopia. We aim to investigate the role of lens water transport...
transport in accommodation, and whether there is a decline in lens water transport in presbyopia. The results of this study have the potential to reveal pharmaceutical treatments to delay the onset of presbyopia, thereby alleviating the need for reading glasses.

Eligibility
You have been invited to take part as you have healthy vision, either with or without presbyopia. You are eligible to participate if you are between 20 and 55 years old and can achieve 20/20 vision without requiring glasses or contact lenses (have close to zero refractive error).

You are not eligible to participate if
- you have significant refractive error (check with us)
- you have any other eye diseases, conditions or previous eye surgery
- you have a personal or family history of epilepsy or seizures
- you have a history of neurological disorders or disease
- you have a cardiac pacemaker or other metal implants that prevent you from having an MRI scan
- you have experienced a serious head injury or skull fracture
- you are pregnant

What does the study involve?
This study is non-therapeutic. The study has an initial eligibility test (eye exam), which if passed, is then followed by an MRI scan. All assessments for this study will take place in the University of Auckland’s Grafton campus. The eye exam and MRI scan(s) will be done on separate visits within a relatively short time frame (no more than a month apart). The total amount of time you could dedicate to this study is between two to three hours.

Eye Exam
You will be asked to come to the University of Auckland Optometry Clinic first to be seen by a qualified optometrist. Here, we will assess your eligibility to participate in the study through a screening eye examination. We will ask a few questions about your medical history, your previous eye care and any eye problems. We will then check your glasses prescription, visual acuity, near focussing ability and eye health using standard optometric tests. Dilating eye drops will be used for the eye health assessment. Imaging of the eyes with optical biometry, retinal photography, optical coherence tomography (OCT) scans and Scheimpflug photography will be also performed as part of our routine exam.

The total testing time for the eye exam is anticipated to take 1 hour. You will be informed at the end of this session whether or not you are eligible to proceed with the remainder of the study.

MRI Scan
The MRI scan will take part at the University of Auckland’s Centre for Advanced MRI (CAMRI). The MRI modalities employed here are completely safe and non-invasive.

Before entering the scanner, you will be asked to complete a checklist to ensure that it is safe for you to participate in an MRI study. You will be asked to change into a dressing gown prior
to entering the machine. Once in the scanner, you will be asked to lie supine on a table with
your head stabilised by foam pads. The scanner is quite noisy when it is operating, so you will
be given earplugs to wear. The radiographer will communicate via an intercom system
regarding when each scan is starting and what to expect.

For this study we will be doing approximately 5 sets of short scans. You will be given a pair of
glasses to wear for each set of scans, each with differing powers. During these scans you will
be asked to fixate on a letter target presented on a screen that you will view through a mirror.
People who are prone to claustrophobia can find lying in the MRI scanner difficult to tolerate
as the tunnel is quite narrow. If at any time you want to stop the scan, you can press a safety
button, and the scanning will stop straight away. The entire scanning session will take
approximately one hour, including changing time and plenty of rest breaks between scans.

If you do not have presbyopia (i.e. are below 40 years of age), you will be asked to return for
another MRI scan on a separate visit within a relatively short time frame (within a week). The
same MRI protocol will be performed but with the instillation of dilating eye drops in order to
simulate the inability to accommodate (or presbyopia).

**Risks and Benefits**

There are no direct benefits for participation in this study. You will be offered a copy of your
spectacle prescription and any images of your eyes that we obtain. You will also be offered a
copy of your MRI scan on CD.

There is a small risk of adverse side effect from the use of dilating eye drops and you will be
assessed by a qualified optometrist for suitability prior to instilling the drop. The potential side
effects are blurred vision, burning sensation, dry mouth, headache, nausea, sensitivity to
sunlight, and temporary stinging. You may prefer not to drive to the appointment, or allow
some time before driving home. In very rare cases, allergic reactions, eye pain, irregular or
rapid heartbeat, paleness or flushing of the skin, rigid muscles, shortness of breath, or vomiting
may occur. If you have any concerns after your visit, you can contact us.

Some subjects may get a claustrophobic reaction while lying supine in the MRI chamber due
to the enclosed environment. If this occurs, the scan will be stopped immediately. During the
MRI scan you may also experience some eye fatigue or boredom as you will be required to
focus on a letter target through a pair of glasses designed to defocus your vision. Participants
are free to stop and discontinue the process on account of any discomfort during the scan.

In the event that any abnormality is detected during the eye examination performed, the
findings will be treated as they would be in normal optometric examination. The appropriate
management will be conducted, which may include referral to the University of Auckland
Optometry clinic, the Hospital Eye Department or another ophthalmic specialist as
appropriate.

Likewise, in the event that any abnormality is detected through performing an MRI scan on
you, you will be informed of this and advised to consult your general practitioner or referred
appropriately. Because the MRI scans are not routinely reviewed by a radiologist we are
unable to perform diagnostic scans for medical purposes of areas where you have known
abnormalities.
If you are unwilling to be informed of any incidental findings then you are not eligible to participate in this study.

**Participation**
Participation will not cost you anything other than your time. Your participation is entirely voluntary (your choice). If you choose not to take part this will not affect the standard of care you receive at the University of Auckland Optometry Clinic or Centre for Advanced MRI in any way.

If you do agree to take part, you are free to withdraw from the study at any time without having to give a reason. You have the right to withdraw any data collected as part of the study from the time of your participation up to one month after data collection.

In addition, if you are a student at the University of Auckland, withdrawal from the study will have no impact whatsoever on your academic assessment or teaching. If you are a student of the School of Optometry and Vision Science, the Head of School has given assurance that participation or non-participation will have no effect on your grades or standing. If you are a staff member of the School of Optometry and Vision Science, your non-participation will not affect your employment.

**Confidentiality**
The de-identified results of this study will be post-processed using common available image processing tools. These outcomes may be presented at conferences, used in doctoral theses, and included in published journal articles. No material that could personally identify you will be used in any reports on this study. The information and data collected from you will be stored securely, in locked cabinets and on secure computer networks at the University of Auckland. Only the investigators will have access to this information, and your data will be made anonymous by assigning a unique code to it. Data will be securely destroyed after 6 years.

**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. For more details, refer to [http://www.acc.co.nz](http://www.acc.co.nz). If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this trial.

**Summary of Your Rights**
- Your participation is entirely voluntary. If you choose not to take part you will still receive the usual treatment/care at the University of Auckland Optometry Clinic.
- You may withdraw from the project at any time without providing a reason. This will not affect your continuing or future care at the University of Auckland Optometry Clinic.
• Your agreement to participate in this study will be obtained in writing on a consent form.
• You may have your data withdrawn from the study within one month of your participation.
• Your participation in the study is confidential and this information will not be divulged to anyone outside the research group.
• You may obtain results regarding the outcome of the project from the researchers upon completion of the study.
• Your identity will be kept strictly confidential, and no identification of you or your data will be made at any time during collection of the data or in subsequent publication of the research findings.
• Ongoing discomfort or incapacity have not been reported from any of the procedures that will be used in this project, however, if the procedures cause you concern, you may withdraw from the project at any time.
• You are encouraged to consult with your whanau/family, hapu or iwi regarding participation in this project.
• You are welcome to have a family member or support person with you during the study sessions.

Who should I contact if I have further questions?
Thank you for giving us your time to consider participating in this study. If you have any further questions about this study, or would like to participate, please contact:

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Other contacts:
Head of School: Professor Steven Dakin
Phone: (09) 923 8898
Email: s.dakin@auckland.ac.nz

For any queries regarding ethical concerns, you may contact the Chair of the University of Auckland Human Participants Ethics Committee at:

Phone: 09 373-7599 ext. 83711
Email: ro-ethics@auckland.ac.nz
Mail: The University of Auckland Research Office
      Private Bag 92019
      Auckland 1142

Approved by the University of Auckland Human Participants Ethics Committee on 04-Apr-2017 for a period of three years, Reference Number 018868