Participant Information Sheet

Can eye drops safely replace reading glasses in older adults?

Formal study title: *Do Vuity eye drops alter posterior eye structure or function in presbyopic adults.*

Study location: Faculty of Medical and Health Sciences, Grafton campus, University of Auckland
85 Park Road, Grafton, Auckland 1023, NZ

Lead researcher: **Dr Alyssa Lie**
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021 0266 4662

Approved by the Health and Disability Ethics Committee (HDEC), reference number: 20945

TO THE PARTICIPANT:

You are invited to take part in a study that examines whether using eye drops in place of reading glasses can change the structure or function of the tissues at the back of the eye.

Whether or not you take part is entirely 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 may receive at the Grafton Optometry Clinic. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

To help you decide whether you would like to take part in this study, this Participant Information Sheet explains why we are doing this study, what taking part would involve for you, 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, you need to sign the Consent Form on the last page of this document before you can begin the study. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 10 pages long (including a Consent Form). Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Presbyopia is the loss of the eye's near focusing ability with age. Most people notice the symptoms of presbyopia at 40-50 years old, when they start experiencing difficulty reading small print. For this reason, people usually rely on reading glasses to see near objects clearly from middle-age onwards.

Recently, a new eye drop (known as Vuity) has been approved in the United States to treat blurry near vision from presbyopia. Clinical trials suggest that using this eye drop can improve near vision without needing to wear reading glasses. However, very little research has been done to understand whether Vuity affects the structure and function of the eye—particularly the retina at the back of the eye that is essential for healthy vision.

The goal of this study is to assess whether using Vuity eye drops to treat presbyopia can change the thickness or blood flow to the choroidal tissues, or the function of the retinal layers, compared to conventional reading glasses. The results of this study will ensure that new treatments for presbyopia are both safe and effective for widespread use.

WHO CAN TAKE PART IN THE STUDY?

You have been invited to take part in this study as you are between 40 and 55 years old, and require reading glasses to correct your presbyopia, with otherwise healthy vision.

You will **not** be eligible to participate if you:

- Wear or require glasses to correct your distance vision (*check with us*)
- Have any eye diseases or eye conditions that affect your vision (*check with us*)
- Have had previous eye surgery (*check with us*)

You will be asked to remove all face make up (such as skin foundation and eyeliner) when attending study visits, as the use of these products may affect the quality of data obtained.

HOW IS THE STUDY DESIGNED?

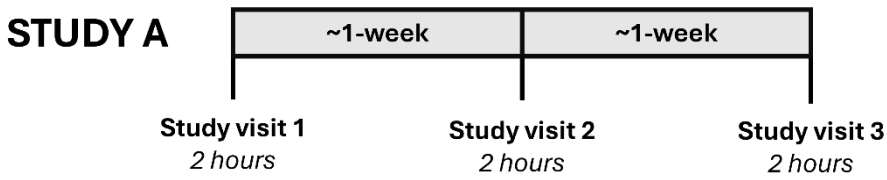
This study is made up of two parts. Study A will examine how the eye responds to **short-term** (one-off) use of Vuity eye drops, and Study B will examine how the eye responds to **long-term** (3-month) use of Vuity eye drops.

You can choose whether you would like to participate in Study A, or Study B, or both. Participating in one of the studies does not mean that you must participate in the other.

Study A will involve 3 separate visits (2 hours each) to The University of Auckland Grafton Optometry Clinic. The visits will be spaced at least 1 day apart but no more than 1 week apart. The total amount of time you could dedicate to this part of the study is 6 hours.

At the start of each visit, you will asked to watch a movie in a dim room for 20 minutes to stabilise your vision. You will then undergo non-invasive, standard optometric testing to obtain baseline measurements from your eyes, before Vuity eye drops are instilled into one of your eyes. For the following 60 minutes you will be asked to continue watching the movie. At the end, you will undergo optometric testing to obtain measurements again.

For 2 of the 3 visits, you will also receive eye drops to dilate your pupils, and be given glasses to wear while watching the movie. The specific visits at which these will be done, as well as which eye will receive the Vuity drops, will be randomly assigned to you before your first study visit.



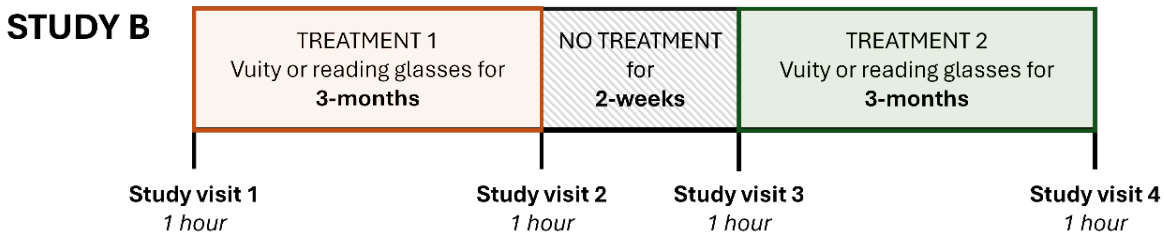
Study B will involve 4 separate visits (1 hour each) to The University of Auckland Grafton Optometry Clinic over a period of 6 months. For 3 months of the study, you will be asked to use Vuity eye drops every day to correct your near vision, and for the other 3 months you will be asked to use your own reading glasses. The total amount of time you could dedicate to this part of the study is 4 hours.

You will be invited to attend study visits on the first and last days of using a treatment. For the following 2 weeks, you will be asked to stop using Vuity eye drops and to use your reading glasses to correct near vision. Then, you will be invited to attend study visits again on the first and last days of using the other treatment.

At the start of each visit, you will be given eye drops to dilate your pupils. Then, you will be given reading glasses to wear while watching a movie in a dim room for 20 minutes to

stabilise your vision. At the end, you will then undergo non-invasive, standard optometric testing to obtain measurements from your eyes.

The treatment (Vuity eye drops or your own reading glasses) that you receive first will be randomly assigned to you before your first study visit. If you do not routinely wear reading glasses, at the beginning of the trial you will be given a pair of "ready readers" with the appropriate power to correct your near vision.



WHAT DOES TAKING PART IN THE STUDY INVOLVE?

Pre-enrolment screening

If you are interested in participating in this study, you will first be asked a few questions to help us determine your overall eligibility. This includes your medical history, your previous eye care and any eye problems. We will also ask for your permission to obtain past medical or health records from your GP and/or optometrist to check your eligibility to take part in the study.

Optometric examination

Before you begin either Study A or Study B, you will be asked to come to the Grafton Optometry Clinic so that we can assess in more detail whether you are eligible to participate. We will check your spectacle prescription, vision, near-focusing capabilities, and eye health using standard optometric tests. Common eye imaging modalities such as optical biometry, retinal and anterior segment photography may be also performed if a valid medical reason to perform the test arises. Once this is complete, a member of the study team will review the results and inform you whether you are eligible to proceed.

All optometric tests will be performed by a NZ-registered optometrist, or by optometry student(s) under the supervision of a NZ-registered optometrist. The total testing time for this study visit is anticipated to be up to 2 hours.

2 types of tests will be performed at each study visit (for both Study A and Study B):

Optical coherence tomography (OCT) is a standard, non-contact imaging technique used by optometrists to see the structures at the back of the eye and to estimate blood flow to these structures. This procedure will involve looking at a cross on a screen while we obtain scans of the back of your eyes. The total time to complete OCT scanning is approximately 5 minutes.

Global flash multifocal electroretinography (gmfERG) is a standard, non-invasive technique used by optometrists to assess the function of the retina, by recording how the retinal cells respond to light. It is the equivalent of an electrocardiogram for the heart (EKG or ECG).

To perform gmfERG, the area of skin around your eyes and forehead will first be cleaned with an exfoliant gel. Then your eyes will be numbed with eye drops, and a thread-like electrode will be placed beneath your lower eyelids. Usually there is only a very small (or no) sensation in your eye when the electrode is in place. During the test, you will be asked to look at a pattern of black-and-white flashing hexagons on a computer screen for 8 short

sequences, each about 45 seconds in length, and you will be given time to rest between each one. The total time to complete gmfERG is about 10 minutes.

Online survey of your experiences using Vuity eye drops:

Each week of the trial, you will be invited to complete an online survey. The length of time required to complete the survey will vary between ~2 to 15 minutes. The survey will ask you to estimate how often you used the treatment (Vuity or spectacles), and to answer questions about how well you could see without using spectacles. At the end of the trial, you will also be asked additional questions about your treatment preferences, and you will have the opportunity to describe your experiences using Vuity eye drops.

WHAT ARE THE POSSIBLE RISKS OF THE STUDY?

Risks of Eye drops

To reduce your risk of side effects from the use of eye drops in this study, you will be assessed by a NZ-registered optometrist for suitability prior to instillation of any drops. The potential risks and side effects of each type of eye drop used are described below.

Vuity eye drops: The most common side effects (more than 5 in every 100 people) are headache and red eye. Less common side effects (fewer than 5 in every 100 people) are blurred vision, dim or dark vision, eye irritation, visual impairment, eye irritation, and watery eyes. Rare cases of vitreous detachment, or retinal detachments or tears (an emergency situation where the layer of tissue responsible for detecting light pulls away from its usual position) have been reported.

Pupil-dilating eye drops: blurred vision, eye irritation, dry mouth, headache, nausea, sensitivity to light, and temporary burning/stinging sensation in the eyes. In very rare cases, allergic reactions, eye pain, irregular/rapid heartbeat, paleness/flushing of the skin, skin rash, constipation and abdominal pain, rigid muscles, shortness of breath, dizziness/fainting, or vomiting may occur.

Numbing (anaesthetic) eye drops: transient stinging/irritation in the eyes, blurred vision, and very rarely, allergic reactions or nausea and vomiting.

You are allowed to **bring a support person** along to attend the study visits with you. Free carparking will be provided to you for each study visit. However, as the eye drops used may cause blurry vision especially **at night**, **driving should be avoided immediately after receiving Vuity or pupil-dilating eye drops.** Please ask your support person to drive you home or arrange to use public transport after your appointment. If this is not possible, please ask the study team to arrange free taxi transport. If any concerns arise after your visit(s), please contact us immediately.

Risks of using an unapproved medicine

Vuity has not been approved by Medsafe in New Zealand but has received United States Food and Drug Administration (FDA) approval as a treatment for presbyopia. However approval has been received from the Standing Committee on Therapeutic Trials (SCOTT) to use Vuity eye drops in this study.

Reproductive Risks for Sexually Active Participants of Child-Bearing Potential

No adequate and well-controlled studies of Vuity have been conducted in pregnant or breastfeeding women. **If you do become pregnant during the study, you must tell the study team as soon as possible.** As a precautionary measure, it is preferable to avoid the use of Vuity during pregnancy and you will be withdrawn from further study participation.

Incidental findings

In the event that any incidental findings are detected during your optometric examination, the findings will be treated as they would be in standard clinical practice. A NZ-registered optometrist will review the finding and explain the condition and its potential visual consequences (if any) to you.

Where the finding requires further investigation or management, you will be referred to the appropriate healthcare professional (e.g. ophthalmologist, optometrist, or GP). If the finding is not clinically significant, you will be offered the option to have the information about the incidental findings sent to your optometrist and/or GP, to ensure the long-term continuity of care.

A comprehensive eye examination will **not** be conducted as part of this study. Therefore, we are unable to perform diagnostic eye tests for medical purposes of areas where you have known abnormalities. The electrophysiology methods used in this study can be used clinically to diagnose some eye conditions. However, we will **not** be conducting any clinical assessments of your vision using this method.

If you do not consent to being informed of any incidental findings arising as part of this study, then you are not eligible to participate in this study.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

There will be no direct benefits for you in this study. However, when you receive Vuity eye drops as the study intervention, your near vision may improve for up to 6 hours after.

WHO IS PAYING FOR THE STUDY, AND WILL ANY COSTS BE REIMBURSED?

There is no cost involved for taking part in this study. This study is funded by a research grant from the Association for Research in Vision and Ophthalmology Foundation. This study is in **no way** affiliated with or sponsored by AbbVie (the manufacturer of Vuity).

Upon the completion of each visit, you will be given a $50 petrol or supermarket voucher (up to $200 in total for Study A or Study B) as a token of our appreciation for your time contribution toward the study (koha). You will receive this regardless of whether you withdraw partway through the study.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event of a physical injury as a result of your participation in this study, you may be eligible **to apply** for compensation from 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, 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 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 research investigators.

For more details, please refer to http://www.acc.co.nz. If you have any questions about ACC, please feel free to ask the researchers for more information before you agree to take part in this trial. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, the researchers will record information about you and your study participation. If needed, information from your optometrist, GP and/or hospital records may also be collected for the purposes of confirming the eligibility and safety of your participation prior to study enrolment. **You cannot take part in this study if you do not consent to the collection of this information.**

Identifiable information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). In addition to the researchers within the study team, the following groups may have access to your identifiable information:

- Your doctors (GP and/or other specialists) and optometrist, if a study test reveals an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.
- The University of Auckland (as the organisation with responsibility for the initiation, management, and financing arrangements of the study), 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.

De-identified (Coded) information

To make sure your personal information is kept confidential, you will not be identified in the processing and analysing of data. Instead, your data will be identified by a unique code. Only the lead researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Information that personally identifies you will not be included in any report generated about this study. Results of this study may be presented at conferences, published in research theses and international scientific journals, but not in any form that would reasonably be expected to identify you.

Security and storage of your information

Your identifiable information is stored on secure computer networks at the University of Auckland during the study. After the study, it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic forms and sent through a secure server to the University of Auckland. 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 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 study research team. Please ask if you would like to access the results of your optometric examination from the study. You also have the right to request that any information you disagree with is corrected. If you have any questions about the collection and use of information about you, you should ask a member of the study research team.

Rights to withdraw your information

You may withdraw your consent for the collection and use of your information at any time, by informing a member of the study research team. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. Alternatively, you may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Māori data sovereignty

During the study, data may be collected from participants identifying as Māori. Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise personal and health information is a tāonga (treasure). To help protect this taonga:

- We have consulted with Māori researchers within the University of Auckland (Waipapa Taumata Rau) about the collection, ownership, and use of study data.
- We allow relevant Māori organisations to access de-identified study data, for uses that may benefit Māori.
- We understand that Māori consider the head tapu and the study researchers will be mindful of this and act respectfully.

Should you have any feedback, suggestions, or concerns regarding appropriate practice/ tikanga to address cultural issues, we would be interested in discussing these with you.

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 Southern HDEC has approved this study. The scientific aspects of this study have been approved by the Standing Committee on Therapeutic Trials (SCOTT), which is part of Medsafe.

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

If you choose not to take part, this will not affect the standard of care you may receive at the Grafton Optometry Clinic in any way. If you do agree to take part, but change your mind later, you are free to withdraw from the study at any time without having to give a reason.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. Alternatively, you may ask for it to be deleted when you withdraw, unless you withdraw after analyses have been undertaken.

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 of the University of Auckland, non-participation will not affect your employment.

You <u>will not</u> be able to continue using Vuity eye drops after you have completed the study, regardless of the study outcomes.

CAN I FIND OUT THE RESULTS OF THE STUDY?

If you would like a summary of the study findings, please indicate this on the consent form. Please contact the lead researcher and let them know you would like to also receive any publications resulting from the study. Any reports arising from the study will not contain any identifying details for any participants.

Note that this study will be run over a long period of time and there is often quite a delay between when the data is collected and when the findings are published, so there may be a 1-2 year gap between when you participate and when you receive the summary.

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

Thank you for giving us your time to consider participating in this study. If you would like to take part, or have any questions, concerns, or complaints about the study at any stage, you can contact:

Lead researcher: **Dr. Alyssa Lie**
Email: a.lie@auckland.ac.nz
Phone: (+64)21 0266 4662

Dr Andrew Collins (Head of School of Optometry and Vision Science)
Email: a.collins@auckland.ac.nz
Phone: (+64) 9 923 6484 | Extn: 86484

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

Email: advocacy@advocacy.org.nz
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, please contact:

Name: He Kamaka Waiora, Provider Arm Services
Phone: (09) 307 4949
Address: Level 15, Building 4, Auckland City Hospital, Grafton, Auckland

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Email: hdecs@moh.govt.nz
Phone: 0800 400 569

Consent Form

Can eye drops safely replace reading glasses in older adults?

Please read and tick to indicate you consent to the following.

I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whānau/family support, or a friend to help me ask questions and understand the study.		
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.		
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 services that may be provided to me by the Grafton Optometry Clinic. I also understand that I cannot withdraw data if analyses have already been performed on it.		
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 ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health.		
I consent to my GP and any relevant healthcare provider (specialists and/or optometrist) being informed of my participation in the study and of any significant abnormal results obtained during the study.		
I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.		
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.		
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.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant		
I wish to receive a summary of the results from the study. If **yes**, please write your email address below:	Yes ☐	No ☐
I am happy to be contacted by researchers within the school about taking part in future research (up to a maximum of 4 times a year).	Yes ☐	No ☐

Turn page over

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: