Waipapa Taumata Rau University of Auckland

Mātauranga Hauora | Faculty of Medical & Health Sciences
School of Optometry and Vision Science
Building 503, Level 3, Room 503-351A, 85 Park Road
Grafton, Auckland, New Zealand

PARTICIPANT INFORMATION SHEET

Project title: Exploring the impact of menopause on anterior eye health

Location: Grafton Eye Clinic
Faculty of Medical and Health Sciences, University of Auckland
85 Park Road, Grafton, Auckland 1023, NZ

Lead investigators: Dr Alyssa Lie & Associate Professor Stuti Misra
Contact details: a.lie@auckland.ac.nz
021 0266 4662
Student investigators: Emily Muspratt & Yuting Guo

To the participant:

You are invited to take part in a research study that aims to better understand how menopausal changes may affect eye health.

To help you decide whether you would like to take part in this study, this Participant Information Sheet explains why we are doing it, what taking part would involve for you, what the benefits and risks to you might be, and what would happen after the study ends. You do not have to decide today whether you want to take part in this study.

This document is 8 pages long (including a Consent Form). We highly encourage you to take your time to read and understand all the information provided below. Please feel free to discuss it with your whānau, family, other significant support people and/or healthcare providers. We will also go through this information with you and answer any questions you may have about the study.

Whether or not you take part is entirely your choice. If you do not wish to take part, you do not have to give a reason, and it will not affect any standard care you may receive at the Grafton Eye Clinic in any way. If you decide to take part now, 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 to take part, you will be asked to complete an electronic version of the Consent Form found 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.

What is the purpose of the study?

Dry eye disease (DED) and cataract are two of the most common conditions affecting the front of the eye. Both can significantly impact vision, eye comfort, and everyday quality of life. Research has shown that females experience these conditions more often and more severely than males, with this difference becoming even more noticeable around the time of menopause. This has led to suggestions that menopause may play a role in increasing the risk of developing DED and cataract.

Menopause is a natural stage in the female reproductive life that involves major hormonal changes. It usually occurs between the ages of 45 and 55 and is marked by a decline in the body's production of oestrogen. While menopause affects many parts of the body, its specific effects on the front of the eye are not well understood, and existing studies have shown mixed findings.

The aim of this study is to investigate how the different stages of menopause and the symptoms that women experience during this transition period may relate to the health of the tissues at the front of the eye. We will use a combination of clinical eye assessments and validated questionnaires to explore these relationships. The results of this study may help improve our understanding of how menopause influences eye health and could support the development of better prevention and management strategies that can improve eye health for women.

Who can take part in the study?

You are eligible to participate if you are aged **45 to 55 years old (inclusive)** and are **in good general health**. Although this study focuses on eye health around the time of menopause in women, we also need **men** in the same age range to take part as a control participant.

You *may* not be eligible to participate if:

- **You have a medical condition, had previous surgery, or take medication that affect your natural hormone cycle**, e.g. hysterectomy, ovarian suppression caused by chemotherapy, or medications like GnRH analogues and hormonal contraceptives. *Note: Using menopausal hormone therapy (MHT) is okay and does not exclude you*.
- **You are currently pregnant or breastfeeding**, as these involve major hormonal changes that could affect the study results.
- **You have very high levels of short- or long-sightedness** (more than ±6.00 Dioptres) **or astigmatism** (more than 2.00 Dioptres)
- **You have eye disease, had previous eye surgery, or take medication that affect your risk of developing dry eye disease or cataract**, e.g. Sjögren's syndrome, LASIK, eye problems caused by diabetes, antidepressants/SSRIs and corticosteroids. *This will be assessed on a case-by-case basis*.
- **You have a known allergy or sensitivity to the dilating eye drops used in the study**, or to similar types of medications.
- **You have a serious or unstable medical condition** that might make participation unsafe or affect the study findings.

If you are unsure about your eligibility to take part, our study team can review your medical history and list of medications together with you in a confidential discussion to confirm whether you can safely and appropriately take part in the study.

What does taking part in the study involve?

This study involves **one 1-1.5 hour visit** to the University of Auckland Grafton Eye Clinic, plus completing a **few short online questionnaires** beforehand.

Eligibility check

Before we can enroll you into the study, we may ask you a few questions your general health and eye health history to make sure you are eligible to take part in the study. If necessary, we may also ask for your permission to obtain past medical records from your GP and/or optometrist. We will only access these records after you have completed the consent process and have clearly agreed to this.

If we find that you do not meet the study's eligibility criteria, we will let you know as soon as possible and explain the reason for this. Any information reviewed up to that point will not be used in the study.

Before your visit

After we confirm you are eligible to take part, we will send you several short online questionnaires to complete before your study visit. These questionnaires ask about your eye comfort, lifestyle factors that can affect the eyes, and your menopausal stage and symptoms (if applicable). Completing these questionnaires beforehand allows us to focus fully on the eye imaging and assessments during your study visit. Your questionnaire responses will be stored separately so the study investigators performing the clinical testing at the study visit will not see them and remain unbiased.

Preparing for your visit

You will be instructed to avoid using eye drops, warm compresses, contact lenses, and eye makeup for at least 24 hours before the time of your study visit, as the use of these products may affect the quality of the data obtained.

During the visit

The study visit will take place at the University of Auckland Grafton Eye Clinic. Here, we will begin imaging of the front surface of your eyes using a common eye-imaging device called the Oculus K5M. This device takes detailed scans and videos to help us assess tear stability, tear volume, and the health of the oil glands that keep your eyes comfortable. All imaging with the Oculus K5M is completely non-invasive and non-contact (nothing touches your eyes at any point).

After the Oculus K5M assessments are completed, we will carry out standard optometric tests to make sure it is safe for you to receive pupil-dilating eye drops. At this stage, you will be informed whether it is safe to continue with the remainder of the visit. If suitable, 1–2 dilating eye drops will be placed in each eye to temporarily enlarge your pupils. These drops usually take 30–45 minutes to work. Once your pupils are dilated, we will take detailed photographs and scans of the lens inside your eye to assess its clarity.

The total duration of the study visit (including 45 min wait time for pupil dilation) is expected to be 1 to 1.5 hours. All eye imaging will be performed by optometry students under the supervision of an NZ-registered optometrist (Dr Lie).

After the visit

It is strongly recommended to avoid driving immediately after receiving pupil-dilating eye drops, so please arrange a way to get home safely (e.g. public transport, bring a support person to drive you). If you plan to drive yourself to the appointment, you will need to allow enough time after your appointment for your vision to return to normal before driving.

If any concerns arise after your visit, please contact us immediately.

What are the benefits and risks?

There are no direct personal benefits for you from taking part in this study. However, this research will contribute valuable information to help clarify the impact of the hormonal changes that occur during the female menopausal transition period on anterior eye health. The results may support the development of more tailored management strategies to achieve more equitable eye health outcomes for the female population.

You will also receive a $20 petrol voucher to acknowledge the time and costs involved in attending the study visit.

Risks of dilating eye drops

The study will involve instillation of pupil-dilating eye drops to facilitate assessment and imaging of the lens. There is a small risk of side effects from using 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 or rapid heartbeat, paleness or flushing of the skin, skin rash, constipation and abdominal pain, rigid muscles, shortness of breath, dizziness/fainting, or vomiting may occur. For this reason, you will be assessed by an NZ-registered optometrist (Dr Lie) for suitability prior to receiving the eye drops.

It is strongly recommended to avoid driving immediately after receiving pupil-dilating eye drops, so please arrange a way to get home safely (e.g. public transport, bring a support person to drive you). If you do plan to drive yourself to the appointment, you will need to allow enough time after your appointment for your vision to return to normal before driving. If any concerns arise after your visit(s), please contact us immediately.

Incidental Findings

As part of the clinical assessments performed in this study, we may discover incidental findings about your eye health or vision that you were not previously aware of. If this occurs, an NZ-registered optometrist (Dr Lie), will review the findings, explain the condition and its potential visual consequences (if any) to you, and the findings will be treated as they would in standard optometric practice.

Where the incidental finding requires further investigation or management, you will be referred to an appropriate health care provider (e.g. GP, ophthalmologist, or optometrist). If the finding is not clinically significant, you will be offered the option to have the information about the incidental findings sent to your GP and/or optometrist, 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. **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.**

Who is paying for the study?

There is no fee involved for taking part in this study. This study is funded by the University of Auckland. Upon completion of the study, you will be given a $20 petrol voucher as a token of our appreciation for your time contribution toward the study (koha). You will receive this regardless of whether you withdraw during the study. You will not receive koha if you were screened but deemed ineligible to participate.

What are my rights as a participant?

Voluntary participation

Whether or not you take part is entirely your choice. If you agree to take part, you will be asked to sign an online version of the Consent Form found 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. If you do not wish to take part, you do not have to give a reason, and it will not affect any standard care you may receive at the Grafton Eye Clinic in any way. If you decide to take part now, but change your mind later, you are free to withdraw your participation at any point during the study without having to give a reason.

Withdrawing your information

You may withdraw your consent for the collection and use of your information at any time before data collection for the study is completed, by informing a study investigator. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. **However, you will not be able to withdraw data if analyses have already been performed on it at the time of your withdrawal.**

Accessing your information

You have the right to request access to your information held by the study investigators. Please ask if you would like to access the results of your eye imaging and/or online questionnaires during 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 study investigator.

Your confidentiality and anonymity

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

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). In addition to the lead study investigator (Dr Lie), 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.

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 investigator (Dr Lie) will keep a list linking your code with your name, so that you can be identified by your coded data if needed (e.g. if you wish to withdraw your data, or if you request a copy of your study results).

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, included in research theses, and published in international scientific journals, but not in any form that would reasonably be expected to identify you.

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.

Security and storage of your information

During the study, study-specific source documents will be stored securely on password-protected databases via password-protected computers located in locked rooms. After the study has concluded, study-specific source documents will be archived on secure Cloud computer servers at the University of Auckland. Source documents containing participant identifiers (e.g. the electronic spreadsheet linking the study code with participant identifiers and eConsent Forms) will be retained for 10 years, then securely destroyed in accordance with University of Auckland policies. Coded information will be stored indefinitely on secure Cloud-based servers at the University of Auckland. All data storage will comply with local and international data security guidelines.

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 tāonga:

- We have undertaken Māori consultation with the University of Auckland (Waipapa Taumata Rau) as part of the Locality Approval Process about the collection, ownership, and use of data in this study.
- We allow 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 investigators will be mindful of this and act respectfully.

Should you have any concerns regarding appropriate practice/tikanga to address cultural issues, please let us know.

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.

Can I find out the results of the study?

If you would like to receive a summary of the overall study findings, please indicate this when you complete the online version of the Consent Form. You may also contact the lead investigator (Dr Lie) if you would like to receive any publications that arise from the study.

Because this study will run over an extended period of 3 years, and because publication can take time, there may be a delay between your participation and when the summary or publications become available (typically 1–2 years after study conclusion). Any summary provided will not include any information that could identify you or any other participant.

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 investigator:	**Dr. Alyssa Lie**
Email:	a.lie@auckland.ac.nz
Phone:	(+64)21 0266 4662
Postal address:	School of Optometry and Vision Science Private Bag 92019, Auckland 1142, New Zealand
Academic Head:	Dr. Andrew Collins (Head of School of Optometry and Vision Science)
Email:	a.collins@auckland.ac.nz
Phone:	(+64)9 373 7599 ext 86484

If you require Māori cultural support, talk to your whānau in the first instance. You may also contact the administrator for He Kamaka Waiora (Māori Health Team) by phoning 09 486 8324 ext 2324, or the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204 to discuss any questions or complaints about the study.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

This study has been approved by the Auckland Health Research Ethics Committee on 19/03/2026 for three years. Reference number: AH30918.

Waipapa Taumata Rau University of Auckland

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School of Optometry and Vision Science
Building 503, Level 3, Room 503-351A, 85 Park Road
Grafton, Auckland, New Zealand

CONSENT FORM

(This form will be held for a period of 6 years)

Project title:	Exploring the impact of menopause on anterior eye health
Location:	Grafton Eye Clinic Faculty of Medical and Health Sciences, University of Auckland 85 Park Road, Grafton, Auckland 1023, NZ
Lead investigators:	Dr Alyssa Lie & Associate Professor Stuti Misra
Contact details:	a.lie@auckland.ac.nz 021 0266 4662

	Yes	No
I have read, or have had read to me in my first language, the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study and to ask questions, and was offered support from whānau/family or a friend to help me understand what the study involves.		
I am satisfied with the answers given to me, I understand the nature of the research, and why I have been invited to participate.		
I understand my participation is voluntary (my choice) and that I may withdraw from the study and any data traceable to me at any time before data collection for the study is completed. I also understand that I cannot withdraw data if analyses have already been performed on it.		
I understand that my participation, withdrawal, or non-participation in the study will not affect any services that may be provided to me by the Grafton Eye Clinic.		
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 any significant abnormal results obtained during 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 have been informed of and understand the risks involved with pupil-dilating eye drops in 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 wish to receive a summary of the results from the study. If **yes**, please write your email address: Click or tap here to enter text.	☐	☐
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).	☐	☐

I agree to take part in this research.

Signature:

Name: Click or tap here to enter text.
Email address: Click or tap here to enter text.
Date: Click or tap here to enter text.

X

Yes ☐ No ☐

Approved by the Auckland Health Research Ethics Committee on 13 March 2026 for three years.
Reference number: AH30918