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PARTICIPANT INFORMATION SHEET

Project Title: Unveiling Meibomian Gland Dysfunction Impact and Risk Factors

Researcher(s): Professor Jennifer P. Craig, Dr Phil Turnbull, Mr Jordan Cooper, Dr Kalika Bandamwar, Dr Ally Xue, Ms Catherine Jennings

Researcher Introduction and Project Background:

Thank you for taking the time to read this information sheet. You are being invited to participate in a study on meibomian gland dysfunction, a condition that is often associated with dry eye, to help us understand how common and impactful it is within New Zealand. You do not need to have dry eye or meibomian gland dysfunction to participate.

This information sheet covers many study details so please feel free to contact us if you have any further questions. You are welcome to share and discuss this information sheet with friends and/or whānau, before deciding to participate in this study.

I'm **Jordan Cooper**, a NZ registered therapeutic optometrist pursuing a PhD in Health Science under the supervision of **Professor Jennifer Craig** who is a Professor in the Department of Ophthalmology and **Dr Phil Turnbull**, a Senior Lecturer in the School of Optometry and Vision Science, both are NZ registered therapeutic optometrists. This study is conducted in the Ocular Surface Laboratory at the Eye Clinic at the University of Auckland's Grafton site, where I may be assisted by therapeutic optometrists, **Dr Ally Xue** and **Ms Catherine Jennings,** and research fellow, **Dr Kalika Bandamwar**.

Dry eye disease is a common eye disorder. Patients typically experience gritty, irritated, sometimes watery eyes and poor vision. The thin moist film of tears that bathes the exposed surface of the eye can be affected. A common cause of dry eye disease is meibomian gland dysfunction. Meibomian glands are oil glands found within the upper and lower eyelids. They produce a lipid-rich (oily) secretion which coats the surface of the tear film, minimising evaporation of the underlying watery tear layer. With better understanding of the different risk factors associated with this condition, clinicians could better target the underlying causes and offer tailored treatment and management recommendations that may help to improve patient outcomes.

In this study, we are evaluating the prevalence, risk factors and impact of meibomian gland dysfunction within New Zealand. We will be using standard, non-invasive clinical imaging devices [Keratograph 5M (Oculus) and LipiView (Johnson & Johnson)], as well as common in-office procedures including slit lamp examination of the eye. We hope that at the conclusion of this research that we will better understand the burden of meibomian gland dysfunction.

Study Description:

In the first instance, contact will be made over phone or by email where you will be invited to answer some general questions to confirm your likely eligibility for the study. If eligible, we will schedule, at your convenience, a single study visit (lasting up to 1 hour) at Grafton Eye Clinic, to undergo clinical assessment.

Our team is committed to establishing strong partnerships which support Te Tiriti o Waitangi and an increase in positive health outcomes for all New Zealand. Eye health services are an area of health that requires greater access for Māori, and in addressing this, the current project is incorporating and applying methods of engagement to increase participation from communities which have historically been underrepresented. Collaboration and consultation with individuals and organisations to support Māori health outcomes in this area of research are a consistent feature within our work.

Project Procedures:

Various features of the eye's surface will be observed using standard clinical techniques that are performed routinely for assessing dry eye. The test procedures are largely non-contact imaging techniques (do not touch your eye), posing minimal risk of harm. The procedures include:

1. Brief validated questionnaires for grading of ocular comfort and dry eye symptoms (if any). These will take around 5 minutes to complete.
2. Examination of the anterior eye, including the eyelids, tear film and ocular surface, using a slit-lamp biomicroscope (the instrument found in all eye examination rooms). These tests are used routinely in the clinical setting and do not directly touch your eye.
3. Grading of the tear film quality with computerised imaging instruments (such as the Oculus Keratograph 5M and LipiView). These devices capture high magnification images and video clips of your eye's surface and do not involve direct contact with your eye. You are not identifiable from the images.
4. Clinical evaluation of tear osmolarity, which might feel ticklish on your eyelashes but doesn't directly touch the eye's surface.
5. Assessment of tear film evaporation rate with a non-contact evaporimeter, this device is housed in a goggle and also doesn't involve direct contact with the eye.

Possible Benefits:

In taking part in this study, you will receive a comprehensive ocular surface review free of charge and can be provided with feedback about your ocular surface condition. Your contribution will help us determine the impact of meibomian gland dysfunction in Aotearoa. You will be offered a $20 retail voucher (Woolworths or MTA) to thank you for your time.

How the Data will be Used:

This study has been initiated and designed by researchers at the University of Auckland. It is anticipated that the results of this study will be written up as a PhD thesis, 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.

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. If you are a patient of the Eye Clinic, you may contact the Clinic Director should you feel that this assurance has not been met. Similarly, if you are a student at the University of Auckland, your decision to participate or not participate will not influence your academic progress in any way, and nor will it impact on your employment status as a staff member. As a student or staff member, you may contact your HoD should you feel that this assurance has not been met.

Eligibility:

You must be 18 years of age or older to participate in this trial. However, there are a number of reasons you might not be suitable for this project. These include:

- Wear of contact lenses within 24 hours of study participation
- Active ocular allergies
- Unwillingness to be advised of incidental findings
- Ocular surgery or dermatological treatments in the previous 3 months
- History of ocular surgery (such as refractive or cataract surgery) in either eye within 3 months of study participation
- An ocular or systemic disorder or condition, current treatment, disease or trauma judged by the investigator to be incompatible with study participation

Incidental Findings:

The researchers are trained investigators who are highly practised in tear film and ocular surface assessment, but it is not their role, nor may they be qualified, to identify, provide a diagnosis, or offer advice on other eye conditions, during the course of this research. If, however, an abnormality, is detected incidentally, this will be assessed by a New Zealand registered health professional on our team who will be able to discuss this with you and offer you advice on how best to manage the condition or, with your consent, refer you directly to your GP or a specialist to ensure you receive appropriate care, consistent with standard clinical protocols. If you do not wish to be advised of incidental findings, you will not be eligible to take part.

Data Storage/Retention/Destruction:

Study data (paper copies and in electronic form) are de-identified immediately on collection and will be stored securely in a locked cabinet at the University of Auckland or on password protected University computers, as appropriate, for at least 10 years for publication purposes and to allow comparison to future data sets (that would require further ethical approval separately in the future) before being securely destroyed. A master list of participant names and contact details, that allows

us to get in touch with you as needed during the study, is kept separately from your data, in a locked cabinet with access restricted to the research team only. This list will be destroyed at the conclusion of the study, and within a period of 6 years.

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

High magnification digital images of your tear film will be collected in the course of the assessment. These are stored briefly on the device on which they are collected in a locked clinical room (under your participant code, not name, and only to enable the required measurements to be obtained from the images). These are used for analysis only and you are not identifiable from them.

Any information collected about you during this study will be stored securely and treated with confidentiality. You have the right to access your information and request corrections if you identify any errors.

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, up to two weeks after your clinic appointment.

Anonymity and Confidentiality:

Your data will be stored under a unique alpha-numeric identification code rather than your name to protect your confidentiality. A document linking the code with your name will be stored independently of the clinical data and will be available only to the study investigators. All data will be collected, recorded, stored, and analysed under your unique code. The linking document will be destroyed within 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 clinical assessments is minimal and is the same level of risk you would be exposed to during a conventional eye exam. The investigators are trained to carry out these procedures safely. You will be given detailed instructions during the test procedures to minimise risks as far as possible. The investigators are trained to anticipate patient movements, however, in the unlikely event you move suddenly or unexpectedly during the test procedure, there is a small risk that contact could be made with your eye surface, and an abrasion could occur. This would usually take several hours to fully resolve, during which time your eye could be slightly uncomfortable. The abrasion would be treated, and you would be followed up according to standard clinical protocols. The risk of a reaction to the clinical dyes used in the assessment is extremely low. In the event of a reaction, this would be apparent during your clinical visit and would be managed appropriately, according to standard clinical protocols.

Compensation

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.

Contact Details and Approval:

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

Jordan Cooper, BOptom (Optometrist / PhD student investigator)
Email: jordan.cooper@auckland.ac.nz

Prof. Jennifer P. Craig, PhD FCOptom FAAO (Optometrist, Principal Investigator and PhD Supervisor)
Email: jp.craig@auckland.ac.nz
Telephone: 09 923 8173

Dr Phil Turnbull, PhD BOptom (Optometrist, Co-investigator and PhD Supervisor)
Email: p.turnbull@auckland.ac.nz
Telephone: 09 923 2352

Dr Kalika Bandamwar, PhD FBCLA (Post-doctoral research fellow / Research Assistant)
Email: kalika.bandamwar@auckland.ac.nz

Dr Ally Xue, BOptom PhD (Post-doctoral research fellow / Research Assistant)
Email: a.xue@auckland.ac.nz

Catherine Jennings, BOptom (Optometrist / Research Assistant)
Email: c.jennings@auckland.ac.nz

Prof. Charles N.J. McGhee (Ophthalmologist / Head of Department)
Email: c.mcghee@auckland.ac.nz
Telephone: 09 923 6712

If you require Māori cultural support, we will gladly assist. Please include whānau in discussion of your needs and contact Iwi United Engaged consultant Misty Edmonds by emailing misty@iue.net.nz for additional support.

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: humanethics@auckland.ac.nz

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE ON 28/05/2025 FOR 3 YEARS, REFERENCE NUMBER 29283