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PARTICIPANT INFORMATION SHEET

Project Title: Handheld thermal pulsation vs Standard of Care in Meibomian Gland Dysfunction Management.

Researcher(s): Prof. Jennifer P. Craig, Ms Catherine Shon, Dr Alex Muntz, Ms Dian Zhuang, Ms Karien Nel

Study site: Grafton Eye Clinic, Grafton campus, University of Auckland
85 Park Road, Auckland, 1023

Contact phone number: 022 EYE PAIN (022 393 7246)

Ethics committee ref: 21/NTB/159

Study Sponsor: The University of Auckland

Study Funder: Alcon Australia Pty Limited

Researcher Introduction and Project Background:

Thank you for taking the time to read this information. We are researchers from the Ocular Surface Laboratory within the Department of Ophthalmology at the University of Auckland. Catherine Shon is a clinical researcher and NZ-registered therapeutic optometrist. Professor Jennifer Craig an NZ-registered therapeutic optometrist is the Primary Investigator for this clinical trial. Dr Alex Muntz, Ms Karien Nel, Ms Dian Zhuang are clinical researchers and optometrists within the Ocular Surface team.

You are invited to participate in this study to undergo treatment for the symptoms of dry eye disease. We would like to investigate the treatment efficacy of a hand-held thermal pulsation device against the current standard of treatment used for evaporative dry eye disease. This device is currently available overseas but has not yet been launched in New Zealand.

This is a very carefully designed study (randomized, investigator masked) held at the Ocular Surface Laboratory, Eye Clinic, University of Auckland Grafton Campus. We would encourage you to read this information sheet along with your whānau to ensure you are satisfied with the study protocol,

study requirements and data management. Our details are at the end; please contact Catherine in the first instance to clarify any of the information or further questions you might have.

People who suffer from dry eye disease often complain of irritated, burning and gritty eyes. Common reasons for this include reduced quality oil production (lipid layer) from the eyelid glands malfunctioning (meibomian gland dysfunction). The lack of oils in the tear film has been known to cause faster evaporation of the tears, leading to the dry eye sensations you experience.

Existing management strategies are not sufficient for most dry eye sufferers. There is an ongoing search for novel, effective therapies that can provide relief from the symptoms and signs of dry eye disease. Thermal pulsation therapy was introduced over a decade ago. This technique allows the meibomian glands to reach higher temperatures by safely applying heat to the inner surface of the eyelid, next to the glands. Heat is applied at the same time as gland expression to encourage unblocking of the glands. A single treatment may provide benefits for up to 9 – 12 months. However, the treatment currently available in NZ is very costly for patients and very few centres are therefore able to offer the treatment.

The iLux device is an exciting development for clinicians and patients alike. It is a more affordable, hand-held device. It allows the clinician to deliver the right amount of heat directly to the glands in a controlled manner. The iLux device allows clinicians to adjust the pressure applied for gland expression. This has the potential to become an affordable personalised treatment for patients.

Our team is committed to establishing strong partnerships which support Te Tiriti o Waitangi and an increase in positive health outcomes for all New Zealanders. Eye health services are an area of health that requires greater access for Māori, and in addressing this, the current project is incorporating and championing 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 embedded in this work.

In consultation with our partners, we have set a plan in place regarding tikanga and individual study visits. We refer to the Te Whare Tapa Wha model of addressing the entire person in establishing a relationship of trust and understanding. Briefly, this begins with greeting the participant at the study clinic room and reviewing the purpose of the visit. This is important in terms of tikanga because it acknowledges the individual's ability to choose to continue or not continue in this study. Questions are asked in order to obtain consent for the remaining time spent together. Additionally, explanations are offered around all of the manipulations in the study which is focused on the eyes, directly touching them and moving materials around the face. Again, this addresses the tikanga around the individual and their right to self-determine participation. In keeping with Te Whare Tapa Wha, we proceed in a manner which looks at each participant holistically, taking into account their wairua, hinengaro, tinana and whānau. Our confidence in this model is such because it crosses all cultural boundaries, although focussing on Māori, is easily translated to every participant, regardless of ethnicity.

Project Description

We would like to evaluate the ability of the iLux device to improve tear film stability and thereby reduce symptoms of dry eye. Specifically, we would like to look at the clinical course of ocular benefits, including how quickly improvements in signs and symptoms might occur and the time taken to reach maximal treatment effect. We'd also like to learn the outcomes compared to the current standard of care (daily patient-applied warm compresses and gland expression).

Study design:

This study design has been chosen to minimize bias and help us to learn the true benefits of the treatment. Participation in the study will involve us testing two active therapies. You will be randomized to receive one thermal pulsation treatment session using the iLux device or be assigned to perform daily patient-applied warm compress (MGDRx Eyebags®, Eyebag® Company, UK) and meibomian gland expression via silicone eyelid massage aid (Eyepeace, Cathedral Eye Care, UK). Neither you nor the clinician assessing your eyes is able to influence which treatment you receive through this study – this will have been predetermined to reduce risk of bias. However, should you be randomized to the standard of care group, you will have the opportunity to receive the study treatment (iLux) free of charge at the end of the study if you wish.

After the baseline visit, we will then compare the baseline measurements to those collected after starting your assigned therapy. We ask you to return once a month for 6 months for repeat measurements to be collected. You will be required to attend seven (7) clinic visits in total:

- Visit 1 (up to 2 hours in length) at which we will check that you are eligible to be a participant in the study and, if so, conduct baseline measures and apply the treatment.
- Visits 2-7 (each up to 1 hour in length) where measurements are repeated for comparison to baseline and evaluation over time.

Project Procedures:

Various features of the eye's surface will be observed using standard clinical techniques that are performed routinely for assessing dry eye. These include:

1. Grading of ocular comfort, risk factors for dry eye, and dry eye symptoms (if any), using brief, validated, dry eye questionnaires (taking a total of 10 minutes to complete).
2. Examination of the tear film and the eye's surface with the Oculus Keratograph 5M. These are used routinely in the clinical setting and do not directly touch your eye.
3. Examination of the anterior eye, including the eyelids, eyelashes and ocular surface, using a slit-lamp biomicroscope, the instrument found in all eye examination rooms,
4. Evaluation with standard clinical dyes that confirm the health of your eye's surface. There is no stinging sensation when the dyes are applied.
5. Clinical evaluation of tear osmolarity, which might feel ticklish on your eyelashes during measurement but doesn't touch the ocular surface.

Possible benefits

In taking part in this study, you will receive a thorough dry eye workup and can be provided with feedback about your ocular surface condition. You will also have the opportunity to trial a therapy that might help your dry eyes, free of charge. Your contribution, together with those of others, will help us understand the true benefits of the various therapies for dry eye disease. You will receive a koha of up to \$140 in petrol/retail vouchers over the course of approximately seven visits as a token of our appreciation for your participation in the study (\$20 per visit). **You will also have the opportunity to receive the iLux therapy free of charge at the end of the study, should you be randomized to the standard of care group.**

How the data will be used

This trial has been initiated and designed by the researchers at the University of Auckland. There are obligations for us to report the results of the trial to our industry partner, the manufacturers of the iLux device (Alcon, Australia). It is important for you to know that they have no influence over the trial design, its conduct, or its publication after completion, regardless of the outcomes. It is anticipated that the results of this study will be written up and presented orally 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. If at any time in the study duration you decide not to take part, your clinical care and/or academic progress will not be affected. 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. If you are a staff member, your involvement in this study will not impact your employment status. If you are a student or staff member, you may contact your HoD should you feel that this assurance has not been met. This does not apply to non-students and staff of the University of Auckland.

Eligibility

There are several reasons you might not be suitable for this project. These include:

- If you are not willing or able to stop your current eye drops for at least 48 hours before you attend the eligibility clinic visit and for the duration of the study. It is important that the only eye drops you are using are the ones provided in the study.
- Eye surgery in either eye in the 3 months prior to the baseline visit or scheduled in the study duration.
- A systemic condition, disease or trauma judged by the investigator to be incompatible with participation in the study
- The history or presence of any ocular disorder or condition in either eye that would likely interfere with the interpretation of the study results.
- Warm compress and lid hygiene – if these are applied currently, this can be maintained as long as the form and frequency do not change during the course of the study.
- Contact lens wear – contact lens wearers are eligible as long as the contact lenses have been removed at least 48 hours prior to participation, but they must remain unworn for the duration of the study.
- Permanent makeup or tattoos on your eyelids

Incidental Findings

Any abnormalities unrelated to dry eye that are noted by chance during the examination of your eye will be discussed with you, and you will be offered advice about management and/or referral. If you do not wish to be advised of incidental findings, you will not be eligible to take part. We will ask if you would like us to contact any of the health professionals who currently provide you with health care. If you would like us to do so, we will ask for their contact details and request your permission to contact them on your behalf to let them know about your participation in the trial.

What will happen to my information?

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments. 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). Only study researchers will have access to your identifiable information.

Rarely, it may be necessary for the principal investigator 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 study researchers. 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 results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information.

Your identifiable information is held at the University of Auckland during the study. After the study it is transferred to a secure archiving cabinet on the same site and stored for at least ten years, then destroyed. Your coded information will be entered into electronic case report forms. Coded study information will be kept by researchers on a password protected University research drive indefinitely. All storage will comply with local 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.

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

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

You may withdraw from the study at any time during the study and up to two weeks on completion of the study, unless you withdraw 2 weeks after the study analyses have been undertaken.

Withdrawal from the study:

If you would like to withdraw from the study, please contact the lead investigating researcher in the first instance. If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw from the study. If you have completed the study and have changed your mind, you have up to two weeks to inform the researchers to withdraw your data collected from the study.

Results from the study:

If you would like to receive results from the study, please fill in your email address at the bottom of the consent form. Alternatively, please contact the lead investigator and let them know you would like to receive any publications resulting from the study.

Risks

The risk of harm during the clinical assessments is minimal and is the same level of risk you would be exposed to in a standard therapeutic dry eye clinic. The investigators are trained to carry out all of these procedures safely. You will be given detailed instructions during the test and treatment procedures to minimize risks as far as possible.

Potential adverse effects of the iLux treatment include but are not limited to:

- Eyelid/eye pain requiring discontinuation of the treatment procedure
- Eyelid irritation or inflammation
- Temporary reddening of the skin
- Ocular surface irritation or inflammation (e.g., corneal abrasion, conjunctival swelling or conjunctival redness)
- Ocular symptoms such as burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance and/or sensitivity to light.

The investigators are fully trained in the application of the iLux device and will ensure that any potential adverse effects are avoided as much as possible, and treatment will be provided immediately should any unwanted symptoms occur.

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. This could result in an abrasion which 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 clinic protocols.

What if something goes wrong?

As this study is investigator-led (sponsored by the University of Auckland) and not principally for the benefit of the funder (Alcon Australia Pty Limited), 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

Ms Catherine Shon (Lead Investigator)

Mobile: 022 EYE PAIN (022 393 7246)

Email: jsho341@aucklanduni.ac.nz

Professor Jennifer P. Craig (Principal Investigator)

Email: jp.craig@auckland.ac.nz

Telephone: 09 923 8173

Professor Charles N. J. McGhee (Head of Department of Ophthalmology)

Email: c.mcghee@auckland.ac.nz

Telephone: 09 923 6712

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact Iwi United Engaged consultant Kevin Roos by emailing kev@iue.net.nz.

If you have any questions or complaints about the study, you may contact the Auckland and Waitemātā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

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/>

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

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. Northern B HDEC has approved this study. Ethics ref: 21/NTB/159



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New Zealand

**CONSENT FORM
THIS FORM WILL BE HELD FOR A PERIOD OF 10 YEARS**

Project Title: Handheld thermal pulsation vs Standard of Care in Meibomian Gland Dysfunction Management

Researcher(s): Prof. Jennifer P. Craig, Ms Catherine Shon, Dr Alex Muntz, Ms Dian Zhuang, Ms Karien Nel

I have read and understood the details of the study included in the Participant Information Sheet provided. I have had the opportunity to ask questions and have them answered to my satisfaction. I confirm that I am providing my consent prior to any study-related activities being conducted.

- I agree to take part in this research study to evaluate the potential benefits of a standard clinical thermal pulsation device used on the eyelids to assess changes to the tear film and ocular surface quality over the course of 6 months.
- I understand that I have the right to withdraw my participation in the study at any time and to withdraw any details traceable to me up to two weeks after my clinic visit.
- I understand that clinical data will be kept for ten years in locked filing cabinets, after which time they will be safely destroyed, and that de-identified data will be stored for a minimum period of ten years on a password protected University network drive.
- I understand that the study results might be submitted for scientific publication or presentation at conferences but that I will not be individually identifiable in any report.
- I understand that the de-identified data originating from this project may be collated with existing and/or future data to strengthen the study and allow the provision of better information for clinicians treating patients who suffer from dry eye.
- I understand that procedures carried out during the research may reveal underlying eye conditions that will be managed or referred to an appropriate specialist as required.
- I understand that if I am not willing to be informed of such incidental findings, I am not eligible to participate in this study.
- I understand that if I am a student, my participation or non-participation will not influence my academic progress in any way. If I am a patient receiving eye care at the University of Auckland, my ongoing clinical care will not be affected.
- I wish to receive the summary of the research findings at the end of the study. YES / NO

If YES, please include your contact details (**email address**) below:

Name:
(Please Print in Capital Letters).....

Signature:.....**Date:**.....

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. Northern B HDEC has approved this study. Ethics ref: 21/NTB/159