School of Optometry and Vision Science

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Changes in ocular surface sensitivity with computer use

Scientia Professor Fiona Stapleton

1. What is the research study about?

You are invited to take part in this research study. The research study aims to investigate the potential changes in the sensitivity of the eye surface after working on a computer screen using an instrument called the Liquid Jet aesthesiometer, which uses small drops of sterile saline to stimulate your eye. Your participation will help to better understand the underlying mechanism behind the effects of digital display use on the eye surface.

2. Who is conducting this research?

The study is being carried out by the following researchers: Scientia Professor Fiona Stapleton, Associate Professor Blanka Golebiowski, Adjunct Professor Klaus Ehrmann and PhD student Cristian Talens-Estarelles at the School of Optometry and Vision Science at UNSW Sydney.

Research Funder: This research is being funded by UNSW.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

Group 1: Asymptomatic control

1. 18 to 40 years old
2. Frequent computer use (≥ 4 hours of computer use per day)
3. Able to read and comprehend English
4. Few to any symptoms of digital eye strain and dry eye (OSDI score < 13 and CVS-Q score < 6)

Group 2: symptomatic

1. 18 to 40 years old
2. Frequent computer use (≥ 4 hours of computer use per day)
3. Able to read and comprehend English
4. Symptoms of digital eyestrain and moderate or greater symptoms of dry eye (OSDI score ≥ 23 and CVS-Q score ≥ 6)

Exclusion criteria for those who are not eligible to participate in the study include:

1. Have any eye or general health conditions which may affect your eyes, for example severe dry eye, active eye allergy, Graves' disease, diabetes, Sjögren syndrome or multiple sclerosis
2. Have any eye infections or inflammation
3. Current use of use eye and/or general medication which is known to affect eye health or eye comfort, such as chloramphenicol, prednisolone acetate, Accutane, antidepressant medications, topical glaucoma drops, or anti-allergy drops
4. Have any history of eye surgery like corneal refractive surgery or cataract surgery
5. Mild symptoms of dry eye (OSDI score 13 – 22)
6. Use of soft contact lenses, no matter how brief, in the past 7 days[2]
7. History of orthokeratology or rigid gas permeable contact lens wear no matter how intermittent or brief
8. Are pregnant or breastfeeding
9. Have a history of binocular disorders including amblyopia, strabismus or anisometropia.

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

If you agree to participate you will be asked to complete the following research procedures:

Screening: An initial phone call with the investigators will determine if you are initially eligible to take part. Completing the screening will take approximately 5 minutes. If you meet the criteria for inclusion (see section 3), then you will be able to continue with the research project. If you do not meet the criteria for inclusion, then you will not be able to participate in the study and your information will be withdrawn from the research project.

Procedure: During the study visit you will be asked to complete four short questionnaires about eye symptoms (duration for questionnaires administration ~15 mins). Depending on your answers to the questionnaires you may be allocated to the asymptomatic group or the symptomatic group or excluded as per the inclusion/exclusion criteria. Both groups will undergo the same measurements and test procedures: You will be examined with a help of a slit lamp with your chin and forehead rested on a chin and forehead rest in front of the Liquid Jet Aesthesiometer and the room lights will be turned off. You will then be directed to look at a light on the wall behind the examiner. A demonstration run of the Liquid Jet Aesthesiometer will be administered in one eye for you to familiarise yourself with the instrument. Micro volumes of sterile phosphate buffered saline will be projected onto the front surface of the eye at randomised time intervals. You will be given a buzzer to press to indicate when a sensation has been felt. A sensitivity measurement will be taken on the cornea of your eye. Next you will sit on a chair and work on a computer display for one hour. After the specified period corneal sensitivity measurements will be repeated to assess any potential changes arising from computer use. Finally, your vision will be measured and the health of the front of your eye examined again to ensure no damage has occurred to your eye during the procedures.

Risks involved: The risks involved in this research are minimal. Your vision and hearing during the measurements will be muted with earmuffs and dark room lighting in order for us to control external factors influencing the results. Any possible hazard of tripping will be minimised because you will be seated and carefully instructed about the procedure before earmuffs are put on and room lights are turned off. There may be some mild discomfort when the saline touches your eye's surface. This will be minimised by careful explanation of the process so that you are aware of what to expect.

A very unlikely risk is the possibility of an infection of the eye. However, this risk will be managed by ensuring the solution used in the procedure is sterile saline. The instrument will also be disinfected at

least once weekly with 5% sodium hypochlorite purged with the phosphate buffered saline multiple times to ensure that there no ethanol remains within the instrument.

We do not expect the questionnaires, slit lamp examination or Liquid Jet Aesthesiometer measurements to cause any harm or discomfort. If you do experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time. You can also tell a member of the research team and they will provide you with assistance. Alternatively, a list of support services and their contact details are provided below on page 5 of this consent form.

Medical Devices: Medical devices have to be approved for use by the Australian Federal Government before they are used within Australia. The following medical devices will be used in this research:

The Liquid Jet Aesthesiometer has been used previously under the TGA CTN scheme for an approved clinical trial (HC200277)

During the initial phone call, your initial eligibility to participate will be assessed. If the inclusion criteria are met, then you will be able to move to the next part of the research project. If the inclusion criteria are not met, then you will not be able to participate in the study.

During the visit, you will be asked to respond to four questionnaires of ocular symptoms, including the computer vision syndrome questionnaire (CVS-Q) and the Ocular Surface Disease Index (OSDI). If you obtain a score ≥ 6 in the CVS-Q and a score ≥ 23 in the OSDI you will be allocated to the symptomatic group. Conversely, if you obtain a CVS-Q score < 6 and an OSDI score < 13 you will be allocated to the asymptomatic control group. Otherwise, you will be excluded from the study and your information will be withdrawn from the research project.

Randomisation: The study does not involve randomisation to any groups. The test eye will be randomly selected via an online randomization generator.

Sample Collection: The study does not involve collection of any samples.

Intervention: The study does not involve any intervention in the form of device or drugs.

Medical Drugs: There are no medical drugs used in this study.

Additional Costs and Reimbursement: There are no costs associated with participating in this research project, nor will you be paid. Participants will not be reimbursed for their participation, nor will their participation incur any expenses.

6. What are the possible benefits of taking part?

While there is no personal gain or benefit to the participant, we expect the outcomes of this research to provide more insight into the areas of eye sensation and discomfort. Ultimately, we hope the information from this research to contribute towards new methods of diagnosis and treatment of conditions and diseases affecting the eye surface.

7. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study. The research team will store the data collected from you for this research project for a minimum of 7 years after the completion of the study. The information about you will be stored in a re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code.

You will be asked to provide your consent for the research team the share or use the information collected from you in future research that will be an extension of, or closely related to, the original project; or is in the same general area of research. You can decide not to let us use your data for future research by not checking the optional boxes on the consent form. Your information will only be shared in a format that will not identify you. Any data included in the reports or publications or presented at scientific meetings will be provided in the form of group response and/or anonymously. Your personal and health information (either identifiable or potentially identifiable) will not be disclosed to any external parties without your consent unless required by law.

Information collected from you in an electronic format will be stored on a UNSW password protected OneDrive only accessible to the approved research investigators and backed up regularly onto the UNSW network server. Information collected from you using paper-based measures will be stored in a locked filling cabinet at the School of Optometry and Vision Science and only approved research investigators will have access to this information.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the UNSW Privacy Management Plan.

8. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document, or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

10. What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Complaints Contact

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	**HC220450**

11. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Cristian Talens-Estarelles
Position	PhD Student
Telephone	02 9385 4375
Email	z5434490@ad.unsw.edu.au

Chief Investigator

Name	Fiona Stapleton
Position	Scientia Professor
Telephone	+61 293854375
Email	f.stapleton@unsw.edu.au

Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	Dr Kath Watt
Position	Clinic Director
Telephone	02 9385 4624

Additional Services

- **UNSW Red Eye Clinic**
  Ground Floor,
  Rupert Myers Building (North Wing)
  Gate 14 Barker Street
  UNSW, Sydney NSW 2052
  Tel: (02) 9385 6859

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I understand that I will be given a signed copy of this document to keep.
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.

Name: _____

Address: _____

Email Address: _____

Optional Consent for reuse of data and future research

- ☐ I provide my consent for the information collected about me to made available to other researchers as described at section 7 of this document.
- ☐ I understand that this information will be used for future research purposes in deidentified format and my privacy will never be breached;
- ☐ I understand that this consent is separate to the study that I am agreeing to participate in and understand that providing my consent to have my data used for future research purposes is optional;
- ☐ I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future by UNSW School of Optometry and Vision Science.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

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Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales.

- ☐ I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
- ☐ I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Scientia Professor Fiona Stapleton
Email:	f.stapleton@unsw.edu.au
Phone:	+61 293854375
Postal Address:	School of Optometry and Vision Science Level 3, North Wing, Rupert Myers Building Gate 14 Barker Street UNSW Sydney 2052