PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Characteristic Changes of Visual Functions using Multifocal Contact Lenses.

Sieu Khuu, Alex Hui, Pauline Kang, Eman Alzghoul

1. What is the research study about?

You are invited to take part in this research study because you responded to our study advertisement/email and you may be eligible to participate in this study. The research study aims to understand the impact of using Multifocal Contact Lenses (MFCLs) on myopes' visual functions and particular the ability to discriminate object motion/temporal frequency, contrast, and color at different light levels. These basic visual functions play an integral role in visual performance and quality of life, particularly, at different light levels.

This Participant Information Statement and Consent Form (PISCF) informs you about the research study. It explains the research and tests involved so that you can decide if you would like to participate in the research. Please read this information carefully and ask any questions you may have.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Role	Name	position	Organisation
Chief Investigator	Sieu Khuu	Associate professor	UNSW, School of Optometry and Vision Science
Co-investigator	Dr. Alex Hui	Senior Lecturer	UNSW, School of Optometry and Vision Science
Joint supervisor	Dr. Pauline Kang	Senior lecturer	UNSW, School of Optometry and Vision Science
Student Investigator	Eman Alzghoul	PhD student	UNSW, School of Optometry and Vision Science

Research Funder: This research is being funded by UNSW.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research project, 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:

Inclusion criteria:

- Aged 18-35 years-old with good general health.
- An experienced soft contact lens wearer or willing to wear soft contact lenses.
- Have a prescription between -0.50 and -4.00D, with less than -1.50D of astigmatism.
- Have good ocular health.
- Have 'normal' vision, measuring 6/7.5 or better with correction.
- Have normal colour vision
- Are willing to attend two study visits.
- Have normal intraocular pressure.

Participants who meet the following criteria will be excluded from the study:

Exclusion criteria:

- Fitted with RGP, Bifocal or OK lenses within 4 weeks prior to study enrolment.
- Any eye diseases including inflammation, infection or allergy.

- Previous eye surgery within the last 6 months.
- Moderate to severe dryness or any disease might affect ocular surface integrity such as Pteryguim.
- Using ocular medications or eye drops.
- Any other condition which would prevent contact lens wear.

Do I have to take part in this research study?
Participation in any research project 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 project 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);
- If you would like to participate, sign the consent form and;
- Take a copy of this form home with you to keep.

4. 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 in 2 visits study:

Screening and Baseline Visit
- You will be asked to attend a screening visit to determine your eligibility. This screening visit involves taking your current ocular and medical history, checking your vision, having a general exam of the front of your eyes, and determining the power of the eye, and your corneal curvature. This will take approximately 20 minutes and you will be informed of your eligibility directly after this session. In the event that you are not eligible, you will be verbally informed and advised of the reasons why and will be asked to not continue the study.
- Once eligibility is confirmed, you will be fitted with a daily disposable single vision soft contact lens on both eyes to wear during the session, and after 10 minutes, baseline measurements will be taken on the same visit. This involves measuring your distance and near vision in high and low contrast conditions, pupil function, and three visual tasks using a customised computer program (contrast sensitivity, colour contrast sensitivity, and motion detection function), This will take around 1hour and 40 minutes
- You will be asked to return for a final visit. In this visit, you will be first fitted with a daily disposable soft MFCL and after 15 minutes, the same measurements as during the baseline will be taken again. Then one drop of atropine will be installed and the same measurements will be repeated. In between these times, you will be free to leave the clinic. This visit will take approximately 1 hour and 22 minutes.

Randomisation:

This study will be a single-blinded randomised study. The study will be conducted at the School of Optometry and Vision Science, UNSW Sydney. The aim of the research is to understand the change in your ability to discriminate objects, object's motion, and colour while using a daily disposable centre-distance MFCL commonly used to slow the progression. The participants in this group will be placed based on their interest. No randomisation is required.
An overview of the research procedures that you will be asked to complete after wearing MFCL lens are described below:
- Lens fit will be evaluated using slit lamp examination to assess lens movement in primary gaze, lag movement, tightness, lens coverage, and the overall acceptance.
- Best visual acuity at distance and near will be recorded using computerized and handheld vision charts (Test Chart 2000 Pro, UK) in low and high contrast.
- Pupil function measurements using the Neuroptics PLR-3000 pupilometer.
- Contrast sensitivity test using a custom software modified in MATLAB. (10 minutes duration)
- Colour contrast sensitivity using a custom software modified in MATLAB. (10 minutes duration)
- Localisation visual acuity test using a custom software modified in MATLAB. (5 minutes duration)

- Central and peripheral objective refraction across the horizontal meridian out to 30° in the nasal and temporal visual using (NVision K-5001; Shin-Nippon, Tokyo, Japan).

Intervention:
MiSight multifocal-distance soft contact lens used to treat myopia progression will be used in this research.

Medical Device:
The MiSight, daily disposable MFCL (ARTG ID 165286) is approved to be used in Australia to correct and control myopia progression. MFCL is primarily marketed to presbyopia (age-related reading conditions). In our study, we will use the MiSight MFCL. These lenses are commercially available by Coopervision Australia Pty Ltd. A copy of the ARTG summary for (ARTG 165286) has been enclosed with the application.

Risk of MFCL.
Soft Multifocal contact lenses are most commonly used for presbyopia (age related reading condition). It helps people with age related loss of reading ability by providing focused images of near and distance objects. Recent studies have shown that MFCLs can slow myopia and prevent progression in younger subjects. Generally, contact lenses complications might be resulted from extend wearing time, risky contact lens behaviours such as napping or showering while wearing CL, care system induced complications, and hygienic related problems. Contact lens complications can be ranging from mild discomfort due to protein deposit to vison threaten microbial keratitis.
The most common MFCL complications are initial discomfort after lens insertion, feeling dryness after period of wearing lenses, distorted distance visual acuity, problems with driving at night, and reduced contrast. In our study, the participants will be asked to wear CL less than 2 hours. Therefore, no complications or risks are anticipated. However, if you experience discomfort, pain, or redness after lens insertion you can let the investigator know and you will be provided with the required assistance.
Risk of Atropine Eye Drops
Atropine eye drops are known to temporarily widen your pupils as well as affect your ability to focus on near objects and read. Atropine may thus cause you to have blurry vision near and experience light sensitivity. However, with low concentrations being used in this study, these symptoms are expected to be minimal. In the event that these symptoms occur, the use of reading glasses and sunglasses may help relieve these symptoms. Due to the potential risk of these visual changes, you are advised not to drive a motor vehicle, ride a bicycle or operate heavy machinery for 4 hours after instillation of eye drops.

It has been reported that systemic absorption of atropine in high doses, which is not anticipated in this study, can cause dry mouth, dizziness, nausea, hypersensitivity reaction, and increased heart rate. In a large-scale study using atropine eye drops, there were no reported no serious adverse events that occurred during the five-year testing period with daily use of low dose atropine eye drops and so these systemic effects are not anticipated.

In very rare cases, atropine can cause a sudden increase in eye pressure and is estimated to occur 1 to 6 in 20,000 people. This risk is minimized with the study's inclusion and exclusion criteria by excluding individuals with an elevated risk of this complication. If you feel any related symptoms of an adverse reaction to the drops either in the eyes or in the rest of your body and need medical intervention, you will be referred to an appropriate health care practitioner or be seen at the **Red Eye Clinic at UNSW** at no cost to you and be closely monitored by health professionals. Alternatively, you may contact us on **(02) 9385 4624** if you have any concerns or emergency issues. There is also a 24-hour emergency contact number: **0498 633 010.**

You are free to withdraw from the research at any time. If you withdraw from the research, we will destroy any information that has already been collected and your decision will not affect your relationship with UNSW and the research team members.

Risks of testing procedures
The testing procedures that will be performed in this project are non-invasive and generally require no direct contact with eye. Therefore, it is not expected that any of the study procedures or measurements will cause any adverse reactions. The most important tests will be conducted using a computer base program connected to monitor. Table 1 includes the tests and measurements will be conducted in this study, there associated risks, and how these risks will be minimized. The procedure will be conducted by Eman Alzghoul as part of her PhD candidature. She has previously trained and practised as an optometrist in Jordan. The multifocal contact lenses will be prescribed by either Dr Alex Hui or Dr Pauline Kang, who are both registered optometrist in Australia and who will also supervise their use.

Table 1 Research procedures, Associate Risk, and Management

Procedure	Risk	Management
Eye health examination using a high magnification clinical microscope	Your eye health will be assessed using a high magnification clinical microscope. No risks are anticipated from this procedure. Mild discomfort may be experienced by the light from the microscope	No risks are anticipated with this procedure. If discomfort from the microscope light is experienced, the assessment will be ceased and attempted again after 10 minutes.
Corneal curvature measurement	Your corneal curvature will be measured in mm using a videokeratoscope (E300; Medmont Pty. Ltd., Melbourne, Victoria, Australia) with the accompanying software (Studio 4, version 4.12.2; Medmont Pty. Ltd.) to analyse the data	No risks are anticipated with this procedure.
Contrast sensitivity test	Your contrast sensitivity function will be measured using a custom computer-based program. The experiment begins with presenting series of striped pattern target at different range of contrast and spatial frequencies on a monitor. Participants are asked to look at the target and determine whether the lines are directed to the right or left. The participant will respond to the test by pressing buttons on a computer keyboard. This task will be repeated twice.	This procedure is non-contact and non-invasive. No risks are expected with this procedure.
Colour contrast sensitivity test	Your colour contrast sensitivity will be measured using a custom computer-based program. A series of two targets will be presented, one with a parallel black and white striped pattern and the other with black lines and one of the following colours: red, green, and blue. Participants will be asked to detect which of the two images contains colour. The participant will respond to the test by pressing buttons on a computer keyboard. This task will be repeated twice.	This procedure is non-contact and non-invasive. No risks are expected with this procedure.

Motion/temporal detection test	Temporal flicker sensitivity will be measured using a custom computer-based program. A series of two targets will be presented, one fused (steady) stimulus and one with a flickering stimulus. Participants will be asked to detect which of the two images contains flicker. The participant will respond to the test by pressing buttons on a computer keyboard. This task will be repeated twice.	This procedure is non-contact and non-invasive. No risks are expected with this procedure
Autorefractor (NVision K-5001; Shin-Nippon, Tokyo, Japan).	Central and peripheral objective refraction across the horizontal and vertical meridian, at the centre and out to 30° in the nasal, temporal, superior and inferior point.	This procedure is non-contact and non-invasive. No risks are expected with this procedure.
Ocular wavefront aberration and pupil size	Ocular wavefront aberration and pupil size will be measured using Topcon KR-1W	This procedure is non-contact and non-invasive. No risks are expected with this procedure.

Additional Costs and Reimbursement:

There are no additional costs associated with participation in this research study. All participants will receive a free eye test and a $20 Coles voucher gift at the end of each visit (with a total of $60).

5. What are the possible benefits of participation?

We cannot guarantee or promise that you will receive any benefits from this research; however, we hope to use the information we get from this research study to benefit others who are using MFCLs to treat their myopia by understanding the effects of using MFCLs on the basic visual functions.

6. What are the alternatives to taking part in the research?

You do not have to take part in this research project to receive treatment at the "UNSW Optometry Clinic". Other options are available; these include fitting MFCL in a laboratory setting by a trained investigator. Your study investigator will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

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 15 years after the project completion. The information about you will be stored in a re-identifiable format where any identifiers such as your name, address, date of birth, and any personal details will be replaced with a unique code at the School of Optometry and Vision Science, UNSW Sydney. All aspects of the study will be kept confidential and only those conducting and monitoring the study will have access to the study results. Information collected from you in an electronic format will be stored on a UNSW password protected "One Drive" and only accessible to the approved research investigator. All record forms will be kept securely in locked

cabinets at the School of Optometry and Vision Science at UNSW with access limited to the research team.Your information will only be used for the purposes of the research study**.**
Any data included in reports, publications and/or presented at scientific meetings will be provided in the form of group responses and/or study identity numbers. 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. You have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. You can do this by contacting a member of the research team using the contact details provided below. This information will be used for future purposes, in de-identified format and your privacy will never be breached.
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 compliant 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/report the results as a PhD thesis. All information published will be done 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 adding your email or postal address within the consent form. We will only use these details to send you the results of the research. The results will also be made available via the school's website (www.optometry.unsw.edu.au).

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	200100

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

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

Research Team Contact Details

Name	Eman Alzghoul
Position	PhD candidate /Student Investigator.
Telephone	+61293854750
Email	e.alzghoul@unsw.edu.au

Name	Dr. Sieu Khuu
Position	Associate professor/ Chief investigator
Telephone	+61 2 93859816
Email	s.khuu@unsw.edu.au

Name	Dr. Alex Hui
Position	Senior Lecturer, Optometrist/ Co-supervisor
Telephone	02 9385 9228
Email	alex.hui@unsw.edu.au

Name	Dr. Pauline Kang
Position	Lecturer, Optometrist/ joint supervisor
Telephone	02 9385 5749
Email	p.kang@unsw.edu.au

Support Services Contact Details

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

Name/Organisation	**UNSW Optometry Clinic**
Position	**N/A**
Telephone	**+61 2 9385 4624**
Email	**optometryclinic@unsw.edu.au**

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research project.
- ☐ I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.
- ☐ I understand the purposes, study tasks and risks of the research described in the project.
- ☐ 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 project and withdrawal will not affect my relationship with any of the named organisations and/or research team members.
- ☐ 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.

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☐ I understand that I will be given a signed copy of this document to keep.
☐ I understand that the results of the research will be made available on the school of Optometry and Vision Science website.
☐ 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: _____

Participant Signature

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

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 and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

Participant Signature

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

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The section for Withdrawal of Participation should be forwarded to:

CI Name:	Dr. Sieu Khuu
Email:	s.khuu@unsw.edu.au
Phone:	+61 2 93859816
Postal Address:	Level 3, Rupert Myers Building, North Wing School of Optometry and Vision Science UNSW Sydney Sydney, NSW, 2052