PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Characteristic Changes of Visual Functions using Atropine Eye Drops

Sieu Khuu, Alex Hui, Pauline Kang, Eman Alzghoul

1. What is the research study about?

You are invited to participate in this research study because you responded to our study advertisement/email, and you may be eligible to participate. The research study aims to understand the impact of 0.05% concentration of atropine eye drop on myopes' visual functions, particularly the ability to discriminate an object's motion, contrast, and colour at different light levels. These essential visual functions play an integral role in visual performance and quality of life.

This Participant Information Statement and Consent Form (PISCF) informs you about the research study. It explains the research and tests involved to decide if you would like to participate in the study. 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	Organisation
Chief Investigator	Associate professor Sieu Khuu	UNSW, School of Optometry and Vision Science
Co-investigator	Dr. Alex Hui Senior Lecturer	UNSW, School of Optometry and Vision Science
Joint Supervisor	Pauline Kang Senior Lecturer	UNSW, School of Optometry and Vision Science
Student Investigator	Ms Eman Alzghoul	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 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:

Inclusion criteria:

- Are aged18-35 years and have normal general and eye health.
- Have a prescription between -0.50 and -4.00D; with less than -1.50D of astigmatism.
- Have 'normal' vision, measuring 6/7.5 or better with correction.
- Have a normal colour vision.
- Willing to attend two study visits.

Exclusion criteria:

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

- Have used an atropine eye drop within 2 weeks prior to study enrolment.
- Have any eye diseases including inflammation, infection or allergy.
- Have history of allergic reaction to eye medications.
- Are at risk of glaucoma.
- Women who are pregnant, planning to become pregnant or breastfeeding.
- Are currently using any eye medications or antidepressants.

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.

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:

Screening, Baseline, and Atropine Visits:

- You will be asked to attend a screening visit to determine your eligibility to take part in this study. This screening visit involves taking your current ocular and medical history, checking your vision, determining the power of the eye, and examining the eye's health and pressure. 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 in 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, central and peripheral objective refraction, 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. A 0.05% atropine eye drop will be instilled in both your eyes and the same measurements as during the baseline will be taken again. These measurements will be taken 30 minutes after eye drop instillation. In between these times, you will be free to leave the clinic. This visit will take approximately 1 hour and 22 minutes.

Intervention:
Atropine eye drop is a non-selective muscarinic antagonist that is used in ophthalmic as a cycloplegic and mydriatic agent to assess refractive errors in children, to treat amblyopia, and is used clinically to manage myopia progression, will be used in this research.

Medical Drugs:
Atropine eye drops at a 1% concentration (ARTG ID 32256) is approved to be used in Australia for pupil dilation and to paralyze the accommodative apparatus. The concentration used in this study (0.05%) will be 20 times less concentrated than these commercially available preparations and will be prepared by a compounding pharmacy. The test drops will be used to examine similar effects on the pupils and accommodative apparatus that the commercially available preparations have ARTG approval for.

Atropine eye drops often cause side effects; however, we do not expect the low doses of atropine to cause any harm. You may have none or some of the effects listed below **(Risk of Atropine Eye Drop)**. These side effects may be mild, moderate, or severe. If you experience any of these side effects or are worried about them after drop installation, you can let the investigator know and you will be provided with the required assistance. Alternatively, lists of services are provided in the contact details below to assist you if necessary.
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.

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Risk of contact lens

In this study, the participants will be asked to wear daily disposable contact lenses for only 1 hour and 40 minutes during baseline measurements. The contact lens will be cleaned, inserted, and removed by a trained investigator and under the supervision of an Australian registered optometrist. Therefore, no complications are anticipated. Risk of complications will be further reduced by assessing suitability of contact lens wear prior to contact lens insertion. **The risks associated with contact lens use will be managed with the following:**

- Initial discomfort after insertion and during lens wear: Insertion of contact lenses may cause short-term discomfort due to the normal interaction between the lens and eyelid. This should disappear after 10-15 minutes of lens wear, if not, the lens will be removed, cleaned, and inserted again. If discomfort is experienced during lens wear, which may a result of foreign bodies or inverted contact lenses, the lens will be removed and checked for deposits, the ocular surface will be assessed, and the lens will be inserted again if appropriate

- Feelings of dryness after a period of wearing lenses: Contact lenses wear may cause a feeling of dryness after a long period of lens wear. In this study, participants will wear the lens for less than two hours. Unpreserved artificial tears/lubricants may be used if the participant feels dryness.
- Lens adherence: Soft contact lens ocular adherence is very rare, and it is typically a result of napping with lenses or a longer period of wear. Participants are required to wear the contact lens for a short period in this study, thus lens adherence is not anticipated. However, in case of lens adherence, or difficulty while removing the contact lens, an ocular lubricant drop will be used to rewet the lens.

- Ocular Irritation/burning/mild pain: contact lens wearers may experience some irritation and burning sensation after lens insertion due to the care solution system that is used to clean and store contact lenses. In this study the participants will be fitted with new daily disposable contact lenses, thus no solution complications are expected. If any participant feels burning, the contact lens will be removed, rinsed with sterile saline, and reinserted if appropriate. Ocular rinsing using sterile saline can also be used to flush out any solution material. Although pain is not common among contact lens wearers, if any participant feels significant pain, the lens will be removed and the eye thoroughly assessed before any additional lens use.

- Eye infection: Daily disposable contact lenses have been shown to have a 12.5 times low lower risk of inflammatory events than soft contact lenses that are cleaned, reused, and replaced on a frequent basis(23)**.** Therefore, this is not anticipated to be an issue. However, if we suspect that any participant to have an eye infection due to the lens wear, the participant will be referred to the Red Eye Clinic at the UNSW optometry clinic.

At the end of the experiments, the investigator will remove the contact lens for disposal. Afterward, the participant's ocular surface will be assessed using microscopic slit lamp to rule out any possible complications.

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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 at 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 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 occurred in 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 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 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. 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**

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.

The study procedures will be conducted by Eman Alzghoul as part of her PhD candidatures, under the supervision of Dr. Pauline Kang and Dr Alex Hui who are both registered therapeutically endorsed optometrists in Australia. Miss Alzghoul has previously trained and practised as an optometrist in Jordan. The atropine eye drops 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.

The following table includes the tests and measurements swill be conducted in this study, their associated risks and how these risks will be minimized:

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.
Intraocular measurements using the Nidek Tonoref III	Your intraocular pressure (IOP) measurements will require a very small puff of air being directed to the eye. No risks are anticipated from this procedure. Mild discomfort may be experienced by the small puff of air from the instrument.	No risks are anticipated with this procedure. If discomfort from the puff of air from the instrument is experienced, the assessment will be ceased and attempted again after 10 minutes.

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Contrast sensitivity test	Your contrast sensitivity function will be measured using a custom computer-based program. The experiment begins with presenting a 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 a black line 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.	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:

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There are no additional costs associated with participation in this research study. All participants will receive a free eye test and $20 Coles voucher gift at the end of each visit (with total of $40).

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5. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, we hope to use information we get from this research study to benefit others who are using Atropine to treat their myopia by understanding the effects of 0.05 % concentrations of this drug on 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 giving the assigned atropine dose at laboratory setting. 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. 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. Information collected from you in an electronic and visual format will be stored on a UNSW password protected "OneDrive" and only accessible to the approved research investigator. 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 and/ report the results of the research study as part of PhD thesis. 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. The results will also be made available via the schools 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.

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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	HC200099

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

Name	Associated Professor Sieu Khuu
Position	Chief investigator
Telephone	+61 2 93859816
Email	s.khuu@unsw.edu.au

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

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Name	Dr. Pauline Kang
Position	Lecturer, Optometrist/ joint -supervisor
Telephone	+61 2 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.
- ☐ 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*

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☐ 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.

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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	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Associated Professor 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