Plain Language Statement

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Location of testing Department of Optometry and Vision Sciences
The University of Melbourne

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Introduction

You are invited to participate in a research study designed to assess how the visual system adapts to brief changes caused by covering one eye. The purpose of this study is to explore the effect of age and of exercise on this type of neural adaptation. This project is recruited adults aged between 18 and 77 years of age who have healthy vision and physical fitness for their age.

There are 2 phases to this project. You may participate in either phase or both. Phase 1 requires 4 test visits, where your vision will be measured before and after one eye has been covered (for a different duration at each visit, using an eye patch). Phase 2 is a single test session that will also measure vision before and after you cover one eye, but will add some mild-moderate exercise conducted on an exercise bike coupled with external heart rate monitoring.

It is hoped that the results of these tests will provide new knowledge regarding the maintenance and regulation of brain function in adulthood.

This study has been approved by The University of Melbourne Human Research Ethics Committee.

What will I be asked to do?
If you choose to participate in the study, you will be invited to attend a series of testing sessions where the following tests will be conducted. You may choose to withdraw from the study at any time.

> *These tests do not form a full eye examination, and do not substitute for the examinations supplied by your regular practitioners.*

(1) Screening clinical eye examination
During this session, we will conduct a series of screening tests to determine whether you are eligible to participate in the study. All tests are routine clinical tests and will be performed by a qualified optometrist. We will ask you questions about your vision and general health. You will also be asked to complete a physical activity questionnaire and an online physical readiness assessment. We will also check your reasoning and thinking abilities using the Mini-Mental State Examination (MMSE), a widely used, brief, quantitative measure of cognitive status in adults. This test will involve basic comprehension, reading, writing, and drawing tasks.

Part of the screening involves the use of a retinal imaging device (Heidelberg Spectralis) to obtain a three-dimensional picture of your retina and optic nerve at the back of the eye. This is a standard clinical test that only takes a few minutes to perform. None of the tests require eye drops.

The following testing will be performed (over up to 4 test sessions on 4 separate days):

(2) Phase 1: Computer-based vision tests after eye patching
You will sit in a dimly lit room and perform a series of vision tests that require you to observe a variety of visual stimuli of varying contrasts presented on a computer screen from a distance of approximately 50cm. You will be asked to respond to what you see by pressing a button. Each vision test will take 5-10 minutes. After these vision tests, you will be given an eye patch to cover one eye for a period of time (30 mins, 1 hour or 2 hours). While you have one eye patched, you can watch a movie or television show of your choice on an iPad. You will then be asked to repeat the vision tests after the eye patch is removed. The same series of vision tests will be repeated every 15 minutes after eye patch removal for 1 hour. The total session time will be between 2 to 4 hours (depending on the occlusion duration). There are 4 test sessions for this study phase (3 different eye patch durations, and one different test contrast).

(2) Phase 2: Computer-based vision tests after eye patching and mild exercise

This single test session of up to 4 hours will involve the same test procedure as in a single session in Phase 1, but instead of watching a movie while your eye is patched, you will perform mild exercise on an exercise bike (10 minutes on, 10 minutes off, for a period of 1 hour). You will also wear a wristband heart rate monitor (Fitbit Surge) during this period with heart rate monitored to be approximately 120 beats per minute during the exercise phase for younger adults and 95 beats per minute for older adults. This heart rate is designed to be at approximately 60-70% of maximum heart rate for your age. We will also check your heart rate occasionally by simple measure of wrist pulse and make sure that your exercise rate is at a level where you can still talk comfortably, and are otherwise comfortable.

Possible risks associated with the vision testing and exercise

The computer based testing of vision poses no greater risk than working on a personal computer in the office or the home.

Physical activity involved in this experiment will be done in segments of 10 mins on and 10 mins off to increase heart rate up to 120 beats per minute during the exercise phase for younger adults and up to 95 beats per minute for older adults (age adjusted heart workload estimation). During such physical activity, you will experience increased heart rate, increased breathing rate and some increased perspiration during the activity. Exercise can cause some shortness of breath however this will be monitored during the session. Some muscle soreness and general tiredness can occur after any exercise and is quite normal. Sometimes there is a delayed onset of muscles soreness that will occur 24-48 hours after exercise, which is quite is also quite normal. Importantly this soreness should be felt in muscles and not within joints such as the knee or hip. If soreness continues after this time or is felt deep within joints then participants should advise the study coordinator.

How long will it take?

We need people who can participate in up to 4 test sessions of up to 4.5 hours duration for Phase 1, or a single session for Phase 2. You are welcome to volunteer to participate in either (or both) arms of the study. You are free to withdraw from the research at any time you choose.

Will I be reimbursed for my time?

Each participant will be reimbursed $20 per session in the form of a gift voucher to contribute to any travel expenses incurred in attending.

How will my confidentiality be protected?

We will protect your anonymity and confidentiality of your responses to the fullest possible extent, within the limits of the law. All records taken as part of this study will remain confidential. Any information supplied and data collected will be kept in a password-protected computer or in a locked drawer. Your name will not appear in any

publications or reports arising from this study, and if needed you will be referred to by a pseudonym. We will remove any references to personal information that might allow someone to guess your identity. The data is being collected for the specific purposes described in this Plain Language Statement, however, in order to maximize the benefit of the data collected, we may also reuse the data to pool with that collected from future highly related studies in our laboratory. The data will be kept securely in the Department of Optometry and Vision Sciences for a minimum of ten years from the date of publication, before being destroyed.

How will I receive feedback?
A written summary of the clinical research study group findings will be made available after the study has been completed.

What if I do not want to be involved?
Your decision to take part in this study is entirely voluntary. Whether you choose to participate or not, or if you withdraw from the study at any time, will not affect your relationship with the Researchers, or the University of Melbourne. You may withdraw from the study at any time and/or withdraw any unprocessed data you have supplied without prejudice.

What if you are a student of the University of Melbourne?
As with all research projects, your participation will not affect your standing as a student, the way you are treated by the University or your academic results.

How do I agree to participate?
If you would like to participate, please indicate that you have read and understood this information by reading and signing the accompanying consent form, and returning it to the investigators.

Where can I get further information?
Should you require any further information, or have any concerns, or to reschedule your appointment time, please contact:

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If you have any concerns about the conduct of this research, you can also contact:

Executive Officer
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