PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Retinal photoreceptor contributions to circadian rhythms

QUT Ethics Approval Number 1700000699

RESEARCH TEAM

Principal Researcher:	A/Prof Beatrix Feigl	Associate Professor
Associate Researchers:	Prof Andrew Zele	Professor
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DESCRIPTION

The purpose of this research is to understand the contribution of human eye photoreceptors in circadian health and sleep. There are three types of photoreceptors in the back of the eye (retina) that transmit signals to the brain for vision; rods, cones and melanopsin ganglion cells (MGCs). Each photoreceptor type also contributes to non-vision forming functions such as circadian rhythms (how the body adjusts to a 24-hour cycle), sleep and the pupil response (the movement of the pupil in the light and dark). Retinal eye diseases can affect rods, cones and MGCs differently, while neurodegenerative diseases such as Parkinson's disease can lead to loss of retinal ganglion cells. People with eye and neurodegenerative diseases are known to have disrupted circadian rhythms and poor sleep but the exact mechanisms by which each photoreceptor's dysfunction contributes to circadian health are unknown.

Participation in this study will require two sessions. In session one (at QUT or QEI), your suitability for the study will be determined through a basic eye examination to determine how well you see (~ 30 minutes), along with assessment your sleep quality and mood through three questionnaires (~ 20 minutes). After this, you will be required to wear a wrist worn watch, for two weeks continuously, that measures body temperature, movement and light exposure levels. During this period, you will be also asked to maintain a sleep diary to record your sleep and wake timings (which will be detailed before the experiment).

A day before the second session, your will be required to measure your melatonin levels, a hormone that is naturally produced in your body to make you fall asleep. You will be provided with a kit to collect saliva samples in pre-labelled tubes, starting 6 hours prior to your habitual sleep time up to 1 hour after habitual sleep time. You will be asked to simply chew on a cotton swab for a minute, put it in the tube and store it in your fridge. For your last saliva collection we ask you to sit up in bed. With your permission, to prevent from missing a sample collection, an hourly reminder will be given through phone call or text messages.

The second session (~1 hour) involves measurement of your pupil response to light stimuli, with the pupil response recorded by video camera (only the eye will be visible). This session also involves the electroretinogram (ERG) and visual evoked potential (VEP) measurements which are standard clinical

procedures. The ERG and VEP are similar to an electrocardiogram but measure the electrical responses generated by retinal cells and visual cortical cells, respectively in response to light stimuli. Small electrodes are attached to the forehead, the skin next to the eye, and the skin on the back of the head. A fine thread will be placed across the lower lid of the eye. Tropicamide (0.5% or 1%) eye drops may be used to dilate the pupil of your eye. This is a very safe drug and is used in routine eye examinations with extremely rare side effects. This session will be held at QUT.

If you are having diabetes, you will be also asked to view an artificial light source (i.e. desk lamp) every morning for about 30 min over 4 weeks. The light is less bright than experienced when being outside on an overcast day and you can either look directly into the light or you can expose yourself indirectly: e.g have breakfast next to it or read). You will be provided with the artificial light on your first visit and will perform the same eye tests as above (tests that determine how well you can see, sleep and mood questionnaires and a measurement of the pupil response to light stimuli). You will be asked to provide salivary samples (as above) on the afternoon/evening before starting the artificial light intervention (in the morning after your first visit) and the last evening of the 4 weeks (before the second visit) and wear the actiwatch for 4 weeks. On your second visit (after 4 weeks) we will collect the saliva samples, actiwatch and light box from you, repeat the pupil testing and sleep and mood questionnaires you performed on your first visit.

PARTICIPATION

Your participation in this project is entirely voluntary. If you agree to participate, you do not have to answer any questions or complete any tasks you are uncomfortable doing. Your decision to participate or not participate will in no way impact upon your current or future relationship with QUT or QEI (for example your grades or your standard of care at the QUT Optometry Clinic or QEI). If you do agree to participate, you can withdraw from the project at any time without comment or penalty. Any information already obtained from you will be destroyed.
For the testing sessions we can arrange parking or cab vouchers if needed.

EXPECTED BENEFITS

It is not expected that this project will directly benefit you, however this research may benefit society by increasing our knowledge of the basic mechanisms that allows us our body to perform, and how these might be affected in disease. We can provide a brief summary of the research outcomes if you wish.

In acknowledgment of your time contribution, you will be offered a $30 Coles/Myer gift voucher at the completion of the test.

RISKS

There are minimal risks associated with your participation in this project. Light stimuli will be presented which are within the safe standards and ensures no risk of eye damage. As we also aim to collect your saliva samples, we ensure that all the cotton swabs are sterilized and would not harm you in any manner. In case tropicamide eye drops are used, one possible risk is raised pressure in the eye, the drops may sting for a few seconds, and make you unable to perform fine near work and more sensitive to bright light for a couple of hours. We will conduct clinical tests beforehand to determine whether you are susceptible to increase in the eye pressure with these eye drops. We recommend you to wear sunglasses after the session. We also advise you not to drive or cycle and take care with walking (especially on stairs or uneven surfaces) and using machinery until the drops wear off. With the ERG there is a very minor risk of causing a superficial erosion of the cornea. With the ERG and VEP, there is a minor risk of inducing an epileptic seizure, as with any prolonged viewing of flickering lights. If you have a history of epilepsy you should not participate in this study.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially unless required by law.
Any data collected as part of this project will be stored securely as per QUT's Management of research data policy. Please note that non-identifiable data from this research project may be used as comparative data in future research projects or stored on an open access database for secondary analysis. Individually identifiable data will not be published or disseminated.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE RESEARCH PROJECT

If you have any questions or require further information please contact one of the listed researchers:

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CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE RESEARCH PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the QUT Research Ethics Advisory Team on 07 3138 5123 or email humanethics@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

THANK YOU FOR HELPING WITH THIS RESEARCH PROJECT.
PLEASE KEEP THIS SHEET FOR YOUR INFORMATION.