Pilot study to determine photoreceptor contribution to Non-Image Forming effects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42603

Source
ToetsingOnline

Brief title
Photoreceptor Pupil Response

Condition

- Other condition

Synonym
photoreceptor adaptation, pupil response

Health condition

Daytime pupil response and alertness

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: STW grant "On Time"

Intervention

Keyword: Adaptation, Alertness, Chronobiology, Photoreceptors, Pupil response

Outcome measures

Primary outcome

Pupillary unrest index, pupil response (constriction and adaptation during

exposure to light)

Secondary outcome

n.a.

Study description

Background summary

When we are looking at the pupilresponse during long-duration light exposure, the usual response consists of a transient contraction followed by a relaxation towards the dark-adapted state of the pupil. Although it has long been thought that this relaxation is finished after a few minutes of time, recent research suggests that this relaxation takes place for at least half an hour after lights-on (Gooley et al., 2013). This slow relaxation can be countered by exposing the eye to flickering light, and the researchers think that this is because the cones have the opportunity to increase their sensitivity during lights-off, which increases the contribution of the cones. We want to test how different photoreceptors (s,m and l-cones, but also melanopsin ganglion cells) are involved in this effect. To test this, we will make use of the spectral composition protocol, in which the spectrum of the light source is dynamically altered in such a way that only 1 photoroceptor "sees" the difference. Also, we want to know at what frequencie aforementioned effect will be largest (as little as possible relaxation towards dark-adapted state), which is why we want to test multiple frequencies. With this protocol, we will isolate 3 cone classes and the melanopsin ganglion cells. This means that each person needs to come to the lab multiple times, to test each frequencies for a randomly assigned photoreceptor modulation. Besides adaptation in the pupil response, we

are also interested in alertness during office hours, which we will assess by means of the pupillary unrest index, which is a proxy for alertness.

Study objective

The main goal of this study is to answer the following questions: What is the relative contribution of the photoreceptors for the NIF effects of pupil constriction and alertness? What are the frequencies of light which minimise the adaptation of the pupil and maximise alertness for each photoreceptor (melanopsin, S-cone, M-cone and L-cone)?

Study design

This experiment follow a between/within-subject experimental design. The between-factor will be the isolated photoreceptor. The within-factor will be the frequency of the oscillation. The intervention consists of exposure to different (dynamic) lighting protocols.

Intervention

Licht met een fluctuatie in intensiteit met een frequentie van 0, 0.5, 1, 2, 4 en 8 Hz.

Study burden and risks

There are no risks associated with this study. The device is used according to its intended use and has been extensively tested for safety.

The total burden for participants consists of 6 visits to the lab (65 minutes per visit, 390 minutes in total), to comply with set sleep/wake times which will be checked with daqtometer data, and to fill in a number of forms before the actual experiment (~30 minutes)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy men and women (18-30 y)
normal chronotype
normal sleep duration
women using a hormonal form of birth control (steady hormone levels)

Exclusion criteria

short (<6.5h) or long sleeper (>9h)
going out more than two nights a week until minimally 7AM
extreme early or late chronotype
chronic (psychiatric or somatic) disease
sleep disorder
eye complaints or eye surgery in the past (excluding use of contact lenses)
use of chronic (photosensitizing) medication in 3 months prior to start of stydt
regulary use of sleep medication or stimulating drugs
colour blindness
more than 3 glasses of alcohol on working days, and or the regularly use of drugs
more than 8 caffeinated drinks per day
regularly napping (more than 2 times a week)
shiftwork in 3 months prior to the start of the study
travelled across more than 1 timezone in the month prior to the start of the study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2015
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	30-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53779.042.15