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The effects of long-term reduction of short wavelength light in humans.

Submission date	Recruitment status	[_] Prospectively registered
04/04/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/05/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/04/2021	Other	

Plain English summary of protocol

Background and study aims
Humans are a diurnal species (active during daylight) usually exposed to light which is necessary not only for vision but also for regulating the sleep-wake cycle. This regulation is based on the neural system beginning in the retina through subcortical and cortical parts of the brain. This system is specifically sensitive to blue parts of the visual spectrum.
Ironically, in the consequence of the natural age-related process of eye lens yellowing, less blue light reaches the retina and the brain. This pivotal fact may be related to an age-related decline in four aspects of human functioning: sleep quality, circadian rhythmicity, cognitive and emotional processing. The aim of this study is to verify the effects of blue light blocking on healthy and young participants, who do not suffer the same detrimental processes as older adults.

Who can participate?
Young, healthy volunteers participated in the study. Inclusion criteria were age 20-35 yo, experience in contact lens wearing as well as no psychological or neurological conditions. We excluded those volunteers that did not meet criteria for MRI scan or had other that myopia eye conditions (ophthalmological examination was performed before starting the study).

What does the study involve?
The study involved conducting a series of functional MRI brain scans on a weekly basis with additional measurements related to sleep-wake cycle, such as wearing actigraphs, which monitor movement on a daily basis, filling several questionnaires and measuring hormonal level in saliva every week.

What are the possible benefits and risks of participating?
Participants could have experience worsening of their state of well-being - feeling sleepier during the day or having problems with falling asleep. Their emotional and cognitive functioning could also potentially deteriorate on a mild level.
The opposite effect - better sleep and, in consequence, feeling better during the day - may also be considered.

Where is the study run from?
Malopolska Centre of Biotechnology, Krakow, Poland

When is the study starting and how long is it expected to run for?
May 2015 to May 2017

Who is funding the study?
Narodowe Centrum Nauki (National Science Centre of Poland)

Who is the main contact?
Prof. Tadeusz Marek, marek@uj.edu.pl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2013/08/W/NZ3/00700

Study information

Scientific Title
The effects of long-term reduction of short wavelength light on circadian regulation, neural aspects of cognitive and affective functioning in humans - a behavioural, questionnaire, actigraphy, biochemical and neuroimaging study.

Study objectives
The following research questions were posed:
How does the condition of blocking the blue light influence sleep quality?
Will blue light reduction cause circadian rhythm desynchronization over time?
Will blue light reduction have impact on cognitive functioning and emotional state?
How does the condition of blocking the blue light influence neural activity related to cognitive processes?
How does the condition of blocking the blue light influence activation of brain structures involved in processing positive and negative emotions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2013, Bioethics commission at the Polish Military Institute of Aviation Medicine (54/56 Krasińskiego Street, 01-755 Warsaw, Poland; +48 26 185 26 01; wiml@wiml.waw.pl), ref: 01/2013

Study design
Randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Participants were young, healthy volunteers.

Interventions
The study concerns young healthy volunteers, which were asked to wear blue light blocking lenses for the period of four weeks. Their functioning under the condition of blocking the blue light was compared to the control group wearing regular contact lenses. The study was planned to be conducted during spring to fall months to have a higher level of insolation.

The experiment lasted six weeks. For each participant, the measurements were obtained once a week on the same day of the week in the evenings. For the first two weeks, all participants wore regular, daily disposable contact lenses. At the first session, participants were familiarized with experimental procedures and the laboratory. The second session was treated as a baseline. For

the next four weeks, participants wore monthly disposable contact lenses with different filter properties according to group. At each session, participants had MR scanning, they performed experimental tasks and filled in questionnaires. Also, saliva samples were collected. During the whole 6 weeks, participants wore actigraphs.

Participants assigned to BLB group wore the amber contact lenses reducing the transmittance of BL by approximately 90% on the 24-hour basis (UltraVision, Igel RX, water content 77%, orange tint density 40%), whereas CTRLs wore the regular contact lenses.
Each participant underwent an ophthalmologic examination to exclude, other than myopia, sight problems and were under ophthalmologist care throughout the whole experiment.

Participants were assigned to groups as a result of drawing lots. In one round of experiment (lasting 6 weeks), we could collect data from a maximum of 10 subjects. Due to the low number of people applying for participation in the study and our inclusion/exclusion criteria we usually did not have more than 8/10 volunteers per round. We always tried to have even number of participants per round to match the photoperiod for each group.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
contact lenses

Primary outcome measure
Measured at baseline and 6-weeks:
1. Brain activations involved in cognitive task - that is performance and neuronal activity for two cognitive tasks measured using fMRI
2. Brain activations involved in emotional task - neuronal activity measured using fMRI during presentation of emotionally positive and negative stimuli
3. Performance in cognitive tasks directed to measure alertness, working memory and visuo-spatial memory.

Secondary outcome measures
Measured at baseline and 6-weeks:
1. Sleep quality measurement - assessed with subjective sleep quality questionnaires (PSQI - Pittsburgh Sleep Quality Index and ESS - Epworth Sleepiness Scale) in different experimental conditions;
2. Circadian rhythm measurement - assessed with diurnal salivary cortisol pattern (morning and evening levels) and DLMO (dim light melatonin onset, five samples taken each session);
3. Sleep-wake cycle assessed with the use of actigraphs;
4. Emotional functioning - assessed with mood questionnaires (positive and negative affectivity and hedonic tone). Questionnaires used: PANAS - Positive and Negative Affect Schedule and SHAPS - Snaith-Hamilton Pleasure Scale.

Overall study start date
14/07/2015

Completion date

17/08/2017

Eligibility

Key inclusion criteria
1. Age: 20-35 years old
2. Handedness: right
3. Regular sleep-wake cycle and sleep time between 6 and 9 hours per night
4. Experience in contact lens wearing (especially monthly disposable contact lenses without necessity to remove them for night)
5. Low level of daytime sleepiness, good sleep quality and non-extreme chronotype (on the basis of questionnaires).

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
30 +30 in control group

Total final enrolment
48

Key exclusion criteria
1. Any MR exclusion criteria (metal parts in the body, pacemaker, etc.)
2. Pregnancy
3. Chronic diseases (eg diabetes), neurological and psychiatric conditions.
4. Other than myopia eye conditions.

Date of first enrolment
05/05/2015

Date of final enrolment
05/05/2017

Locations

Countries of recruitment
Poland

Study participating centre
Malopolska Centre of Biotechnology
Gronostajowa 7A

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Sponsor information

Organisation
Narodowe Centrum Nauki

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Sponsor type
Government

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ROR
https://ror.org/03ha2q922

Funder(s)

Funder type
Government

Funder Name
Narodowe Centrum Nauki

Alternative Name(s)
National Science Centre, NCN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Poland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal by 2020.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

Neuroimaging data will be available in the OpenFMRI repository (https://openfmri.org) in the time of results publication. Other data (questionnaires, biochemical) will be available upon request from the authors of the publication. All the data will be anonymised.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	results	18/03/2019	04/04/2019	No	No
Results article		03/07/2020	19/04/2021	Yes	No