

Testing the effects of residing in an evening blue-depleted hospital light environment

Submission date 13/12/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 17/12/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2024	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims

This study is based on new research about how exposure to blue light in the evening can have a large effect on circadian rhythms and sleep, and laboratory studies have shown that blue-depleted light could have the opposite effects. Furthermore, blocking blue light could be a promising treatment for patients with severe mental disorders. By dimming the blue and green diodes, new LED technology can be used to create a blue-depleted light environment in the evening and night between 1830h and 0650h, while having normal light during the day. Such a light technology has been installed in one half (20 beds) of a newly built psychiatric unit at St. Olavs Hospital, Department Østmarka, Trondheim, Norway. The other half (20 beds) of the unit has normal lights. The two units are otherwise identical. Previous studies on the effects of different light spectrums have largely been conducted in laboratory settings and it is not known if it is possible to create an evening hospital light environment that can also have an effect on circadian rhythms and sleep, or if it will be acceptable to reside in such a light environment. The main aims of the current study are to test whether residing for five evenings in this hospital will have an effect on circadian rhythms and sleep. The study will also test if residing in such a unit has an effect on arousal, neurocognitive function, ability to discriminate colors, and if it is acceptable or if there are any side effects.

Who can participate?

Healthy volunteers aged 20-30

What does the study involve?

Participation includes two phases: the first phase lasts 7 days where the participants stay at home like usual and keep a regular sleep-wake pattern. During this phase the participants keep a sleep diary and use a movement sensor on the wrist (actigraph). On the final evening of this phase the participants stay at the hospital in a dark room from 1800h to 2300h and provide saliva samples each hour. The second phase lasts 12 days, where the participants reside in the new hospital unit for a total of ten days, five days in each light environment. Participants are randomly allocated to stay in the blue-depleted evening light or in the normal light. They then have another evening in a dark room and provide saliva samples, before residing for another five

days in the opposite light environment, followed by another evening in a dark room with saliva samples. During the five days in each light environment, the participants go through different tests and complete questionnaires at specific times.

What are the possible benefits and risks of participating?

There are no direct benefits for the participants in the study. There are no known risks involved with participation, but there will be at least two nurses present in the unit when the participants are residing there. One of the test-procedures involves having electrodes on the scalp and other parts of the body that may be uncomfortable to some. The unit will have locked doors when in ordinary clinical use, but all participants will be given key cards so they can leave the unit at any time.

Where is the study run from?

St. Olavs University Hospital (Norway)

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

January 2017 to October 2017

Who is funding the study?

1. St. Olavs University Hospital (Norway)
2. Norwegian University of Science and Technology (Norway)
3. Norwegian Foundation for Health and Rehabilitation (Norway)

Who is the main contact?

Dr Håvard Kallestad

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

REK 2017/916

Study information

Scientific Title

A proof-of-concept, randomized cross-over trial to test the effects of exposure to blue-depleted compared with normal lighting in individuals who volunteered to reside in a hospital inpatient unit

Study objectives

Main hypothesis: In healthy adult volunteers, 5 days of exposure to blue-depleted light in the evening will phase advance dim light melatonin onset (DLMO) and attenuate melatonin suppression compared to 5 days exposure to a normally lit hospital environment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethics committee, Central Norway, 28/06/2017, ref: 2017/916/REK midt

Primary study design

Interventional

Study design

Randomized cross-over trial

Study type(s)

Other

Health condition(s) or problem(s) studied

Healthy individuals

Interventions

This study examines the benefits and risks of residing in an environment with blue depleted lighting compared to residing in an environment with normal lighting. The trialists will recruit adult volunteers to reside in a newly built 40-bedded acute psychiatric unit (prior to the unit opening for patient admissions). Twenty beds are located in a hospital ward with normal lighting conditions that has 3000K (Kelvins) color temperature (which is the same as found in other hospital wards and many homes). The other 20 beds are located in a ward that has tunable light emitting diode (LED) sources and provides blue-blocking filters in front of all the windows in the evening. The layout, facilities and light intensity (photopic lux) are the same in both wards, but individuals are exposed to a different spectrum of light in each ward.

1. Normal indoor light (control condition): The 20 patient rooms, their corresponding bathrooms and all common areas in the ward have ordinary indoor lighting installed (Glamox, Norway). The light intensity is dimmed to 20% (of the maximum) during the night (from 23:00 to 07:00).

2. Blue-depleted light (experimental condition): The tunable lighting system uses LED-based lamps (Glamox, Norway) that contain three independently controllable LEDs (red, green, and blue). A central light controller allows light exposure to be programmed to dim the green and blue LEDs in each lamp to achieve an amber colored light that has negligible blue frequencies (and exposure has been tested using a light spectrometer in different parts of the ward). Individuals are also provided with blue-blocking screens that can be attached to the front of all electronic devices. At 18:00 a 30-minute transition period starts where the lights are changed to the blue-depleted amber color. From 18:30 to 06:50 the light is amber. At 06:50 a new 10-minute

transition changes the light color to ordinary indoor lighting. From 07:00 to 18:00, there will be ordinary indoor lighting (3000K). The light is dimmed to 20% (of the maximum) light intensity at night (from 23:00 to 07:00). The amount of blue light exposure for individuals in this part of the unit compares to that shown to minimally suppress melatonin in laboratory settings.

12 healthy participants will voluntarily spend 5 days in each ward. Individuals will be randomized to reside in the normal lighting environment initially, then cross-over to the blue depleted light environment (n=6) or to reside first in the blue depleted light environment and then cross over to the other ward (n=6).

Using objective (e.g. polysomnography, neurocognitive tests, actigraphy, EEG, saliva samples to measure the timing of dim light melatonin onset), and subjective assessments (e.g. self-rated questionnaires), the trialists will assess circadian phase, sleep-activity patterns, sleepiness, neurocognitive function, color perception and acceptability of residing in the different lighting conditions.

Intervention Type

Other

Primary outcome(s)

Melatonin levels assessed using saliva samples: Timing of Dim Light Melatonin Onset (DLMO) after 5 days residency in each ward as compared to baseline; melatonin levels on the 5th evening in each condition compared to melatonin levels in dim light on the 6th evening (melatonin suppression)

Key secondary outcome(s)

1. Sleep, assessed using: polysomnography on the 4th and 5th evening in each condition; actigraphic recording of sleep-activity cycles and self-rated sleep diaries for 1 week prior to residing at the unit and throughout the study period; Xethru radar assessment of movement when participants are in their rooms, including sleep-activity cycle during residency in each ward
2. Sleepiness, assessed using: Karolinska Sleepiness Scale scored every second hour from 1800h to bedtime and again at 0700h; EEG drowsiness test at 2100h and 2200h the final two evenings in each condition along with Karolinska Sleepiness Scale at 2100h and 2300h
3. Neurocognitive function, assessed using Connors Continuous Performance Test 3 on the third evening in each condition
4. Color discrimination, assessed using the Farnsworth-Munsell 100 hue test on the first evening in each condition
5. Acceptability of lighting, assessed using self-report questionnaires on the first evening in each condition and the final evening in each condition
6. Perceived side-effects of residing in each ward assessed using the UKU questionnaire the day after each condition (6th day)

Completion date

06/10/2017

Eligibility

Key inclusion criteria

1. Age 20-30 years
2. No evidence of circadian dysrhythmia (defined as a self-reported bed-time of about 2300h /2400h and rise-time of about 0700h/0800h and <2 hours variation in bed-time and rise-time

between weekdays and weekends

3. Normal color vision

4. No known physical or mental disorder

5. No known family history of severe mental disorder (e.g. unipolar, bipolar, psychotic disorders, etc)

6. Not currently being prescribed any medication

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 Years

Upper age limit

30 Years

Sex

All

Total final enrolment

12

Key exclusion criteria

1. Score on the Morningness-Eveningness Questionnaire (MEQ) that indicates that the individual has an extreme morning or evening chronotype

2. Not fluent in Norwegian

Date of first enrolment

06/09/2017

Date of final enrolment

21/09/2017

Locations

Countries of recruitment

Norway

Study participating centre

St. Olavs University Hospital

Østmarkveien 15

Trondheim
Norway
7040

Sponsor information

Organisation

Norwegian University of Science and Technology

ROR

<https://ror.org/05xg72x27>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Olavs University Hospital

Funder Name

Norges Teknisk-Naturvitenskapelige Universitet

Alternative Name(s)

Norwegian University of Science and Technology, The Norwegian University for Technology and Sciences, Universidad Noruega de Ciencia y Tecnología, NTNU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Norway

Funder Name

EkstraStiftelsen Helse og Rehabilitering

Alternative Name(s)

Norwegian Foundation for Health and Rehabilitation, Dam Foundation, Stiftelsen Helse og Rehabilitering, ExtraStiftelsen Helse og Rehabilitering

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Norway

Results and Publications

Individual participant data (IPD) sharing plan

Data will not be available outside the core research group until completion of key analyses and relevant manuscripts have been published. However, researchers who are interested in this study can contact the main investigator (Håvard Kallestad) if they have any questions regarding the data. The participants will receive written information about what the study involves and sign a consent form before entering the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/03/2021	27/09/2021	Yes	No
Protocol article		01/08/2019	04/01/2024	Yes	No