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

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Registration date 17/12/2018	**Overall study status** Completed	[_] Statistical analysis plan [X] 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
Dr Håvard Kallestad

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomized cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
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)

Secondary outcome measures
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)

Overall study start date
02/01/2017

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

Age group
Adult

Lower age limit
20 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
12

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

Sponsor details
NTNU
Trondheim
Norway
7491

Sponsor type
University/education

Website
NTNU.no

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 an 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, EkstraStiftelsen Helse og Rehabilitering, ExtraStiftelsen, Stiftelsen Dam & Dam Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Results and Publications

Publication and dissemination plan

Findings regarding the main hypothesis and data on circadian rhythms and sleep, sleepiness, neurocognitive function, and color perception will be published first. Later publications will include further explorations and new analytic strategies for assessing sleep-activity patterns such as non-linear dynamic models for assessing motor activity recorded by actigraphy.

Intention to publish date
01/02/2019

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