Manipulating alertness using (exogenous) melatonin and light

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

Summary

ID

NL-OMON47885

Source
ToetsingOnline

Brief title
Manipulating alertness

Condition

- Other condition

Synonym
alertness

Health condition

alertheid

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Philips Drachten

Intervention

Keyword: Alertness, Light, Melatonin, Time of day

Outcome measures

Primary outcome

The main study parameter is subjective alertness measured by the Karolinska

Sleepiness Scale (KSS).

Secondary outcome

Secondary parameters are objective alertness, measured by physiological

correlates: pupillary parameters and skin temperature. In addition, indirect

parameters, measured through the auditory reaction time task, are used.

Study description

Background summary

Visible light does not only influence visual processes, but also affects non-visual processes such as mood, performance, and alertness. These processes show systematic changes over the course of the day and night. In a previous experiment conducted by our department, we attempted to improve daytime alertness using a polychromatic white light source in a dose-dependent manner. Based on the limited amount of literature on this topic, a positive effect of light on alertness was expected. If confirmed, this could be exploited, for instance in a work environment. However, contrary to these expectations, we did not find significant improvements in alertness in response to light during the daytime. Informal contact with other labs revealed that others also investigated the effects of daytime light on alertness, without significant effects. This suggests to us that the limited number of earlier studies with positive results might be chance observations. Our hypothesis is that light at night is much more effective in increasing alertness than light in the day. We

are interested in the underlying mechanisms.

Study objective

This study aims to investigate 2 factors that may explain the differences in alerting effects of light between day and night.These are a possible ceiling effect of alertness during daytime and a more prominent role of the hormone melatonin in alertness regulation at night (Melatonin is only endogenously produced at night).

Study design

This study will be a placebo controlled study, taking place at two different times of day; daytime (11:30 - 16:00) and nighttime (23:30 - 04:00).
Intervention will comprise of encapsulated, oral melatonin administration (empty gelatin capsule filled with 5 mg melatonin) compared to a placebo (empty gelatin capsule).
1.5 hours after ingestion, either bright or dim light will be administered.
Half hourly alertness assessments will be made before, during and after melatonin or placebo administration and bright- or dim light exposure, in the form of a questionnaire, pupillary measurements, temperature measurements and a reaction time task.

Every participants will participate four times on only one of the two choosen timepoints.
Four different interventions will be applied, consisting of:
1) placebo + dim light
2) placebo + bright light
3) melatonin + dim light
4) melatonin + bright light

The order of intervention will be randomized per subject.

Ten participants will undergo all four interventions (placebo + dim light, placebo + bright light, melatonin + dim light, melatonin + bright light) at one time interval of the day (starting at 11:30. Ten different individuals will take part in the same experiment, starting at 23:30.
This will result in a within the individual (intervention) and between the individual (time of day) design. Although a (full) within subject design would be preferred (meaning that individuals would participate at both times of day, enduring all four conditions two times), we do not think that this is optimal, when considering the burden of participating.

Intervention

Intervention comprises of:

1) placebo + dim light
2) placebo + bright light
3) melatonin + dim light
4) melatonin + bright light

The light conditions are simulated with the use of a Philips EnergyUp light. Philips EnergyUp lights are IEC certified according to IEC 62471 (photobiological hazard). Lights will be placed in front of the participants at 50 cm distance, at an intensity of either 2 lux or creating an intensity of 2000 lux (bright light). To create the dim light condition of 2 lux, 8 neutral density filters, decreasing light intensity with 0.5 log-units each, will be put in front of the lamp. Neutral density filters will be used to ensure that only intensity is altered, without affecting spectral composition.

Participants will be treated with either 5 mg of oral encapsulated melatonin or placebo. To ensure that no differences exist between placebo and intervention, the placebo will exist of an empty gelatin capsule (Capsugel) whereas the intervention will consist of the same gelatin capsule (Capsugel) filled with 5 mg melatonin (Melatomatine).

Study burden and risks

No risks are associated with participation. Light intensities and composition is within the safe range.
A possible burden might be that participants have to swallow a capsule for four times, which could be experienced as unpleasant. In addition, some sleepiness as a consequence of melatonin administration might be expected

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

- Age between 20-30
- Healthy
- Dutch speaking
- Women have to use hormonal contraceptives

Exclusion criteria

- Diagnosed color blindness (ishihara's color blindness test)
- Use of photosensitizing medication or sleep medication
- Drug use
- Moderate to high levels of caffeine intake during a day (5 or more cups)
- Smokers
- Diabetic disease
- Shift work schedule in the 3 months prior to participation
- Travel over 2 or more time zones in 1 month prior to participation
- Epworth Sleepiness Scale >18
- PSQI < 6
- Problems with swallowing pills
- Usage of oral melatonin

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-03-2018
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	NL61863.042.17