PBM for health and wellbeing

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25688

Source
NTR

Brief title
TBA

Health condition

none

Sponsors and support

Primary sponsor: Seaborough Life Science B.V.
Source(s) of monetary or material Support: Seaborough Life Science B.V.

Intervention

Outcome measures

Primary outcome

Mood, sleepiness, subjective/objective performance, need for recovery, cortisol.
Sleep timing and quality, melatonin rhythms, heart rate variability, immune response.

Secondary outcome

Vitamin D and skin temperature

Study description

Background summary

Rationale: In Western societies, people spend ~87% of their waking hours indoors. This leads, between many other things, to light deprivation. While outdoor lighting can easily reach a hundred thousand lux in intensity with a broad spectrum, going from the very (near) infrared (NIR) up to UV light, indoor light intensities barely reach the 500 lux and it often represents only some small wavelengths peaks within the visible range. NIR exposure (760–940 nm) is completely lacking. Light is not only needed for vision but it can also assert a broader spectrum of responses such as affecting sleep-wake rhythms, sleep quality, alertness, mood, and performance. Focus for these effects has recently been on the short-wavelengths, while near infrared light (NIR) has been used to treat a broad range of medical aspects such as wound healing, inflammation, and pain. This last topic, exposure to near infrared light, is known as photobiomodulation (PBM). One of the mechanisms underlying the health effects of NIR is thought to be by stimulating mitochondria. Mitochondrial dysfunction has been discussed to underly several health complaints and one of the reasons why people may suffer from mitochondrial dysfunction has been suggested to be a chronic sleep deficit and/or circadian misalignment. The hypothesis tested in the current explorative study is that PBM will improve health and well-being in subjects suffering from sleep deficits.
Objective: Main objective of the current study is to explore in a dose response manner the potential short and long term effects of PBM on several aspects related to health and well-being; output measures are: subjective mood, subjective and objective performance, need for recovery, sleepiness, subjective and objective sleep quality, sleep timing, immune outputs, cortisol level, melatonin phase and total overnight amounts, heart rate variability. Secondary objective includes skin temperature measurements as a positive control of the PBM intervention since vasodilation is expected to be a direct result of PBM and vitamin D will be assessed in order to control for outdoors light exposure and as a baseline for future studies with PBM outdoor.
Study design: The study is a double-blind placebo-controlled dose response study with two phases. In phase 1, short term (acute and days) effects will be measured. In phase 2, long term (weeks) effects will be investigated. Three different doses and a placebo condition of PBM will be tested and subjects will be randomized by stratification so that each subject is assigned to 1 of the 4 conditions
Study population: The study population consists of healthy men and women, aged 25-40 years old with a clear sleep deficit and some complaints because of this lack of sleep, e.g. sleepiness and minor mood complaints.
Intervention (if applicable): The four different doses are: 0 J (placebo), 0.25 J, 1 J, and 4 J. The PBM dose will be established by changing the duration of the PBM, synchronized at turning off at 1:30 p.m. An irradiance of 5 mW/cm2 on the skin surface and pulsed with an 8% duty cycle, leads to a dose of 24 mJ/cm2/min. To reach the medium dose of 1 J, thus requires an exposure time of 42 minutes, for 0.25 J of 11 minutes and for 4 J of 168 minutes. Dose and timing will be programmed into the device, so that no user intervention will be necessary.
Main study parameters/endpoints: The main question is whether a dose response relationship exists between PBM and the different responses.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects need to come to the facility to receive PBM twice, this lasts 4 hours each day. During the next 18 days, divided over 3.5 weeks, they have to use the PBM device at home or at their office, during 3 hours between 10:30 am and 1:30 pm. This is not really a burden, since the device is a normal desk light, the only limitation is that they need to stay at their desk during this time. In addition, subjects will collect data at home during 5 nights in total: one baseline night, two consecutive nights after the first two PBM sessions and 2 nights after 2 and 4 weeks respectively. In these periods they will complete questionnaires, collect saliva and overnight urine. At baseline, after 2 weeks and after 4 weeks, a blood sample and a hair sample (not after 2 weeks) will be taken. During the total period of 4 weeks, they will wear a wrist activity-rest monitor and an OURA ring; during the first two days, they will also wear a heart-rate monitor. All devices are used for ambulatory recordings and do not inhibit the person’s behaviour. There are no risks associated with participation. If PBM works, subjects may benefit with better sleep, mood, performance etc.

Study objective

Can PBM lead to beneficial effects on the following outputs: Mood, sleepiness, subjective/objective performance, need for recovery, cortisol, sleep timing and quality, melatonin rhythms, heart rate variability, immune response.

Study design

1. Subjective mood (baseline, day1, day 2, end week 2, end week 4)
2. Subjective performance (baseline, night 2, end week 2, end week 4)
3. Objective performance (day 1, day 2)
4. Need for recovery (baseline, night 2, end week 2, end week 4)
5. Sleepiness (baseline, day1, day 2, end week 2, end week 4)
6. Subjective sleep (baseline, end week 2, end week 4)
7. Objective sleep quality (daily)
8. Sleep timing (daily)
9. Immune outputs (baseline, end week 2, end week 4)
10. Cortisol (baseline, day 1, day 2, end week 2, end week 4)
11. Melatonin phase and total amounts (baseline, day 1, day 2, end week 2, end week 4)
12. Heart rate variability (daily)

Intervention

Photobiomodulation (PBM)

Contacts

Public
Chrono@Work B.V.

Marijke Gordijn

050-2111946
Scientific
Chrono@Work B.V.
Marijke Gordijn

050-2111946

Eligibility criteria

Inclusion criteria

• • Healthy, no chronic disease
• Age between 25 – 40 years
• Average sleep duration during a week <= 6.5 hours and/or an accumulated sleep deficit of at least 2 hours (sum of accumulated difference in sleep duration of working days with weighted average sleep duration per week) – measured with MCTQ
• Suffer from daytime sleepiness (ESS>5)
• Dutch speaking
• Participants will have to have a desk type of work and/or have 3 hours per day between 10:30 am and 13:30 at their office/home in which they could sit in front of the lamp.

Exclusion criteria

1. Depressive mood (BDI -II > 13)
2. Pregnancy
3. Drug use during the last three months known to interfere with sleep, alertness, the biological clock and/or light sensitivity (i.e. regular usage of sleep medication or stimulating substances)
4. Use of immune suppressants.
5. High levels of caffeine intake during a day (5 or more cups)
6. High alcohol intake (more than 4 for men and more than 3 for women) for more than 5 days in the past month
7. Participant is not able to refrain from using recreational drugs during the 4 weeks of the study.
8. Shift work schedule in the 3 months prior to participation and/or planned during the 4 weeks of the study
9. Environmental factors in everyday life that may disturb sleep and cannot be prohibited (e.g. young children, noisy environment)
10. Travel over 2 or more time zones in the month prior to participation
11. Travel to sunny holiday locations/wintersports 1 month before participation

12. Personal plans that prevent them for using the intervention during 4 consecutive weeks

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55059
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8800
CCMO	NL74857.042.20
OMON	NL-OMON55059

Study results