EFFECTS AND UNDERLYING MECHANISMS OF PHOTOBIOMODULATION (PBM) ON HEALTH AND WELL-BEING

Published: 15-02-2023
Last updated: 28-12-2024

To follow up on the previous study on PBM effects on well-being by prospectively assessing mood, drowsiness and depression as well as energy/tiredness/tension/calmness, and sleep parameters, and on health by prospectively assessing resting heart...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53954

Source
ToetsingOnline

Brief title
PBM for health and wellbeing

Condition

- Other condition

Synonym
health, well-being

Health condition

Mood, drowsiness, depressive mood, Energy/Tiredness/Tension/Calmness, sleep parameters, resting heart rate, IFN-gamma, TNF-alpha, TGF-beta1, il-1 & il-6, dim light melatonin onset, cortisol (at bedtime), and metabolomics

Research involving

Human

Sponsors and support

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

Intervention

Keyword: health, photobiomodulation, well-being

Outcome measures

Primary outcome

PBM effects on immune system and its dependency on wavelength and/or pulse, as well as the role of the eyes in facilitating PBM effects.

Secondary outcome

PBM effects on other aspects of health (resting heart rate) and well-being (and their dependency on wavelength and/or pulse, as well as the role of the eyes in facilitating PBM effects. We will also assess pathways of action by means of metabolomics analysis.

Study description

Background summary

Light plays key roles in human health and wellness. Despite of this, Western societies spend about 85% of their waking hours indoors. In particular, near-infrared (NIR 750- 1100 nm) light is completely absent indoors, while it accounts for about 54% of the solar radiation reaching the earth. The biological effect of NIR on human bodies has been termed photobiomodulation (PBM) and it has roots in the medical environment. The FDA has approved PBM as treatment for pain relief in cases of head and neck pain, arthritis and carpal tunnel syndrome and more recently it became part of WALT/MASCC/ISOO guidelines. New technologies have made it possible to safely introduce PBM outside the medical framework, testing the possible beneficial effects on health and well-being in a much larger population. Our previous study NL74857.04.20, has

revealed positive effects of PBM on mood, drowsiness, resting heart rate and immune related outputs as well as some positive trends in reducing cortisol just before sleep and shifting the dim light melatonin onset. This was the first time that a double blind and placebo-controlled study shows positive systemic effects of PBM in a generally healthy population (results are currently under review for publication).

Study objective

To follow up on the previous study on PBM effects on well-being by prospectively assessing mood, drowsiness and depression as well as energy/tiredness/tension/calmness, and sleep parameters, and on health by prospectively assessing resting heart rate, cortisol at bed time, dim light melatonin onset, TNF-alpha, IFN-gamma, and TFG-beta1, as well cytokines IL-1 and IL-6. We will further explore more mechanistic related questions by assessing a) whether the eyes are needed for the observed PBM effect (eyes + skin vs skin only), b) what are the effects of a different wavelength, or c) a different pulse, as well as d) metabolomics quantification which will be used to find the most likely pathways of action.

Study design

In a carefully conducted double-blind placebo-controlled field study, the experiment will consist of a baseline measurement followed up by 2 weeks (5 PBM sessions per week) of PBM intervention. A week before the baseline measurement, participants will have to start wearing a Fitbit Versa 3, and will have to continuously wear until the end of the study. In the afternoon of the baseline day as well as in the afternoons after 5 and 10 PBM sessions (week 1 and week 2, respectively), participants will have to go to the lab for blood withdraw. In the evening of the baseline day as well as in the evenings after 5 and 10 PBM sessions (week 1 and week 2, respectively), participants will have to collect saliva samples as well as to complete questionnaires.

Intervention

5 conditions will be tested: 2 PBM doses: 0 J.cm-2 (placebo), and 6.5 J.cm-2. The PBM dose will either have a wavelength of 850 or 940 nm and a pulse of either 15 Hz/8 ms or 100 Hz/1.2 ms, respectively (both resulting in a duty cycle of 12%). Further, the PBM dose will also be tested with eyes blocked by means of filtering glasses that provide almost clear visibility of 75% in wavelenght used for vision, but filter wavelengths between 850-5200 nm. Dose and timing will be programmed into the device, so that no user intervention will be necessary.

Study burden and risks

The full protocol will be performed at the participants* home and/or workplace. Participants will have to sit in front of the PBM module during 3 hours in the morning (from 9:30 to 12:30) 5 days per week during 2 weeks. 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. During exposure to PBM they should not cover the skin of their arms, hands and face nor wear any cream. In addition, a week before the baseline measurement, participants will have to start wearing a Fitbit Versa 3, and will have to continuously wear until the end of the study. In the afternoon of the baseline day as well as in the afternoons after 5 and 10 PBM sessions (week 1 and week 2, respectively), participants will have to go to the lab for blood withdraw. In the evening of the baseline day as well as in the evenings after 5 and 10 PBM sessions (week 1 and week 2, respectively), participants will have to collect saliva samples as well as to complete questionnaires. 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 from it.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Healthy, no chronic disease
• Age between 25 - 65 years.
• Suffer from daytime sleepiness/drowsiness and or a mild mood disturbance (ESS >5 or BDI equal to or higher than 13 but lower than 20)
• Participants will have to have a desk type of work and/or have 3 hours per day between 9:30 am and 12:30 at their office/home in which they could sit in front of the lamp.

Exclusion criteria

. Depressive mood (BDI -II > 20)
• Pregnancy
• Menopause symptoms
• 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)
• Use of immune suppressants.
High levels of caffeine intake during a day (5 or more cups, according to https://www.voedingscentrum.nl/encyclopedie/cafeine.aspx#blok7, there are no negative effects expected from 4 caffeine products in normal adults)
• High alcohol intake (more than 4 for men and more than 3 for women, drinks per day) for more than 5 days in the past month, including binge drinking and heavy drinking according to
https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/alcohol-facts-and-statistics.
• Participant is not able to refrain from using recreational drugs during the 4 weeks of the study.
• Shift work schedule in the 3 months prior to participation and/or planned during the 2 weeks of the study
• Environmental factors in everyday life that may disturb sleep and cannot be prohibited (e.g. young children, noisy environment)
• Travel over 2 or more time zones in the month prior to participation
• Travel to sunny holiday locations/wintersports 1 month before participation
• Personal plans that prevent them for using the intervention during 2 consecutive
weeks

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2023
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-02-2023
Application type:	First submission
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
Other	in afwachting
CCMO	NL83005.042.22