Blue light therapy for late chronotypes

Published: 06-05-2011
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Main objective of the study is to shift rhythms in late chronotypes and thereby lengthen sleep on workdays and align endogenous rhythms

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

Summary

ID

NL-OMON35907

Source
ToetsingOnline

Brief title
GoLate

Condition

- Other condition

Synonym
evening types, late chronotypes

Health condition

circadian alignment

Research involving
Human

Sponsors and support

Primary sponsor: Philips Consumer Lifestyle
Source(s) of monetary or material Support: Philips Consumer Lifestyle B.V.

Intervention

Keyword: chronotype, light therapy, phase shift, sleep

Outcome measures

Primary outcome

Main study parameter is the timing and quality of the sleep wake cycle

Secondary outcome

Secondary study parameters are the rhythm of melatonin, performance and

sleepiness during wakefulness, adverse events and movements during sleep

Study description

Background summary

Sleeping out of phase with the external light-dark cycle, especially late sleep, is a phenomenon in our society that often results in sleep deficits and a mismatch between endogenous and external rhythms, leading to difficulty in waking up and being alert at work, and to health problems. An estimate of the number of people suffering from an extreme late phase (more than 3 hours out of phase with regular sleeping hours) amounts to 4% in the Netherlands. There are indications that even living 1 hour out of phase has detrimental health effects in vulnerable people, and it has been demonstrated that modifying the start time of school in adolescents by only 30 minutes improves alertness, mood and health. A recent analysis of the Dutch MCTQ database shows that 18% of the people older than 18 years sleep more than 1h later than the average of the database population. This means that a large number of people in the population could theoretically benefit from a correction of their timing of sleep.

Study objective

Main objective of the study is to shift rhythms in late chronotypes and thereby lengthen sleep on workdays and align endogenous rhythms

Study design

In a matched placebo controlled trial we will test whether several days of advancing blue light exposure is capable of inducing a phase shift of the sleep

wake cycle.

Intervention

Blue light exposure with sleep hygiene instructions

Study burden and risks

There are no clear risks of participating in this study. The device is tested for ocular safety and has been proven to be safe. Burden of the subjects is mainly an investment of time. Subjects participate in one condition each, that lasts 30 days. They have to wear two devices continuously, they have to collect saliva at regular intervals, and perform some tests. All measurement will be carried out at home. The volunteers may benefit from the treatment with an improvement of sleep, a reduction of daytime sleepiness and better performance.

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

• Healthy men and women ages between 18 and 65 years
• Social jetlag (difference between midsleep on workdays and days off), of at least 1 hour.
• Sleep duration is shorter on workdays than on days off
• If subjects are allowed to sleep at the time they choose, they have no sleep complaints
• Subjects are motivated to phase advance their sleep times.
• Subjects should be fluent in Dutch (because of the use of Dutch rating scales).

Exclusion criteria

Other sleep disorders, eg sleep apnoea, narcolepsy, restless legs, primary insomnia; depressive disorder; shiftwork during the period 3 months prior to participation or transmeridian flights during one month prior to participation; colour blindness or visually impaired; serious eye problems, e.g. glaucoma; chronic use of medication; excessive daily amounts of caffeinated drinks, alcohol or drugs; the use of photosensitizing medication

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2011
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	GoLite Blu HF3330
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-05-2011
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
CCMO	NL36018.042.11