Decreasing social jetlag with blue light blocking (reducing) glasses

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To elucidate the changes in the timing of sleep and waking, sleep quality and endogenous circadian phase in different chronotypes (e.g. *owls* vs. *larks*) with different amounts of social jetlag shielded from short wavelength (blue) light in the...

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

Summary

ID

NL-OMON40410

Source
ToetsingOnline

Brief title
Decreasing social jetlag

Condition

- Other condition

Synonym
daytime deprivation

Health condition

chronic sleep deprivation/social jetlag

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: 2nd level funding by STW Perspectief 2010 program (project number P10-18)

Intervention

Keyword: blue light, chronobiology, sleep, social jetlag

Outcome measures

Primary outcome

Sleep timing and sleep quantity from sleep diaries (subjective) and actimetry

(objective)

Secondary outcome

Sleep quality from subjective sleep diaries, rest-activity profiles from

objective actimetry, light exposure from sleep diaries (subjective) and from

actimetry (objective). In addition, secondary parameter in this study is the

rhythm of melatonin concentration in saliva. The start of the rhythm will be

measured: dim light melatonin onset (DLMO). A shift in DLMO is interpreted as a

shift in the endogenous circadian pacemaker.

Study description

Background summary

Sleep is a basic human need and essential for good health, quality of life and performing well during the day. The timing of sleep is regulated by a homeostatic process (sleep pressure increasing with time awake) and circadian process. The latter is synchronised (entrained) to the 24-hour light-dark cycle by light. The relationship between external (social) and internal (biological) time is called phase of entrainment. People that differ in this trait have different chronotypes. The distribution of chronotypes is (almost) bell-shaped, with few extreme chronotypes at both ends. Chronotype is assessed via the

Munich Chronotype Questionnaire (MCTQ; appendix F1b) based on calculating the mid-point of sleep on free days (MSF) and workdays (MSW), with the MSF being corrected for sleep deficit accumulated across the workweek (MSF sleep corrected, MSFsc). Social jetlag is quantified as the difference between MSF and MSW, and is a marker for circadian rhythm disruption and chronic physiological stress. The modern 24/7-society ignores that sleep timing is individual, affecting sleep quality and quantity, leading to sleep deprivation and directly impacting recuperation and long-term health. About three quarters of the general population rely on their alarm clocks on workdays, which especially concerns later chronotypes with early work schedules. From controlled laboratory studies, there is ample evidence showing the detrimental effects of sleep deprivation on health and performance, with consequences that would be catastrophic in real life - especially in e.g. shift-work occupations. These studies also show that the thresholds for the effects of sleep deprivation are hard to identify by an individual (6), meaning we need solutions that provide individuals with ways to better acknowledge their state of sleep loss.

The American Academy of Sleep Medicine (AASM) defines *inadequate sleep hygiene* as sleep disruption associated with poor sleep hygiene practices (AASM, 2010). The International Classification of Sleep Disorders defines inadequate sleep hygiene as a *sleep disorder due to the performance of daily living activities that are inconsistent with the maintenance of good quality sleep and full daytime alertness*. These same sleep hygiene guidelines recommend sleeping at the same times on every day of the week, hence irrespective if workday or work-free day. However, we do know that sleep loss accumulated over the workweek is being compensated by longer sleep episodes on free days, which is most pronounced in later chronotypes. This phenomenon has been termed social jetlag, which is positively correlated with smoking and body mass index (BMI). Therefore, the recommendation to ignore ones* chronotype and to keep work-schedule fixed sleep times on free days clearly eliminates any possibility for recovery sleep, which reinforces the increase of chronic sleep deprivation with to date unknown consequences to society. One solution to this problem would be to delay sleep on workdays until it matches sleep on free days, meaning to fully taking account of an individual*s chronotype. Such strategy would require delaying working hours, an approach of obviously little success for plenty social reasons and constraints. The alternative solution is to advance sleep onset on workdays using controlled light exposure, so as to allow for longer sleep duration and to decrease the workweek daily sleep loss. We hypothesise that a continuous earlier sleep onset across weeks and months on workdays will result in an advance of sleep onset also on free days. Previous studies from our group (GoShort, METC2010/127 and GoLate METc 2011/056) have shown, for example, the potential of morning light exposure to advance the circadian phase significantly. In turn, recent studies strongly suggest that it is both outdoor and artificial blue light in the evenings from primarily TV*s, LED*s and computer/tablet screens that delay sleep timing, hence resulting in higher social jetlag. However, no study to date has tested whether shielding

healthy people from short wavelength (blue) light in the evenings is sufficient to decrease social jetlag and increase sleep quality, applying both subjective and objective measures. Two recent studies tested blue wavelength light blocking glasses (worn from 3 hours before bedtime) to treat patients with insomnia and showed significant improvements in sleep quality. However, although the numbers of participants in these studies were small with about only 20 participants in total, the authors did find a non-significant trend towards an advance in sleep timing. Therefore, we here adapt this simple protocol and study more individual to increase statistical power and we will add objective sleep timing measures (actigraphy). We aim to assess the effect of shielding participants form blue light exposure when they are indoors to push the circadian clock towards the social one. This study will give important insights into the effectiveness of home-based interventions to decrease social jetlag/chronic sleep deprivation.

Study objective

To elucidate the changes in the timing of sleep and waking, sleep quality and endogenous circadian phase in different chronotypes (e.g. *owls* vs. *larks*) with different amounts of social jetlag shielded from short wavelength (blue) light in the evenings using short wavelength (blue) light blocking (reducing) orange glasses (experimental condition) compared with amber glasses (placebo/control).

Study design

This longitudinal and interventional field study entitled *Decreasing social jetlag with light* is an integrated project in the research consortium *OnTime - How to fix a (broken) circadian clock* funded by STW Perspectief 2010 program (project number P10-18). In a matched design placebo controlled trial we will equip 81 participants (with a social jetlag of at least 2 hours) with short wavelength (blue) light blocking (reducing) orange glasses to be worn in the evenings for 16 days. In a sex-age-social jetlag matched control group (81 participants), the same paradigm will be used but participants will instead be equipped with amber glasses (blocking (reducing) ultraviolet light, blue and longer wavelengths being transmitted). When waking up during the night, e.g. to use the toilet, participants will be asked to also put on the glasses before switching on the room lights. These filters are approved in previous studies and do not interfere in any way with the visual comfort of watching TV or working at a computer screen. Our workgroup has experience with applying similar applications in human studies (METc2007/129). Effects will be measured by comparing the intervention period with a 14-day baseline period. In two recent studies participants were asked to wear similar glasses from 3 hours before bedtime. We here base our study on chronotype, meaning that each participant will wear the glasses from 8 hours before mid-sleep (MSFsc, chronotype, as assessed by the Munich Chronotype Questionnaire at before the

study) until actual sleep time (lights out), and hence defined individually for each participant. Each participant will be informed via SMS about when to put on the glasses. During four evenings (hourly) separated by each one week, participants will collect saliva.

Intervention

For 16 consecutive days from 8 hours before mid-sleep (MSFsc, chronotype, as assessed by the Munich Chronotype Questionnaire before the study) until actual sleep time (lights out) participants will wear either of the two *special* glasses (see point 6.1 below). Each participant will be informed via SMS about when to put on the glasses. When waking up during the night, e.g. to use the toilet, participants will be asked to put on the glasses before switching on the room lights. These filters are approved in previous studies and do not interfere in any way with the visual comfort of watching TV or working at a computer screen. Our workgroup has experience with applying similar filters in human studies (METc2007/129).

Study burden and risks

There are no known or expected adverse events from participating in our study. The only intervention is to wear orange/amber glasses in the evening and to complete questionnaires. We do not apply any severe or acute sleep deprivation protocol. All participants will have at all days the possibility to sleep at home without interfering with their normal daily routines.

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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 between 18 and 45 years of age
Social jetlag = difference between mid-sleep on workdays and days off of minimum 2 hours
Written informed consent*

Exclusion criteria

Sleep disorders, e.g. sleep apnoea, narcolepsy, restless legs, primary insomnia (will be asked in the General Questionnaire, appendix F1a) Mood disorder; because of the possibility of depressive mood as co morbidity in late chronotypes we will set the criterion for exclusion based on depressive mood on a BDI-II (appendix F1h) rating equal to or higher than 16 (indicating severe dysphoric or depressed mood) Two or more time zones crossed 1 month before study participation Shift-work during 5 years prior to participation Recent eye surgery (last year), glaucoma or other eye disease History of chronic diseases, and/or use of chronic medication for 3 months or longer before study participation Alcohol or drug problems (based on answers to the General Questionnaire, appendix F1a) The use of sleep and photosensitizing medication

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2014
Enrollment:	162
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	19-09-2014
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	NL43440.042.13