Randomized and controlled study of the effects of low intensity monochromatic 'blue light' compared to the standard light treatment of seasonal complaints (winter depression and winterblues)

Published: 18-11-2010
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To investigate the effects of exposure to low intensity monochromatic blue light compared to the effects of standard light trherapy in the treatment of SAD and winterblues

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON34402

Source
ToetsingOnline

Brief title
monochromatic blue light vs standard light treatment in seasonal complaints

Condition

- Mood disorders and disturbances NEC

Synonym
seasonal affective disorder (winter type), winterblues

Research involving
Human

Sponsors and support

Primary sponsor: Philips Consumer Lifestyle/ S. Hermans
Source(s) of monetary or material Support: Philips Consumer Lifestyle

Intervention

Keyword: light therapy, monochromatic blue light, seasonal affective disorder, winterblues

Outcome measures

Primary outcome

Sores on the SIGH-SAD interviews

Secondary outcome

none

Study description

Background summary

Seasonal affective disorder, wintertype, according to DSM-IV is depreesion with a seasonal pattern in wich the complaints exist in fall/winter and remission tooks place in spring/summer at an almost yearly basis.Epidemiological research in the Netherlands shows that 3% of the adults suffer from SAD and 8% from winterblues..

It has been shown that light treatment is effective, but the etiology of SAD and the working mechanism of light treatment are still unknown. One of the hypotheses is the phase shift hypothesis, which postulated that some biological processes are shifted compared to the 24 h rhythm of the environment. Exposure to bright light can cause a phase shift. If the biological clock is running in phase, SAD complaint can improve..

Recently novel photoreceptors in the eye are discovered. They have no influence on the visual system, but are sensitive for light, especially for light with a short wavelength (blue light). If blue light with a low intensity can have the same effect s compared to standard light therapu with a high intensity, than it is possible to ssimplify the traetment an to incorperate it in the life style of the

Study objective

To investigate the effects of exposure to low intensity monochromatic blue light compared to the effects of standard light trherapy in the treatment of SAD and winterblues

Study design

A treatment stud in which in the experimental condition teh effects of exposure of low inetnsity blue monochromatic light is compared to the effects of exposure tot standard light treatment in the treatment of SAD and winterblues

Intervention

Experimental treatment is exposure to low intensity blue monochromatic light, compared to standard light treatment

Study burden and risks

The risk that the experimental treatment is less effective compared to standard light treatment. Participants needs 5 minutes a day for filling out small questionaires an weekly 45-75 minutes for a visit to teh clinic (total 3.5 h) to participate in an inteview and filling out questionnaires.

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 18-65 yr
- no other treatments for seasonal complaints during the same time
- no traveling to southern counties during study period
- no use of tanning fixtures during study period
- informed consent;1. seasonal affective disorder (SAD), winter type, according to DSM-IV
score of at least 18 on the first 24 items of the SIGH-SAD
2. sub-syndromal seasonal affective disorder (sub-SAD, winterblues) acording to the Kasper et al. (1988) criteria:
- SPAQ-GSS score of 8,9 or 10 and at least light seasonal complaints or
- SPAQ-GSS score of 11
score of 12-17 on the first 24 items of the SIGH-SAD

Exclusion criteria

other Axis -I disorders according to DSM-IV
acute suicidal risk
use of pschopharmaca or photosensitsizing drugs
eye diseases or complaints exept aging
diabetes
epilepsy
night shifts

Study design

Design

Study phase: 4

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	EnergyLight and GoLite
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-06-2013
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

ID: 22649
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL33067.042.10
OMON	NL-OMON22649