

# monochromatic blue light vs standard light treatment in seasonal complaints

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON22649

### Source

Nationaal Trial Register

### Health condition

Seasonal affective disorder, wintertype, according to DSM-IV is depression with a seasonal pattern in which the complaints exist in fall/winter and remission takes 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 winter blues..

## Sponsors and support

**Primary sponsor:** Philips Consumer Lifestyle/ S. Hermans

P.O. Box 20100

9200 CA Drachten

NL

## Intervention

## Outcome measures

### Primary outcome

Scores on the SIGH-SAD interviews

## Secondary outcome

N/A

## Study description

### Background summary

Background of the study:

Seasonal affective disorder, wintertype, according to DSM-IV is depression with a seasonal pattern in which the complaints exist in fall/winter and remission takes 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 winter blues..

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 effects compared to standard light therapy with a high intensity, then it is possible to simplify the treatment and to incorporate it in the life style of the

Objective of the study:

To investigate the effects of exposure to low intensity monochromatic blue light compared to the effects of standard light therapy in the treatment of SAD and winter blues

Study design:

A treatment study in which in the experimental condition the effects of exposure of low

low intensity blue monochromatic light is compared to the effects of exposure to standard light treatment in the treatment of SAD and winter blues

Study population:

Patients suffering from SAD are recruited from the SAD outpatient clinic of the UMCG. Participants suffering from winter blues are recruited by means of advertisements in local newspapers

Intervention (if applicable):

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

Primary study parameters/outcome of the study:

Scores on the SIGH-SAD interviews

## **Study objective**

Seasonal affective disorder, wintertype, according to DSM-IV is depression with a seasonal pattern in which the complaints exist in fall/winter and remission takes 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 winter blues..

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## **Study design**

In a 15 days study design, assessments by means of a standardized structured interviews (SIG-SAD) at iselection/inclusion and at day 1, 8 and 15 (primary outcome)

Daily self ratings (KSS; GSQS; AMS; AD-ACL)

Self ratings at inclusion (expectation, SPAQ and MEQ) and at day 15 (evaluation)

## **Intervention**

1. Patients with Seasonal Affective Disorder, age 18yr. or older

A comparison of the effects of exposure to monochromatic light (blue light) vs standard light treatment

5 consecutive days from 8.00-8.30 a.m. in the clinic, at day 4, 5, 6, 7, 8 of the 15 days study design

2. Subjects with sub-syndromal Seasonal Affective Disorder (winter blues), age 18 yr. or older

A comparison of the effects of exposure to monochromatic light (blue light) vs standard light treatment

5 consecutive days from 8.00-8.20 a.m. or earlier after awakening at home, at day 4, 5, 6, 7, 8 off the 15 days study design

## **Contacts**

### **Public**

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### **Scientific**

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# Eligibility criteria

## 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) according 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 psychopharmaca or photosensitizing drugs  
eye diseases or complaints except aging  
diabetes  
epilepsy  
night shifts

## Study design

## Design

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

## Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Recruiting  |
| Start date (anticipated): | 01-11-2010  |
| Enrollment:               | 100         |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 20-12-2013       |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 34402  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

| Register | ID     |
|----------|--------|
| NTR-new  | NL4193 |

**Register**

NTR-old

CCMO

ISRCTN

OMON

**ID**

NTR4342

NL33067.042.10

ISRCTN wordt niet meer aangevraagd.

NL-OMON34402

## Study results

**Summary results**

N/A