The effect of light therapy on depression in adults with intellectual disabilities.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24095

Source
NTR

Health condition

The primary outcome is depressive symptoms. Depressive symptoms will be primarily studied, because diagnosing a major depressive disorder is not always possible in people with intellectual disabilities due to diagnostic difficulties related to their limited cognitive abilities. Secondary outcome measures are major depression, circadian rhythm and stress.

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam
Ipse de Bruggen, Zwammerdam
Amarant Groep, Tilburg
Abrona, Huis ter Heide
Source(s) of monetary or material Support: Ipse de Bruggen, Zwammerdam
Amarant Groep, Tilburg
Abrona, Huis ter Heide

Intervention

Outcome measures

Primary outcome

The primary outcome measure in this study is the severity of depressive symptoms as measured with the depressive mood subscale of the Dutch version of the Anxiety, Depression And Mood Scale (ADAMS). The depressive symptoms of participants in both light therapy groups are compared with the depressive symptoms of participants who don't get light therapy (care as usual group) immediately after the two week period of light therapy and four weeks after light therapy (follow-up). The ADAMS has to be completed by a professional caregiver.

Secondary outcome

Secondary outcomes are whether there is a significantly different effect on depressive symptoms as measured with the depressive mood subscale of the ADAMS of both light devices (10.000 lux versus 100-499 lux) immediately after the two week period of light therapy and four weeks after light therapy.

The presence of major depressive disorder according to the DSM-IV criteria will be studied using the Dutch version of the PAS-ADD Clinical Interview before the start of light therapy and afterwards in participants with a prior diagnosis of major depression. (PAS-ADD: Psychiatric Assessment Schedule for Adults with Developmental Disability). Depressive symptoms will be further investigated using two other additional scales for depressive symptoms: the signalizing depression list and the Aberrant behavior checklist, which both have to be completed by a professional caregiver.

Next to depressive symptoms, the effect of light therapy on circadian rhythm and stress will be studied. Circadian rhythm will be studied by studying the sleep-wake pattern and measuring the melatonin curve. Stress will be studied by investigating cortical level is hair samples. Also, the expectations concerning the effect of light therapy of the participant or their professional caregiver will be collected prior to the light therapy using a questionnaire and the compliance to light therapy will be collected daily during the two week period of light therapy using a log.

The amount of life events in the year prior to the enrolment in the study will be completed by the professional caregiver. Life events are related to depression and to stress.

Personal (level of intellectual disability, presence of psychiatric disorders, physical medical conditions) and environmental characteristics will be retrieved from participants' medical en psychological files.

Study description

Background summary

Two bright light boxes will be compared with care as usual and with each other in their treatment-effects of depressive symptoms. Participants will be randomly assigned to one of

the study groups. Participants assigned to one of the two light therapy groups will receive two weeks of light therapy in the morning. Depressive symptoms will be studied before the start of the two week period of light therapy, directly after the period of light therapy and four weeks after the period of light therapy. The group with care as usual will be monitored with the same time intervals. Stress (cortisol) and circadian rhythm will be studied prior and after light therapy in the two groups who receive light therapy. Participants will be recruited in the Netherlands.

Study objective

A major depressive disorder is a common mental disorder in the general population. It has major influence on functioning in daily life. Depression can lead to cognitive, social and physical problems and has a negative impact on the quality of life. In the general population, depression may be associated with the mergence of a number of physical illnesses and disrupted circadian rhythms. Also in adults (¡Ý18 years) with intellectual disabilities, depression occurs frequently and this has a negative impact on their daily functioning. Regular treatments for depression, such as cognitive behavioural therapy, can only be used among a small proportion of people with intellectual disabilities. As a result, the current treatment options for adults with intellectual disabilities are often limited tot lifestyle changes and pharmacological treatment. In the general population, light therapy is an effective intervention for both seasonal and non-seasonal depression. However, little is known about the effect of light therapy in depressed people with intellectual disabilities. The study results in the general population can not be merely generalized to adults with intellectual disabilities, because light therapy can have a different effect due to brain injuries (prenatal, perinatal of postnatal), congenital malformations, syndromes, genetic abnormalities and environmental variables.

The purpose of the current study is to investigate the effects of light therapy with two different light boxes on depression in people with intellectual disabilities (IQ ¡Ü 70) compared with care as usual.

Study design

- T0: Prior to two week period of light therapy. Completion of three depression questionnaires and the PAS-ADD interview in group I, II and III. Collection of first salvia sample in group I and II. Completion of expectation questionnaire in group I and II. Start of four days of actigraphy in group I and II.

- During light therapy: compliance of light therapy is registered in a log. Start of second period of four days of actigraphy in group I and II at the end of the two week period.

- T1: Directly after two week period of light therapy. Completion of three depression questionnaires in group I, II and III. In case of a major depression at T0 the PAS-ADD interview will be completed for participants of group I, II and III. Collection of second salvia sample in group I and II.

- T2: Completion of three depression questionnaires in group I, II and III. Four days of actigraphy in group I and II.

- 8 weeks after T0: collection of hair sample in group I and II.

Intervention

Participants will be randomly divided into three groups:

- Group I: this group will receive two weeks of morning light therapy (30 min with 20 cm distance or 60 min with 30 cm distance) with a 10.000 lux bright white light device.

- Group II: this group with receive two weeks of morning light therapy (30 min with 20 cm distance or 60 min with 30 cm distance) with a bright white light device of 100 to 499 lux.

- Group III: this group continues their regular care with no additional intervention.

Contacts

Public
Wytemaweg 80

Pauline Hamers
Rotterdam 3015 CN
The Netherlands
06-51861657
Scientific
Wytemaweg 80

Pauline Hamers
Rotterdam 3015 CN
The Netherlands
06-51861657

Eligibility criteria

Inclusion criteria

- Minimal age of 18 years

- Intellectual disability (IQ ¡Ü 70)

- Informed consent

- Major depression or observable symptoms of depression

Exclusion criteria

- Bipolar disorder type 1 or type 2

- When the diagnosis dementia is made by a physician or behavioural scientist/psychologist

- If there is suicidal behaviour or currently suicidal expressions.

- When an individual has or has had a hypomanic episode, manic episode of psychotic episode.

- When there is or has been a prepartum and/or postpartum depression.

- If the participant has a delirium.

- When the lens of the eye is missing (aphakia).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	219
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-04-2015
Application type:	First submission

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
NTR-new	NL5016
NTR-old	NTR5162
Other	METC Erasmus MC, Rotterdam, The Netherlands : MEC-2014-632

Study results