The effects of bright light therapy for depression in adults with intellectual disability.

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The purpose of the present study is to investigate the effects of light therapy (with two different light boxes) on depression in people with intellectual disability (IQ *70) compared to standard care (care as usual).

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

Summary

ID

NL-OMON44100

Source
ToetsingOnline

Brief title
RCT Bright Light Therapie ID

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
Depression, sadness

Health condition

Verstandelijke beperking

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: via de zorgorganisaties Ipse de Burggen;Abrona en Amarant Groep.

Intervention

Keyword: Bright Light Therapy, Depression, Intellectual disability, Randomized Controlled Trial

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 Anxiety, Depression and Mood Scale (ADESS). 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).

Secondary outcome

Besides the primary study parameter we will also investigate whether there is a significantly larger effect when light therapy is given with lamp model 1 compared to lamp model 2. And we examine whether any observed effect of light therapy still exists after a period of 4 weeks (follow-up measurement). For these two secondary study parameters we will also use the Depressive mood subscale of the Anxiety, Depression and Mood Scale (ADESS).

Any existing diagnosis of major depressive disorder according to the criteria of the DSM IV is made prior to the intervention. The researcher will (after extensive training) decline a diagnostic interview for all participants. We use

the Dutch translation of the PAS-ADD (Psychiatric Assessment Schedule for Adults with Developmental Disability, Clinical Interview).

Besides depressive symptoms we will also investigate the effect of lighttherapy on the circadian rhythm (Actiwatch and DLMO) and stress level (cortisol level), expectations of the caregiver (and, if possible, of the participant) over the effect of light therapy on depressive symptoms of the participant and the number of days the intervention is deployed (compliance). Personal and environmental characteristics will be retrieved from the participants' medical and psychological files and we investigate the number of life events of the participant in the past year.

Study description

Background summary

In the general population a major depressive disorder is a common mental disorder which has great influence on daily life. Depression can lead to cognitive, social, emotional and physical problems and has a negative impact on the quality of life. In the general population, depression may be associated with the emergence of a number of physical illnesses and disrupted circadian rhythms. Also in adults (*18 years) with intellectual disabilities, depression occurs frequently and this can have a negative impact on daily life. In older adults with intellectual disabilities research has shown that both the accumulation of life events as well as specific individual life events are associated with depression. Regular treatments for depression, such as cognitive behavioral 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 to lifestyle changes (keep good day-night rhythm and enough activities during the day) 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 people with an intellectual disability. The research outcomes of the effect of bright light

therapy for depression in the general population cannot be generalized to adults with intellectual disabilities. Bright light therapy can have a different effect in this population because of brain injuries (prenatal, perinatal or postnatal), congenital malformations, syndromes, genetic abnormalities and environmental variables.

Study objective

The purpose of the present study is to investigate the effects of light therapy (with two different light boxes) on depression in people with intellectual disability (IQ *70) compared to standard care (care as usual).

Study design

Randomized controlled trial.

Intervention

Each individual participant from the two light therapy groups (the group with the 10,000 lux light box and the group with the 100-499 lux light box) will receive bright light therapy (in the morning before noon) for a period of 14 contiguous days. The bright light will be used for 30 minutes per day (20 cm) or 60 minutes per day (at 30 cm distance).

Study burden and risks

The study question can only be studied in this group because people with intellectual disabilites have specific characteristics. Participation requires little effort from the participants. In this research there are negligible risks for the participant.

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

- Minimal age of 18 years.
- Intellectual disability (IQ*70).
- Informed consent.
- A depression or observable symptoms of depression.

Exclusion criteria

- Bipolar disorder type 1 or type 2 (because the risk of the occurrence of a manic episode).
- When the diagnosis 'dementia' is made **by a physician or behavioral scientist.
- If there is suicidal behavior or currently suicidal expressions.
- When an individual has or has had a hypomanic episode, manic episode or 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)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2015
Enrollment:	171
Type:	Actual

Medical products/devices used

Generic name:	Philips EnergyLight HF 3319
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-04-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51263.078.14