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

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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.…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24095

Bron
NTR

Aandoening

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.

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam
Ipse de Bruggen, Zwammerdam
Amarant Groep, Tilburg
Abrona, Huis ter Heide
Overige ondersteuning: Ipse de Bruggen, Zwammerdam
Amarant Groep, Tilburg
Abrona, Huis ter Heide

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Wytemaweg 80

Pauline Hamers

Rotterdam 3015 CN
The Netherlands
06-51861657

Wetenschappelijk

Wytemaweg 80

Pauline Hamers
Rotterdam 3015 CN
The Netherlands
06-51861657

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Minimal age of 18 years

- Intellectual disability (IQ ¡Ü 70)

- Informed consent

- Major depression or observable symptoms of depression

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	219
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5016
NTR-old	NTR5162
Ander register	METC Erasmus MC, Rotterdam, The Netherlands : MEC-2014-632

Resultaten