Bright light therapy in people with a moderate to severe dementia and a depressive disorder

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

Summary

ID

NL-OMON41993

Source
ToetsingOnline

Brief title
Bright light therapy in people with dementia and a depressive disorder

Condition

- Mood disorders and disturbances NEC

Synonym
depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: stichting

Intervention

Keyword: Brightlighttherapy, Dementia, Depressive disorder, Nursing homes

Outcome measures

Primary outcome

-Number of clients that fully completed the BLT treatment protocol

-Description of the way the protocol is executed

-Frequency and nature of the required adjustments to the protocol

-Frequency and nature of side effects

Secondary outcome

Change in level of depressive symptoms.

Study description

Background summary

Dementia is a disease characterized by cognitive impairment and neuropsychiatric behavioral symptoms such as a depressive disorder. The *Addendum ouderen bij de MultiDisciplinaire Richtlijn Depressie* shows that the prevalence of depressive disorders in nursing homes is on average 15% and the prevalence of a limited depression 25%. These percentages are significantly higher than in other groups. In people with dementia the prevalence is even higher: 25 to 35% of people with dementia have depressive symptoms. Less treatment methods for depression are available for people with dementia than for other target groups. Non-drug interventions such as psychotherapy and psychoeducation are problematic as a result of the cognitive problems of the clients. Pharmacotherapeutic interventions, such as antidepressants, have many unwanted side effects, such as extrapyramidal effects and cognitive decline. Moreover, it is clear from recent reviews that antidepressants are not proven effective as a treatment for a depressive disorder in people with dementia. All in all there is a need for an effective and safe treatment for people with dementia and a depressive disorder.
BLT (Bright Light Therapy) is a treatment method that is used for depressive disorders in adults for several decades. The method is known as effective, safe, cheap and well tolerated. It is more attractive than antidepressants because the effects show up earlier (usually within a week), it is more cost

efficient and there are significantly less side effects. In addition, the treatment has been shown to have a durable effect after the end of the treatment period. For older people with dementia, however, there is still no protocol developed for this therapy, and in addition, the effectiveness has not yet been reviewed. In "good clinical practice" there are positive effects found when applying BLT in people with advanced dementia and a depressive disorder. The latter is known by peer contact.

Hypotheses:
-We expect the protocol for this target group is feasible, i.e. 'be able to complete the treatment according to the protocol'. However, there will be differences between subgroups of clients with respect to the influence of behavioral symptoms.
-Other client properties might also play a role in whether or not completing the treatment. However, we expect that agitation is involved as an 'underlying factor'.
-Possibly some adjustments to the protocol are needed for our target group or for certain subgroups.
-There may be side effects, for example an increase in behavioral problems. It could also happen that lamp is threatening or frightening for the clients. In addition, physical side effects may occur.
-It is expected that the feasibility of the protocol will, to a large extent, relate to the extent to which the health professionals support the treatment.
-Also the extent to which family members or other client representatives support the treatment, is important for the feasibility of the treatment. We expect many family members/client representatives will agree with the treatment.
-Contra-indications could be: increased rate of agitation/anxiety, too little understanding of the treatment, fearfulness or a negative reaction to the lamp.
-Based on the literature, we expect that treatment with BLT will be an effective treatment for clients with a Major Depressive Disorder or a limited depressive disorder. In case of very mild depressive complaints we do not expect the treatment to be effective. Not for all clients the effects will be noticeable right after finishing the treatment; this may take several weeks.

Study objective

This explorative feasibility study will focus on developing a treatment protocol for light therapy in older adults with dementia and a depressive disorder. However, it is important to first consider whether the treatment is feasible at this target group. After that, we will look at the preliminary effectiveness on the basis of a number of individual treatments. The follow-up study will look at the effectiveness with a larger sample size.

In summary, the following research questions are posed:

1) Is the treatment protocol for BLT as used for non-demented adults feasible for institutionalized demented elderly with a depressive disorder?

a) What behavioral problems affect the feasibility of BLT?
b) Which client characteristics (such as gender, form and severity of dementia, form and severity of depression) affect the feasibility of BLT?
c) What kind of adjustments are needed to make the protocol feasible for institutionalised elderly people with dementia?
d) Are there any side effects during the treatment period, which compromise the execution the protocol?
e) Is there sufficient support for BLT by the nurses? What are bottlenecks?
f) Is there sufficient support by the caregivers of the clients to give permission for BLT?

2) What is the preliminary effectiveness of the customized BLT-protocol as a treatment method for elderly people with dementia and a depressive disorder?

Study design

Exploratory feasibility study.

Study burden and risks

First there will be a preparatory phase in the study, which focuses on support from the employees of the departments and caregivers of the clients. For the first group mentioned, there will be asked for support in the form of a clinical lesson and a focus group. The second group is informed and requested permission through a permission letter. Next, 80 nursing home residents with dementia will be screened through a short depression-observation list, completed by the employees of the department. In case of an indication for a depressive disorder, determined with a cut-off score, the diagnosis is officially made by the psychologist. Also, the other in-and exclusion criteria as stated in the research proposal, will be investigated. Given the prevalence of depression in people with dementia (15%), the in-and exclusion criteria and the permission procedure that is followed, it is expected that there are about 5 people left that could be treated with BLT. Within 2 weeks after finishing the inclusion procedure therapy will start. Before treatment is started two questionnaires about behavioral symptoms will be filled out by the employees of the department. In addition, a questionnaire will be completed by the doctor, which gives an indication about the severity of dementia. Patients will be offered 10 days of BLT in 2 weeks with a Philips Energylight with a strength of 10,000 lux. At the end of week 2 and 3 the observer will fill out instruments and questionnaires related to depressive symptoms and behavioral problems. Three weeks after the last treatment session the same measurements will be carried out again.
On the basis of previously performed research at other target groups it is expected that there will be no or only mild side effects. The side effects that could occur are headache, nausea, irritated eyes, disruption of the sleep-wake rhythm, increased agitation and manic symptoms. The clients may quit the

treatment at any time, although at first the client will be motivated to continue. If side effects occur, the researchers will determine if it is necessary to stop the treatment in consultation with the doctor of the department.

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: 65 years and older
* Diagnosis of dementia. The patient must be diagnosed by a doctor (general practitioner, geriatrician, neurologist, geriatric specialist).
* Diagnosis of depression: either major depressive disorder, or limited depression. This diagnosis is made by the (GZ-) psychologist of the nursing home department, according to the Multidisciplinaire Richtlijn Depressie, addendum Ouderen, of Trimbos Instituut, from

which the ' Provisional Diagnostic Criteria for Depression in Alzheimer's Disease ' (Olin et al., 2002) are used. The Cornell Scale for Depression in Dementia (CSDD) is used as a screening instrument.

Exclusion criteria

* Other neurological disorders (such as non-congenital brain damage or Korsakov's syndrome, Parkinson and Huntington), except for CVA belonging to vascular dementia.
* Other psychiatric disorders (such as bipolar disorder, anxiety disorder or psychosis)
* Serious eye conditions (for example, macular degeneration or eye conditions as a result of diabetes), where there is a contraindication to BLT
* Sensitivity to light (e.g. as a result of epilepsy)
* Highly elevated blood pressure syst > 200
For each participant the doctor of the nursing home department will determine whether BLT is medically justified.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2016
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Philips EnergyLight HF3319/01
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-10-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL50795.058.14