Dynamic lighting and Dementia: the impact of biodynamic lighting on sleep quality, depression, emotional distress and agitation in people with dementia and their caregivers

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The main objective of the study is to examine whether dynamic light has a positive influence on the sleep-wake rhythm, depression, emotional distress and agitation in people with dementia. Healthcare innovations, intended for at home use, are used...

Ethical review	Approved WMO
Status	Pending
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON46807

Source
ToetsingOnline

Brief title
Dynamic light and Dementia

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer, dementia

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)
Source(s) of monetary or material Support: GGzE;Health Tech Yard

Intervention

Keyword: (bio)dynamic light, caregiver, dementia, sleep

Outcome measures

Primary outcome

Does the frequency of nightly bedwandering decrease?

Does the duration (minutes) of lying in bed during the night increase?

Secondary outcome

Does the frequency of naps decrease during the day?

Does the duration (minutes) of lying in bed during the day (in minutes)

decrease?

Does the participant receive significantly more light (in lux) when exposed to

biodynamic light?

Do the symptoms of depression improve on the GDS-15?

Do the symptoms of distress improve on the HADS-A?

Do the symptoms of agitation improve on the CMAI?

Do the symptoms of emotional distress of informal caregivers improve on the CSI?

These variables are measured using a wearable in the last week of each

condition that detects movement and a light logger that can record the amount

of lux received per participant.

Study description

Background summary

People with dementia are often not easy to live with because of their sleeping problems, e.g.nightly bedwandering and depression, emotional distress and agitation. Their irregular sleep-wake rhythm, caused by disturbance of the biological clock, is one of the main reasons that primary caregivers ask for a placement in a nursing home.
The sleep-wake rhythm is regulated by the biological clock in the suprachiasmatic nuclei (SCN), which has an intrinsic cycle of just over 24 hours. The light-dark pattern that falls on the retina of the eye throughout the day trains the SCN on this 24-hour rhythm and coordinates and stimulates biological rhythms at the right times of the day and night so that one can live and survive. Without exposure to a regular, daily pattern of light and dark, biological rhythms become irregular and threaten our health and well-being (Carvalho-Boss et al., 2007). In people with dementia, this rhythm can be more disturbed than in normal aging. The function of the SCN also deteriorates more strongly in the case of dementia and the aging eye needs more light than a young eye (Revell & Skene, 2010).
Light therapy, intended to train this rhythm well, offers a promising nonpharmacological method to regulate sleep-wake rhythm in people with dementia. Research shows that when sufficiently exposed to light, the sleep-wake rhythm improves, improves mood and concentration and reduces agitation (Dowling et al., 2005., Van Someren et al., 1997., Ancoli-Isreal et al., 2003. Riemersma-van der Lek et al., 2008).
However, research has also shown that people who are getting older are less likely to go outdoors and that the lighting conditions in nursing homes and care institutions are insufficient. On average, young people go outside 5 hours a day, older people 1 hour and people in a nursing home only 1.6 minutes a day. This means that their biological clock is not sufficiently stimulated (Aarts & Westerlaken,
2005).

From research by Riemersma- Van Der Lek et al. (2008), Fontaneous Gasio et al. (2003) and Figueiro et al. (2014) the circadian rhythm and sleep pattern have improved at a strong light intensity of 1100 Lux and the color temperatures bright, blue and white light. The colour and intensity of the light is important. The aging eye tolerates indirectly vertically offered light with less intensity better. That is why a regular light therapy lamp is not suitable. Dynamic light has a variable range of light intensity and colour temperature and follows the rhythm of the day. During the day more blue and intense light is offered, and in the evening less intense, reddish warm light. It mimics a 'real life' pattern relative to continuous light intensity.

Study objective

The main objective of the study is to examine whether dynamic light has a positive influence on the sleep-wake rhythm, depression, emotional distress and agitation in people with dementia. Healthcare innovations, intended for at home use, are used in this study. The research is a promotion study and consists of two separate studies, which are carried out sequentially. The first study has been realised within a clinical psychiatric department for the elderly of the GGzE in Eindhoven. This study focuses on people with dementia still living at home.

This follow-up study is in line with and uses the infrastructure of Innovate Dementia (www.innovatedementia.eu). With this follow-up study we hope to be able to make a contribution to the long and pleasant living at home of people with dementia and to relieve the burden on primary caregivers, by gaining insight if offering dynamic light leads to an improved sleep rhythm and an improved mood, less anxiety and less agitation and consequently its effect on the caregiver distress. Based on a previous research in the clinical setting, it is expected that the nightly restlessness, wandering, of people with dementia will decrease. It is also expected that people take fewer naps during the daytime. This would mean that the sleep rhythm is improved, but also the quality of life is enhanced if people will be more active during the day. Finally, we expect that light can reduce medication consumption and that primary caregivers will have less need for care themselves.

Study design

Participants participate for 16 weeks in this study. Movement data will be collected during every last week of each condition, in total four weeks, through a movement sensor that registrates acitvation when someone goes into or out of bed at any time of the day. This period of 16 weeks is divided into four periods of 4 weeks (design is ABAB). In one period (B) the person being exposed to biodynamic lighting by using dynamic light bulbs in each lamp in the participant's home. The other period (A) dynamic light is not offered, but normal lighting still is. The participant will participate in both conditions twice which makes this a strong design. The research design is an ABAB-design. In addition, a wearable, light logger is used to measure the amount of light received during the day, in order to measure as objectively as possible the amount of lux received. The primary caregiver will also wear the lightlogger every last week. Before the start of the investigation a move test is assessed to check if the participant is physically able to participate in the study. After each condition four short questionaires are assessed to registrate the symptoms of depression, emotional distress and agitation of the client, and the perceived burden on the informal caregiver. Because a wash-out period of two weeks is used, both conditions do not influence each other.Before start of the study mental competence is judged, a short neuropsychological test ((MMSE) is

administrated to determine the cognitive level of the participants, a short sleeping questionnaire (SCOPA and NPI-Q question nighttime behaviors) is administrated to determine if participants have nighttime sleeping problems..

Intervention

The intervention consists of exposure to biodynamic light.
This is done by equipping each lamp in the room where the participant is regularly (at least daily) with dynamic lighting through replacing each light bulb with a dynamic light bulb, which "plays" a progromma on smartphone or tablet by means of an app that mimics a light pattern according to a normal daylight curve. That means more blue colored and more intense light in the morning and more warm colored, less intense light in the evening, so that the biological clock adapts to this rhythm.

Study burden and risks

There are no health risks associated with the research.
A possible benefit is that the subject may experience an improved sleeping pattern and consequently improved wellbeing.
A second possible benefit is that the primary caregiver might experience less distress due to the improved sleeping pattern of the participant.

When the intervention results in an improvement in sleeping pattern and/or wellbeing, it can easily be implemented in the homes of people with dementia and in general mental health care and in homes or hospitals. The benefits for health and quality of life are expected to far outweigh the costs of this study. The benefits for society imply a considerable reduction in the burden on the health care system.
Burden for the patients is investment of time and an adjustment of the light plan in their home they need to adjust to. After a screening procedure in which subjects have to undergo a short neuropsychological test and a moventest, the time investment for subjects (participants and caregivers) is 300-360 minutes for questionnaires (distributed over 6 meetings in 16 weeks). Before the start of the adjustment of the lighting at home and the measurements, participants and caregivers get a meeting of approximately 1 hour to receive specific instructions related to this procedure and the measurement device. This meeting will take place in the home situation so this is less burden fort he participants. The adjustment of the lighting plan will take place in the at home situation but does not need any investment from the participants.
In sum, the investment of time after screening procedures and instruction comprises for all subjects 360 minutes.

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

-Diagnosis of dementia
-Score MMSE > 22
-nighttime sleep problems (Scopa night >7, NPI-Q nighttime behaviors question answered with "yes")
-mentally competent

Exclusion criteria

-sleeping disorder, like narcolepsy
-eye problems, like blindness
- physical disabilities (eg wheelchair dependence)

- age under 55 years

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-08-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL63355.028.17