The difference between Bright Light Therapy and Biodynamic Lighting for patiënts with moderate-to-severe dementia: a double-blind, randomized, placebo-controlled trial.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29349

Source
Nationaal Trial Register

Health condition

Dementia, Alzheimer's disease, Frontotemporal dementia, Vascular dementia, Lewy-body dementia, bright light, biodynamic light, circadian rhytm, cognition, mood, quality of life

Sponsors and support

Primary sponsor: Arnold Oosterbaan Hersenstichting
Source(s) of monetary or material Support: Atlant Zorggroep, Apeldoorn The Netherlands

Intervention

Outcome measures

Primary outcome

- Cognition (SIB-II, MMSE)

- Quality of life (QUALIDEM)

- Depression (MADRS)

- Apathy (NPI-NH Apathy scale)

- Agitation (CMAI)

- Rest-activity Rythm (actigraphy)

- Activities of Daily Life (Katz-ADL)

Secondary outcome

- Dementia Severity (GDS)

- Year diagnosis dementia

- Dementia Types

- Age

- Gender

- Education Level (according to verhage criteria)

- Medical comorbidities in the last 6 months

- Medication use in the last 6 months

- Presence/absence of walking function

- falls incidence (number of falls a month before and during the study).

- Lux measurement: Before, after and during the intervention the light intensity will be measured by the supplier. During the intervention the light intensity will be independently measured by a luxmeter at the eye level in the gaze direction. The measurements take place two times in the week at the same time (12 o'clock PM)

- Light colour: Before, after and during the intervention the light colour (kelvin) will be measured by the supplier.

Study description

Background summary

Since the early 1990s, several studies have evaluated the effect of bright light in eldery people with dementia. Frequently reported positive effects are improvements of sleep quality, cognition, mood and agitation. Recently biodynamic lighting is upcoming and already implemented in several nursing homes for patients with dementia. Biodynamic lighting is a technical method of achieving the biological effects of daylight in an artificial lighting environment. This method of lighting mimics the cycle of natural daylight, changing colour temperature and intensity throughout the day. The changing colour temperature and intensity throughout the day stimulates the production of sleeping hormones like melatonine and corticol, and in turn improve sleep-wake rhythm. The reported effects from clinical practice seems promising. However limited research has been done on the effectiveness of biodynamic lighting on the sleep quality, mood, cognition and quality of life In patients with dementia. The added value of biodynamic lighting to bright light therapy is also unclear. This study investigate the effectiveness of biodynamic lighting in community-dwelling patients with dementia. 60 patients with dementia (randomly placement) are exposed to either bright light therapy (3 months) and biodynamic lighting (3 months) in the living room of a psycho-geriatric ward, including two delayed periods (3 months each) with standard lighting (placebo intervention). The short-term effect (3 months) and long-term effect of the interventions (6 months) will be investigated and compared between de different lighting conditions.

Study objective

the present study investigates whether Circadian adjusted LED-based (biodynamic) lighting improve cognitive functions, circadian rhytm, behavioral problems (apathy and agitation), Quality of life and mood (depression) in patiënts with moderate- to severe dementia in comparison with a placebo.

Second, the present study investigates whether bright light therapy improve cognitive functions, circadian rhytm, behavioral problems (apathy and agitation), Quality of Life and mood (depression) in patiënts with moderate- to severe dementia in comparison with a placebo.

Third, the present study investigate whether the effects on the outcome measurements differs between bright light therapy and circadian adjusted LED-based lighting. So the question arise what is the added value of circadian adjusted (biodynamic) LED-based lighting to bright light therapy?

Study design

Every patiënt starts with bright light therapy, followed by a wash-out period (placebo). After

the wash-out period of bright light therapy, circadian adjusted LED-based lighting will be implemented, followed by again a wash-out period.

Every intervention start with a pre-measurement (one week before intervention starts), a post measurement (3 months after start intervention) and a follow-up measurement (6 months after start intervention). In total the patiënts will be followed for 12 months and there will be five measurements in total.

There will be controlled for seasonal effects by starting the intervention (N = 30) in the autumn (october 2018) and spring (N = 30, april 2019).

Intervention

The group patiënts (N = 60) are divided over 6 living rooms of a nursing home 'Atlant' in Apeldoorn, The Netherlands.

All patiënts are exposed to bright light therapy (lux 1000-2500, 10 AM- 6 PM), Circadian adjusted LED-based lighting (0 - 2500 lux, 2700-6500K, 9 AM- 11 PM) and placebo light (standard light intensity, 300 lux, 10 AM - 6 PM). Every intervention and placebo periods lasts 3 months.

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Eligibility criteria

Inclusion criteria

- Patiënts with a clear diagnosis of dementia according to the ICD-10 and/or DSM criteria

- Patiënts with dementia staying in a long-term care nursing home 'Atlant Zorggroep' in Apeldoorn - The Netherlands

Exclusion criteria

- Patiënts without a clear diagnosis of dementia according to the ICD-10 and/or DSM criteria

- Patiënts who are terminally ill (life expectation < 4 weeks according to physican)

- Patiënts and legal representatives who refused to complete the informed consent form.

- Patiënts with a serious eye disease incompatible with light therapy, such as aphakia or retinitis pigmentosa.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL7258
NTR-old	NTR7480
Other	METC VUmc Amsterdam : 2018.173

Study results