ISRCTN29863753 https://doi.org/10.1186/ISRCTN29863753

Prevention of depression and sleep disturbances in elderly with memory-problems by activation of the biological clock with light

Submission date	Recruitment status	[ ] Prospectively registered
17/09/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/10/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/05/2010	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMW project ref: 0028.300.30; METc VUmc protocol ref: 2005/10

Study information

Scientific Title
Prevention of depression and sleep disturbances in elderly with memory-problems by activation of the biological clock with light: a double-blind randomised controlled trial

Study objectives
1. Long-term daily bright light exposure attenuates the development of depressive symptoms

Secondary hypotheses:
1. Long-term daily bright light exposure attenuates the development of sleep-wake rhythm disturbances
2. Long-term daily bright light exposure ameliorates the decline of cognitive performance
3. Long-term daily bright light exposure ameliorates caregiver burden
4. The effects of light on mood and cognition are in part mediated by its effect on the circadian pacemaker, as read out from the rhythms in activity, body temperature and cortisol

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the VU University Medical Centre (METc VUmc), approved on 03/08/2005 (Protocol 2005/10)

Study design
Single centre randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Alzheimer dementia, mild cognitive impairment, cognitive deficits

Interventions
Light boxes installed at the patients' home, 10,000 lux (gaze direction). Identical light box +/-300 lux (gaze direction) are used in the placebo condition.

Intervention period is two-years, exposure is daily. Sessions last 30 minutes every morning and evening, during a 90 minutes fixed time-window for both sessions, when light is automatically switched on and cannot be switched off. A maximum of four follow ups, every five to six months.

Joint/Secondary Sponsor Details:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depression, measured with the Geriatric Depression Scale (GDS), using the complete 30 items version. The GDS is a list of statements and patients are asked to rate whether these statements are applicable to them during the last week, answering 'yes' or 'no'. The range of the cumulative score is 0 to 30; scores labelled: 0-9 as 'not depressed', 10-19 as 'mildly depressed', and 20-30 as 'severely depressed'.

All primary and secondary outcomes will be assessed at 1 pre-randomisation assessment and 4 half-yearly post-randomisation assessments (i.e. 2 years of follow-up).

Secondary outcome measures
1. Subjective sleep is measured with the Athens Insomnia Scale, the Dutch Sleep Disorders Questionnaire and the Pittsburg Sleep Quality Index
2. Cognition is measured with a neuropsychological test battery
3. 24-hour recording of skin temperature (9 temperature loggers are placed on thighs, abdomen, soles of the hands and feet), and of heart rate
4. Two weeks monitoring of rest-activity rhythms by actometry
5. Bed times are estimated with a pressure pad connected to a data logger, placed on the patients' bed
6. Saliva samples are collected on one day, from which the diurnal pattern of cortisol levels are determined
7. The primary caregiver fills out the Zarit Burden Interview and the Self-Perceived Pressure from Informal Care questionnaire

All primary and secondary outcomes will be assessed at 1 pre-randomisation assessment and 4 half-yearly post-randomisation assessments (i.e. 2 years of follow-up).

Overall study start date
01/05/2005

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. For experimental group:
1.1. Patients between 50 and 80 years of age
1.2. Clinical diagnosis of probable (presenile) Alzheimer's Disease (AD), Mild Cognitive Impairment (MCI) or Subjective Memory Complaints provided by a neurologist or gerontologist; AD according to the Diagnosis Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) or the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria and MCI following the MCI-standard set by Petersen (Petersen RC, et al: Neurology 2001, 56(9): 1133-1142).
1.3. Mini Mental State Exam (MMSE) score >=14

2. For healthy control group:
2.1. Healthy controls (age 50-80 years)
2.2. Free of any clinical diagnosis of dementia
2.3. Those without subjective memory complaints
2.4. MMSE score ≥28

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
72 patients (36 in each limb of the random assignment) + 25 healthy controls

Key exclusion criteria
Patients nor healthy controls are admitted to the study if any of the following are diagnosed:
1. Any other neurological disorder, including narcolepsy
2. Any psychiatric disorder, with the exception of mild depressive symptoms
3. Serious problems with activities of daily living (ADL)
4. Sleep apnoea or restless legs syndrome
5. A serious eye disease incompatible with light therapy, such as aphakia or retinitis pigmentosa

Date of first enrolment
01/05/2005

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Netherlands Institute for Neuroscience
Amsterdam
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Sponsor information

Organisation
Netherlands Institute for Neuroscience (Netherlands)

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Sponsor type
University/education

Website
http://www.nin.knaw.nl/

ROR
https://ror.org/05csn2x06

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands), Prevention Programme (ref: 0028.300.30)

Funder Name
The Netherlands Organisation for Scientific Research (NWO) (Netherlands) (ref: 453-07-001)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/02/2010		Yes	No