

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

<b>Submission date</b> 17/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/10/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 04/05/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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)

## **Primary study design**

Interventional

## **Study design**

Single centre randomised double blind placebo controlled parallel group trial

## **Study type(s)**

Prevention

## **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(s)**

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).

## **Key secondary outcome(s)**

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).

## **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  $\geq 14$
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  $\geq 28$

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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

Netherlands

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**Sponsor information****Organisation**

Netherlands Institute for Neuroscience (Netherlands)

**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

## 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?
<a href="#">Protocol article</a>	protocol	23/02/2010		Yes	No