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The effect of light and/or melatonin on sleep, mood, cognition and behavior in demented elderly

Submission date 12/09/2005	**Recruitment status** No longer recruiting
Registration date 12/09/2005	**Overall study status** Completed
Last Edited 18/07/2008	**Condition category** Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 no: 28-3003; NTR83

Study information

Scientific Title

Study objectives
A large proportion of the demented elderly show fragmented sleep-wake patterns and disturbed circadian rhythms. It appears that the amplitude of the circadian rhythms is attenuated with age, with an exaggerated decline in demented elderly. Decreased input of entraining stimuli, due to diminished stimulation by environmental light and by lower levels of the pineal hormone melatonin to the SupraChiasmatic Nucleus (SCN), the pacemaker of the circadian timing system, might contribute to these disturbances.

So far hopeful results have been found for light and melatonin in relatively small groups of patients. We now want to test the effect in a large group of patients to be able to differentiate the effects according to different subject related co-variables and to test the combination of light and melatonin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo-controlled, parallel group, single blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dementia, dementia symptoms

Interventions
Ceiling mounted indirect bright light (1000 lux in gaze direction) or ceiling mounted placebo light (300 lux in gaze direction), six homes in each condition. Furthermore, all participants were randomised to melatonin (2.5 mg) or placebo, daily administered one hour before bedtime.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Before starting the supplementation of light and melatonin all subjects were tested for their rest-activity rhythm by actometry, 24-hour salivary melatonin and cortisol levels were measured as was the 24-hour ear temperature. Neuropsychological assessment was done to test cognitive abilities and dementia severity and caregivers were asked about mood, behaviour, sleep and abilities in activities of daily living of the subjects.

All these measures are again tested six weeks after the start of the change in light and the supplementation of melatonin, to test the relatively short-term effects on changes in rest-activity, rhythmicity of endogenous melatonin, cortisol and temperature rhythm and alterations in mood and behaviour. The long-term effects are tested every six months after the start of light and melatonin as long as a subject participates in the study with a maximum of 3.5 years.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/1999

Completion date
01/04/2003

Eligibility

Key inclusion criteria
Demented elderly, living in the assisted care facilities of 12 different homes for the elderly in different places in the Netherlands.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
189

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/06/1999

Date of final enrolment
01/04/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Netherlands Institute for Brain Research
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Netherlands Institute for Brain Research (The Netherlands)

Sponsor details
Meibergdreef 33
Amsterdam
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Sponsor type
Research organisation

ROR
https://ror.org/05csn2x06

Funder(s)

Funder type
Research organisation

Funder Name
Hersenstichting Nederland (The Netherlands)

Funder Name
Foundation Reserves Voormalige Vrijwillige Ziekenfondsverzekering (RVVZ) (The Netherlands)

Funder Name
Japan Foundation for Aging and Health (Japan)

Funder Name
Foundation 'De Drie Lichten' (The Netherlands)

Funder Name
Cambridge Neurotechnology (UK)

Funder Name
Braun (The Netherlands)

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name
Philips (The Netherlands)

Alternative Name(s)
Koninklijke Philips N.V., Royal Philips, Royal Philips N.V., Philips & Co

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Netherlands

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?
Results article	Results	11/06/2008		Yes	No