The effects of bright light and physical activity at circadian rhythm disturbances in persons with MCI.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35034

Source
ToetsingOnline

Brief title
The DYNAMO project

Condition

- Other condition
- Structural brain disorders

Synonym
Mild Cognitive Impairment (MCI), mild dementia

Health condition

slaapproblemen

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bright Light Therapy, Circadian Rhythm System, Exercise, Mild Cognitive Impairment (MCI)

Outcome measures

Primary outcome

The main study parameters are objective outcomes related to sleep-wake and

rest-activity rhythms of the participants assessed by Actigraphy.

Outcomes related to the sleep-wake cycle are:

1. total sleep time

2. number and length of wake bouts during the night

3. sleep efficiency (ratio of total sleep time and time spent in bed).

Outcomes according to rest-activity rhythm are:

1. acrophase (time of peak activity)

2. amplitude

3. mesor (mean) of the 24 hour activity curve

4. relative amplitude (RA; difference between 10 most active hours and 5

least active hours)

5. intradaily variability (IV; change in activity level from hour to hour)

6. interdaily stability (IS; measures strength of activity rhythm to

environmental zeitgebers, based on chi square periodogram).

Secondary outcome

Secondary outcome measure is subjective quality of sleep, assessed by the

14-item Groningen Sleep Quality Scale (GSQS)

Study description

Background summary

Sleeping problems are frequently reported in the older non-demented population and in patients with Alzheimer*s Disease (AD). Mild Cognitive Impairment (MCI) might be a relevant marker to examine pre-AD processes, and since disconnections of suprachiasmatic nucleus (SCN) structures appear from preclinical stages of AD onwards, MCI is an interesting research field in order to prevent or delay further neurodegeneration. Light and physical activity both influence the circadian rhythm system, but their interactions are complex and not frequently investigated yet. Nevertheless, research reports and theoretical frameworks are promising considering improvements in sleep-wake cycle and the rest-activity rhythm with light treatment or physical exercise. Therefore it is important to investigate the complex interactions of light and physical activity on the circadian rhythm system, especially in persons who are already suffering from decline in structures involved in the circadian rhythm system as observed in MCI patients

Study objective

The objective of the study is to investigate the effects of bright light combined with physical activity during the morning on subjective and objective outcomes related to sleep-wake cycle and the rest-activity rhythm in persons with MCI, aged 65 years or older and having at least one sleeping problem.

Study design

A randomized control trial will be used to investigate the effects of bright light and physical activity on sleep-wake and rest-activity parameters in older persons with MCI. There will be four groups: morning bright light, morning physical activity, morning bright light combined with physical activity or no treatment, wait list control, group. Participants will be assessed by using two short questionnaires: The 5-item Athens Insomnia Scale (AIS-5) to assess the presence of sleeping problems and the PAR-Q to screen for medical risks. Included persons will be randomly assigned to one of the four treatment groups. After that, questionnaires will be assessed to control for confouning factors. To control for comorbidities, a comorbidity questionnaire of Van den Berg & Van den Bosch (1989)will be assessed. Depression will be assessed by the 30-item Geriatric Depression Scale (GDS-30). Anxiety will be assessed by the Geriatric

Anxiety Inventory (GAI). Frailty will be assessed by the Groningen Frailty Indicator (GFI). The chronotype will be assessed by the Munich Chronotype Questionnaire (MCTQ). The 6CIT will be assessed to investigate the amount of cognitive impairment . Participants are already diagnosed with MCI, but in order to better compare participants of this study, this short questionairre is added. The amount of cognitive impairmant will be assessed by the Mini Mental State Examination (MMSE). The latter is added because the MMSE is known as the gold standard in the cognitive research area. All questionnaires are reliable and valid.
Subjective slaap quality is assessed by the Groningen Sleep Quality Scale (GSQS). Objective slaap quality and rest-activity outcomes are assessed by Actiwatch, which is a wrist-worn accelerometer. During the intervention a pedometer has to be worn to control for additional physical activity. Also a diary/checklist to check the time spend on the intervention and to control for additional outdoor activities during the intervention has to be filled in daily.
In order to predict maximal oxygen consumption to perform 60% VO2max intensity exercise in de morning physical activity group and the combined morning bright light and physical activity group, a submaximal bicycle test will be assessed. The predicted VO2max will be calculated by the Astrand Rhyming nomogram.

Intervention

There are four treatment groups:
1. morning bright light
2. morning physical activity
3. morning bright light combined with physical activity
4. no treatment group (wait list control)

Persons in the morning physical activity group will receive a home based exercise program. The exercise sessions exists of moderate intensity endurance training (60% VO2max) for 30 minutes each day. The 30 minutes were split up in 2 sessions of 15 minutes cycling with 10 minutes of rest in between. Participants are free to choose the timing of their exercise training as long as it was performed between 7 and 11am.
The morning bright light group will be exposed to 10.000 lux for one hour between 7and 11 am. The combined morning bright light and physical activity group will receive a home-based exercise program which should be performed in front of the light box. After finishing the exercise program, the participant has to sit in front of the light box for the remaining 20 minutes. In total, the participant receives 60 minutes of bright light, of which 30 minutes during exercise. The exercise program protocol is the same as the morning exercise group protocol. Persons in the wait list control group will receive a morning bright light program after termination of the study. Persons are free to choose their own preference intervention time between 7.00am and 11.00am. Persons in the wait list control group recive a light box to accomplish the morning light program after termination of the study. During the intervention period of 10 days the persons of the control group recieve a pedometer to control for

physical activity. They will also be asked to fill in a diary/checklist for additional outdoor activities during these ten days.

Study burden and risks

Participating in the DYNAMO project is of markedly burden for the participants, but there are advantages for the participants. The burden consists of:
1. Filling in multiple questionnaires and wearing an Actiwatch for 14 days preceding the intervention
2. One hour of one of the prescribed interventions for 10 days combined with wearing a pedometer for the whole day. During these ten days a chacklist has to be filled in daily to control for additional outdoor activities and the time spend on the intervention.
3. Wearing an Actiwatch for 14 days after the intervention period
Besides, we tried to lower the load for the participants by letting the participants choose their own preference time of the intervention, as long as it will be performed between 7.00am. and 11.00am.
Participating in this study is of low risk, because there will be no invasive procedures and the bright light exposure is comparable to the light intensity on a cloudy day. The intensity and duration of the exercise intervention is in accordance with the Dutch Recommendation for Daily Physical Activity.
The advantages consists of the direct effects of the intervention, that is hypothesized as improved sleep outcomes and strengthening of the rest-activity rhythm.
With the results of this study, we await to develop a relevant program to enhance activities of daily living (ADL) and prevent circadian rhythm disturbances of persons with MCI. This will be beneficial for the quality of life of persons with MCI and their caregivers. In the optimal situation hospitalization may be delayed without extra burden for the caregivers.

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

Mild Cognitive Impairment (MCI)
Having at least one sleeping problem
age 65 years or older
able to walk independently, use of walking aids (no wheelchair) are allowed

Exclusion criteria

use of photosensitizing medication
presence of diseases of the eye other than due to normal aging
presence of diabetes Mellitus, epilepsy
history or presence of alcoholism, cerebral traumata, normal pressure hydrocephalus or neoplasm
presence of consciousness disturbances

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	15-04-2010
Enrollment:	48
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL31727.042.10