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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28032

Bron
NTR

Verkorte titel
Light and melatonin in dementia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Before starting the suppletion 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, behavior, sleep and abilities in activities of daily living of the subjects. All these measures are again tested 6 weeks after the start of the change in light and the suppletion 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 behavior. The long-term effects are tested every 6 months after the start of light and melatonin as long as a

subject participates in the study with a maximum of 3.5 years.

Toelichting onderzoek

Achtergrond van het onderzoek

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. To test this we changed the lights in the common room of 12 different homes for the elderly. Half of them got lights with an intensity of about 1200 lux, half of them got lights of the same intensity they had before, and functions as a placebo condition. In the evening all participants get a tablet with either 2.5 mg melatonin or placebo approximately one hour before bedtime. Before starting the suppletion 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, behavior, sleep and abilities in activities of daily living of the subjects. All these measures are again tested 6 weeks after the start of the change in light and the suppletion 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 behavior. The long-term effects are tested every 6 months after the start of light and melatonin as long as a subject participates in the study with a maximum of 3.5 years. The endpoint for participating in the study is set at the moment that a subject changes from the participating home for the elderly to a nursing home or when a subject passes away. 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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Ceiling mounted indirect bright light (1000 lux in gaze direction) or ceiling mounted placebo light (300 lux in gaze direction), 6 homes in each condition.
Furthermore, all participants were randomized to melatonin (2.5 mg) or placebo, daily

administered 1 hour before bedtime.

Contactpersonen

Publiek

Netherlands Institute for Brain Research,
Meibergdreef 33
R.F. Riemersma-van der Lek
Meibergdreef 33
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5665488

Wetenschappelijk

Netherlands Institute for Brain Research,
Meibergdreef 33
R.F. Riemersma-van der Lek
Meibergdreef 33
Amsterdam 1105 AZ
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-1999
Aantal proefpersonen:	189
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-05-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL54
NTR-old	NTR83
Ander register	: ZON-MW no: 28-3003
ISRCTN	ISRCTN93133646

Resultaten

Samenvatting resultaten
JAMA. 2008 Jun 11;299(22):2642-55.