The influence of sleeping time and sleep efficiency, measured with actigraphy, on daytime functioning of adults with a moderate intellectual disability

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The aim is to establish a correlation between sleep time and sleep efficiency, measured by actigraphy and daytime functioning (irritability, drowsiness and physical activity) of adults with a moderate intellectial disability.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sleep disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON41080

Source
ToetsingOnline

Brief title
Sleep problems and daytime functioning in ID

Condition

- Sleep disorders and disturbances

Synonym
sleep problems; insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: actigraphy, daytime functioning, Intellectual disability, Sleep

Outcome measures

Primary outcome

Quality of sleep: sleep time and sleep efficiency

Daytime functioning: irritability, physical activity and daytime sleepiness.

Secondary outcome

There are many factors that might influence sleep and behaviour in this population, and therefore have to be taken into account. They concern demographic information (gender, age, level of ID), co-morbidity (dementia, epilepsy, spasticity, obesitas), use of medication with sedative effects (anti-epileptics, benzodiazepines, antidepressants, antipsychotics and melatonin) and mobility.

Study description

Background summary

In the general population many studies are conducted on sleep and sleep problems. There is a clear definition for insomnia, defined by the Dutch general practitioners as: sleep deprivation and poor sleep, such as frequent awakenings or restless dreams, accompanied by daytime functioning complaints, like fatigue, drowsiness, irritability, impaired concentration and performance. Less is known about the consequences of a bad sleep quality in persons with ID. A large part of this population is not able to mention sleep problems reliably and risk factors for sleep disorders are prevalent in this group. Therefore objective measurement of sleep and daytime functioning is highly desirable

Study objective

The aim is to establish a correlation between sleep time and sleep efficiency, measured by actigraphy and daytime functioning (irritability, drowsiness and physical activity) of adults with a moderate intellectial disability.

Study design

All clients living in the participating institutions with a moderate intellectual disability will be listed. Sixty clients will be selected at random from this list using a random number generator (http://www.random.org). Informed consent will be acquired from all participants and from their legal representatives.

1. After informed consent is provided, all participants are instructed to wear the Vivago® accelerometer 7 days and nights continuously.
2. Caregivers are asked to fill in the ESS on the last day that the watch will be worn.
3. Caregivers are asked to fill in the ABC subscale I, on the last daythat the watch will be worn.

Study burden and risks

The client will wear a accelerometer on his/her wrist, which he/she has to wear day and night during 7 days. No further actions or behaviour will be asked from the client. He/she can undertake all his/her normal activities.
After 7 days a caregiver will be asked to fill in 2 questionnaires.
The vivagowatch has the size of a watch. Therefore we expect no or minimal load for the client. In case the client does experience a negative load, the vivagowatch will be taken off and the client will be excluded from the research.

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

18-50 years of age
receiving care from participating care-organisation
a moderate intellectual disability

Exclusion criteria

Participants who refuse to wear the actigraph, or are known by their professional caregivers to easily lose or break things will be excluded from the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	04-07-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	28-05-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL47672.078.14