Validation of the Actiwatch for older people with intellectual disability; a feasibility study

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The first objective of this study is to investigate the feasibility of performing home sleep EEG registrations in older people with intellectual disability. The second objective of this study is the determine which sensitivity setting of the Sleep...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON35404

Source
ToetsingOnline

Brief title
Validation of the Actiwatch; feasibility

Condition

- Sleep disturbances (incl subtypes)

Synonym
normal sleep, sleep problem

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: actigraphy, aging, intellectual disability, sleep registration

Outcome measures

Primary outcome

Feasibility of performing home sleep EEG registrations, together with a

Actiwatch measurement, in older people with intellectual disability.

Secondary outcome

Sensitivity, specificity and accuracy of two different types of Actiwatch

compared to sleep registratrion (for the low, medium, high and auto sensitivity

setting)

Differences between the sleep parameters Total Sleep Time, Sleep Efficiency,

Sleep Onset Latency, Wake After Sleep Onset (for the low, medium, high and auto

sensitivity setting)

Study description

Background summary

In the *Healthy aging with an intellectual disability study* (GOUD, METC 2008-234, NL 23941.078.08) the Actiwatch (Cambridge Neurotechnology Ltd, Cambridge, United Kingdom) was used to investigate the rest - activity pattern. This instrument is increasingly used in sleep research. The Actiwatch is a small watch-like device which contains an accelometer, and is worn on the wrist. It is non-invasive and can be used in the home environment. To register sleep, the Actiwatch Sleep Analysis software uses an algorithm that looks at each data point and calculates a total score, based on the activity counts from each epoch and those surrounding it. The software provides four sensitivity settings to analyze the data files: low sensitivity= 80 counts per epoch, medium sensitivity=40 counts per epoch, high sensitivity=20 counts per epoch and auto sensitivity=variable counts per epoch (the auto sensitivity setting approximates the medium sensitivity setting). At the low sensitivity setting (80 counts per epoch) more movement is necessary to score an epoch as awake,

than at the high sensitivity setting (20 counts per epoch). For example when the sensitivity setting is set on medium, an epoch is scored as *asleep* when the total activity score is <40 counts, and awake when the total activity score exceeds 40 counts per epoch. To gain first information on the applicability and outcomes of the Actiwatch in older people with intellectual disability, data collected in the first year of GOUD were analyzed for the low and high sensitivity setting. The first results show that the chosen sensitivity setting has major influence on the values of different sleep parameters. In order to make the right choice for sensitivity setting we want to validate the Actiwatch with sleepregistration (golden standard) for older people with intellectual disability. The feasibility of EEG-investigation in older people with intellectual disability is investigated.

Study objective

The first objective of this study is to investigate the feasibility of performing home sleep EEG registrations in older people with intellectual disability. The second objective of this study is the determine which sensitivity setting of the Sleep Analysis software gives most valid results, in favor of the data analysis of the healthy aging (GOUD) study.

Study design

Pilot study with a cross-sectional design

Study burden and risks

Participants will be measured for 48 hours with two types of Actiwatch (on the wrist) and with sleepregistration (electrodes on head and face). The measurement takes place in the home environment of the participant, so there is no need for an overnight sleep in a sleep laboratory.
Participants have to be able to understand the measurements and give informed consent themselves.
Burden can occur in terms of experiencing discomfort of the sleepregistration electrodes and the data recorder. There is a small risk of skin irritation caused by the Actiwatch or skin electrodes.

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

- at least 50 years of age
- intellectual disability
- competent to provide informed consent
- 5 participants with a known sleep problem
- 5 participatns without a sleep problem

Exclusion criteria

- active epilepsy
- behaviour problems that negatively influence the measurement
- not able to give informed consent themselves

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2011
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	NL37485.078.11