Development and validation of a questionnaire for the assessment of sleep in individuals with mild intellectual disability

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The purpose of this study is to develop a sleep self-report instrument for people with a mild intellectual disability (SSR-ID) and to assess construct validity of the SSR-ID by showing its association with sleep parameters measured by actigraphy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40493

Source
ToetsingOnline

Brief title
development and validation of the SSR-ID

Condition

- Other condition

Synonym
Sleeppattern

Health condition

slaappatroon

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: Intellectual disability, Questionnaire, Sleep, Validation

Outcome measures

Primary outcome

Participants wear the actiwatch for seven consecutive days. In this period, every morning the participant fills in the SSR-ID. At the end of the week, the Actiwatch and the answers of the SSR-ID will be collected by the researcher and the participant will be asked to evaluate their experience with the SSR-ID, by answering the questions on the last pages included to the SSR-ID.
Then, data from the Actiwatch will be extracted using the Sleep Analysis Software (see above). For the questionnaire, a sumscore of each item is derived and a mean or median is calculated for respectively normal and non-normal distributions. These scores eventually are correlated to the sumscores of the actiwatch parameters

Actiwatch:

• Time in bed (TIB); total time the participants spend in bed.

• Sleep onset latency (SOL); the interval between bedtime and sleep start.

• Total sleep time (TST)

• The time awake between sleep start en sleep end (WASO)

• The percentage of time asleep during the total time in bed (sleep efficiency, SE)

• Interval between sleep and get-up time (get-up time latency, GTL).

Sleep Self Report Questionnairre:

The development of the questions will be part of this research project. The answers to the final questions can be correlated against parameters of the actiwatch. Each item on the questionnaire will be answered for 7 times (7 consequetive days). We will use a weigthed mean of each item in our analysis.

For details, see the questionnaire in the protocol's attachment.

Secondary outcome

inapplicable

Study description

Background summary

Sleep problems are common in people with intellectual disabilities (ID) and could lead to serious physical, mental health or behavioral problems. Early recognition and prevention or treatment of sleep problems is necessary in prevention of secondary health problems and behavioral issues. To assess sleep in people with mild ID, nowadays caregivers should use methods, like polysomnography and actigrapy, that are not always well tolerated by this group and are often expensive and time-inefficient. It would be desirable if sleep assessment can take place by a more easy and feasible instrument like a self-report questionnaire. A sleep- self report questionnaire developed and adapted to cognitive functioning and experience of people with mild ID, might be a helpful tool in the communication between caregiver and patient. For there are no sleep-self-report questionnaires for people with mild ID, we will develop and validate the sleep self- report questionnaire for people with mild ID (SSR-ID).

Study objective

The purpose of this study is to develop a sleep self-report instrument for people with a mild intellectual disability (SSR-ID) and to assess construct validity of the SSR-ID by showing its association with sleep parameters measured by actigraphy.

Study design

We will use an observational study in which a newly developed self-report sleep questionnaire is compared to sleep quality as measured with actigraphy

Study burden and risks

wearing the actiwatch might be experienced as annoying and troublesome for a few people.
Every time the patient wakes up the button should be pushed. For participants that are fully independent, it might be a challenge not to forget to push this button
Daily questionnaires will be filled in by the participants every morning for seven days. This requires several minutes a day and some effort and attention of the participants.
In rare cases, the Actiwatch has caused eczema at the wrist around the device

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 intellectual disability

Exclusion criteria

People with spasms.
people with known destructive behavior directed at property

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-04-2014

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	NL47495.078.14