Optimal vigilance;The influence of learning effects, time of day and napping in between test sessions on the Sustained Attention to Response Task

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The study objective is to assess whether a learning effect, time of day, and the occasion of napping in between tests could influence SART results.

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

Summary

ID

NL-OMON35234

Source
ToetsingOnline

Brief title
SART App's: aspects possibly perturbing the score

Condition

- Other condition

Synonym
NA

Health condition

slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Giften

Intervention

Keyword: Healthy controls, MSLT, Sustained Attention to Response Task, Vigilance

Outcome measures

Primary outcome

SART error score.

Secondary outcome

Errors of commission and omission

Subdividing total error score into errors of commission and errors of omission

is important, as these error types could reflect different cognitive processes.

Reaction time data (mean reaction time, coefficient of variation)

Measuring reaction time data is important because of the so-called

speed-accuracy trade-off.

Study description

Background summary

The Sustained Attention to Response Task (SART) is computerized vigilance task, taking 4:20 minutes to perform. Following a pilot study, the SART has been used in various studies with slightly different study methods in the Leiden University Medical Centre.

Results of these studies pose the question whether SART error score could possibly be influenced by time of day or by the occasion of napping in between tests, and whether there is still a brief learning effect in the first

SART-session.

Study objective

The study objective is to assess whether a learning effect, time of day, and the occasion of napping in between tests could influence SART results.

Study design

Observational study in the Leiden University Medical Centre.

Study burden and risks

Time to proceed through the study is about two hours for each subject. Subjects are free to do whatever they want in 70-90 minutes of these two hours, except sleeping and going outside. The actual study time consists of two SART sessions, and for half of the subjects also an MSLT-session. Eight EEG electrodes measure the occurence of sleep during the two hours of this study. The study does not hurt, takes little time, and does not carry any risks for the participant.

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

Healthy adults aged between 18 and 55, subdivided into four categories matched on age, gender and level of education.

Exclusion criteria

- Complaints of excessive daytime sleepiness.
- Conditions significantly influencing attention and/or sleep.
- An Epworth Sleepiness Scale Score > 10.
- Use of psychotropic medication.
- Being unable to completely understand the informed consent and/or the test instructions.
- Abnormal sleep-wake pattern: frequently a very short nightsleep duration (< 6 hours), whether or not combined with excessive daytime sleepiness; fluctuating bed times (> 2 hours of variation in bed times on 3 or more days a week); shift-schedule workers; travelling trough multiple time zones in the past two weeks.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2012
Enrollment:	80

Type:	Actual

Ethics review

Approved WMO Date:	04-11-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL37732.058.11