Digital Measures of Neuropsychological Tests

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27881

Source
Nationaal Trial Register

Health condition

80 healthy participants and 80 Early Stage Alzheimer Disease (AD) patients.

Sponsors and support

Primary sponsor: Philips Research Eindhoven
Source(s) of monetary or material Support: Philips Research

Intervention

Outcome measures

Primary outcome

The aim of the study is to collect digital data for the (digital) tests that are currently hosted on the Cognitive Dx platform and to use this data to develop and refine the existing algorithms that automatically score the test. The algorithms will be developed and refined based on the manual scores from the neuropsychologist.

Secondary outcome

1.To compare specific digital measures, or combination of digital measures, that are gen-

erated by the algorithms and to discover if these are different for Alzheimer patients as compared to healthy individuals.

2.Evaluate the usability of the digitized test platform in the healthy and AD population

Study description

Background summary

Rationale: There is a need for digital neuropsychological tests. Philips created a digital Cognitive Dx platform with neuropsychological tests that are derived from digitizing existing tests. Digital tests make automatic scoring and analysis possible. In order to exploit the full value to the Cognitive Dx platform we need to develop state-of- the-art algorithms to both automatically detect relevant features but also to classify these and provide automatic scoring.

Objective: The main objective of the study is to collect digital data for the tests that are currently hosted on the Cognitive Dx platform and to use this data to develop and refine the existing algorithms that automatically score the test. Secondary objectives are comparing specific digital measures, or combination of digital measures, that are generated by the algorithms and to discover if these are different for Early Stage Alzheimer Disease (AD) patients as compared to healthy individuals and the evaluation of the usability of the digitized
test platform in the healthy and AD population.

Study design: The digitized tests will be administered to 80 healthy participants and 80 AD patients. The participants will be recruited by the company Silverbrains. They will recruit AD patients and their partner or relative (as healthy participants) from a proprietary database of elderly individuals. The study requires a single home visit with a maximum study duration of 1,5 hour for the partner or relative and 2 hours for the AD patient.

Study population: This study will include 80 healthy participants and 80 Early Stage Alzheimer Disease patients.

Main study parameters/endpoints: The main study parameters are the algorithmic outcome of the automated scoring of the tests and the manual scoring of the tests.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are negligible risks of using the software, Ipad and laptop in the current set up. The research will be performed by a trained psychologist, who has experience in conducting neuropsychological tests with AD patients. The duration of participation is limited to 1,5 hours for the healthy participants and 2 hours for AD patients. To mitigate the risk of fatigue in patients with AD we will split the 2 hours into two equal halves. The patients will rest for 1,5 hours between each halve. There will only be one home visit required. There is no direct benefit to the participants, but they will contribute and enable the development

of
a product which can contribute to the improvements of neuropsychological tests and improve the existing diagnostics of cognition. In conclusion, the risks associated with participation can be considered negligible and the burden minimal.

Study design

Day 1= Day of questionnaire completion

Intervention

The digitized tests will be administered to 80 Early Stage Alzheimer Disease (AD) patients and 80 healthy participants (their partner or relative) and. The study requires a single visit to the patients' home with a maximum duration of 1.5 hour for the partner or relative and 2 hours for the AD patient.

Participants will complete 10 digital neuropsychological tests, the cognitive screening questionnaire and the usability questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, an AD patient must meet all of the following criteria:

1. Aged 60 and older

2. Fluent/correct speaker in Dutch

3. AD patient is able to give consent

4. AD diagnosis by a clinical specialist, such as a geriatrician or neurologist

5. Being able to perform the neuropsychological tests with an Ipad

6. AD patient living at home (not at a nursing home)

7. Date of AD diagnosis < 2yr

In order to be eligible for participation in this study, a healthy participant must meet the following criteria:

1. Partner of relative of a patient with AD

2. Fluent/correct speaker in Dutch

3. Able to provide informed consent

4. Aged 60 and older

Exclusion criteria

A potential AD patient who meets any of the following criteria will be excluded from participation in this study:

1. Unable or incompetent to give written informed consent

2. Severe communication deficits

3. Unable and/or unwilling to use a tablet to perform the tests

4. Medical history of neurological and/or psychiatric disorders (except for AD)

5. Mild Cognitive Impairment (MCI), vascular dementia, frontotemporal or mixed dementia diagnosis

6. Traditional neuropsychological assessment in the last 6 months

7. Bad eyesight or hearing, even with correction

8. Unable to properly use hands

9. An average alcohol consumption of 4 or more units per day

10. Use of one or more of the following types of medicine: antipsychotics, benzodiazepines, antidepressants, opioids, lithium, anti-epileptics, anti- Parkinson medication

11. Use of drugs

A potential healthy participant who meets any of the following criteria will be excluded from participation in this study:

1. Unable or incompetent to give written informed consent

2. Medical history of neurological and/or psychiatric disorders

3. Traditional neuropsychological assessment in the last 6 months

4. Bad eyesight or hearing, even with correction

5. Unable to properly use hands

6. An average alcohol consumption of 4 or more units per day

7. Use of one or more of the following types of medicine: antipsychotics, benzodiazepines, antidepressants, opioids, lithium, anti-epileptics, anti- Parkinson medication

8. Use of drugs

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47745
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6617
NTR-old	NTR6801
CCMO	NL61122.041.17
OMON	NL-OMON47745

Study results