Digital Measures of Neuropsychological Tests in AD patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON47745

Source
ToetsingOnline

Brief title
Digital Measures of Neuropsychological Tests

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's disease, dementia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: automatic scoring, cognitive tests, digital, neuropsychological tests

Outcome measures

Primary outcome

Algorithmic outcome of the automated scoring of the tests mentioned and manual scoring of the tests

Secondary outcome

A list of measures that are significantly different for the two groups and a profile of combined measures that is significantly different for the two groups. Results of the questionnaire and interview of how the system was experienced by the two different groups and a list of recommendations on how the system can be improved for assessing people with Alzheimer*s Disease

Study description

Background summary

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

Study 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 either a proprietary database of elderly individuals or via healthcare institutions that often see AD patients. The study requires a single visit to the patients' home with a maximum study duration of 1 hour for the partner or relative and 2 hours for the AD patient.

Study burden and risks

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.

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

For AD patient:
1. Aged 18 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;For healthy participant:
1. Partner of relative of a patient with AD
2. Fluent/correct speaker in Dutch
3. Able to provide informed consent
4. Aged 18 and older

Exclusion criteria

For AD patient;
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;For healthy participant:
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:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2017
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	07-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27881
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61122.041.17
Other	NTR identificatienummer nog niet toegekend
OMON	NL-OMON27881