

Digital Measures of Neuropsychological Tests

Gepubliceerd: 13-03-2017 Laatste bijgewerkt: 19-03-2025

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27881

Bron

Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Philips Research Eindhoven

Overige ondersteuning: Philips Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

Day 1= Day of questionnaire completion

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 or relative of a patient with AD
2. Fluent/correct speaker in Dutch
3. Able to provide informed consent
4. Aged 60 and older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2017
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	13-03-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47745
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten