Remote assessment of Disease and Relapse - Alzheimer's Disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cranial nerve disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON52829

Source
ToetsingOnline

Brief title
RADAR-AD

Condition

- Cranial nerve disorders (excl neoplasms)

Synonym
Alzheimer's Disease, Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Eli Lilly,IMI,Janssen-Cilag,Novartis,Software AG,Takeda

Intervention

Keyword: Alzheimer's Disease, Digital technology, Remote assessment

Outcome measures

Primary outcome

Difference between healthy volunteers, preclinical AD, MCI due to AD, and mild-to-moderate AD and FTD in outcome measures of ADL using selected RMTs.

Secondary outcome

Difference between healthy volunteers, preclinical AD, MCI due to AD, and mild-to-moderate AD and FTD in the following assessments performed in the clinic or in real-life of the following: 1) difficulties at work; 2) spatial navigation & memory; 3) planning skills; 4) managing finances; 5) self-care; 6) self-management; 7) acquiring new skills; 8) sleep quality and cardiac rhythms; 9) use of technology/devices; 10) dysnomia, word finding difficulties; 11) gait; 12) difficulties driving; 13) interpersonal interaction; 14) motivation, signs of apathy or withdrawal.

Study description

Background summary

Alzheimer*s Disease (AD) is associated with staggering costs and suffering, which are particularly related to the social impacts of caring for increasingly disabled individuals. These functional disabilities can be almost undetectable in the early stages of the disease, worsening over time often and at a varying rate of progression in different people. The measurement of such functional disabilities is typically blunt and relies on direct observation or caregiver recall. Digital technologies, particularly those based on the use of smartphones, wearables and/or home-based monitoring devices, here defined as *Remote Measurement Technologies* (RMTs), provide an opportunity to change radically the way in which functional assessment is undertaken in AD, RMTs

have the potential to obtain better measurements of behavioral and biological parameters associated with individual Activities of Daily Living (ADL) when compared to the current subjective scales or questionnaires. Divergence from normative ADL profiles could objectively indicate the presence of specific functional disabilities even at the very early stages of AD. Therefore, the main hypothesis of this project is that RMTs should allow the detection of impairments in functional component of ADLs that occur below the threshold of clinical scale detection or disability questionnaires.

Study objective

The primary objective of this study is to assess the performance of selected RMTs against standardised rating scales of ADLs in subjects with preclinical AD, MCI due to AD, and mild-to-moderate AD, and FTD. Secondary objectives are, (a) to evaluate associations between RMTs and standard clinical scales used to characterise people with AD diagnosis, (b) to investigate the patient acceptability of selected RMTs used for the duration of the study, and (c) to assess the technical performance of RMTs and digital platform in a real-life setting.

Study design

A multicentre observational cross-sectional cohort digital assessment study. Tier 1 lasts 8 weeks and involves wearable technologies such as smartphones and -watches. Tier 2 lasts 4 weeks and involves fixed sensors at home. Tier 1 and 2 can be in parallel or start after each other. If tier 2 starts after tier 1, the Fitbit will be worn for an additional 4 weeks.

Study burden and risks

Tier 1: subjects will visit the clinic at least twice: once for a baseline visit and once at the end of the study. During these visits, information gathering, clinical profiling, neurophysiological testing and training in the use of RMTs will be performed. Up to three telephone interviews will be held during the study duration of 8 weeks to assess user experience, technical problems with the RMTs and adverse events. The study will not have any direct benefits for participants. Tier 2: participants from tier 1 can participate optionally in tier 2. A house visit will take place in which movement sensors will be installed in the house and in the car. After 2 weeks, a telefphone interview will be held to assesss user experience, technical problems and adverse events. After 4 weeks, another house will will take place to deinstall the devices.

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

All subjects:
- Over 50 years of age
- Study partner available
- In otherwise good health condition or with diagnosis mild chronic disorder or any other affections that are controlled by therapy and/or do not impair function on a secondary basis to that of AD-related symptomatology.
- Subject and study partner own a smartphone

Additional for subjects with Alzheimer's Disease:
- Diagnosis of Alzheimer's Disease based on the presence of amyloid load AD biomarkers
Additional for healthy controls:

- No cognitive deficits at the screening visit

Additional for probable bvFTD (n =15)
- Diagnosis of probable bvFTD based on diagnostic criteria of Rascovsky et al., 2011
- FTDL-CDR (0-1)

Exclusion criteria

- Presence of an additional neurological or psychiatric disease that may affect ADL or social interactions.
- Any other kind of disorders that relevantly affect mobility and/or ADL or social interac-tions

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):	21-08-2020
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO

Date:	14-07-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL70374.029.19