Excitability Modeling And Correction of Hyperactive Brain Networks in Alzheimer*s disease

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56020

Source
ToetsingOnline

Brief title
ExMachina

Condition

- Other condition

Synonym
Alzheimer's dementia, memory loss

Health condition

neurodegenerative disorders, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Alzheimer's, MEG, Modeling, tDCS

Outcome measures

Primary outcome

The main study endpoint consists of MEG-based measures of oscillatory brain activity, functional connectivity and network topology, which indicate the degree of disruption or improvement in brain functioning.

Secondary outcome

Optimal stimulation parameters as determined by the model, and working memory scores.

Study description

Background summary

Improving disrupted brain network function in the early phase of Alzheimer*s disease (AD) may reduce cognitive impairment, but human brain networks are highly complex, dynamic, and patient-specific. This project will combine computational modelling with brain stimulation and simultaneous measurement of brain network activity to find optimal, personalised strategies for preserving cognition in AD. Brain activity-targeting treatment development will become more efficient and faster, and will reduce patient burden because of a more rational, patient-specific intervention selection. This unique approach will also contribute to a better understanding of disrupted brain activity in early AD, to the desired further integration of neuroscience and computer modelling, and to uniting fundamental and clinical researchers by offering an integrated simulation/stimulation framework.

Study objective

The overall objective is to perform simulations in a computer model of the human brain to map out the optimal parameters for non-invasive brain stimulation in AD. Simulations will be performed in both general and personalised models, the latter using patient-specific models based on functional and structural connectivity results from their magnetoencephalography (MEG) scans during clinical screening. Model predictions will then be verified via simultaneous brain imaging during stimulation. The hypothesis is that the stimulation will improve measures of brain network function.

Study design

A cross-sectional, sham-controlled simulation and intervention study.

Intervention

One intervention session using transcranial direct current stimulation (tDCS) with a simultaneous MEG recording.

Study burden and risks

MEG recording is non-invasive and involves lying in a supine position in a shielded room. The recording procedure is not painful in any way, is not considered to be difficult or stressful (except for patients with extreme claustrophobia), and has negligible risks. There is no individual benefit from the MEG. Brain stimulation using tDCS is non-invasive and uses very low (up to 2 mA) currents, therefore posing no risk. Possible transient side effects include tingling on the scalp, dizziness or sensation of phosphenes at the onset and outset of stimulation. There are clinical benefits associated with tDCS, for example in the treatment of depression, but benefits are yet to be fully established in AD.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria: fulfilling the diagnostic criteria for probable AD; between 50-80 years of age; known amyloid status.

Additionally, a signed informed consent for Amsterdam Dementia Cohort (ADC) (P2016.061) or AHR (P2016.409) is required.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: cardiac pacemakers, ICD's and other intracorporeal devices or medication interfering with MEG-signals; severe claustrophobia.

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-06-2023
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	NuroStym Transcranial direct current stimulation device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-09-2023
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	NL81479.029.22