Memory enhancement using transcranial alternating current stimulation

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Transiently improve episodic memory in early AD patients with precuneal gamma (40 Hz) tACS (main objective) and identify what functional brain activity/network changes underlie this memory improvement (secondary objective)

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

Summary

ID

NL-OMON56846

Source
ToetsingOnline

Brief title
Memento

Condition

- Other condition

Synonym
amnestic mild cognitive impairment, memory impairment

Health condition

neurodegeneratieve aandoeningen, dementie

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Alzheimer Nederland

Intervention

Keyword: Alzheimer's disease, Episodic memory, MEG, tACS

Outcome measures

Primary outcome

Change in episodic memory task score (Rey Auditory Verbal Learning test total

and long delayed recall score (a) and Face-Name Association Task score (b))

from before to after tACS

Secondary outcome

Canges in brain (network) activity from before to after tACS

Study description

Background summary

The 32 million Alzheimer*s disease (AD) and 69 million prodromal AD patients worldwide contribute to a large economic burden. Effective and safe therapies that slow or prevent the progression from mild cognitive impairment (MCI) to AD are therefore of high priority. Transcranial alternating current stimulation (tACS) is a safe and patient-friendly non-invasive brain stimulation technique that serves as a potential candidate for reducing and/or slowing cognitive impairment. Application of tACS in the gamma frequency range, specifically around 40 Hz, has been studied in patients with AD and MCI due to AD. In these patients, a single session of 40 Hz tACS at the precuneus showed to improve episodic memory, and to increase gamma power, as measured with electroencephalography. These findings will be replicated in the current study in patients with MCI due to AD, using magnetoencephalography (MEG) recorded before, during and after tACS. In this way, brain activity and network changes that underlie this improvement in episodic memory can be studied with greater temporal and spatial detail.

Study objective

Transiently improve episodic memory in early AD patients with precuneal gamma (40 Hz) tACS (main objective) and identify what functional brain activity/network changes underlie this memory improvement (secondary objective)

Study design

A double-blind, randomized, sham-controlled, cross-over trial with concurrent tACS-MEG

Intervention

Gamma (40 Hz) and sham tACS at the precuneus region for 48 minutes

Study burden and risks

Skin irritation and a tingling of slight burning/itching sensation on the scalp at the start and end of stimulation as common side effects of tACS. These side effects are transient and actions are taken to minimize their occurrence as much as possible. The risk of inducing an epileptic seizure remains negligible. Transient improvements in episodic memory and underlying brain network activity are expected in the participants after active stimulation. Importantly, more knowledge about the working mechanisms of the cognitive deficits in early AD and possible treatment options is obtained by this study. Thus, the potential benefits outweigh the negligible risks.

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

Recent (not more than 6 months ago) amnestic mild cognitive impairment diagnosis, corroborated by abnormal ratio of phosporylated tau and beta-amyloid-42 ratio (of >0.023).
Additionally, a signed informed consent for the Amsterdam Dementia Cohort (P2016.061) is required.

Exclusion criteria

Suffering from serious neurological, psychiatric or somatic comorbidity.
Suffering from epileptic seizures or severe claustrophobia.
Intensive use of psychoactive medication.
Having a cardiac pacemaker, internal cardiac defibrillator or other intracorporeal device that interferes with MEG-recordings.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2024
Enrollment:	27
Type:	Actual

Medical products/devices used

Generic name:	NuroStym transcranial alternating current device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-04-2024
Application type:	First submission
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
ClinicalTrials.gov	NCT06202872
CCMO	NL85863.018.23