Investigating the neural correlates of repeated tDCS in MCI and healthy ageing with fMRI

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON43086

Source
ToetsingOnline

Brief title
Neural correlates of repeated tDCS

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's disease; dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO/DFG

Intervention

Keyword: functional connectivity, memory, neuroplasticity, tDCS

Outcome measures

Primary outcome

The main outcome measures are the Blood Oxygenation Level Dependent (BOLD) reflecting brain activity during the functional task and functional connectivity changes reflecting network integrity.

Secondary outcome

Secondary study parameters are performance on a pattern separation episodic memory task (accuracy and reaction times). Performance on the task will be correlated with BOLD-signal per session.

Study description

Background summary

Healthy ageing and pathological ageing in the context of a neurodegenerative disease are both associated with changes in brain network integrity. Episodic memory is especially affected in Alzheimer*s disease, but is also decreased in healthy ageing. Consequently, the memory-relevant brain networks are especially altered. Transcranial direct current stimulation (tDCS) has previously been implemented in different clinical- and non-clinical settings and has shown to beneficially influence network connectivity. The neural correlates of single-session tDCS have been investigated, however, the neural effects of repeated tDCS remain unknown. Furthermore, knowledge about the (long-term) neural mechanisms of repeated tDCS can give valuable insights and possibly pave the ground for exploring tDCS as a treatment option in future studies.

Study objective

Our objective is to use magnetic resonance imaging (MRI) to investigate the neural changes after repeated transcranial direct current stimulation during an episodic memory task in patients with mild cognitive impairment and in healthy

age-matched controls. A secondary objective is to investigate whether the observed neural changes after stimulation correlate with behavioural changes on an episodic memory task.

Study design

This is an experimental MRI study with a double-blind randomised design.

Intervention

Participants will receive either active tDCS or sham tDCS on five consecutive days. Participants and the experimenter will be blind to the stimulation condition. Participants are randomly assigned to a stimulation condition.

Study burden and risks

The expected risks and burden are expected to be minimal, since strict inclusion and exclusion criteria for participation in the MRI and non-invasive brain stimulation procedure are maintained. Participants will complete a standard medical questionnaire that screens for contraindications. When included, the burden and risks associated with this study involves the participation in 7 sessions on 7 separate days, of which three sessions can be carried out at the participant*s home (total duration: 10,5 hours). The first day will start with the administration of several neuropsychological tests and questionnaires (60 minutes) and a training session in a dummy scanner (30 minutes). On the second, sixth and seventh day, patients will be scanned in the MRI scanner for 1 hour. MRI is a non-invasive method and the risks are negligible (temporary dizziness in some individuals). On the third to fifth day the participants will perform an episodic memory task at home or at the university with concurrent active tDCS. TDCS is a safe and well tolerated non-invasive brain stimulation method. No complications have been reported. Some individuals report a tingling sensation on the skin where the electrodes are placed, in rare cases skin irritation has been reported. The risks are thus minimal.

Contacts

Public
Universiteit Maastricht

Dr Tanslaan 12
Maastricht 6229ET
NL
Scientific

Universiteit Maastricht

Dr Tanslaan 12
Maastricht 6229ET
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients
- Diagnosis of MCI based on the latest research criteria (clinical assessment at the memory clinic (prof. Frans RJ Verhey): presence of at least a memory impairment, memory complaints expressed by the patient or informant, no problems in daily life functioning, no dementia and presence of biomarkers (Albert et al., 2011)
- Clinical Dementia Rating score of 0.5 (CDR distinguishes a stage of questionable dementia (CDR 0.5) from people termed healthy (CDR 0) and those with mild dementia (CDR 1)
- Mini-Mental State Examination (MMSE) 23 and being mentally competent (in general, individuals with a MMSE 18 are considered mentally competent)
- Age: between 60 and 85 years old
- 50% female
- Right-handedness
- Average level of education (CBS level 3-4-5-6);Healthy controls
- Average neuropsychological test results, in accordance with normative data, corrected for age, education and gender
- No substantial memory complaints (according to the participant)
- Age: between 60 and 85 years old
- 50% female
- Right-handedness
- Average level of education (CBS level 3-4-5-6)
- Normal or corrected to normal vision

Exclusion criteria

- Psychoactive medication use
- Abuse of alcohol and drugs
- Cognitive impairment due to alcohol/drug abuse or abuse of other substances
- Past or present psychiatric or neurological disorders (major depression, schizophrenia, bipolar disorder, psychotic disorder (or treatment for it), epilepsy, stroke, Parkinson*s disease, multiple sclerosis, brain surgery, brain trauma, electroshock therapy, kidney dialysis, Menière*s disease, brain infections)
- Major vascular disorders (e.g. stroke)
- Heart diseases or pacemakers
- Contraindications for scanning (e.g. brain surgery, cardiac pacemaker, metal implants, claustrophobia, body tattoos)
- Large scars or fresh wounds on the scalp

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	15-02-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL57751.068.16