Improving cognitive performance in MS by transcranial alternating current brain stimulation (tACS): a pilot study

Published: 19-06-2017
Last updated: 13-05-2024

Here we will test the hypothesis that tACS (theta-tACS at 6 Hz) will enhance brain synchrony in MS patients, thereby improving their cognitive functioning. We further want to achieve the increase in fronto-temporal brain synchronization measured by...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON49662

Source
ToetsingOnline

Brief title
Cognitive function in MS after tACS

Condition

- Neurological disorders NEC

Synonym
cognitive impairment, MS, nervous system

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: For pilot study by Stichting MS Research;16-949-MS;to B. Curcic-Blake for project entitled:"Improving cognitive performance

in MS by transcranial alternating current brain stimulation (tACS); proof of concept"

Intervention

Keyword: cognition, MS, tACS

Outcome measures

Primary outcome

The changes in EEG coherence and in speed of information processing in patients

with MS using tACS.

EEG coherence will be estimated between frontal and parietal regions from RS

EEG recordings. The information processing speed will be measured using the

Vienna Reaction Time Task (VRTT).

Secondary outcome

n.a.

Study description

Background summary

Mild to severe cognitive impairment in MS is widespread (45-70 %) and highly detrimental to quality of life. Minimizing cognitive decline, which is due to the deterioration of brain connections involved in cognitive processing, will thus be of great benefit. Current treatment does not target affected brain connections directly and involves long and intensive cognitive training in the clinic, presenting a heavy burden to patients. Therefore, an alternative treatment that would speed up or replace the cognitive training would decrease the load on patients and make treatment more feasible.
Transcranial alternating current stimulation (tACS) is a novel treatment modality that directly influences brain oscillations and thereby increases cognitive performance and speed of processing in healthy volunteers. tACS application and safety procedures are the same as the transcranial direct current stimulation (tDCS) that is already used in clinical trials of psychiatric patients within our group at the UMCG. tACS has also been successfully applied in neurological patients (e.g. Mild Cognitive impairment and Alzheimer*s disease). Furthermore, tACS can be delivered in patients*

homes, and potentially by remotely controlled self-treatment. tACS has not yet been investigated in MS patients, likely since it is relatively novel (<10 years) and requires knowledge of brain oscillations and connectivity. Due to brain lesions in MS patients, the question is if tACS can deliver any effect in these patients.

Study objective

Here we will test the hypothesis that tACS (theta-tACS at 6 Hz) will enhance brain synchrony in MS patients, thereby improving their cognitive functioning. We further want to achieve the increase in fronto-temporal brain synchronization measured by EEG induced by the tACS.

Study design

Participants in the study will be randomly assigned to one of the two groups. One group will receive real brain stimulation (tACS) and the second group will receive sham stimulation (sham tDCS). Before brain stimulation, participants will undergo an EEG and MRI scanning session. EEG will be recorded for 10 minutes: patients will rest with their eyes open. During MRI, we will collect various anatomical brain measures such as anatomical MRI, Diffusion tensor imaging (DTI), magnetic transfer ration (MTR) and functional resting state (RS). Prior to the stimulation, participants will also fill in a few questionnaires and perform cognitive tests. During tACS patients will perform a cognitive task that enhances the effect of stimulation. The stimulation will be repeated for 3 consecutive days. After the last tACS session, patients will repeat the EEG RS recording and cognitive tests.
Healthy controls will undergo 1 MRI scan, 2 EEG recordings, 1 NPE and VRTT, and 1 tACS session. Resting state EEG will be measured immediately before and after the tACS.

Study burden and risks

Participants in the study will go through 5 steps that will take place across five or six consecutive days. The initial step will be NPE testing (60 minutes). If the patients fulfill CI criteria, she/he will undergo the second step a pre-stimulation EEG measurement and an MRI scanning session. The EEG session will last 10 minutes (including twenty minutes preparation time, total 30 minutes). The MRI session will last for ~ 40 minutes. After the MRI, participants will fill perform cognitive Vienna reaction time task. This takes 14 minutes. On the third and the fourth day, participants will undergo brain stimulation (tACS or sham tDCS). The stimulation session will last 25 minutes (preparation: 10 minutes, stimulation: 15 minutes). On the 5th day, participants will undergo the brain stimulation followed by brief EEG recording, VRTT and NPE. If patients express that the second step or the final step last too long, we might split it in two days, or for example couple the

pre-stimulation EEG session with the first day of stimulation. This will be adjusted solely to decrease the burden to patients as much as possible. It is important to measure the post-stimulation EEG and the VRTT immediately after the last stimulation thus the final tACS has to be coupled with the post-stimulation VRTT and EEG.
The experiment will not involve more than minimal risks for the participants. MRI is a standard brain imaging technique with no known negative effects on health. The only risks are for subjects with cardiac pacemaker and metal implants. These individuals will not be allowed to participate. In terms of burden, MRI involves lying still in a confined environment during one hour. In addition, during data acquisition, the MRI scanner makes a loud noise, and although participants are provided with earplugs, the residual noise can be a burden for some individuals.
During the tACS procedure participants are exposed to a very low electrical current of 2 mA. The use of tACS to date has not resulted in adverse effects, apart from mild headache or a mild tingling sensation underneath the electrodes. Finally, EEG involves a measurement of brain currents and is not associated with any contraindication.
Healthy participants will undergo 1 MRI and 2 EEG sessions, 1 NPE and VRTT, and 1 tACS session.

Contacts

Public
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 2 Ant. Deusinglaan 2
Groningen 9713 AW
NL
Scientific
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 2 Ant. Deusinglaan 2
Groningen 9713 AW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

MS Patients:
Diagnosis of MS according to the MacDonald criteria
Age: 30 - 60 years
Cognitive impairment (CI): CI patients will have decreased values (1.5 standard deviations below the normative control values or below cut-off value for deviation) on at least 2 tests from NPE battery.
Signed written informed consent and right handedness.
Healthy participants:
Age: 30 - 60 years
Signed written informed consent and right handedness.

Exclusion criteria

1. History of psychiatric or neurological illness other than MS for MS patients or History of psychiatric or neurological illness for healthy participants
2. Metal implants (e.g., pacemaker, heart valves, vascular clips, eye-implants, copper containing intra-uterine devices, non-removable piercing, cerebral implants)
3. Any risk of having metal particles in the eyes
4. Tattoos containing iron oxide (often found in red pigments)
5. (Suspected) Pregnancy or breast feeding
6. Claustrophobia
7. Alcohol or drug abuse
8. Excessive intake of coffee (>5 units per day) or alcohol (>2 units per day);
9. Recent use of alcohol (2 days before the EEG and/or fMRI measurement).
10. Recent use (within one week) of cannabis, benzodiazepine, baclofen or any other nonprescription psychopharmaca;
11. Refusal to be informed of structural brain abnormalities that could be detected during the experiment
12. Diagnosis of epilepsy, Parkinson*s disease, Myasthenia Gravis, epilepsy and dementia.
13. Severe scalp skin lesions
14. Color blindness

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2017
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	19-06-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-04-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL60761.042.17