# Modulating connectivity with noninvasive brain stimulation during spatial neglect rehabilitation

Published: 19-02-2020 Last updated: 10-04-2024

To investigate whether the application of dual-site tACS during cognitive training ameliorates spatial neglect symptoms to a larger extent than the application of sham stimulation during cognitive training.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

# Summary

### ID

NL-OMON52644

**Source** ToetsingOnline

**Brief title** Brain modulation during neglect rehabilitation / ModNeglect

# Condition

• Central nervous system vascular disorders

# **Synonym** obstruction of a blood vessel or bleeding in the brain, stroke

### **Research involving**

Human

# **Sponsors and support**

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

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### Intervention

Keyword: Neglect, Non-invasive brain stimulation, Rehabilitation, Stroke

#### **Outcome measures**

#### **Primary outcome**

To investigate whether the application of dual-site transcranial alternating current stimulation during cognitive training improves spatial neglect symptoms to a larger extent than the application of sham stimulation during cognitive training.

#### Secondary outcome

To investigate whether the application of dual-site transcranial alternating current stimulation during cognitive training ameliorates neglect behaviour in activities of daily living (ADL) to a larger extent than the application of sham stimulation during cognitive training.

# **Study description**

#### **Background summary**

Hemispatial neglect is a common symptom in stroke patients and is marked by the inability to attend to the contralesional side of space. The standard cognitive training for neglect in the subacute phase of stroke is visual scanning training (VST). However, VST requires many sessions to have a long-lasting effect. Here, we aim to increase the effectiveness of VST by applying transcranial Alternating Current Stimulation (tACS) to the frontoparietal attention network in patients with neglect following subacute stroke.

#### **Study objective**

To investigate whether the application of dual-site tACS during cognitive training ameliorates spatial neglect symptoms to a larger extent than the application of sham stimulation during cognitive training.

#### Study design

Double-blind randomized placebo-controlled intervention study. After enrolment and completion of baseline measurements, patients are randomly assigned to either the active tACS group or sham (control) group.

#### Intervention

We will combine an evidence based VST with 30 minutes of (active or sham) dual-site tACS at theta frequency. The intervention is administered 5 times a week for a duration of 2 weeks.

#### Study burden and risks

The risks of tACS are very small. The occurrence of any severe adverse consequence of this intervention on stroke recovery has never been reported in any clinical transcranial electrical stimulation (tES) study so far. Only minor side effects of tES such as a slight tingling or itching sensation at the stimulation site that disappears within the first minutes have been reported by participants. Other minor side effects include a burning sensation, mild headache, nausea, and fatigue.

Concerning benefits associated with participation, we expect an improvement of neglect-related symptoms and neglect behaviour in daily life situations after 10 sessions of VST with tACS treatment compared to sham stimulation. Concerning discomforts, a conductive paste is applied to the tACS to stick them to the scalp of the patient. After the session has ended the patient will be given the opportunity to wash his/her hair.

# Contacts

**Public** Universiteit Maastricht

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

**Age** Adults (18-64 years)

### **Inclusion criteria**

- 30-80 years of age

- Subacute stroke (stroke occurred more than 2 weeks and less than 6 months ago; first or recurrent, ischemic or intracerebral haemorrhagic lesion)

Diagnosed visuospatial neglect and/or spatial neglect symptoms (either left or right sided) on the basis of clinical judgement (i.e. by the cooperating clinical (neuro)psychologist based on intake and neuropsychological assessment).
Sufficient comprehension and communication skills to benefit from training, on the basis of clinical judgement

(i.e. by the cooperating clinical (neuro)psychologist based on intake and neuropsychological assessment).

# **Exclusion criteria**

- Physically or mentally unable to participate (e.g. to perform the neglect training)

- Severe communicative disability, including aphasia
- Local scalp injuries
- Eczema on scalp or psoriasis

- (Neuro)psychiatric or neurodegenerative diseases including epilepsy (in case patient had one or more seizures in the last 2 years and/or had anti-epileptic medication in the last 2 years), dementia, serious depression, multiple sclerosis, Parkinson\*s disease, Huntington\*s disease on the basis of clinical judgement (i.e. cooperating (neuro)psychologist)

- Current alcohol and/or drug abuse or a history of abuse within the last 6 months

- Pregnancy

# Study design

# Design

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

# Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	09-04-2021
Enrollment:	40
Туре:	Actual

# Medical products/devices used

Generic name:	Transcranial Alternating Current Stimulator
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO	
Date:	19-02-2020
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** CCMO Other **ID** NL71371.068.19 NL8145