Rebalancing the brain with non-invasive brain stimulation during stroke recovery

Published: 30-12-2014 Last updated: 20-04-2024

Investigating the effectiveness of tCS on the recovery of neglect in sub-acute ischemic stroke patients suffering from neglect to complement conventional treatment

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON40140

Source ToetsingOnline

Brief title StrokeRebal

Condition

· Central nervous system vascular disorders

Synonym

obstruction of a bloodvessel or bleeding in the brain, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: EU;ERC starting grant by Prof. Dr. Alexander Sack

Intervention

Keyword: Neglect, Non-invasive brain stimulation, Stroke, Transcranial current stimulation

Outcome measures

Primary outcome

Performance on standard neuropsychological tests as assessed prior to, during

and immediately following tCS intervention.

Secondary outcome

None

Study description

Background summary

Stroke is a leading cause of neurological impairments in motor functions, attention, or language. In the Netherlands each year 40.000 people suffer a stroke and approximately 0.8% of the general population in the Netherlands lives with the consequences of stroke. Hemispatial neglect is a common consequence of unilateral brain damage, occurring in approximately 30% of stroke-affected individuals, with the prevalence increasing substantially if the right hemisphere is affected (Corbetta, Kincade, Lewis, Snyder, & Sapir, 2005). Individuals with neglect syndrome demonstrate failure to attend or respond to items in their contralateral side of space. Neglect has been demonstrated as an important prognostic component for stroke recovery, with cognitive impairment up to three times more common for individuals suffering from severe neglect, suggesting a need for early rehabilitation of neglect symptoms in stroke-affected individuals (Johansson, 2011). Current therapeutic interventions try to reduce stroke-related symptoms by pharmacological, physical, and occupational therapy. Over the last twenty years, cognitive neuroscience has gained key insights into the workings of the brain. Implementing this knowledge into stroke rehabilitation offers the potential to enhance effectiveness of treatment and thus improves patients* guality of life and reduces the burden on social health care systems.

Study objective

Investigating the effectiveness of tCS on the recovery of neglect in sub-acute ischemic stroke patients suffering from neglect to complement conventional

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treatment

Study design

The current study will use tCS as a potential neglect rehabilitation treatment. Every patient will first receive a baseline measurement to reliably assess his/her performance level in a neuropsychological test battery. After that, the experimental treatment will start. The treatment will exist of 2 sessions of non-invasive neuromodulation for every patient: tCS treatment and placebo treatment. At the beginning of each session, patients will perform a neuropsychological task battery together with a computerized computerised Visual Detection Task (CVDT). Then they will receive real or placebo tCS whilst performing the CVDT. After the stimulation, there will be 3 post measurements consisting of neuropsychological and computerized tasks, namely right after stimulation, 20 minutes after stimulation and 40 minutes after stimulation. One day later, they will do the second treatment session, where they again receive either real of placebo tC stimulation. The order of the sessions will be counterbalanced, where one half of the patients will start with the tCS treatment and the other half with the placebo treatment. Patients will thus have three sessions. In one session, the severity of their neglect is determined with the help of a neuropsychological test battery. The first session will last no longer than 1 hour. The other two sessions will both last about 2 hours. The total time investment is thus 5 hours.

Study burden and risks

The participants may potentially have direct benefit from the project. All patients will be offered the standard revalidation programme in the rehabilitation centre.

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determined with the help of a neuropsychological test battery. The first session will last no longer than 1 hour. The other two sessions will both last about 2 hours. The total time investment is thus 5 hours. The occurrence of any negative consequences of the tCS intervention on stroke recovery has never been reported in any clinical tCS study so far.

Contacts

Public Universiteit Maastricht

Oxfordlaan 55 Maastricht 6229EV NL **Scientific** Universiteit Maastricht

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- * Age ><= 18 years
- * Subacute stroke
- * Spatial neglect symptoms on the left visual field
- * Feasible to start a rehabilitation therapy

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Exclusion criteria

- * Severe communicative disability
- * History of epilepsy
- * Local scalp injuries
- * Excema on scalp
- * Pregnancy
- * Known psychiatric diseases including dementia
- * Known history of alcohol and/or drug abuse

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2015
Enrollment:	30
Туре:	Actual

Medical products/devices used

Generic name:	Transcranial current stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMODate:30-3Application type:First

30-12-2014 First submission

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Review commission:

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 **ID** NL47215.068.14