The effect of transcranial direct current stimulation on processing speed in patients after ischemic stroke

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To evaluate the effects of tDCS on information processing speed in comparison to sham tDCS in patients after stroke with ascertained reduced processing speed. A proof of principle study.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON43023

Source
ToetsingOnline

Brief title
tDCS and processing speed in chronic stroke

Condition

- Structural brain disorders

Synonym
CVA, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Klimmendaal
Source(s) of monetary or material Support: door de instelling zelf.

Intervention

Keyword: ischemic stroke, non-invasive brain stimulation (NIBS), processing speed, rehabilitation

Outcome measures

Primary outcome

Primary research outcome: reaction time measured during a test of attentional performance (TAP-test) which consists of a divided attention task and a go - no go task at two different levels.

Secondary outcome

Secondary outcome: differences in performance of time pressure activities in normal life and the perceived consequences of slow information processing speed before and after tDCS measured by the mental slowness observation test (MSOT) and mental slowness questionnaire (MSQ).

Study description

Background summary

Cognitive deficits are common after stroke. There is evidence from the scientific literature to suggest that transcranial direct current stimulation (tDCS) can enhance cognitive functioning and thereby ameliorate the outcome of the rehabilitation of cognitive deficits. tDCS is a non-invasive and safe brain stimulation method that applies weak direct currents (1-2 mA) to the brain through electrodes applied to the skull to influence cortical excitability levels. The aim of this study is to test the hypothesis that tDCS as compared to sham tDCS will enhance reaction times in patients with reduced processing speed after stroke.

Study objective

To evaluate the effects of tDCS on information processing speed in comparison to sham tDCS in patients after stroke with ascertained reduced processing

speed. A proof of principle study.

Study design

A randomized sham-controlled double blind within subjects design.

Intervention

tDCS will be delivered by a battery-driven constant DC current stimulator (Eldith DC Stimulator (CE 0118), Ilmenau) using two 5-7 cm electrodes (35 cm2) and one 10-10 cm return electrode (100 cm2) in saline-soaked synthetic sponge at an electric current intensity of 1 mA (peak-to-peak) for a maximum of 20 minutes.

Study burden and risks

The currently proposed tDCS procedure and experiment does not carry any significant risks. Potential side-effects of tDCS are light tingling, itching or burning sensations under the electrodes, light headache and/or fatigue. These are mild discomforts that respond promptly to common analgesics. Volunteers can withdraw from the study at any given time and there are no direct benefits for the participants. The novel insights will broaden our understanding of the brain and may contribute to the feasibility and development of possible new ways to improve reaction time using non-invasive brain modulation.

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

• Between 18 - 65 years of age
• Ischemic cerebral infarction
• Postonset of > 4 months (chronic stage)
• Reduced processing speed as assessed by neuropsychological assessment
• Willingness and ability to give written informed consent and willingness and ability to understand the nature and content, to participate and to comply with the study requirements.

Exclusion criteria

• History of previous stroke
• Pre-existent cognitive problems
• Severe aphasia (unable to understand instructions)
• Neglect
• Hemianopia
• Average use of more than 3 alcoholic beverages daily
• Use of psychotropic medication or recreational drugs
• Skin disease
• Pregnancy
• Serious head trauma or brain surgery
• Neurological or psychiatric disorders (other than stroke)
• Large or ferromagnetic metal parts in the head (except for a dental wire)
• Implanted cardiac pacemaker or neurostimulator
• Somatic symptom and related disorders

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	transcranial direct current stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-04-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56869.091.16