Optimizing Transcranial Direct Current Stimulation for Motor Learning

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Identify the effect of tDCS parameters on motor learning in healthy individuals by measuring effects on visuomotor adaptation rate and retention, and study the influence of a common BDNF mutation.

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

Summary

ID

NL-OMON38970

Source
ToetsingOnline

Brief title
Optimizing tDCS for Motor Learning

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Motor learning, tDCS, Visuomotor adaptation

Outcome measures

Primary outcome

The main objective of the study is to determine the effect of different tDCS parameters on motor learning in healthy individuals. As a paradigmatic motor learning task, we will use a well-described visuomotor adaptation paradigm during reaching movements. During these fast reaching movements, an unexpected 30-degree rotation is introduced which requires subjects to learn a new visuomotor transformation. Visuomotor adaptation performance will be quanti*ed in each trial using the angular end point error, de*ned as the angle between the line connecting the starting position to the center of the target and the line connecting the starting position to the end point. Retention will be quantified as the rate of deadaptation without visual feedback. Thus, the goal of the study is to define specific parameters of tDCS stimulation that obtain the optimal stimulation configuration for achieving rapid adaptation and extended retention.

Secondary outcome

To determine the main effect of each of the (isolated) tDCS parameters on motor learning in healthy individuals with regard to visuomotor adaptation rate and retention.

To determine if interactions are present between the different tDCS parameters with regard to visuomotor adaptation rate and retention in healthy individuals.

To determine the size of the interaction effects with regard to visuomotor adaptation rate and retention in healthy individuals.

To determine if the presence of a common BDNF mutation modifies the effect of tDCS on visuomotor adaptation rate and retention.

To determine the main effect of the BDNF mutation on motor learning with regard to visuomotor adaptation rate and retention.

To determine the wash-out period (period of time in which the effects of tDCS are still present without stimulation) for tDCS effects on motor learning in healthy individuals with regard to visuomotor adaptation rate and retention.

Study description

Background summary

About 80% of stroke patients suffer motor impairments. The first months of rehabilitation are critical to regain motor function and avoid limitations in mobility. Therefore, optimizing the effects of early motor therapy in stroke patients is crucial for their quality of life. Transcranial Direct Current Stimulation (tDCS) is a form of non-invasive electrical stimulation where a weak current is applied through electrodes over the scalp. This stimulation is known to induce changes in neuronal excitability in a polarity and site-specific manner, and facilitate motor and cognitive learning. Evidence is accumulating that it can have a positive effect on stroke recovery. However, there is great variability in the details of how tDCS is applied. These details include the precise geometry of the stimulating electrodes, electrode placement, stimulus amplitude and duration, and the number and frequency of sessions. None of these variables have been either standardized or carefully explored. In addition, there is increasing evidence that the effect of tDCS is modified by a very common BNDF mutation that affects approximately 30% of the population. Thus, our study proposes to vary the different tDCS variables in a

controlled manner and to test the efficacy of tDCS under different stimulus configurations. The outcome of this study can provide important guidelines on effective motor therapy during stroke rehabilitation.

Study objective

Identify the effect of tDCS parameters on motor learning in healthy individuals by measuring effects on visuomotor adaptation rate and retention, and study the influence of a common BDNF mutation.

Study design

Double-blinded, randomized within-subjects trials

Intervention

Subjects receive real or sham tDCS over the motor cortex or cerebellum for at most 30 minutes with an intensity up to 2mA.

Study burden and risks

Subjects are asked to provide a sputum sample for BDNF analysis and have to visit the Erasmus Medical Centre up to 6 times for visuomotor experiments. Each session will take up to 80 minutes. During each session, subjects will receive real or sham stimulation over the motor cortex and/ or cerebellum. tDCS is reported to be safe; side effects are mild. There will be financial compensation for expenses related to participation.

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

Healthy
Aged 18-55

Exclusion criteria

History of neurological or psychiatric disorders
History of neurosurgery
Taking acute or chronic psychoactive drugs
Alcoholism

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-08-2014
Enrollment:	330
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	14-01-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL46430.078.13