Improving transcranial direct current stimulation by targeting the motor network

Published: 27-03-2018
Last updated: 10-04-2024

To investigate if conventional tDCS can be improved by using a new electrode configuration. To find a relation between ongoing EEG and MEP magnitude. To investigate the effect of tDCS on cortical excitability (measured with TMS), brain activity (...

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

Summary

ID

NL-OMON48855

Source
ToetsingOnline

Brief title
Motor network tDCS

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: STW,Rijndam Revalidatie,Rijndam Revalidatie;TMSi,TMSi

Intervention

Keyword: EEG, Motor learning, tDCS, TMS

Outcome measures

Primary outcome

Participant 1 to 20:

To explore what type of brain activity is related to motor learning and what activity is related to simple motor action.

Participant 21 to 55:

The main objective of the study is to reproduce the findings of Fischer et al. (2017), who demonstrated that stimulating the M1 motor network increases the cortical excitability, assessed with TMS. Participants will receive all three types of stimulation (conventional, motor network and sham network), separated by at least 48 hours, for 10 minutes. Transcranial magnetic stimulation (TMS) will be applied to assess cortical excitability at fixed time points after stimulation. The average cortical excitability will be compared between conditions at all time points.

Participant 56 to 105:

The main objective of the study is to investigate the influence of transcranial direct current stimulation (tDCS) on brain activity. Participants will receive all three types of stimulation (conventional, motor network and sham network). Participants will be asked to execute a motor learning task before, during and after brain stimulation. During the motor learning task, brain activity will be

measured by using electroencephalography (EEG). Before and after the motor learning task, brain activity at rest will be measured. The three sessions will be separated by at least 48 hours. The influence of tDCS will be investigated by comparing brain activity before and after tDCS.

Secondary outcome

Participant 21 to 55:

To assess correlation between pre-TMS cortical activity (measured with EEG) and TMS amplitude (TMS/EMG). To assess the relation between tDCS-induced changes in TMS excitability and EEG signals.

Participant 56 to 105:

To investigate the influence of transcranial direct current stimulation (tDCS) on motor learning.

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, optimising 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 electric stimulation where a weak current is applied through electrodes on the scalp. The effectiveness and working mechanism of tDCS is not yet completely known, but numerous studies demonstrate positive effects on cortical excitability and motor learning.

Recently, a multi-electrode array to stimulate the entire motor network was proposed and found to introduce higher motor evokted potential amplitudes than the conventional way of stimulation. In the present study, we would like to reproduce these results in a larger sample of the healthy population. Additionally, we would like to investigate the relation between background

cortical activity and the magnitude of the cortical excitability. Furthermore, we would like to investigate the effect of tDCS on brain activity and motor learning. The study will give guidelines on the steps to take to improve the effectiveness of tDCS in motor recovery after stroke.

Study objective

To investigate if conventional tDCS can be improved by using a new electrode configuration. To find a relation between ongoing EEG and MEP magnitude. To investigate the effect of tDCS on cortical excitability (measured with TMS), brain activity (recorded with EEG) and motor learning.

Study design

Single-blinded, randomised repeated-measures design

Intervention

Participant 21 to 55: Subjects receive conventional, motor network or sham network tDCS over the motor cortex for 10 minutes at an intensity of no more than 2 mA per electrode and at most 4 mA in total in the sessions where cortical excitability is assessed. Subjects receive conventional, motor network or sham network tDCS over the motor cortex for 10 minutes at an intensity of no more than 2 mA per electrode and at most 4 mA in total.

Participant 56 to 105:
Subjects receive conventional, motor network or sham network tDCS over the motor cortex for 10 minutes at an intensity of no more than 2 mA per electrode and at most 4 mA in total.

Study burden and risks

Participant 1 to 20:
Participants are asked to visit the Erasmus MC once for 2.5 hours. During the experimental session, EEG and EMG are applied, after which test subjects perform the motor task for about 90 minutes. The burden on the participants is small. During the motor task, participants have the opportunity to pause if they need it. Participants are compensated for travel expenses and additionally receive financial compensation for participation.

Participant 21 to 55:
Participants are asked to provide a saliva sample for BDNF analysis, demonstrated to be a determinant for tDCS effectiveness, and have to visit the Erasmus Medical Centre up to three times for the different stimulation configurations. Each session takes up to 150 minutes. During each session, subjects will receive conventional, motor network or sham network stimulation

over the motor cortex. TDCS is reported to be safe; side effects are mild. Transcranial magnetic sitmulation (TMS) has been proven to be a safe method. There is little to no risk involved in the application of single pulse TMS. Discomfort can be experienced by the participants due to the muscle twitches and sounds generated by TMS. There will be financial compensation for travel expenses and participation.

Participant 56 to 105:
Participants are asked to visit the Erasmus MC three times. Each session takes up to 2.5 hours. During the first session, participants are asked to provide a saliva sample for BDNF analysis, because it is demonstrated that the BDNF polymorphism can be a determinant for tDCS effectiveness. During the experimental session, EEG, EMG and EOG are applied and participants are asked to execute a motor learning task, which takes approximately 45 minutes. The burden on the participants is small. During the motor learning task, participants have the opportunity to pause if they need it. During each session, subjects will receive conventional, motor network or sham network stimulation over the motor cortex. tDCS is reported to be safe; side effects are mild. Participants are compensated for travel expenses and additionally receive financial compensation for participation.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age between 18-35 years
Healthy (no history of neurological disorders)
Right-handedness

Exclusion criteria

History of neurological or psychiatric disorders
Implants or metal parts in the head
Usage of medication or drugs that effect the nervous system
Neuromodulatory stimulation in the last month
Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-05-2018
Enrollment:	105

Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	27-03-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-10-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2019
Application type:	Amendment
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	NL64529.078.18