

# Predicting the effect of transcranial direct current stimulation on brain excitability

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Primary Objective: To verify the main effect of TDCS on brain excitability and the interaction effects of BDNF genotype and APLM latency on this main effect. Secondary Objectives: Compare different prediction models for the main effect of TDCS in a...

|                              |                                           |
|------------------------------|-------------------------------------------|
| <b>Ethical review</b>        | Approved WMO                              |
| <b>Status</b>                | Pending                                   |
| <b>Health condition type</b> | Central nervous system vascular disorders |
| <b>Study type</b>            | Interventional                            |

## Summary

### ID

NL-OMON45810

### Source

ToetsingOnline

### Brief title

Predicting the effect of TDCS

### Condition

- Central nervous system vascular disorders

### Synonym

CVA, Stroke

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** TDCS, TMS

## Outcome measures

### Primary outcome

MEP-amplitude ratio: Measure for brain excitability. The height of the MEP amplitudes will be measured at a constant stimulation intensity. The grand average after TDCS will be divided by the average before TDCS. APLM (latency): Difference in MEP latencies between TMS pulses with an anterior-posterior current direction and lateral-medial current direction. Denoted in milliseconds. BDNF (val66met genotype): non-carrier or met-carrier. Derived from genotyping saliva samples.

### Secondary outcome

MAIN1: The MEP-ratio of the first anodal session minus the MEP-ratio of the second placebo session i.e. the main effect in the first measurement pair.

MAIN2: The MEP-ratio of the second anodal session minus the MEP-ratio of the second placebo session i.e. the main effect in the second measurement pair.

IO-curve ratio: Alternative measure of brain excitability. The height of the MEP amplitudes at a range of stimulation intensities (the input output curve). The average area under the curve after TDCS will be divided by the average before TDCS.

## Study description

### Background summary

Transcranial direct current stimulation (TDCS) has been shown to increase the excitability of the brain, enhance the effect of motor training, and improve recovery after stroke. However, the results of TDCS are variable. Therefore, a recently updated Cochrane review advised that \*future studies should particularly engage those who may benefit most from TDCS\*. In healthy subjects, two subject specific factors that could influence the effect of tDCS on brain excitability have been described: BDNF genotype and APLM latency (a measure for brain connectivity). In these, studies brain excitability is measured by applying Transcranial Magnetic Stimulation (TMS) over the motor cortex and measuring the amplitudes of the subsequent motor evoked potential (MEP) in the Electromyography (EMG) signal of the target muscle. However, the large limitation in these previous studies is the complete absence of a placebo TDCS condition. This means that the subject specific factors (BDNF genotype and APLM latency) could have interacted with other sources of increased variability over time, such as such as an accumulation effect of single-pulse TMS or increasing fatigue. Therefore, the primary goal of this study is to verify the main effect of TDCS on brain excitability and the interaction effects of BDNF genotype and APLM latency on this main effect, in a randomized placebo-controlled trial. A secondary goal of this study is to assess if BDNF genotype and APLM provide additional predictive value for the effect of TDCS in a second set of measurements (placebo and anodal). The results of this study will aid in the overarching goal within rehabilitation medicine for a more personalized application of neuromodulation treatment.

## **Study objective**

Primary Objective: To verify the main effect of TDCS on brain excitability and the interaction effects of BDNF genotype and APLM latency on this main effect. Secondary Objectives: Compare different prediction models for the main effect of TDCS in a second measurement pair (anodal - placebo). Compare effect size of the main effect of anodal TDCS when two different outcome measures for brain excitability are used: MEP amplitude and input-output curve (IO curve).

## **Study design**

randomized double-blind placebo controlled intervention study

## **Intervention**

TDCS will be applied over the primary motor cortex with 2mA during 90 seconds (placebo), or with 2mA for 20 minutes (anodal).

## **Study burden and risks**

Participants will visit the Erasmus MC on 4 days for a total of 6,5 hours. In this study the state of the art safety measures are applied as described in

recent brain stimulation reviews. Therefore, there is no elevated risk of seizures or other serious events. The risks associated with this study are small. TDCS stimulation can induce an itching sensation of the skin. Discharging of the TMS coil at higher intensity levels can produce loud sounds. Furthermore, discharging the coil could cause temporary discomfort in the muscles on the head.

## Contacts

### Public

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### Scientific

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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  
Age 18-55 yr  
Intact skin on the scalp

## Exclusion criteria

History of neurological or psychiatric disorders  
Implants or metal parts in the head  
Use of psychoactive drugs in the last month  
Pregnancy  
Left-handedness  
Skin disease on the scalp, such as eczema

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Interventional                |
| Intervention model: | Crossover                     |
| Masking:            | Double blinded (masking used) |
| Control:            | Uncontrolled                  |
| Primary purpose:    | Diagnostic                    |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-10-2018  |
| Enrollment:               | 80          |
| Type:                     | Anticipated |

### Medical products/devices used

|               |                       |
|---------------|-----------------------|
| Generic name: | DC-Stimulator         |
| Registration: | Yes - CE intended use |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Approved WMO      |                  |
| Date:             | 23-10-2018       |
| 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     | NL66581.078.18 |