# The role of the cerebellum in response inhibition and error processing: A transcranial direct current stimulation study

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To demonstrate a direct relation between the cerebellum and electrophysiological and behavioural indices of response inhibition and error processing in healthy volunteers.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45501

**Source**
ToetsingOnline

**Brief title**
Cerebellum tDCS and executive functioning

### Condition

- Other condition

**Synonym**
not applicable

**Health condition**

Onderzoek bij gezonde vrijwillgers

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Radboud Universiteit Nijmegen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cerebellum, Executive functioning, Transcranial direct current stimulation

## Outcome measures

### Primary outcome

EEG: Error-related negativity (ERN) and feedback-related negativity (FRN) brain

potentials associated with response inhibition and error processing. Behaviour:

% Error-rate and post-error slowing of reaction times.

### Secondary outcome

not applicable

# Study description

### Background summary

Growing evidence point to a role of the cerebellum in non-motor related executive functions related to response inhibition and error processing to support frontal cortical executive functions. However, the available evidence is correlational and based on a limited number of cerebellar patient studies. The examine the direct involvement of the cerebellum in action monitoring and error processing we want to use an established method of transcranial direct stimulation to modulated cerebellar activity to examine its effects on electro-cortical potentials as measured with the electroencephalogram (EEG) and behaviour.

### Study objective

To demonstrate a direct relation between the cerebellum and electrophysiological and behavioural indices of response inhibition and error processing in healthy volunteers.

### Study design

Double-blind placebo controlled cross-over design.

### Intervention

Transcranial direct current stimulation (tDCS) will be delivered by a battery-driven electric current stimulator (Eldith DC Stimulator (CE 0118), Ilmenau) using a pair of electrodes: (1) cathodal electrode over the medial cerebellum (35 $cm^2$); (2) anodal electrode over the right deltoid muscle (25 $cm^2$). Stimulation will be delivered for 20 minutes during an inhibition response task. Stimulation comprises either: (1) cathodal tDCS (2 mA); and (2) placebo (sham) tDCS (0 mA).

### Study burden and risks

The currently proposed tDCS procedure and experiment does not carry any significant risks. Stimulation will be performed in line with the Standard Operating Procedure Non-Invasive Brain Stimulation of the Donders Institute for Brain, Cognition and Behaviour. Potential side-effects of tDCS are itching or burning sensations on the 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 fundamental understanding of the cerebellum

## Contacts

**Public**
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525HR
NL
**Scientific**
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525HR
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

Between 18-35 years of age years; Right-handed; Non-smoking; Normal or corrected-to-normal vision; 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

1) Average use of more than 3 alcoholic beverages daily; (2) Use of psychotropic medication or recreational drugs; (3) Skin disease; (4) Pregnancy; (5) Serious head trauma or brain surgery; (6) Neurological or psychiatric disorders; (7) Large or ferromagnetic metal parts in the head (except for a dental wire); (8) Implanted cardiac pacemaker or neurostimulator; (9) Participation in a NBS study in the past 28 days; (10) Previous participation in 10 or more NBS studies.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-05-2017 |
| Enrollment: | 26 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 04-05-2017 |
| 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 | NL60322.091.17 |

## Study results

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| Date completed: | 13-06-2017 |
| Actual enrolment: | 26 |

**Summary results**

Trial is onging in other countries