# The role of the cerebellum in reversal learning

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON51434

**Source**
ToetsingOnline

**Brief title**
The role of the cerebellum in reversal learning

### Condition

- Other condition

**Synonym**
not applicable

**Health condition**

onderzoek bij gezonde vrijwilligers

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Utrecht
**Source(s) of monetary or material Support:** VI.C.181.005

## Intervention

**Keyword:** cerebellum, cTBS, impulsivity, reversal learning

## Outcome measures

### Primary outcome

The main study parameter is reversal learning performance (e.g., how fast participants notice and implement a change in reward-punishment contingencies) as a function of cTBS condition during a computer task.

### Secondary outcome

The secondary study parameters are risk-taking as a function of cTBS condition during a computer task, and the moderating effects of state anger, state anxiety, trait aggression, trait impulsivity and vagally mediated HRV on risk-taking and reversal learning performance by cTBS condition.

# Study description

### Background summary

The cerebellum plays a role in controlling and adapting motor-related behaviour across contexts. Thus far, however, within the cognitive domain no study has yet examined the role of the cerebellum in reversal learning (cognitive flexibility) and risk-taking by manipulating cerebellar activity. The aim of this study is to test whether transient disruption of cerebellar functioning using transcranial magnetic stimulation will affect reversal learning in healthy volunteers. Continuous theta burst stimulation (cTBS) will be applied to the cerebellum before participants engage in a validated reversal learning gambling task. We anticipate that medial and right lateral cerebellar cTBS will increase risk-taking and reduce reversal learning performance as compared to cTBS over the visual cortex (active control site), respectively. In addition,

the involvement of the cerebellum in reversal learning will be explored while accounting for levels of state anger, state anxiety, trait aggression, trait impulsivity and vagally mediated heart rate variability (HRV).

### Study objective

The primary objective of the study is to demonstrate the specific involvement of the cerebellum in reversal learning. The secondary objective is to investigate whether the behavioural effects of cerebellar cTBS on reversal learning are moderated by state anger, state anxiety, trait aggression, trait impulsivity and vagally mediated HRV.

### Study design

Single-blind randomized between-subjects design.

### Intervention

Participants will receive standard 600 pulses of continuous theta-burst stimulation (bursts of three pulses at 50 Hz every 200 ms) at 45% of machine intensity for 40 seconds, to either the medial cerebellum, right cerebellum or visual cortex (depending on the condition). CTBS is a brief and safe TMS protocol which is routinely used in fundamental research and temporarily lowers neural excitability (Huang et al., 2005, Neuron, 45, 201-206).

### Study burden and risks

Participants will visit the lab once for a maximum of 1,5 hours. Participants* heart rate will be recorded before and after cTBS during resting-state and during the task. The cTBS protocol will take 40 seconds and does not carry significant risks. Safety guidelines as acknowledged by the International Federation of Clinical Neurophysiology will be followed strictly. CTBS can cause a mild headache, which can be effectively and promptly treated with analgesics. Furthermore, cerebellar cTBS may cause muscle contractions in the neck area which could be perceived as uncomfortable. Participants will fill out questionnaires and will engage in a reversal learning gambling task, during which their heart rate will be recorded as well. There are no direct benefits associated with participation. Volunteers can withdraw from the study at any time.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

Healthy; Between 18 and 35 years of age; Righthanded; Nonsmoking; Normal or corrected-to-normal vision; Willingness and ability to understand the nature and content, to participate and to comply with the study requirements; Willingness and ability to give written informed consent.

## Exclusion criteria

(1) Use of medication and drugs (except oral contraceptives); (2) Pregnancy or possible pregnancy; (3) Head trauma or underwent brain surgery; (4) Neurological or psychiatric condition; (5) Epilepsy or family history of epilepsy; (6) Metal in the head (except for bridges behind the teeth); (7) Heart problems; (8) Pacemaker or neurostimulator; (9) Medication pump; (10) Electronic hearing device; (11) Consumption of more than 3 alcoholic beverages a day; (12) Participation in a non-invasive brain stimulation study in the past 28 days; (13) Previous participation in 10 or more non-invasive brain stimulation studies.

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Other |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-03-2023 |
| Enrollment: | 111 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 27-12-2022 |
| Application type: | First submission |
| Review commission: | METC NedMec |

# 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 | NL82216.041.22 |

# Study results

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| Date completed: | 15-02-2024 |
| Actual enrolment: | 111 |