# Transcranial Direct Current Stimulation to enhance treatment effects in aphasia

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to investigate (1) the additional effect of tDCS on language and communication, when administered during aphasia therapy in the sub-acute phase post stroke (2) its cost-effectiveness, (3) its effect on neural reorganisation of language, and (4) the...

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

## Summary

### ID

NL-OMON56678

**Source**
ToetsingOnline

**Brief title**
tDCS to treat aphasia

### Condition

- Central nervous system vascular disorders

**Synonym**
Aphasia. Language disorder after 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:** aphasia, rehabilitation, stroke, transcranial stimulation

## Outcome measures

### Primary outcome

Boston Naming Test (BNT)

### Secondary outcome

Amsterdam Nijmegen Test voor Alledaagse Taalvaardigheden (ANTAT)

EuroQOL-5D; Stroke and Aphasia Quality of Life Scale (SAQOL)

Werk en Zorg vragenlijst

Size and location of the lesion

fMRI: Laterality index (only for participants from the Rijndam rehabilitation

center)

# Study description

### Background summary

Recent studies have shown that transcranial Direct Current Stimulation may enhance the effect of aphasia treatment in people with post-stroke aphasia. tDCS is promising as a clinical tool, because it is inexpensive and easy to apply. So far, beneficial effects have been reported in small scale studies, mostly of people with chronic aphasia (> 1 year post onset). It is important to investigate the potential benefits of tDCS in people with sub-acute aphasia as well, as the larger proportion of language treatment for stroke patients is provided in the sub-acute phase, during the first weeks and months post stroke.

### Study objective

to investigate (1) the additional effect of tDCS on language and communication, when administered during aphasia therapy in the sub-acute phase post stroke (2) its cost-effectiveness, (3) its effect on neural reorganisation of language, and (4) the side effects and drop out rates.
Study design: double-blind, randomized sham-controlled intervention study with

6 months follow-up.

### Study design

double-blind, randomized sham-controlled intervention study with 6 months follow-up.

### Intervention

The experimental group receives language training + tDCS (transcranial Direct Current Stimulation; 20 min, 1mA: 2x 5 therapy sessions).
The control group receives language training + StDCS (Sham transcranial Direct Current Stimulation, i.e. inactive stimulation; 20 min, 1mA: 2x 5 therapy sessions)

### Study burden and risks

All participants are enrolled in Rijndam*s regular stroke rehabilitation programme/Libra's regular stroke rehabilitation/Revant's regular stroke rehabilitation/De Hoogstraat's regular stroke rehabilitation programme. The application of tDCS during language training, is an additional treatment, which is expected to enhance the effect of their language training. tDCS is reported to be safe; side-effects are mild. For this study, extra test sessions are scheduled, constituting an extra burden for the participant. All formal tests are aphasia tests that are validated for this population and commonly used in regular practice. In addition, participants will get several questionnaires.
In addition, 2 fMRI scans are performed during the study (only for participants from the Rijndam rehabilitation center).

## 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

Aphasia after stroke
Time post onset < 3 months
Age 18-80 years
Right handed
Physical health sufficient to participate in intensive aphasia therapy

## Exclusion criteria

Subarachnoïd Haemorrhage (SAH)
Prior stroke resulting in aphasia
Brain surgery in the past
Epileptic activity in the past 12 months
Excessive use of alcohol or drugs
Insufficient level of Dutch premorbidly
Premorbid (suspected) dementia
Premorbid psychiatric disease affecting communication
Severe nonlinguistic cognitive disturbances impeding language therapy

# Study design

## Design

Study phase: 3

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

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-03-2014 |
| Enrollment: | 58 |
| Type: | Actual |

### Medical products/devices used

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

## Ethics review

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| Approved WMO Date: | 04-06-2013 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 12-11-2014 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-12-2014 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

Approved WMO

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| Date: | 11-08-2015 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 15-09-2015 |
| 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 | NL44115.078.13 |