tDCS and aphasia

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27213

Source
Nationaal Trial Register

Brief title
TEA

Health condition

We will study participants with aphasia, an acquired language disorder caused by stroke.
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De participanten van het onderzoek hebben afasie, een niet-aangeboren taalstoornis die door een beroerte (CVA) is ontstaan.

Sponsors and support

Primary sponsor: Erasmus University Medical Centre. Department: rehabilitation medicine and physiotherapy
Source(s) of monetary or material Support: Erasmus University Medical Centre, M-RACE

Intervention

Outcome measures

Primary outcome

language functioning i.e. word finding (Boston naming test)

Secondary outcome

- Communication. Test: ANTAT
- Quality of life. Questionnaires: SAQOL, Euroqol-5D
- Care consumption. Questionnaires: Werk en zorg vragenlijst (Health care consumption and labour productivity)
- Laterality index. Measurement: fMRI

Other outcomes:
- demographic data (age, gender, handedness, educational level, socio-economic status)
- aphasia type and severity
- Size and location of the lesion (fMRI)
- Participation: CIQ
- overall functioning: Barthel Index
- adverse effects: Wong-Baker FACES Pain Rating Scale

Study description

Background summary

In summary, we will study whether tDCS has an additional effect in the rehabilitation of aphasia. To investigate this, two groups will be studied: 1 group receives real current stimulation and 1 group receives no current stimulation (sham-tDCS).
The intervention (real tDCS or sham-tDCS)will be added to language therapy sessions. We hypothesise that real tDCS will lead to a significant improvement in language functioning, and that this group difference will also be there at 6 months follow-up.

Study objective

We expect that tDCS will enhance speed of language recovery, resulting in improved communication, quality of life and participation - associated with decreased rehabilitation consumption and cost reduction.

Study design

5 timepoints for language tests&questionnaires:
- before intervention week 1
- after intervention week 1
- before intervention week 2
- after intervention week 2
- follow-up: 6 months
For the fMRI, there are 2 timepoints:
- before intervention week 1
- after intervention week 2

Intervention

The intervention is tDCS (Transcraniele Direct Current Stimulation). We will study whether tDCS has an additional effect in the rehabilitation of aphasia. To investigate this, two groups will be studied: 1 group receives real current stimulation and 1 group receives no current stimulation (sham-tDCS).

The intervention (real tDCS or sham-tDCS)will be added to language therapy sessions. Two seperate intervention weeks will be planned, in each week the participants will get 5 1-hoursessions of real tDCS or sham-tDCS+language therapy.

Contacts

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Eligibility criteria

Inclusion criteria

-Aphasia after stroke
-Time post onset < 3 months
-Age 18-75 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 non-linguistic cognitive disturbances impeding language therapy
-Pace maker
-Global aphasia (spontaneous speech 0 AND shortened Token Test < 9)
-Severe Wernicke's aphasia (spontaneous speech 0-1 AND shortened Token Test <9)
-Residual aphasia (spontaneous speech 4-5 AND shortened Token Test > 28 AND Boston Naming Test > 150)

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2013
Enrollment:	58
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-02-2014
Application type:	First submission

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
NTR-new	NL4211
NTR-old	NTR4364
Other	METC : MEC-2013-147

Study results