Reorganising language after left-hemisphere stroke through right-hemisphere recruitment: an exploratory study

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

Summary

ID

NL-OMON47133

Source
ToetsingOnline

Brief title
ReorgLang

Condition

- Other condition
- Structural brain disorders

Synonym
CVA, stroke

Health condition

Afasie en Taalstoornissen in het kader van hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO Zwaartekracht - Language in Interaction Consortium (and possibly NWO Veni vernieuwingsimpuls)

Intervention

Keyword: aphasia, electrophysiology, language production, tractography

Outcome measures

Primary outcome

The correlation between electrophysiological activity in the patients* right hemisphere and the integrity of the corpus callosum.

Secondary outcome

The relationship between patients* functional communication abilities and right-hemisphere recruitment, measured through task-related activity and resting-state activity.

Other variables that will be included are age, gender, education, and aphasia severity. These measures are routinely gathered as part of the standard clinical work-up at the co-investigating sites.

Study description

Background summary

Language impairment is common after left-hemisphere stroke. Evidence suggests that some patients with left-hemisphere damage use their right hemisphere to compensate for the loss of language function. However, it is still largely unknown whether there are structural constraints to right-hemisphere functional reorganisation for language. This lack of knowledge possibly explains the

variable outcomes of interventions targeting right-hemisphere enhancement. In this study, we will employ magnetoencephalography (MEG) and two language tasks to identify brain areas that are active during language use. We will assess the extent to which patients show right-hemisphere activity while performing the language tasks as a function of their structural interhemispheric connectivity (from diffusion-weighted magnetic resonance imaging, MRI).

Study objective

The aim of this study is to identify structural constraints to right-hemisphere reorganisation. It is hypothesised that reorganisation of language function to the right hemisphere is largely dependent on the integrity of the corpus callosum fibres connecting cortical areas in both hemispheres.

Study design

Observational study with a cross-sectional design comparing patients* functional and structural brain measures to that of matched controls.

Study burden and risks

The currently proposed MEG and MRI procedures and experiments are of negligible risk and minimal burden. 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 understanding of brain reorganisation following left-hemisphere damage and may contribute to improving therapeutical strategies offered to the patients.

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

* Between 18 * 78 years of age
* Ischemic or hemorrhagic cerebral infarction of the left hemisphere
* Postonset of > 6 months (chronic stage)
* Native speaker of Dutch
* Pre-morbidly right handed
* 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

* History of previous stroke
* Pre-existent cognitive problems
* Severe aphasia (unable to understand instructions or provide consent). This will be operationalised via scores of the Comprehensive Aphasia Test (CAT-NL) or Aachen Aphasia Test (AAT) or Token Test, which are acquired as part of the standard clinical procedure by the co-investigating sites. The following cut-off scores will be used:
o CAT-NL, part *Mondeling taalbegrip: zinnen*: C-score >= 5, percentile >= 41 (corresponding to average)
o AAT, part *TB-1 Auditief woordbegrip* and *TB-2 Auditief zinsbegrip*: raw score >= 39, corresponding to C-score >= 5, percentile >= 41
o Token Test: raw score >= 37, corresponding to percentile >= 41
* Use of psychotropic medication or recreational drugs
* Pregnancy
* Serious head trauma
* Neurological or psychiatric disorders (other than stroke or epilepsy as a consequence of the stroke)

* Intractable epilepsy
* Large or ferromagnetic metal parts in the head (except for a dental wire)
* Implanted cardiac pacemaker or neurostimulator
* Somatic symptom and related disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-09-2018

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-03-2019
Application type:	Amendment
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	NL58437.091.17