The efficacy of the Melodic Intonation Therapy (MIT)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38221

Source
ToetsingOnline

Brief title
MIT

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
aphasia; language disorder after brain damage

Health condition

CVA

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Kinderrevalidatiefonds Adriaanstichting (toegekend)

Intervention

Keyword: aphasia, efficacy, stroke, treatment

Outcome measures

Primary outcome

CIU's per minute after 6 weeks of MIT therapy/after 6 weeks of control condition

The amount of information conveyed verbally, measured as the amount of correct information units (CIUs) on the Sabadel task (telling a story on the basis of pictures). CIUs are adequate, comprehensible, relevant and informative words in relation to the picture and are often used as an instrument to measure the communicative effectiveness of aphasic speech.

Secondary outcome

Repetition task, Spontaneous Speech interview, Amsterdam-Nijmegen Everyday Language Test (ANELT)

Study description

Background summary

Aphasic patients with limited verbal output often show a beneficial effect of singing on language production. The Melodic Intonation Therapy (MIT) was devised to use this capacity in the treatment of aphasia, aiming at improvement of verbal production. The MIT uses the "melodic" elements of language, such as

rythm and intonation. Many case studies have reported spectacular results after MIT therapy. So far, no systematic effectstudies have been conducted.
THe MIT was based on the RH hypothesis of language recovery, i.e. that RH has the capacity to take over the language functions of the damaged regions in the LH.
Recent neuroimaging studies report both left-hemispheric perilesional activation and RH activiation. However, some studies report that RH activation may be be related to poor recovery. Possibly, time post onset plays an importatn role. Some studies suggest that early post-stroke recovery is related to increased RH activity, whereas late recovery is related with a decrease of RH activity. Thus, persisting RH activation may be related with poor recovery.

Study objective

At the moment there is level III evidence for the efficacy of the MIT, mainly for the chronic phase. This study intends to establish a higher level of evidence, both for the chronic phase and for the post-acute phase, when aphasia treatment is regularly provided.
Furthermore, it will be investigated whether the efficacy of MIT depends on patient characteristics such as age, gender, location and seize of lesion and severity of the aphasia.
fMRI will be used to investigate which brain structures play a role in MIT-induced recovery. The role of the RH in relation to MIT succes is of particular interest.

Study design

effect study: randomised waiting-list control study
fMRI study: observational pre-post intervention study. no randomisation

Intervention

Intensive aphasia treatment, namely Melodic Intonation Therapy, during 6 weeks.

Study burden and risks

The experimental treatment, MIT, is given by the participants' regular speech and language therapist. There are 5 (Group 1) or 6 (Group 2) test sessions of 60 minutes each. These test sessions bring no extra risks. Standard aphasia tests are administered by the researchers, who vist the participants in the centre where they reside or receive treatment. Thus, participants do not have to travel for this study.

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 LH stroke
- eligible for MIT
- native speaker of Dutch
- right handed
- age 18-80 yrs
- time post onset: 3-6 maanden

Exclusion criteria

- severe hearing deficit
- dementia

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2009
Application type:	First submission
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	NL19548.078.09