Rotterdam Aphasia Therapy Study - 2.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25719

Source
Nationaal Trial Register

Brief title
RATS-2

Health condition

1. Experimental condition: CLT 0-6 m.p.o
Control condition: no-CLT 0-6 m.p.o

2. Experimental condition: CLT 0-3 m.p.o. followed by no-CLT 3-6 m.p.o.
Control condition: no-CLT 0-3 m.p.o. followed by CLT 3-6 m.p.o.

Sponsors and support

Source(s) of monetary or material Support: Nuts Ohra Foundation

Intervention

Outcome measures

Primary outcome

The score at 6 months post onset on the Amsterdam Nijmegen Everyday Language Test (ANELT), scale A (Understandability).

Secondary outcome

- Proportion of patients in each treatment group who improve at least 7 points on the ANELT
- A categorization of the ANELT into severe (score, 10-29) and moderate to mild (score, 30-48) communication deficits
- ScreeLing; Semantic Association Test (SAT), verbal version; Semantic Association words with low imageability, Nonwords Repetition and Auditory Lexical Decision (PALPA); semantic word fluency; letter fluency.

Study description

Background summary

Aim: to evaluate the effect of semantic and phonological treatment on verbal communication in patients with aphasia after stroke.
The study consists of two parts. In Part 1, CLT (BOX and/or FIKS) will be compared with no-CLT (nonspecific aphasia therapy directed to functional language behavior). 80 aphasic patients with semantic and/or phonological disorders will receive treatment 0-6 months post onset. Diagnostic or evaluative tests will be administered pre-therapy, after 3 months and after 6 months. The ANELT is the primary outcome measure. In addition, semantic and phonological tests will be administered. Hypothesis: CLT is more effective than no-CLT. Depending on the results of Part 1, the intervention contrast will be changed in Part 2. Aphasic patients with semantic and/or phonological disorders (n=80) will be randomized into 2 groups: (1) CLT from 0-3 months, followed by 3 months of no-CLT; (2) no-CLT from 0-3 months, followed by 3 months of CLT. Hypothesis: application in the acute stage, from 0-3 months, enhances the efficacy of CLT.

Study objective

1. Cognitive linguistic therapy (CLT) is more effective than no-CLT;
2. CLT applied 0-3 months post onset is more effective than applied 3-6 m.p.o.

Intervention

Assessment:
- Amsterdam-Nijmegen Everyday Language Test (ANELT), scale A
- ScreeLing
- Semantic Association Test (SAT), verbal version
- Semantic Association words with low imageability (PALPA)
- semantic word fluency (animals, professions)
- Nonwords Repetition (PALPA)
- Auditory Lexical Decision (PALPA)
- letter fluency (D, A, T)
- Boston Naming Test
- Token Test (short version)
- Spontaneous Speech

- Partner Communication Questionnaire
- Aachen Aphasia Test
- EuroQol
- Rankin
- Barthel

Therapy:
- CLT: cognitive linguistic therapy using BOX or FIKS or a combination of the two, depending on how the language disorder manifests itself in each patient.
BOX is a lexical semantic treatment program, focused on the interpretation of the semantic features of written words, sentences, and texts.
FIKS is a phonological treatment program focused on sound structure and word form, consisting of exercises for selecting and sequencing speech sounds on word-, sentence- and text level.
Both the paper versions (for individual therapy) and the computerized versions (for additional therapy with homework) can be used.

- no-CLT: all therapy tasks other than cognitive linguistic exercises are allowed. Treatment focused on the linguistic levels (phonology, semantics and syntax) is not permitted. In practice, this means that the control therapy will contain exercises aimed at improving communicative strategies.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aphasia due to stroke;

2. Within 3 weeks post onset;
3. Age 18-85 years;
4. Language near native Dutch;
5. Life expectancy > 6 months.

Exclusion criteria

1. Severe dysarthria;
2. Premorbid dementia;
3. Illiteracy;
4. Severe developmental dyslexia;
5. Severe visual perceptual disorders;
6.Existing aphasia;
7. Subarachnoidal haemorrhage;
8. Recent psychiatric disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2006
Enrollment:	160
Type:	Actual

Ethics review

Positive opinion

Date:	21-07-2005

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	NL726
NTR-old	NTR736
Other	: 1
ISRCTN	ISRCTN67723958

Study results

Summary results
Hagelstein, M. (in press). RATS-2: De effectiviteit van cognitief linguïstische therapie in de acute fase van afasie: een gerandomiseerde gecontroleerde trial. Afasiologie.