Rotterdam Aphasia Therapy Study-3: The efficacy of early, intensive cognitive-linguistic therapy in aphasia after stroke (a randomized controlled trial).

No registrations found.

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

Summary

ID

NL-OMON23495

Source
Nationaal Trial Register

Brief title
RATS-3

Health condition

aphasia
afasie
stroke
beroerte

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Hersenstichting Nederland

Intervention

Outcome measures

Primary outcome

The difference in score on the ANELT post therapy (4½ -6 weeks post onset) between the two groups.

Secondary outcome

1. The difference in score on the semantic and phonologic tests: Semantic Association Test verbal version, Semantic Word Fluency, Letter Fluency, Nonwords repetition, Auditory Lexical Decision post therapy (4½ -6 weeks p.o.) and 3 months p.o. between groups and the difference in score on the ANELT 3 months p.o.;

2. The difference in score on the semantic and phonologic tests: Semantic Association Test verbal version, Semantic Word Fluency, Letter Fluency, Nonwords repetition, Auditory Lexical Decision 6 months p.o. between groups and the difference in score on the ANELT 6 months p.o.

Study description

Background summary

Aphasia is present in about a quarter of all stroke patients and has a large impact on their communicative abilities in daily life. Some consider cognitive-linguistic therapy (CLT) as a “practice standard”. Others state that there is a need for well-designed trials in this field. CLT aims at improving processing on one or more of the affected linguistic components, e.g. semantics (word meaning) or phonology (word sound), resulting in a better verbal communication.
The Rotterdam Aphasia Therapy Study-3, a randomized controlled trial, evaluates the effect of intensive semantic and phonological treatment on verbal communication in an early stage of stroke.

Design:

Aphasic patients (n=150) will be randomized into 2 groups: (A) intensive (7 hours per week) CLT for 4 weeks, starting at the latest 2 weeks after stroke; and (B) deferred regular language therapy, starting 5-6 week after stroke. In the 5-6 weeks after stroke, no language therapy is allowed.
Our hypothesis is that early intensive short CLT is more effective than deferred therapy.

Study objective

Early intensive short Cognitive Linguistic Therapy (CLT) with a speech and language therapist is more effective than deferred therapy.

Study design

1. Baseline: In week 1 and/or 2 (between 0 and 14 days) after stroke;

2. Post therapy: Following 4 weeks of intervention (4½ à 6 weeks after stroke);

3. Posttest: 3 months after inclusion;

4. Posttest: 6 months after inclusion.

Intervention

Experimental group:

Intensive cognitive-linguistic language therapy; semantic and/or phonologic:

1. Semantic therapy with the cognitive-linguistic program BOX (E.G. Visch-Brink, I.M. Bajema, 2001) including a digital version: eBOX;

2. Phonological therapy with the cognitive-linguistic program FIKS (M. van Rijn, L. Booy, E.G. Visch-Brink, 2000), including a digital version: eFIKS.

Intensity: 7 hours a week (1 hour a day), of which at least 2 hours of therapy with a speech and language therapist.

Duration: 4 weeks.

Timing: As soon as possible after randomization, at the latest 2 weeks post onset.

Control group:

Deferred therapy.

Speech and language therapy will be deferred for four weeks. During those four weeks the controls receive no speech and language therapy.
Regular speech and language therapy starts four weeks after randomization; thus maximum at six weeks after the stroke.

All patients who meet the additional criteria will be asked to participate in a neuroimaging study subpart of RATS-3, FIAT, (Functional Imaging in Aphasia Therapy). These patients are randomized according to the RATS-3 protocol, but undergo MRI-scans pre-therapy, post-therapy and three months after the first MRI-scan to evaluate the neurophysiological correlate of the possible effect of CLT on verbal communication.

For FIAT an additional control group of chronic aphasic patients (n=40) and healthy participants (n=10) is added. Healthy participants will be scanned twice, with four weeks between sessions. Same RATS-3 randomization and intervention methods are applied to the group of chronic patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aphasia after stroke, determined by neurologist/ rehabilitation physician and speech and language therapist;

2. < 2 weeks after stroke;

3. Testable with ScreeLing (Visch-Brink EG, Van de Sandt-Koenderman M, El Hachioui H. (2010). ScreeLing. Houten: Bohn Stafleu van Loghum);

4. Aphasia measured by the shortened version of the Token Test (De Renzi E, Faglioni P. Normative data and screening power of a shortened version of the Token Test. Cortex. 1978 Mar;14(1):41-9) and/or the Goodglass Severity Rating Scale (Goodglass H, Kaplan E. (1972) The assessment of aphasia and related disorders. Philadelphia: Lea and Febiger);

5. Age between 18 and 85;

6. Language near native Dutch;

7. Life expectancy > 6 months.

Additional inclusion criteria for patients participating in a neuroimaging study (FIAT), subpart of RATS-3:

1. Chronic patients 1-3 years post-stroke.

Exclusion criteria

1. Pre-existing aphasia;

2. Subarachnoid/subdural haemorrhage/hematoma;

3. Severe threats to the success and/or feasibility of language therapy:

A. Severe dysarthria;

B. Premorbid dementia;

C. Illiteracy;

D. Severe developmental dyslexia;

E. Severe visual perceptual disorders;

F. Recent psychiatric history.

Additional exclusion criteria for patients participating in a neuroimaging study (FIAT), subpart of RATS-3:

1. Age >80;

2. Left handedness or ambidexterity;

3. Bilingualism;

4. Prior stroke (acute patients only);

5. Contraindications for MR imaging;

6. Severe motor disability (inability to make independent transfers);

7. Cortical lesions in the right hemisphere as assessed by MRI.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2012
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	NL3121
NTR-old	NTR3271
Other	METC ErasmusMC : MEC-2005-347
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A