

Rotterdam Aphasia Therapy Study - 2

Submission date 12/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/05/2011	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1; NTR736

Study information

Scientific Title

Acronym

RATS-2

Study objectives

1. Cognitive linguistic therapy (CLT) is more effective than no-CLT
2. CLT applied zero to three months post onset is more effective than applied three to six months post-onset

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Aphasia

Interventions

Assessment:

1. Amsterdam-Nijmegen Everyday Language Test (ANELT), scale A
2. ScreeLing: semantic, phonological and syntactic deficits
3. Semantic Association Test (SAT), verbal version
4. Semantic Association words with low imageability (Psycholinguistic Assessment of Language Processing in Aphasia [PALPA])
5. Semantic word fluency (animals, professions)
6. Nonwords Repetition (PALPA)
7. Auditory Lexical Decision (PALPA)
8. Letter fluency (D, A, T)
9. Boston Naming Test
10. Token Test (short version)
11. Spontaneous Speech
12. Partner Communication Questionnaire

13. Aachen Aphasia Test
14. EuroQol quality of life instrument
15. Modified Rankin Scale
16. Barthel Index

Therapy:

Group one: Cognitive Linguistic Therapy (CLT) 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 computerised versions (for additional therapy with homework) can be used.

Group two: 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

1. Proportion of patients in each treatment group who improve at least seven points on the ANELT with a categorisation of the ANELT into severe (score: ten to 29) and moderate to mild (score: 30-48) communication deficits (ScreeLing)
2. Semantic Association Test (SAT), verbal version
3. Semantic Association words with low imageability, Nonwords Repetition and Auditory Lexical Decision (PALPA)
4. Semantic word fluency
5. Letter fluency

Overall study start date

04/09/2006

Completion date

04/12/2008

Eligibility

Key inclusion criteria

1. Aphasia due to stroke
2. Within three weeks post onset

3. Age 18 to 85 years
4. Language near native Dutch
5. Life expectancy more than six months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

160

Key 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

Date of first enrolment

04/09/2006

Date of final enrolment

04/12/2008

Locations**Countries of recruitment**

Belgium

Netherlands

Study participating centre

Erasmus Medical Center
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands)

Sponsor details

P.O. Box 2040
Rotterdam
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3000 CA

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Research organisation

Funder Name

The Nuts-Ohra Foundation (Stichting Nuts Ohra [SNO]) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011		Yes	No