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Rotterdam Aphasia Therapy Study - 2

Submission date 12/10/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/10/2006	**Overall study status** Completed	
Last Edited 16/05/2011	**Condition category** Signs and Symptoms	

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
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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