Rotterdam Aphasia Therapy Study - 2.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25719

Bron
Nationaal Trial Register

Verkorte titel
RATS-2

Aandoening

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.

Ondersteuning

Overige ondersteuning: Nuts Ohra Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	04-09-2006
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL726
NTR-old	NTR736
Ander register	: 1
ISRCTN	ISRCTN67723958

Resultaten

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