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Forced Use Aphasia Therapy in the ACute phase

Submission date 27/11/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 03/01/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 05/01/2007	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

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
05004

Study information

Scientific Title

Acronym
FUATAC

Study objectives
1. Forced Use Aphasia Therapy (FUAT) leads to significant improvements in language skills.
2. FUAT is more effective than classical aphasia therapy.
3. Comparable significant improvements in language skills are reached earlier in FUAT.
4. Effects of treatment can be found in both FUAT-group and control group at six months post treatment.
5. Improvements in language skills will also improve communication skills, with FUAT being more effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission of Medizinische Fakultät Bonn (Germany), date of approval: 09/08/2006 (ref: 107/06).

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
Intervention:
Forced-use aphasia therapy is characterised by various aspects:
1. Treatment is group treatment (two to three persons).
2. Treament per day is three to four hours.
3. Treatment is primarily based on communicative aspects.

Control:
In the control group the people with aphasia receive therapy as usual. Control patients will have individual sessions once a day, and therapy is focussed on language/linguistic skills.

Both groups consist of 26 persons. The intervention will take place for six weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To establish efficacy of FUAT in the acute phase

Secondary outcome measures
1. To establish efficiency of FUAT as compared to standardised aphasia therapy.
2. To establish long-term effects of aphasia therapy (both FUAT and standard)

Overall study start date
01/07/2006

Completion date
31/07/2008

Eligibility

Key inclusion criteria
1. Left hemispheric cerebro-vascular accident maximally three months post-onset
2. Aphasia (by clinical diagnosis and standardised aphasia screening)
3. Monolingual German native speaker

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
52

Key exclusion criteria
1. Aphasia mainly characterised by automatisms
2. Severe jargon
3. Severe apraxia of speech
4. Severe neuropsychological and/or psychiatric disorders

Date of first enrolment
01/07/2006

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
Germany

Study participating centre
NRZ Godeshoehe
Bonn
Germany
53177

Sponsor information

Organisation
Refonet (Germany)

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Sponsor type
Research organisation

Website
http://www.refonet.de/

ROR
https://ror.org/04yeh2x21

Funder(s)

Funder type
Research organisation

Funder Name
Rehabilitations-Forschungsnetzwerk der DRV Rheinland (ReFonet) (Germany) (Project Number: 05004).

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