

Forced Use Aphasia Therapy in the ACute phase

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| Submission date 27/11/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/01/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 05/01/2007 | Condition category Signs and Symptoms | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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. Treatment 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

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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