Trial Description

Title

From Controlled Experimental Trial to Everyday Communication: How effective is intensive aphasia therapy under routine clinical conditions?

Trial Acronym

FCET2EC

URL of the trial

http://fcet2ec.aphasiegesellschaft.de/

Brief Summary in Lay Language

The aim of this study is to examine whether intensive language therapy results in immediate as well as long-lasting improvements of everyday language and communicative functions in aphasia. To this end, several tests examining language and communicative functions will be administered before and after a period of intensive language therapy in participants with chronic aphasia (at least 6 months after the last stroke). A further goal of the study is to examine whether intensive language therapy leads to improvements in other cognitive functions such as attention or memory. Finally, the study examines whether intensive language therapy enables participants to more successfully cope with situations in everday life (such as preparing dinner or making a phone call) and wether it affects participants' confidence of being capable of handling situations in daily life. For methodological reasons, half of the patients have to wait 3 weeks prior to starting intensive language therapy (waiting list control group).

Brief Summary in Scientific Language

This multi-center randomized placebo-controlled clinical study aims to examine whether intensive and integrative language and communication therapy administered under routine clinical conditions translates into a statistically significant functional improvement of everyday communication ("class 1 evidence") in patients with chronic aphasia (i.e. aphasia persisting for 6 or more months after stroke). Fourteen in- and outpatient rehabilitation facilities in Germany participate in the study. Via digital randomization procedure, patients are allocated to one of two groups: an experimental group, starting as soon as feasible with intensive (i.e. >= 10 hours per week) treatment lasting 3 to 6 weeks, and a waiting list control group whose therapy begins after a three-week delay. Both groups receive a combination of language systematic and communicative-pragmatic language therapy. Everyday language ability will be assessed with a standardized outcome measure (the German version of the Amsterdam-Nijmegen Everyday Language Test, ANELT), and compared between groups at several points in time: immediately before (t1) as well as immediately after (t2) completion of (3-6 weeks) intensive language therapy. The primary analysis compares the changes in functional communication ability (as indicated by changes of pre- to post therapy functional communication scores on the primary outcome measure) between the experimental and the waiting list control group in an intention-to-

treat design (ITT, last observation carried forward). Long-term stability of potential treatment gains will be re-evaluated 6 months post therapy (t3). Further exploratory analyses will examine therapy-induced changes (t2/t3 compared to t1) in several secondary outcome measures (specially developed screening measures assessing language and communicative function, quality-of-life questionnaires, and measures of cognitive function) in the experimental compared to the waiting list control group.

Organizational Data

- DRKS-ID: **DRKS00003337**
- Date of Registration in DRKS: **2012/04/10**
- Date of Registration in Partner Registry or other Primary Registry: **2012/02/06**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA1/234/11 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Primary Registry-ID: **NCT01540383 (ClinicalTrials.gov)**

Health condition or Problem studied

- ICD10: **R47.0 - Dysphasia and aphasia**
- ICD10: **I60 - Subarachnoid haemorrhage**
- ICD10: **I61 - Intracerebral haemorrhage**
- ICD10: **I62 - Other nontraumatic intracranial haemorrhage**
- ICD10: **I63 - Cerebral infarction**
- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**

Interventions/Observational Groups

- Arm 1: **Experimental Group: Intensive integrative aphasia therapy (3 weeks, 5 days/week, >=2 hours/day) provided in regular clinical setting and consisting of a combination of language systematic and communicative-pragmatic treatment. Group starts intensive language therapy within 3 workdays (or as soon as possible) after baseline exam.**
- Arm 2: **Waiting list control group. Control group starts intensive language therapy after a 3-week waiting period.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**Therapy-induced mean gain in Amsterdam Nijmegen Everyday Language Test ANELT understandability scores (ANELT A-scale; using the parallel versions ANELT-I and ANELT-II).
Performance at baseline is compared to performance immediately and 6 months post 3 weeks of 3 weeks of intensive language therapy. In patients with therapy allowance of > 3 weeks therapy will be continued, and in cases of a total therapy duration of <=5 weeks performance will be re-assessed after therapy completion.**

Secondary Outcome

Therapy-induced changes (t1 compared to t2/t3) in the following secondary outcome measures: (1) language-systematic and communicative-pragmatic screening measures specially designed to capture indvidual aphasia severity with respect to different language-systematic levels and modalities as well as communication ability in communicative situations of daily life (morbidity measure); (2) the German version of the Stroke and Aphasia Quality of Life Scale-39/SAQOL-39 (life quality measure); (3) the German Version of the Communicative Effectiveness Index/CETI (life quality measure); (4) in the B-scale (intelligibility) of the ANELT parallel versions (morbidity measure); (5) ratings of the syntactic complexity of the ANELT scenarios using the Aachen Aphasia Test/AAT scoring system for spontaneous speech; (6) ratings of nonverbal communication skills on the ANELT scenarios using a previously poublished 4-point-rating of nonverbal efficiency in aphasia; (7) changes with respect to cognitive functioning (.e.g. attention) measured by a neuropsychological test battery.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Tagesklinik für Kognitive Neurologie , Leipzig**
- Medical Center **Brandenburg Klinik Bernau Waldfrieden, Berlin (Bernau)**
- University Medical Center **Neurologische Klinik, Neuropsychologische Therapiestation (Aphasiestation), Aachen**
- Medical Center **Städtisches Klinikum München Bogenhausen, München**
- Medical Center **Aphasiestation der Schön Klinik, Bad Aibling**
- Medical Center **St. Mauritius Therapieklinik , Meerbusch**
- Medical Center **Median-Klinik Grünheide, Berlin (Grünheide)**
- Medical Center <style fontName='DejaVu Sans' isBold='true'>m&i Fachklinik Enzensberg, Hopfen (am See)</style>
- Medical Center <style fontName='DejaVu Sans' isBold='true'>m&i Fachklinik Bad Liebenstein, Bad Liebenstein</style>
- Medical Center **Aphasie- und Seniorenzentrum Josef Bergmann, Vechta**
- Doctor's Practice **Logopädisches und interdisziplinäres Behandlungszentrum für Intensivtherapie, Lindlar**
- Medical Center **Asklepios Neurologische Klinik Falkenstein, Königstein-Falkenstein**
- Medical Center **Wicker-Klinik Bad Homburg v.d.H., Bad Homburg v.d.H.**
- Doctor's Practice **Aschaffenburg**
- Medical Center <style fontName='DejaVu Sans' isBold='true'>m&i Fachklinik Herzogenaurach, Herzogenaurach</style>

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/02**
- Target Sample Size: **168**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

Presence of aphasia for at least 6 months after non-hemorrhagic or hemorrhagic

cortical or subcortico-cortical stroke, native language German, participant's language abilities have to allow the administration of the Aachen Aphasia Test. Minimum level of required language ability defined as a) < 10 errors on the first section of the Token Test subtest of the Aachen Aphasia Test (AAT), b) a score of at least 1 in the AAT subtest 'Spontaneuous Speech' (level 1, communication ability).

Exclusion criteria

1. Aphasia due to non-vascular etiology; 2. No evidence for aphasia (based on AAT subtests 'Token Test' and 'Written Language'; 3. severe untreated medical conditions which prohibit participation in intensive language therapy; 4. severe vision or hearing problems (uncorrected); 5. participation in another interventional or in intensive language therapy within four weeks before anticipated enrollment.

Addresses

■ **Primary Sponsor**

Universitätsklinikum Münster
48149 Münster
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail:
URL:

■ **Contact for Scientific Queries**

Universitätsklinikum MünsterKlinik für Allgemeine Neurologie
Ms. PD Dr. Caterina Breitenstein
Albert-Schweitzer-Campus 1
48149 Münster
Germany

Telephone: **++49 251 83-0 ext -49969**
Fax: **[---]***
E-mail: **fcet.2.ec at uni-muenster.de**
URL: **[---]***

■ **Contact for Public Queries**

Universitätsklinikum Münster
Klinik für Neurologie
Ms. PD Dr. Caterina Breitenstein
Albert-Schweitzer-Campus 1
48149 Münster
Germany

Contact for Public Queries

Universitätsklinikum Münster
Klinik für Neurologie
Ms. PD Dr. Caterina Breitenstein
Albert-Schweitzer-Campus 1
48149 Münster
Germany

Telephone: **++49 251 83-0 ext -49969**
Fax: **[---]***
E-mail: **fcet.2.ec at uni-muenster.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bundesministerium für Bildung und Forschung Dienstsitz Berlin
  Hannoversche Straße 28-30
  10115 Berlin
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/01/31**

Trial Publications, Results and other documents

- Paper **Publikation der Hauptstudienergebnisse in The Lancet, 2017**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*