Intensive speech and language therapy in patients with chronic aphasia after stroke: a randomised, open-label, blinded-endpoint, controlled trial in a health-care setting

Caterina Breitenstein, Tanja Grewe, Agnes Fleol, Wolfram Ziegler, Luise Springer*, Peter Martus, Walter Huber, Klaus Willmes, E Bernd Ringelstein, Karl Georg Haeusler, Stefanie Abel, Ralf Gildenmann, Frank Domahs, Frank Regenbrecht, Klaus-Jürgen Schlenck, Marion Thomas, Hellmuth Obrig, Ernst de Langen, Roman Rocker, Franziska Wiebers, Christine Rühmkorf, Indra Hempen, Jonathan List, Annette Baumgaertner, for the FCET2EC study group†

Summary

Background Treatment guidelines for aphasia recommend intensive speech and language therapy for chronic (≥6 months) aphasia after stroke, but large-scale, class 1 randomised controlled trials on treatment effectiveness are scarce. We aimed to examine whether 3 weeks of intensive speech and language therapy under routine clinical conditions improved verbal communication in daily-life situations in people with chronic aphasia after stroke.

Methods In this multicentre, parallel group, superiority, open-label, blinded-endpoint, randomised controlled trial, patients aged 70 years or younger with aphasia after stroke lasting for 6 months or more were recruited from 19 inpatient or outpatient rehabilitation centres in Germany. An external biostatistician used a computer-generated permuted block randomisation method, stratified by treatment centre, to randomly assign participants to either 3 weeks or more of intensive speech and language therapy (≥10 h per week) or 3 weeks deferral of intensive speech and language therapy. The primary endpoint was between-group difference in the change in verbal communication effectiveness in everyday life scenarios (Amsterdam–Nijmegen Everyday Language Test A-scale) from baseline to immediately after 3 weeks of treatment or treatment deferral. All analyses were done using the modified intention-to-treat population (those who received 1 day or more of intensive treatment or treatment deferral). This study is registered with ClinicalTrials.gov, number NCT01540383.

Findings We randomly assigned 158 patients between April 1, 2012, and May 31, 2014. The modified intention-to-treat population comprised 156 patients (78 per group). Verbal communication was significantly improved from baseline to after intensive speech and language treatment (mean difference 2·61 points [SD 4·94]; 95% CI 1·49 to 3·72), but not from baseline to after treatment deferral (–0·03 points [4·04]; –0·94 to 0·88; between-group difference Cohen’s d 0·58; p=0·0004). Eight patients had adverse events during therapy or treatment deferral (one car accident [in the control group], two common cold [one patient per group], three gastrointestinal or cardiac symptoms [all intervention group], two recurrent stroke [one in intervention group before initiation of treatment, and one before group assignment had occurred]); all were unrelated to study participation.

Interpretation 3 weeks of intensive speech and language therapy significantly enhanced verbal communication in people aged 70 years or younger with chronic aphasia after stroke, providing an effective evidence-based treatment approach in this population. Future studies should examine the minimum treatment intensity required for meaningful treatment effects, and determine whether treatment effects cumulate over repeated intervention periods.

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Introduction Chronic aphasia (ie, persisting for ≥6 months after stroke) affects about 20% of all patients who have had a stroke. Aphasia is one of the most devastating symptoms in stroke survivors, and the presence of aphasia after stroke predicts the extent of rehabilitation services required and likelihood of failure to return to work. Survival rates after initial stroke are increasing, contributing additional financial costs to health-care providers. Aphasia is responsible for roughly 8·5% of stroke-related health-care costs during the first year after stroke.
Evidence before this study
We searched PubMed and PsychINFO on June 28, 2016, for manuscripts published in English from inception until June 28, 2016, with the term “stroke rehabilitation” in combination with “aphasia”, “outcome”, “evidence-based practice”, or “activities of daily living”. We also searched with the term “stroke” in combination with “incidence rates” or “health care costs”. We had no additional inclusion or exclusion criteria for the studies searched.

For decades, it had been postulated that improved verbal communication could not be achieved in patients with chronic (≥6 months duration) aphasia after stroke. Several randomised controlled trials have been done to assess the effectiveness of speech and language therapy in this population, but the reported results were inconclusive because of the low methodological quality of the studies. Previously published randomised controlled trials on treatment effectiveness in chronic post-stroke aphasia had small sample sizes (fewer than 20 patients per group), non-intensive administration of therapy (ie, <5 h per week), and often failed to report long-term outcomes of therapy. Meta-analyses and systematic reviews published in the past 15 years have provided strong evidence that speech and language therapy, if administered with sufficient intensity (≥5 h per week), is effective even in patients with chronic aphasia after stroke. Despite this evidence derived from systematic reviews, patients with chronic aphasia after stroke are frequently denied access to speech and language therapy. The main reason for this failure is the lack of any large-scale multicentre randomised controlled trial with sound statistics that demonstrates lasting improvement in everyday language function after intensive speech and language therapy.

Added value of this study
Our multicentre FCET2EC (From Controlled Experimental Trial 2 Everyday Communication) trial is the largest appropriately controlled randomised trial to date in patients with chronic aphasia after stroke to evaluate the effectiveness of intensive speech and language therapy compared with a control group who received no or only low-intensity treatment during treatment deferral. The findings provide robust evidence for the superiority of 3 weeks of intensive (≥10 h per week) individualised speech and language therapy over 3 weeks of treatment deferral in this patient group. Treatment effects remained stable after the follow-up period of 6 months. The study confirms the results of previous underpowered studies that also suggested a positive and lasting effect of intensive speech and language therapy in patients with chronic aphasia after stroke. By contrast with previous studies, in which performance was usually assessed for isolated linguistic functions with low ecological validity (ie, low relevance for patients’ communicative participation in daily life), the primary outcome of the FCET2EC trial was verbal communication in everyday life scenarios.

Implications of all the available evidence
In combination with the evidence derived from systematic reviews, results of the FCET2EC trial show that intensive speech and language therapy is an evidence-based intervention for patients with chronic aphasia after stroke. In comparison with previous studies, inclusion criteria were liberal with respect to stroke cause (ischaemic, haemorrhagic, and subarachnoid haemorrhage), aphasia type, and aphasia severity, allowing generalisation of the trial results to the population of patients aged 70 years or younger with chronic aphasia after stroke. Furthermore, as no participant dropped out during the 3 weeks of intensive speech and language therapy, which was provided under routine clinical conditions, demonstration of the intervention’s feasibility for routine health-care settings is not necessary. Results of the FCET2EC trial could fundamentally change the allocation of rehabilitation resources for patients with chronic aphasia after stroke.

Methods
Study design
We did a randomised, open-label, blinded-endpoint, multicentre, stratified-by-centre, waiting-list-controlled, parallel-group, superiority trial to evaluate the effectiveness of 3 weeks of intensive speech and language therapy versus 3 weeks of treatment deferral (figure 1). The trial protocol was published previously.21 Speech and language therapy was given in 19 German inpatient or outpatient rehabilitation centres that specialised in stroke rehabilitation; each centre treated a median of 688 patients (IQR 97–1040) who had a stroke per year (reference year, 2013). We used deferral of intensive speech and language therapy as a control because any active control condition has the risk of providing language stimulation.22 No major changes in methodology were required after the trial had started.

The study coordination centre was based at the General Neurology Department at the University Hospital Münster, Germany. The trial steering committee—comprising two neurologists, one neurolinguist, one neuropsychologist, one biostatistician, and one patient delegate (appendix p 4)—monitored study progress during patient recruitment. Except for the patient delegate, the committee

*Dr Springer died in August, 2011. **Correspondence to: Dr Caterina Breitenstein, Department of General Neurology, University of Münster, Albert-Schweitzer-Campus 1, Building A1, D-48149 Münster, Germany caterina.breitenstein@uni-muenster.de

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