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

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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 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.1 Aphasia is one of the most devastating symptoms in stroke survivors,2,3 and the presence of aphasia after stroke predicts the extent of rehabilitation services required4 and likelihood of failure to return to work.5 Survival rates after initial stroke are increasing,6 contributing additional financial costs to healthcare providers. Aphasia is responsible for roughly 8·5% of stroke-related health-care costs during the first year after stroke.7

Such dramatic consequences of aphasia after stroke call for evidence-based effective interventions.8 Results of meta-analyses9–12 have concluded that speech and language therapy after stroke is effective even in the chronic stage, if administered with sufficient intensity (5–10 h per week). However, most of these studies rank below level 2 according to the classification scheme of the Centre for Evidence-Based Medicine. The few high-quality studies had either small sample sizes, no untreated or low-intensity therapy control group,9–12 or low treatment intensity (<5 h per week).9–12 Large, multicentre, randomised controlled clinical trials to...
assess the effectiveness of intensive therapy for aphasia with reliable and valid outcomes are urgently required.

The aims of our multicentre randomised controlled trial, From Controlled Experimental Trial 2 Everyday Communication (FCET2EC), were to assess the effectiveness of 3 weeks or more of intensive (≥10 h per week) speech and language therapy in chronic aphasia after stroke compared with 3 weeks of treatment deferral in terms of improved everyday verbal communication.

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...
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