The Very Early Rehabilitation in Speech (VERSE) after stroke trial: an international 3-arm clinical trial to determine the effectiveness of early, intensive, prescribed, direct aphasia therapy.

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Background

VERSE is a PROBE trial, to determine whether two types of intensive aphasia therapy within 14 days of acute stroke, provided for 20 sessions (minimum 15 hours), deliver greater therapeutic and cost-effectiveness than usual care with particular attention paid to monitoring of trial fidelity.

Methods

Eligible participants with acute post-stroke aphasia were stratified by aphasia severity and randomised to receive usual care, usual care-plus (usual ward-based therapy provided daily) or VERSE therapy (a prescribed aphasia therapy provided daily) starting within the first 15 days following stroke (N=246). UC therapy is usual ward-based aphasia therapy; UC-Plus is usual ward-based therapy provided for 20 x 45-60 minute sessions (15-20 hours) within the first 50 days following stroke; VERSE therapy is a prescribed aphasia therapy provided at the same intensity as UC-Plus therapy. The primary outcome was the Aphasia Quotient of the Western Aphasia Battery at 12 weeks post stroke. Secondary outcomes included discourse analysis, Stroke and Aphasia Quality of Life (SAQoL-39), the Aphasia Depression Rating Scale, and resource use (for full cost evaluation) at 26 weeks post stroke. Therapy fidelity was measured according to the TIDiER statement with treatment adherence and treatment differentiation monitored throughout the trial. Clinicians in the UC-Plus and VERSE treatment arms were required to video record four therapy sessions (sessions 5, 10, 15 and 20). These sessions were reviewed by the independent therapy fidelity monitor and feedback was provided to therapists as part of the ongoing adherence to the treatment protocol. Data analysis will be completed in September 2018.

Results

17 sites recruited participants to this trial. Of 12,462 people with confirmed stroke screened for this trial, 3240 (26%) had aphasia, 526 (16%) were trial eligible and 246 (47%) were recruited. Reasons for non-recruitment of the 280 eligible participants included discharged out of area or to a non-VERSE site (35%), 13% refused to participate, 6% had insufficient staff to cover therapy, and the remaining eligible participants were classified as for palliative

care, recruited to another trial, or had aphasia that was either too mild or too severe for the trial.
To date, data collection is ongoing with the last participant, last visit due late July 2018. Over 10,452 speech pathology service events for all arms have been recorded. Of the received videorecorded sessions, therapy monitoring indicates treatment adherence to protocol is 80% and treatment differentiation is 100%. Full effectiveness and treatment fidelity results will be presented.

Discussion

VERSE is one of the largest clinical trials completed in aphasia intervention. It will be the first to report comprehensive treatment fidelity results that comply with the TIDiER statement for complex clinical trials. With high levels of therapy fidelity, this clinical trial will contribute substantially to the early aphasia therapy debate. When complete, cost evaluation evidence for this trial will further contribute to the evidence base to provide a comprehensive overview of early aphasia recovery after stroke.

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