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Very Early Rehabilitation in SpEech (VERSE) after stroke: trial status and recruitment.

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Background

There is limited evidence to support very early intensive aphasia rehabilitation as a best-practice standard in stroke care. VERSE is a randomised, open-label, blinded endpoint evaluation trial designed to determine whether two different types of intensive aphasia therapy, provided for 20 sessions, beginning within 14 days of acute stroke, provides greater efficacy and cost-effectiveness than usual care.

Methods

246 participants with acute post-stroke aphasia who meet the selection criteria are required. Participants are stratified by aphasia severity and randomised to receive usual care (usual ward based aphasia therapy), usual care-plus (usual ward based therapy provided daily) or VERSE therapy (a prescribed aphasia therapy provided daily). The primary outcome is the Aphasia Quotient of the Western Aphasia Battery at three months. Secondary outcomes include resource use, quality-of-life and depression measures.

Results

14 sites are involved in the trial with 11 sites actively recruiting to date. 3206 people with confirmed stroke have been identified since July 2014. 784 patients had aphasia (24%) and 157 (20%) were trial eligible. Of those, 67 (42%) have been recruited (September 2015). The top two reasons for non-enrolment include: Out of area rehabilitation services (32%) and participant refusal (20%).

Discussion

The post-stroke aphasia rate is lower than predicted. Our recruitment rate is higher than anticipated for this population. A new multi-site network has been built for this trial, which has slowed start up. When complete, this trial will provide Level 1 evidence to support clinical practice guidelines. Site recruitment is still open.