

# **Very Early Rehabilitation in SpEEch (VERSE): A prospective, multicentre randomised, controlled, open-label, blinded-endpoint trial in patients with aphasia following acute stroke**

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## **Background**

Limited evidence exists to support very early intensive aphasia rehabilitation. VERSE is a PROBE trial designed to determine whether two types of intensive aphasia therapy, beginning within 14 days of acute stroke, provide greater therapeutic and cost-effectiveness than usual care.

## **Methods**

Participants with aphasia following acute stroke were recruited from 17 acute-care hospitals across Australia/New Zealand and randomised (stratified by aphasia severity) using a centralised computer-generated system to receive Usual Care (UC), Usual Care-Plus (UC+) (usual care plus 20 sessions of direct aphasia therapy) or VERSE therapy (usual care plus 20 sessions of a prescribed direct aphasia therapy). The sample size required for the primary outcome (20% greater score on the Aphasia Quotient (AQ) of the Western Aphasia Battery) at 12 weeks was 246 patients. Secondary outcomes included AQ, discourse, quality of life, and depression measures at 12 and 26 weeks. Cost evaluation will be reported separately.

## **Results**

13,654 patients were screened; 25% had aphasia and of these 25% were trial eligible. 246 patients were recruited. Median scores were: NIHSS 9, mRS 4; 92% had an ischaemic stroke. Median age was 75 years, 50% were female. Baseline characteristics were equivalent for stroke and aphasia severity, age, gender and aetiology for UC (n=81), UC+ (n=82) and VERSE (n=83). Eighty three percent of participants completed the trial and 'data-lock' occurred on 30/7/2018.

## **Discussion**

The VERSE trial was completed with high fidelity data. The overall results, to be reported in this paper, will influence future aphasia rehabilitation practice after acute stroke.

## **Keywords**

randomised controlled trial, aphasia, rehabilitation, early, intensive