Therapy fidelity and trial progress in the Very Early Rehabilitation in SpEech (VERSE) trial

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Background: Therapy fidelity monitoring is essential in trial evaluations. However, previous adherence to a trial protocol investigating the effect of 28 hours of intensive, early aphasia therapy, was low (29%) and feasibility of adherence reported as 'improbable'. 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 efficacy and cost-effectiveness than usual care with particular attention paid to monitoring of trial fidelity.

Methods: Eligible participants with acute post-stroke aphasia are 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)(N = 246). Therapy adherence is independently monitored with feedback provided to therapists following analysis of video recordings. 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: 15 sites are recruiting. Of 6246 people with stroke 1575 (25%) had aphasia and 325 (20%) were trial eligible. 172 (53%) have been recruited. Monitoring of all therapy sessions and 259 video-recorded sessions indicates treatment adherence is 90% and treatment differentiation is 100%.

Discussion: Clinical trials reported without reference to treatment fidelity risk serious misinterpretation of outcomes. Our rigorous therapy fidelity processes demonstrate that early intensive aphasia therapy can be consistently provided at intense levels. With high levels of therapy fidelity, these data will contribute substantially to the early aphasia therapy debate.