ASSESSMENT OF THERAPY FIDELITY PROCESSES IN THE VERY EARLY REHABILITATION IN SPEECH (VERSE) CLINICAL TRIAL.

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Background: The benefits of intensive, standardised aphasia therapy after stroke are unclear. VERSE is a randomised, open-label, blinded endpoint evaluation trial designed to test whether two forms of daily, prescribed aphasia therapy for 20 sessions, beginning within 14 days of acute stroke, is more effective than usual care in promoting recovery from post-stroke aphasia in 246 eligible patients. Efficacy is determined by between group differences in the Aphasia Quotient of the Western Aphasia Battery at 3 months.
This substudy will describe the process of evaluating therapy fidelity in the three-arm trial: usual care (UC); usual care-*plus* (UC-Plus); or VERSE therapy. UC therapy is usual ward based therapy; UC-Plus is usual ward based therapy but provided daily, and VERSE therapy is a prescribed aphasia therapy provided daily.
Methods: All speech pathology services are being documented in the REDCap™ online database system. The primary outcome is adherence to the prescribed amount of therapy time. Secondary outcomes include adherence measures of therapy task, task instructions, cueing and production of verbal output as contracted to the intervention protocol for UC-plus and VERSE therapy. An independent evaluator will assess therapy fidelity from 4-5 video-recorded sessions (per participant) in UC-plus and VERSE groups. UC sessions will be video-recorded and evaluated as completed. Logistic regression will be used to compare group differences.
Results: This trial is currently running in 10 centres as of 9th January 2015.
Discussion: This methodological process will produce data that will enable the active ingredients of very early aphasia therapy to be determined.