**Establishing large scale therapy fidelity processes in the Very Early Rehabilitation in SpEech (VERSE) clinical trial: Lessons learned.**

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**Background**: Therapy fidelity is rarely reported in aphasia research. This omission contributes to the lack of clarity surrounding the efficacy of aphasia therapy. This paper reports the processes developed, and the barriers and facilitators involved in measuring therapy fidelity in a complex clinical trial - VERSE, an Australian three arm RCT investigating the efficacy of early post stroke aphasia intervention.

**Methods**: Investigators are asked to record one therapy session per week for all trial patients. An independent evaluator will assess therapy fidelity from 4-5 video-recorded sessions (per participant) in the treatment arms of the study. Sessions from the 3rd arm will be video-recorded and evaluated as completed. All therapy sessions are documented in the REDCapTM online database, with data cross-checked with the video recorded sessions. The primary outcome is the amount of time in therapy; secondary outcomes are therapist adherence to therapy protocol.

**Results**: 57 videos have been received and cross-checked. Barriers encountered relate to systems used to transfer large video files from sites to the central research office and time required to analyse videos due to complex nature of intervention. Facilitators relate to ‘people characteristics’ including problem solving skills and innovative thinking and ‘system characteristics’ including clear procedure manuals, measurement tools and systematized operating procedures.

**Discussion:** This level of assessment of treatment fidelity in a large scale aphasia clinical trial has previously not been completed. Problem solving and documentation of data management processes ratify successful monitoring of ongoing therapy fidelity and will contribute significantly to translation of trial findings.