Developing Process-Specific Verbal Memory Interventions for Veterans with TBI

Statistical Analysis Plan

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2.6. Statistical Analysis Plan

The procedure for classifying participants into Encoding, Consolidation, and Retrieval groups is outlined in Section 2.3.2. It is recognized that, although patients will be classified according to their primary memory deficit, some may have relevant impairment in more than one domain. For this reason, each participant will be given a composite score for encoding, consolidation, and retrieval, and all three of these composite scores will be used in exploratory analyses of predictors of treatment response. Phase 2 neuropsychological scores (z-score transformed data using appropriate age- and education corrections) and neuroimaging data (NEW, FA, diffusivity measures, morphological volumes, TI from RS-fMRI for specific ROI pairs) will be analyzed using 1-way (Group: Encoding, Consolidation, Retrieval) ANOVAs followed by pairwise follow-ups with the Tukey HSD test. Dependent variables used to evaluate memory performance in Phase 3 are detailed in Section 2.2 above, and include session-wise percent correct data on VPA and FNP memory probes as well as post-treatment and 1-month follow-up probes. Data from Phase 3 will be analyzed by comparing effect sizes of matched and unmatched treatments at the individual subject level using methods described by Parker et al[83-85]. These measures include (a) percentage of non-overlapping data points, (b) quantitative measures of improvement rate and difference level, and (c) Tau-U, a nonparametric measure of effect size that tests for differences in two treatments after trend adjustment. Additional measures will also be explored, including interrupted time-series/regression approaches and the last-day-of-treatment comparison approach[86]. We will also evaluate the separate influence that severity of memory deficit has on treatment response (independent of patient grouping) by performing hierarchical linear regression in which severity is coded as average z-score on memory indices derived from phase 2, and patient grouping is dummy-coded.