Cover page for statistical analysis plan

Official Study Title:
Virtual Reality-based Rehabilitation for Pediatric TBI (R00 Phase)

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Data Analysis Plan (Updated for 2nd NCE Period)

First, descriptive analysis will be conducted to compute the means and standard deviations of all predictor and outcome variables listed in the Measures section. Means of baseline covariates, including age, sex, injury severity, recency of injury, verbal intelligence, anxiety, and prior VR gaming experience, will be compared using independent samples t-test between intervention and control groups. Due to the randomization, we expect that most of covariates will show non-significant differences between assignment groups. These variables will be considered balanced between groups and not included as covariates in the analyses that follow. For the covariates that are found imbalanced between groups (perhaps due to the small sample size, they will be controlled statistically in the analyses that follow. This approach will reduce the number of covariates in respective statistical models and maximize the statistical power of each proposed analysis.

Next, hypotheses for each specific aim will be evaluated.

- **Aim 1**
  - *H1.1* and *H1.2* will be tested using a *multi-level model* where scores on VR tasks and NIHTB- CB tasks (H1.1) or BRIEF2 scores (H1.2) will serve as respective dependent variables. Study visit (pre, post, follow-up) will serve as a predictor that is nested within subjects and condition will serve as a between-subject predictor.
  - *H1.3* will be tested using a *multi-level model* where time (Day 1 – Day 30) is nested within subjects. The EMA-EF scores will be the DV, allowing each patient to have unique initial level and rate of change in daily EF across the 30-day period.
  - Multi-level models have been used in studies with sample sizes as small as single cases[1]. Therefore, our study with a sample size of 15 will be sufficient to conduct multi-level modeling analyses. Furthermore, in all multi-level models for Aim 1, we will use the Kenward-Roger correction in degrees of freedom[2] to further minimize small sample size bias and prevent inflation of type I error rates in estimation.
- **Aim 2**
  - *H2.1* will be tested using the same approach as H1.1-H1.2 via *multi-level modeling.* Study visit (pre, post, follow-up) will serve as a predictor that is nested within subjects and condition will serve as a between-subject predictor. The only difference is that for this model CPT 3 scores will serve as DV.
  - *H2.2* will be tested using an *independent samples t-test* with BASC- 3 APS scores at follow-up as DVs and condition as the IV.
  - *H2.3* will be exploratory in nature due to the small sample size. It will be tested using the SPSS Macro for 95% bias-corrected bootstrap mediation analysis with condition as the IV, VR and NIHTB-CB scores at post-intervention/follow-up as mediators, and CPT 3, BASC-3 at follow-up as DVs for each model.
- **Aim 3**
  - *H3.1* will be tested using the same approach as H2.2 via *independent samples t-tests.* The only difference is that for this model PedsQL scores at follow-up will serve as DV.
  - *H3.2* will be similar to H2.3 and exploratory in nature. It be tested using the same mediation analysis as in H2.3, but with PedsQL scores at follow-up as DV instead.

References

1. Shadish, W. R., Kyse, E. N., & Rindskopf, D. M. (2013). Analyzing data from single-case designs using multilevel models: new applications and some agenda items for future research. *Psychological methods*, *18*(3), 385.
2. McNeish, D. (2017). Small sample methods for multilevel modeling: A colloquial elucidation of REML and the Kenward-Roger correction. *Multivariate behavioral research*, *52*(5), 661-670.