**Live Video Mind-Body Treatment to Prevent Persistent Concussion Symptoms Following mTBI**

**NCT05524402**

**05/22/2024**

**Pilot RCT Primary Outcome Analysis Plan**. Frequency and proportions will be used to assess feasibility of recruitment and retention procedures. Proportions of patients with scores over the midpoint on the Client Satisfaction Questionnaire and the Credibility and Expectancy Questionnaire will be used to assess satisfaction, and credibility. Participants who drop-out will be counted as not meeting applicable feasibility criteria. Benchmarks that need to be met before an efficacy trial are depicted in the table below. If these are not met, revisions will be necessary. Benchmarks will be reported separately for TOR-C and HE-C. These benchmarks were previously used in NCCIH funded studies by the primary mentor (e.g. #3R34AT009356).

**Power analyses.** This trial is primarily focused on feasibility and acceptability, not statistical significance of efficacy. With a sample size of N=50 and assuming conservatively that the 8 feasibility criteria I will evaluate (see Section 4.9.3, below) are independent, the study will have 80% power to confirm feasibility all criteria if the expected rate of each criterion is at least 83%. Of note, we achieved 100% retention we achieved in some of our other studies, including the TOR study (preliminary study 1), and greater than 80% retention in our previous mind-body studies collected using live video. Importantly, this power analysis is not calculated to detect group differences or significant changes in outcome measures, but rather to establish feasibility. The proposed sample size is consistent with prior similar pilot trials funded by NCCIH, including a grant awarded to my primary mentor (#3R34AT009356).

**Exploratory analyses**: In line with common guidelines for feasibility studies, I do not aim to test efficacy of the TORC. I will focus our quantitative analyses on descriptive statistics for each quantitative measure, estimates of variance components, within-group pre-post comparisons using paired t-tests, calculation of Cohen's d effect sizes (ES) to gauge for signals for improvement in TOR-C, and exploratory correlations (e.g. between changes in anxiety and post-concussion symptoms).

**Sex as a biological variable**: I will assess both biological sex and gender in order to identify and account for potential sex and gender-based effects.