Study Title: Testing Intervention Strategies for Addressing Obesity and Binge Eating (K01 DK116925)
NCT Number: NCT04771455
Date: December 20, 2023

Statistical Analysis Plan

Data will be stored in the Research Electronic Data Capture (REDCap) program on a HIPAA-compliant server with secure access for approved study staff. Analyses will be conducted using SPSS and Supermix. For Aim 2a, I will calculate averages of acceptability ratings, number of sessions completed (retention to treatment), and prescribed strategies documented (compliance). These data will be used to derive expected usage rates for a future trial. For Aim 2b, I will assess the effect of each component on changes in weight and binge eating across time (baseline, post-intervention, follow-up), which will be done by comparing combinations of participants across conditions (see C.5 Research Design). Analyses will be conducted using intent-to-treat linear (for weight) or Poisson (for binge eating) mixed effects models, accounting for data collected at multiple assessment time points nested within individual participants. For each component, I will test differences in change in outcomes across time, with baseline values as the reference. Thus, effects will be modeled as component x time interactions. Cohen's d will be calculated by dividing the mixed effects model derived intervention effect estimate by the pooled standard deviation of the outcome. I also will report results disaggregated by sex and test sex as a moderator to evaluate sex differences in outcomes, which will inform the need for any sex-specific approaches in an optimized intervention. For Aim 3, exploratory analyses using linear mixed models will be performed to test two-way interactions between components on changes in weight and binge eating (e.g., Component 1 x Component 2 x time). Interaction tests are to determine if a set of components impact the overall effect and thus should be retained together in the optimized intervention.