

Improving Weight Loss Outcomes for Binge Eating Disorder
Statistical Analysis Plan
NCT03712462
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Statistical Analysis Plan

Statistical analyses were completed using R software version 4.1.3. Data were imputed via two methods to address missingness. Single imputation was used to impute weight measurements using a return-to-baseline approach, with dropouts assumed to have regained 0.15lb per week up to their baseline weight, consistent with assumptions used by other weight loss clinical trials (Wing et al., 2006). Other missing variables were imputed using R “mice” package (Van Buuren & Groothuis-Oudshoorn, 2011).

Descriptive statistics were generated for all variables at each assessment point by treatment condition. There were no differences in age, sex, racial or ethnic status, and therapist credentials between treatment conditions.

Mixed effects models were conducted for Primary Aim 1 (Efficacy of ABT) and Secondary Aim 2 (Between-Subjects Moderation) given nested data within subjects and group. The R “merTools” package was used for models predicting percent weight change and global eating disorder psychopathology change (Knowles et al., 2023), and the R “cplm” package was used for models predicting binge eating frequency change (due to zero-inflated distribution of percent binge eating change at post-treatment and follow-up) (Zhang, 2013). Models for percent weight and binge eating change included fixed effects for the interaction between linear or quadratic time effects and treatment condition (and baseline moderators for Secondary Aim 2). Only linear time effects were included in the models for global eating disorder psychopathology, since the quadratic time fixed effect did not significantly improve model fit. Model selection criteria (e.g., Akaike information criteria, Bayesian information criteria) and significance testing were used to identify the random effects structure that best fit the model. For percent weight change, models included separate random effects for intercept and slopes of quadratic time effects nested within subjects. For binge eating frequency change, models included random effects for intercept nested within subjects. For global eating disorder psychopathology change, models included separate random effects for intercept and slopes of linear time effects nested within subjects. No differences in results were observed when treatment format delivery (i.e., telehealth vs. in-person groups) was included as a covariate; therefore, results without the inclusion of treatment format delivery as a covariate are reported. Statistically significant interactions were interpreted by plotting simple regression lines for each variable. For all linear mixed effects models, alpha was set at 0.05 and confidence intervals were obtained. Cohen’s f^2 effect size measures were estimated for group x time interaction using methods described by Selya and colleagues (Selya et al., 2012), with $f^2 \geq 0.02$, $f^2 \geq 0.15$, and $f^2 \geq 0.35$ representing small, medium, and large effect sizes, respectively.

For Secondary Aim 1, mediation analyses were conducted using the R “lavaan” structural equation modeling package (Rosseel, 2012). Mediation analyses estimated the indirect effect of treatment condition through change in each mediator from baseline to 3-months on percent change in weight, binge eating frequency change, and global eating disorder psychopathology change at post-treatment and through changes from baseline to 6-months on weight, binge eating frequency change, and global eating disorder psychopathology change at one year follow-up. Baseline levels of the dependent variable and mediator were included as covariates in mediation models. Physical activity minutes and VLQ scores were z-score normalized to correct for significantly larger variances.

References

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