Evaluating an Eating Disorder Prevention Program for Young Women With Type 1 Diabetes

NCT05264376

January 31, 2024

Statistical Analysis Plan

For all outcomes except TIR we fit a linear mixed effect model where we regressed the outcome onto the pretest score for the outcome, treatment group (coded as treatment group 1, 2, 3, 4, or 5 or 0 for control), assessment (coded 0 for post-test and 1 for follow-up), and the interaction of condition (coded 0 for control or 1 for treatment) and assessment. Using treatment group instead of condition as a main effect enabled us to control for the partially nested design, where observations were nested within participants for the control condition and where observations were nested within participants nested within groups for the treatment condition. We included treatment group as a fixed effect rather than a random effect because the number of groups (n = 5) and the number of participants per group were small (n = 6). To control for repeated measurements for each participant we included a random intercept. Models tested for condition differences at post-test and 3 month follow-up. Because TIR was measured only at pretest and 3 month follow-up, we fit a multiple regression model where we regressed TIR at 3-month follow-up onto the pretest TIR score and treatment group. For all models, we examined modeling assumptions and transformed data as necessary. We square root transformed eating disorder symptoms to meet normality and homogeneity of variance assumptions. Missingness at pretest ranged from 0% to 11% for TIR; at posttest ranged from 11% for EDS to 15% for TII, BD, DD, and QOL; and at 3month follow-up ranged from 7% for EDS to 18% for TIR. Missingness was assumed to be missing at random and full information maximum likelihood was used to handle missing data, consistent with an intent-to-treat approach. Models were fit in R using the lavaan package.