Efficacy of Two Novel Behavioral Post-cessation Weight Gain Interventions

NCT03156660

Document Uploaded 21APR2022

Document Created JAN2019

Statistical Analysis

All of the analyses will be performed with SAS/STATv14.1. Data will be examined for distributional normality and outliers prior to any analyses. Descriptive statistics will be generated for all variables of interest included in the analysis, overall and by treatment arm. Univariate comparisons will consist of χ^2 tests and ANOVA. We will use similar analytical methods to compare baseline characteristics between study completers and non-completers at 12 months. Based on these findings appropriate adjustments will be implemented in the regression models.

Consistent with previous studies, outcomes will be analyzed on an intention-to-treat basis, including available data from all randomized cases, regardless of treatment adherence and smoking status. Missing outcome data will be imputed using Markov Chain Monte Carlo model based approach by treatment arm. Monotone missing data pattern will be created by using all available measured outcome data points. This approach is most suitable for an arbitrary missing data mechanism

Our hypotheses include that randomization to the SMALL and LOSS conditions will produce smaller post-cessation weight gain compared to participants in the BIBLIO condition. The main independent variable of interest will be treatment assignment and the outcome will be weight change from baseline to 12-month follow-up. Measures of weight will be obtained at multiple time points to provide feedback, but we will model only the final measure to capture full post-cessation weight gain. Two separate general linear and mixed ANCOVA-like regression models for continuous measures will be utilized, with treatment effect estimated as the distance between the fitted group-specific means at the 12-month data collection visit (SMALL compared to BIBLIO and LOSS compared to BIBLIO), while adjusting for the fitted distance between them at baseline. In addition, we will adjust within the model for demographic factors, baseline weight, and other covariates if needed; however, due to randomization, we do not anticipate significant differences in baseline distributions. We will also test the interactions between treatment assignment and demographic covariates to examine the homogeneity of treatment effects. We will include smoking status within our modeling strategy either as moderator or a confounder. We hypothesize no significant difference in post-cessation weight gain between the SMALL and LOSS conditions. We will compare the two conditions within the scope of the regression models described previously. The main treatment comparison results will be considered significant at $\alpha = .017$ due to three pre-planned contrasts, with all other associations at $\alpha = .05$.

We hypothesize that participants randomized to the SMALL, LOSS, and BIBLIO conditions will have similar rates of smoking cessation at 12-month assessment. Given that the outcome is binary (i.e., prolonged abstinence; yes or no) and the treatment conditions are nominal, we will use categorical analytical methods. To test the differences in prolonged abstinence between the intervention arms, we will apply χ^2 test and then a multivariate logistic regression model, with BIBLIO selected as the referent group compared to the other conditions. We will estimate the relative odds of a treatment effect on prolonged abstinence while adjusting for baseline demographics, smoking history (e.g., onset of regular smoking, quit attempts, use of tobacco products), process measures and other potential confounders. As such, we can test the associations and estimate effects of additional variables, besides treatment effect.