

2/26/2021

Statistical Analysis Plan

Study Title: Get Social: Randomized Trial of a Social Network Delivered Lifestyle Intervention

NCT02646618

Preliminary analysis

Baseline participant characteristics will be examined by condition. If groups differ on certain characteristics, these variables will be included as covariates in the primary analyses. Other preliminary analyses include assessing patterns of missing data, dropout rates, distributional properties of dependent measures, and correlations among outcome measures. A series of sensitivity analyses will be performed to examine the extent of potential bias by assuming the participants who dropped out are (i) missing completely at random (i.e., independent of the outcome), (ii) are responders to the intervention, or (iii) are non-responders to the intervention. Multiple imputation and other methods will be explored to address missing data for variables for which more than 5% of data are missing.

Primary non-inferiority outcome

We will model percent weight loss at 12 months using a linear mixed model, with percent weight loss as the dependent variable and study condition as the independent variable and accounting for repeated measures of weight. Test of the intervention condition indicator will provide a statistical test of the intervention effect and the estimated coefficient, along with the estimated confidence interval. This analytic approach aims to test whether the Get Social condition is not appreciably worse than (i.e., not inferior to) the traditional condition for percent weight loss at 12 months by our a priori inferiority margin of 2%. The effect estimates will reveal clinical non-inferiority of the Get Social condition if the confidence interval lies completely above $-\Delta$ or clinical non-inferiority of the traditional condition if the confidence interval lies completely below $+\Delta$, i.e., 2%.

Secondary non-inferiority outcomes

Linear multivariable models will be used to estimate change in daily caloric intake at 12 months; such models are reasonable given the target sample size and that changes in these outcomes are approximately normally distributed. We will examine the proportion of participants engaging in 150+ minutes/week of moderate/vigorous intensity physical activity (MVPA) using generalized estimating equations with a logit link function and incorporating repeated measures over time. For participants missing MVPA at either follow-up timepoint will use a baseline observation carried forward approach to impute their activity level (150+ vs <150 MVPA mins/week) at that timepoint. The distribution of secondary outcomes will be explored graphically and inform the primary outcome analysis; analyses will be modified as needed through transformation of the data.

Cost

We will calculate total intervention delivery costs per participant by treatment condition using time reported by intervention staff and convert to per-participant costs using national salary data from the Bureau of Labor Statistics. We will conduct sensitivity analyses to estimate a range of per-participant costs after varying the inputs (e.g., time spent conducting intervention, different intervention tasks, salary estimates). While we had originally aimed to examine costs for participants to participate in their respective intervention, we discovered methodologic challenges with collecting accurate and complete data from participants. As a result of what we learned, we have launched a separate study to develop methods for accurately collect participant time spent to participate in a social media delivered behavioral intervention. Without participant-level data, we are unable to conduct the analyses originally planned. Instead, we report the total intervention delivery costs per participant in both hours and dollars per participant for each of the two interventions.