Statistical Design and Power

Official Study Title: Culturally and Linguistically Adapted Physical Activity Intervention for Latinas, 2R01NR011295

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Data analysis will focus on testing differences in MVPA between the Enhanced Tailored Intervention and Original Tailored Intervention at baseline, 6 and 12 months. The primary variable of interest will be MVPA (collected objectively by accelerometer). We will use a single mixed effects regression model implemented with a random intercept, in order to test both the primary question of interest (differences between arms at 6 months) and the additional aim (testing differences in MVPA during maintenance phase). Random intercepts allow for adjustment of standard errors for repeated measures of the outcome over time. Models will adjust for any variables not balanced by randomization. Analysis will be conducted on the Intent to Treat sample with all participants randomized included in the analysis. Mixed effects models use a likelihood based approach to estimation and thus do not require any direct imputation of missing outcomes. To avoid the effects of potential outliers, we will apply a normalizing transformation to the response measure (MVPA at follow-up) before proceeding with the analysis. A similar series of regression models will be used to assess between-group differences in secondary measures (self-reported MVPA, biomarkers).

As a secondary step, we will compare the efficacy of the Original Tailored Intervention in Mexican American women to the results in the original population. That is, after adjusting for study differences (including potential confounders such as acculturation, country of origin), we will compare mean minutes of MVPA between the Original Tailored Intervention (in the proposed study) and the Tailored Intervention arm (from the original parent study) using a mixed effects model, similar to that described above. Our sample size calculation is based on the assumption that we will have 80% power for testing the null hypothesis that the intention to treat effect is zero, versus the two-sided alternative that the effect is different for those randomized to the Enhanced Tailored Intervention versus those randomized to the Original Tailored Intervention. The main outcome in this case is MVPA (objectively measured) at 6 months.

Our sample size estimates are based on mean MVPA at 6 months amongst those randomized to the Tailored Intervention condition in the original parent study (R01NR011295). Mean MVPA at 6 months was 52.51 (SD=98.34) for the Tailored Intervention arm. We hypothesize that the additional enhancements in the proposed study will translate into an additional 35 min/week of MVPA at 6 months compared to the Original Tailored Intervention arm. With 125 participants randomized to each arm at baseline in the current study, we expect to have sufficient power (80%) to detect differences in mean MVPA at 6 months between the Enhanced Tailored Intervention and Original Tailored Intervention conditions, using a two-tailed significance level $\alpha=0.05$. In addition, given a similar assumption of an additional 35 minutes of self-reported MVPA amongst Enhanced Tailored Intervention participants relative to Original Tailored Intervention (which was 73.36 in the original parent study) , the proposed sample size would also yield sufficient power (>80%) to test differences in MVPA at 6 months as collected via the 7 day PAR. It is important to note that this sample size is deliberately conservative as it does not assume the availability of repeated outcome measures that will be taken throughout the study. By choosing models that make use of the longitudinal data, we will be increasing the power to detect differences between treatment arms.