

Testing Adaptive Interventions to Improve Physical Activity for Sedentary Women

3/21/2018

NCT Number (not available yet)

Testing Adaptive Interventions to Improve Physical Activity for Sedentary Women

Statistical Analysis Plan

Under the direction of Dr. Schoeny, SAS (v9.3) and R will be used for statistical analysis. Because multiple outcomes are being evaluated in the primary aim, a two-tailed .01 significance level will be used for the statistical tests of these hypotheses. Secondary and exploratory aims will employ a standard two-tailed significance level of .05 for all statistical tests. All analyses will be performed on an intent-to-treat basis. A one-way analysis of variance will be conducted to look for potential diffusion effects. If significant differences are found, the estimated mean levels of diffusion will be used as weights in the efficacy analyses and cost analysis. Hypothesis testing will address four study aims.

Aim 1. Aim 1 is to compare the two augmented treatments used for non-responders, personal calls and group meetings, in improving physical activity and cardiovascular health after 35 and 50 weeks.

Hypothesis: Group meetings will be more effective than personal calls in improving physical activity and cardiovascular health after 34 and 50 weeks, among non-responders to the initial treatment.

This hypothesis will be tested using a multilevel analysis with time nested within participant (i.e., non-responders only). The hypothesis of the study is that the non-responders who receive group meetings will demonstrate greater improvement in physical activity (self-report life-style and occupational physical activity: minutes of moderate/vigorous physical activity/weeks; device: number of steps/day, minutes of moderate/vigorous physical activity/ week) compared to those who receive personal calls.

Aim 2a. Aim 2a is to compare enhanced physical activity monitor with and without text messaging for improving the level of physical activity from baseline to 8 weeks. These analyses will parallel those used for Aim 1, but consider only two time points (baseline and 8 weeks) and include all participants.

Hypothesis: Participants who receive enhanced physical activity monitor+text messaging as compared to those who receive enhanced physical activity monitor alone will show greater improvement on physical activity at the end of 8 weeks.

Aim 2b. Aim 2b is to compare the four adaptive interventions in improving physical activity and cardiovascular health from baseline to 8, 34, and 50 weeks. The analysis is parallel to that described in Aim 1, except that the participants are not assigned to treatment based on simple randomization. Instead, they are screened on the basis of response status, and, once it has been ascertained that they did not respond to the initial treatment, they are randomly assigned to a treatment condition. Due to this design, the contrasts used to estimate the efficacy of these effects are nonorthogonal. The weights associated with the four interventions are then scored as a 4 for non-responder subgroups and 2 for responder subgroups. This is because responder subgroups are used twice in the design matrix (e.g., subgroup A is used in adaptive interventions 1 and 2; Figures 2 and 3). The estimation of these models is then based on a weighted multilevel linear regression model that has terms for change over time, the initial treatment, the augmented treatment, the interaction between the two treatments, and the effects of baseline and time-varying characteristics. The critical effect in this model is the time-by-adaptive-intervention interaction term. The null hypothesis is that there will be no interaction effect at all, while the alternative hypothesis is that adaptive intervention 4 (enhanced physical activity monitor+text messaging [initial] and enhanced physical activity monitor+text messaging with group meetings [augmented for non-responders]) will produce the largest improvement rates.

Aim 3. Aim 3 will identify mediators and moderators of the initial and augmented treatments on physical activity and cardiovascular health. Using analytic models parallel to those for Aims 1 and 2, we will first test impact on intervention targets (benefits, barriers, self-efficacy, social support).

Hypothesis: The intervention targets (benefits, barriers, self-efficacy, and social support) will mediate the effect of the initial and augmented treatments on physical activity (8, 34, and 50 weeks) and cardiovascular health (34 and 50 weeks).

Research Question: Do characteristics of participants (prior physical activity, demographics, BMI, depression) and their environment (walkability, crime) moderate the effects of the initial and augmented treatments on physical activity and cardiovascular health?

Although we will test the impact of each treatment on all potential intervention targets, we anticipate variation in impact by treatment (e.g., initial treatment is less likely to impact social support). For intervention targets that are significantly impacted by treatment condition, we will test whether they serve as mediators of intervention effects on physical activity and health status outcomes using methods described by MacKinnon. Moderation effects will be tested by adding moderator main effects and interactions of the moderators with condition and time. Significant moderator effects (i.e., significant moderator-by-time-by-treatment effects) will then be used to identify optimal decision rules for individual participants. The estimation of optimal decision rules will be achieved using a Q-Learning analysis, which is a modified regression analysis, adapted to address the SMART design. These optimal decision rules can then be cross-validated in future studies.

Aim 4. The cost-effectiveness analysis will be conducted from the societal perspective, including the program and participant costs. For the cost measurement, quantities of resources used and their associated prices will be collected for the program (either amounts paid or the value of the interventionist's time), and participant (i.e., the value of the participant's time to participate in the program). All costs will be valued in 2017 dollars. Program costs and participant costs will be calculated by summing their respective individual cost components, and these costs will be summed to calculate the total cost per participant.

For the effectiveness measurement, effectiveness will be measured using physical activity and cardiovascular health outcomes for a total of six measures (physical activity steps, self-reported light/moderate/vigorous physical activity, occupational physical activity, aerobic fitness, BMI, waist circumference). Cost-effectiveness will be evaluated by combining the mean total cost per participant with effectiveness (physical activity, cardiovascular health). We will calculate the incremental cost-effectiveness ratios (ICERs) for the four adaptive interventions: (1) enhanced physical activity monitor (initial) and enhanced physical activity monitor with personal calls (augmented); (2) enhanced physical activity monitor (initial) and enhanced physical activity monitor with group meetings (augmented); (3) enhanced physical activity monitor+text messaging (initial) and enhanced physical activity monitor+text messaging with personal calls (augmented); or (4) enhanced physical activity monitor+text messaging (initial) and enhanced physical activity monitor+text messaging with group meetings (augmented), such that the $ICER = (C_i - C_j)/E_i$, where C denotes total cost and E denotes effectiveness. Effectiveness will be measured as the change in each outcome between baseline and study completion at 51-52 weeks. Subscript i denotes 1 of the 4 adaptive interventions, and subscript j denotes the comparison intervention group. We will calculate six sets of ICERs, one for each effectiveness measure; 95% confidence intervals will be calculated to evaluate the uncertainty in these results. We will conduct one-way and multi-way sensitivity analyses for the key parameters to evaluate whether the ICERs are sensitive to plausible changes in their values. We will also plot acceptability curves based on varying threshold (willingness to pay) values for adherence and change in physical activity and cardiovascular health outcomes. Separate ICERs will be calculated from the program and participant perspectives.