Behavioral Economics to improve Antihypertensive Therapy Adherence (BETA)

NCT04029883

Statistical Analysis Plan

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Cedars-Sinai Medical Center Smidt Heart Institute We will determine acceptability and feasibility from participants' program experience described above and the focus groups in Phase 3. To estimate preliminary efficacy, we will perform statistical analyses comparing group-level differences in the primary and secondary outcome measures. We will use an Analysis of Covariance (ANCOVA) framework to test for group differences in each outcome at 3-month intervals, controlling for the client characteristics that are found to differentiate the groups at baseline. For analyses of dichotomous variables, such as hypertension control, we will use a non-parametric McNemar's test and an analogous multiple logistic regression to control for covariates to assess group differences. In addition to static comparisons of group means for each outcome at 3-month intervals, we will take advantage of the longitudinal nature of the data by using repeated measures and time-series techniques. Specifically, a linear mixed model with repeated observations will be fit using maximum likelihood through 'xtmixed' in the software package Stata in order to study group-level temporal dynamics in daily measures of the primary and secondary outcomes.

Specific Aim 2a: The overall impact between the pooled (*Message* group + *Incentive* group) compared to the *Control* group will be evaluated using both: 1) the comparison of group means and 2) a repeated observation regression framework that controls for observable differences between study groups and the correlation between observations of the primary and secondary outcomes for the same individual over time.

Specific Aim 2b: The impact between the more intensive Incentive group compared to the lowerresource Message group will be evaluated using the same methods as above. Through this modeling framework we will utilize a range of variables. The independent variables in the above regression models will be used not only as control variables to improve efficiency but also to learn about the paths through which the intervention works and to identify subgroups that are likely to particularly benefit from the intervention. For example, by estimating regression models with and without measures of participants' intrinsic motivation as independent variables, we can study the mediating role of motivation on the formation of behavioral routines. The conceptual framework allows for additional mediators of behavior such as present bias, which may naturally hinder the capability of some participants to establish healthy routines. One additional method for testing this effect is to form an interaction between the present bias measure and the intervention indicator variable. With respect to the dependent variables, the primary and secondary outcomes are mean antihypertensive adherence and blood pressure control, with an exploratory focus on our quantified measure of adherence routinization. Continuous variables will be assessed for normality and transformed if needed. We will conduct analyses for the whole sample as well as separately by age and sex to better understand potential heterogeneous treatment effects. Logistic models will be estimated for binary outcome measures. We will also test whether routine adherence can be predicted based on observable characteristics; if so, in the subsequent R01 study the intervention may be targeted to those least likely to form healthy pill-taking routines on their own.