Statistical Analytic Plan
Tailored Approaches to Improve Medication Adherence
NCT01643473
05/10/2018

Analysis of the qualitative data: Dr. Schoenthaler and a trained research assistant conducted the qualitative analysis of the audiotaped interview data. Transcripts of the interviews were uploaded to the Atlas.ti program in order to code the data and facilitate content analysis. The transcripts were individually reviewed and analyzed using the grounded theory constant comparison method. Specifically, transcripts were coded line-by-line using open coding (comparing and categorizing data to generate concepts); axial coding (reorganizing data into categories based on relationships within and between these categories); and selective coding (identifying and describing the central themes to generate a conceptual framework) according to issues related to medication-taking (e.g., side effects, cost, forgetfulness). Once the transcripts were independently coded, the research team met to discuss the coding and resolve any discrepancies.

Analysis of study feasibility: We assessed reach of the intervention by examining the ratio of eligible participants invited to participate vs. those that enroll in the study. We also collected data on patients' age and gender to determine if there are any differences between eligible participants that do not enroll vs. enrollees. Independent t-tests and the chi-square statistic were used to determine if there are any significant differences between the groups. Reasons for not enrolling in the program were also documented. In addition to these outcomes, exit interviews were conducted with a subsample of 12 participants to assess acceptability and satisfaction with the program.

Analysis of exploratory outcomes: To test the exploratory aim, we conducted separate differences in differences estimations for each of the outcome measures (i.e., adherence, BP HbA1c) whereby pre-intervention values are subtracted from post-intervention values, and change amounts by study group are compared using t tests. We also conducted linear regression models to examine whether the average baseline scores were significantly different from the average scores at 3 months, when, controlling for baseline levels of the outcome measure (i.e., adherence, BP HbA1c), age, gender socioeconomic status (SES), insurance status and number of medications