Patient-centered services to improve specialty medication adherence: results from a prospective randomized controlled trial

NCT03709277
Protocol Date: 08/17/2022

All outcomes and analyses are prospectively characterized as primary or secondary.

This is a superiority trial with intervention expected to yield superior outcomes, compared to control. However, all outcomes will be tested independently at the two-tailed 5% significance level. All estimates of treatment effects will be presented with 95% confidence intervals.

No formal adjustments will be undertaken to constrain the Type I error associated with planned secondary or exploratory analyses. The information provided by analyses is designed to supplement the evidence from the primary analyses; it will provide a more complete characterization of the treatment effects.

The analyses for all quantitative outcome measures will be conducted on an intention the treat (ITT) basis, i.e. all participants will be analyzed in the trial phase (control or intervention) in which they were recruited, regardless of whether their treatment adhered to the trial protocol or not, assuming they have enough information to calculate the outcome. The ITT strategy for this trial is based on the following principles:

- All available outcome data are collected on all recruited participants
- For the ITT analysis, the outcomes for each participant having at least 2 post-enrollment medication refills (required for primary outcome calculation) will be included in the data for the trial phase (control/intervention) in which the participant was recruited.
- The primary analyses will be reported for all participants having 2 medication refills post-enrollment. If the amount of missing data exceeds 10% at the primary endpoint, missing data will be imputed under the assumption that data is missing at random.

All analyses will be conducted using the R Statistical Programming Language 4.0.2 after data collection is completed.