Study Title: Intervention for Cognitive Reserve Enhancement in delaying the onset of Alzheimer's Symptomatic Expression (INCREASE) Study

ClinicalTrials.gov NCT02849639

Developed: December 14, 2015

Statistical analyses

We will use Student's t-tests (or Wilcoxon rank sum tests for non-normally distributed variables) and chi-square or Fisher's exact tests to assess the comparability of randomized study groups. To examine the effect of the intervention on prescribing appropriateness we will perform analysis of covariance (ANCOVA), with the dependent variables being the difference between MAI scores at baseline and the follow-up measure. We will control for any variables that might be significantly different between groups at baseline that have not already been included in the study protocol in regards to stratification of subjects.

Data evaluating cognitive reserve will be analyzed by intervention groups. For Aim 2, the impact on cognitive reserve will be assessed across the full range of SUVR (i.e., SUVR will be included in the analysis as continuous variable). If imbalance exists between groups after randomization, covariates for analysis will include age, gender, education, NART scores, and the number of targeted inappropriate medications using 2015 Beers Criteria. We will investigate change from baseline in CRCS by group using ANCOVA.

For the perceived health status measure, because the SF-36 does not produce a single overall measure and because of our concern regarding multiple comparisons, multivariate analysis of covariance (MANCOVA) will be used to simultaneously estimate the effect of the intervention on the eight SF-36 health concepts. Similarly, we will also control for any variables that might be significantly different between groups at baseline.