Statistical Analysis Plan

Aides in Respiration (AIR) Health Coaching for Patients with COPD

NCT02234284

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Baseline participant characteristics were compared between study arms and tested for significance using chi-square for categorical variables, t-tests for normally distributed continuous variables, and appropriate non-parametric tests for non-normally distributed continuous variables. Outcomes were compared by group assignment (intention to treat) using generalized linear mixed models (GLMMs) with a normal distribution and identity link for continuous outcomes and Poisson distribution with a log link for count outcomes. GLMMs uses random effects to account for within-participant correlations, nested random effects to account for clustering, and accommodate missing data under the assumption that the outcomes are missing at random.[1-5] In all models, baseline levels of the outcome were entered as a predictor and follow-up levels as the dependent variable, with a nested random effect of practice site to account for clustering. Hypothesis tests were 2-sided with p-values<0.05 considered statistically significant. Models used available data, while sensitivity analyses were conducted repeating primary analyses with multiple imputation procedures. Additional, exploratory per protocol and sub-group analyses were also performed, limiting patients in the coached arm to those receiving at least half of the protocol target for contacts. Differential effects (effect modification) was examined for 3 pre-specified subgroups: English vs Spanish as primary language; current smokers vs other; and COPD classification GOLD category D (high symptoms and high risk) vs other.

O. References

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