

Clinicaltrials.gov Cover Sheet

Official Title: A Randomized Controlled Trial of an Antiretroviral Treatment Adherence Intervention for HIV+ African Americans

NCT03331978

Date: 10.30.2017

Statistical Analysis Plan

Descriptive statistics will be performed on all study variables. If related to the primary study variables, analyses will treat covariates as confounding variables. If we have high retention and find statistically significant differences between respondents and non-respondents at follow-up, we will construct and employ inverse predicted probability nonresponse weights. If item non-response is substantial, we will address it through multiple imputations. We may transform outcomes with skewed distributions (log or other as appropriate) to stabilize error variances and reduce the influence of outliers in regression models.

To assess Rise's effects on adherence and viral load, we will use generalized linear mixed models. Specifically, we will employ a repeated-measures logistic regression approach to predict optimal adherence (i.e., dichotomous adherence) with electronic monitoring data collected at enrollment and each follow-up. We will use as covariates any socio-demographic, psychosocial, and contextual variables that are associated with the adherence outcome. We assume a linear trend over time for adherence. We can also explore non-linear time trends for sensitivity analysis to this specification or assumption. To assess Rise's effects on viral suppression, we will conduct similar logistic regressions predicting viral load (dichotomized as undetectable vs. detectable) at 6- and 12-months post-enrollment. We will use similar repeated-measures linear models to examine Rise's effects on linear adherence (percentage of prescribed doses taken).