Brief Acceptance-Based Retention Intervention for Newly Diagnosed HIV Patients

NCT04201288

Statistical Analysis Plan – 4/23/19

Data analytic plan (Aim 1).

We will use logistic regression to test the hypothesis that compared with ETAU, ABBT will increase the likelihood of meeting minimum DHHS recommended HIV care. To test the hypothesis that ABBT will result in improved virologic suppression, relative to ETAU, MANCOVA will be used. Planned baseline covariates include age, gender, race-ethnicity, HIV viral load, and study site. Any baseline variables associated significantly ($p < .10$) with subject attrition will also be included as covariates. We will also co-vary for cumulative TAU exposure. A 2-tailed probability of Type I error $< .05$ will be used for all null hypothesis tests.

We will use latent growth models (LGM) to estimate the effect of intervention on ART adherence, disclosure of HIV status, perceived social support, and HIV stigmatization. Data will be available from baseline, 1-, 3-, 6-, 9-, and 12-month follow-ups. This approach offers the flexibility to accommodate outcomes with a range of exponential family (e.g., normal, binomial, etc.) error distributions and allows a comparison of possible alternative growth processes (linear, quadratic, unconstrained with freely estimated time values) describing change over time. Initially, the Satorra-Bentler Scaled Chi-Square85 will be used to compare linear change, quadratic change, and models with freely estimated time values. After identifying the best fitting unconditional LGM, conditional LGM models will be estimated in which the intercept and slope growth factors will be regressed on group, age, gender, race/ethnicity, and any baseline measures that significantly ($p < .10$) predict attrition. Significant differences in slope growth factors are consistent with the hypothesis that the ABBT and ETAU arms experience different patterns of change over time.

Data analytic plan (Aim 2).

The hypothesis that the effects of ABBT will be mediated by increased HIV acceptance and increased willingness to disclose HIV status will be tested in a latent growth model framework91. We will extend the LGMs estimated when testing the effects of ABBT on secondary outcomes (AIM 1). The slope growth factors in the LGM are latent variables that represent change trajectories which can be used to account for differences in more distal outcomes. For example, the likelihood of meeting minimum DHHS recommended HIV care. Mediation is tested by specifying an indirect effect defined as the product of the effect of intervention on the slope growth factor of the hypothesized mediator (HIV acceptance, increased willingness to disclose) by the effect of the mediator on meeting DHHS recommended HIV care. Bias-corrected bootstrap resampling is generally recommended for testing the statistical significance of indirect effects92. Simulation studies have generally shown this method to be the most efficient method for testing mediational hypotheses64, 93. Mplus82 statistical software has facilities to specify and estimate the LGM mediation models.