

Statistical Analysis Plan Cover Page

Official Study Title: Assessing HIV Screening in African American Churches
NCT02529644

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Statistical Analysis Plan

Specific Aim 1. Test a religiously/culturally-tailored, eTPB church-based HIV screening intervention against a standard information condition and a waitlist control condition on receipt of HIV screening and HIV sexual risk behaviors among an AA church-population at 6 and 12 months. Hypothesis. The religiously/culturally-tailored, eTPB church-based HIV screening intervention will evidence higher HIV screening rates and lower sexual risk behaviors than the standard information and waitlist control conditions.

Data will be initially summarized using means, standard deviations, and percentages. Our primary outcome is receipt of HIV testing (tested vs. not-tested) at 12 months. We'll also examine outcomes at 6 months. Churches are the unit of randomization and participants nested in churches will be the level of analysis. Therefore, differences between intervention and standard information groups will be analyzed using random effects logistic regression to account for the clusters and the pairing, or matching, of churches. Multilevel, multivariate models will include fixed-effect terms for experimental condition and potential mediators and moderators, as well as random effect terms for church nested in treatment condition and individual nested within church. This approach has been widely used in other church-based studies. Adjusted odds ratios for HIV testing (and confidence intervals) will be computed for mediators/moderators. Other covariates will be added as indicated by univariate analyses conducted on baseline data. A propensity score matched analysis will also be run using all available covariates. We will use R and SAS statistical software generalized estimating equations and generalized linear mixed modeling for data analyses to determine if there is a difference in HIV screening rates over time between intervention and standard information groups with/without adjusting for covariates. We will do a stratified analysis by Wave to explore differences between: a) Wave 1 intervention and waitlist groups and b) Wave 1 standard information and waitlist groups using similar analysis methods described above. A similar process will also be used to analyze HIV sexual risk behaviors using mixed-model ANOVA programs that allows for adjustment of participant nonindependence within churches.

Specific Aim 2. Evaluate the role of potential mediators and moderators associated with HIV screening behaviors among a church-population at 6 and 12 months.

Mediation analyses will examine to what extent possible intervention effects on HIV testing might be explained by potential mediators, including TPB-based variables (attitude, normative beliefs, behavioral control, intentions) and other covariates (HIV stigma, HIV knowledge, intervention exposure). We will assess if: 1) intervention is significantly related to outcome (HIV testing); 2) intervention is significantly related to potential mediators; 3) mediators are significantly related to outcome. Specifically, we will estimate the indirect effects defined in terms of products of path coefficients—linking the intervention to outcomes via each potential mediating variable using multilevel structural equation modeling. The statistical significance and precision of these indirect effects will be addressed by: a) employing the product of coefficients approach and b) obtaining bootstrapped confidence intervals for indirect effects. Mediation will be tested using the Sobel test available as a SAS macro and an R package, *bstats*, and by using structural equation models in MPLUS software as described by MacKinnon et al. Effects of potential moderators' ability to modify the strength/direction of the potential causal relationship will be tested using interaction tests in a multifactorial model.

Specific Aim 3. Conduct a process evaluation to understand study implementation facilitators, barriers, fidelity, and costs and examine relationships between study implementation, intervention dose and exposure, and intervention outcomes to identify and improve essential intervention components.

Implementation dose and fidelity. Direct observation fidelity checklist and online documentation data will be analyzed using means, standard deviations, and percentages to assess study group dose and fidelity. **Intervention program costs** will be assessed overall and per participant using summation of implicit costs (e.g., volunteer time, church in-kind) tracked with the online documentation system and explicit costs (e.g., provision of training/technical assistance, HIV Tool Kit costs). **Focus group discussions** will be audio-recorded, transcribed, coded, and analyzed using NVivo, a qualitative data software program. Coding protocols will include initial transcription "open-coding" (e.g., identifying key words, themes, behavioral descriptions), category grouping (e.g., church-based testing barriers), and code map development to further categorize and retrieve factors (e.g., challenges, facilitators) related to delivery/receipt of church-based HIV testing services and intervention refinement strategies/tools. Intercoder agreement will be assessed with the kappa coefficient.