Statistical Plan
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Title of the study: Implementation of Trauma-informed HIV Care in Memphis, TN
Meharry Medical College
Clinical Trials registry: 22-08-1234
August 15, 2025

C1d. Analysis Plan for Aim 1: (data not included in trial but completed to prepare for trial) To analyze FGD, Dr. Brown (PI) and Research Assistant (RA) will create a codebook by each independently coding data. Themes will be reviewed with mentors Drs. Audet, Pettit, Pichon, and Sales to reach a 95% theme agreement and consensus, with final review to be conducted with the TSC. Framework Method and NVivo software 12 (QSR International) will be used to determine themes according to the ADAPT-ITT framework, eight elements for measuring intervention contextual fit, and the cultural responsiveness sub-scale of the Organizational Trauma Resilience Assessment, while allowing others to emerge. We will also generate code reports and summary tables from "thick descriptions" of activities associated with phases 1-6.

C2d. Analysis Plan for Aim 2:

Primary- and secondary- outcomes will be assessed using mixed effects models. Linear mixed effects models will be used for measures with a continuous outcome (e.g., TIHC attitudes) and ordinal mixed effects models will be used for measures with Likert scales (e.g., professional quality of life Mixed effects models will include a random effect per person to account for the correlation between observations taken from the same individuals over time. Our primary analyses will look at effect of time comparing baseline (time 0) with post-intervention time periods (times 1-4: every six months for two years after baseline) for two years. Covariates included in these models are job position, age, sex, and race. Additional analyses include level of intervention engagement (proportion of attendance in required trainings) as an exposure variable. FGD will be analyzed according to section C1d methods. *Sample Size and Power Calculations:* With a two-sided type I error rate of α=0.05, n=70 personnel, we have 80% power to detect a small-to-medium standardized mean difference (of 0.34) between pre- and post-intervention measurements for trauma resilience (primary measures 1-4 are based on findings from a past study [N=150] showing significant increase between pre: *Mean*=58.0 and post: *Mean*=61.7 measures, with medium effect size, via the validated tool we will use) and professional quality of life (with secondary measures 1-2 based on a past study [N=50] showing significant decrease in burnout between baseline and six month follow-up, from pre: *Mean*=24.5 to post: *Mean*=20.9. Past research with St. Jude personnel found an 85% participation rate, indicating the invited 117 personnel as more than sufficient to reach the needed sample size of 70.

C3d. Statistical Considerations for Aim 3:

Statistical Analysis Plan: We will compute summary statistics and plots to inspect data for missingness and distribution normalcy, including a scatter plot of the time series and bivariate comparisons between pre-post intervention periods to assess outcomes. For appointment adherence, we will use a Poisson regression model to conduct an interrupted time series (ITS) analysis with level change (levels of intervention phases/components and sessions) to detect associations between the patient-level intervention (primary exposure) and changes in appointment adherence, with up to 12 time points possible, with only three points on either side (pre and post intervention) needed for the ITS design. Models will adjust for covariates, including gender, age, race, and ethnicity. For trauma response, we will use linear mixed effects models to investigate impact of the primary exposure on trauma response over time. To ensure rigor and reproducibility, we will only conduct post-intervention adherence after the intervention is complete, in case participants engage with intervention during routine appointment times. We will conduct exploratory analyses to explore dose-response effects by number of intervention sessions completed and impact of the novel component on missed HIV appointments and trauma response as a time-varying covariate in the Poisson regression model; sensitivity analyses may be needed to account for missingness in trauma response (time-varying covariate) when participants miss visits (primary outcome) and fail to complete remote assessments. Qualitative interviews will be analyzed according to Section C1d methods but using the Trauma Symptoms of Discrimination and Multilevel Resilience Scale to determine themes, while allowing others to emerge. *Sample Size and Power Calculations:* The current missed visit rate is ~50%. With a pooled sample size of the total 70 participants, we anticipate having 80% power to statistically detect a change in the missed visit rate from 50% in the pre- intervention period to at least 28% in the post-intervention period, corresponding with a nearly 2.6x increased odds of appointment adherence. This calculation was based on a two-sided type I error rate of 0.05. Our preliminary work shows adults receiving a trauma intervention had 4x increased odds of appointment adherence, indicating this intervention effect on missed visits is plausible. As a secondary goal, we will compare outcomes between intervention groups, expecting similar improvements in appointment adherence but a greater impact on trauma effects in the experimental component.