SUPPLEMENTAL DATA ANALYSIS PLAN

Project Title:	**Hybrid Effectiveness-Implementation Trial for ART Adherence and Substance Use in HIV Care in South Africa**
Principal Investigator:	Jessica F. Magidson, PhD
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DATA ANALYTIC PLAN

Implementation Outcomes

Quantitative. Descriptive statistics will be generated to evaluate implementation outcomes. Total scores from the acceptability and feasibility subscales of the AMHR pragmatic implementation assessment will be created; these scores, alongside data obtained on provider fidelity to the intervention and patient participation and retention will first be evaluated descriptively. The means and standard deviation of provider fidelity at each session will be calculated. The percentage of patients participating and retained in the intervention will be described. These implementation outcomes will be compared with other similar pilot studies and used as pilot data for the subsequent R01 proposal from this K23 award.

Qualitative. Data from individual interviews to assess implementation outcomes will be analyzed iteratively and follow descriptive qualitative thematic analysis. Guided by RE-AIM and Proctor's model for defining implementation outcomes, initial concepts related to the central research questions listed will be identified based on the semi-structured interview guide. Concepts will be used to develop a codebook consisting of a label, a definition, and illustrative quotes from the data. All transcripts will be coded independently by two research assistants. Final themes will be agreed upon and inter-rater reliability of coding assessed. Following recommendations of mixed methods designs, we will integrate findings from the qualitative and quantitative methods using a convergent QUANT + qual mixed methods design to assess implementation outcomes. Specifically, themes from the qualitative interviews will be compared with the quantitative descriptive data on feasibility and acceptability, assessing for both convergence and divergence.

Effectiveness Outcomes

Quantitative. Quantitative longitudinal analysis will examine changes in ART nonadherence, substance use, and viral load from baseline to post-treatment between the conditions. If appropriate after examining descriptive data, normality, and assumptions, T-tests may be used to compare continuous variables (e.g., age, ART nonadherence) and Fisher's exact test may be used to compare categorical variables (e.g., gender, urinalysis). If the appropriate statistical assumptions are met after examining distributions of main outcome variables, longitudinal data analysis using generalized linear mixed models (GLMM) will be used to compare the two study arms over time. This approach increases power by including all available data points. We will adjust the analyses for relevant baseline demographic characteristics (e.g., gender, age) for each analysis, and clinical differences that exist between the two treatment arms. Intent-to-treat analyses will be utilized, where all individuals will be analyzed according to the condition to which they were randomized.