Statistical Analysis Plan

Investigating the Effectiveness of an Entertainment Education Short Film for Internalized HIV

Stigma Reduction, Intimate Partner Status Disclosure Intentions, and Antiretroviral Medical

Adherence Intentions: A Randomized Controlled Trial Among Black Women Living with HIV

in the Southern U.S.

ClinicalTrials.Gov Identifier: NCT03898063

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Introduction: Purpose of the Statistical Analysis Plan (SAP)

The purpose of this Statistical Analysis Plan (SAP) is to detail the study objectives, study hypotheses and research questions, as well as the primary outcome measures and data analyses.

Study Overview

This randomized controlled trial was conducted among Black women living with HIV in the Southern U.S. between the ages of 18 and 50. The study examined the efficacy of a short entertainment education (EE) narrative in comparison to a standard brochure for primarily improving the following: HIV status disclosure intentions, internalized HIV-related stigma, and antiretroviral medical adherence. Once consented, all participants completed a pre-test survey. Upon completing the pre-test, using the randomization feature in Qualtrics, participants were randomly assigned to one of two study arms: 1) EE narrative or 2) Brochure. After viewing the EE stimulus or the brochure, participants immediately completed a post-test survey. The primary aim of the study is listed below.

Aim 1. To investigate the effectiveness of an EE intervention for decreasing internalized HIV-stigma and increasing HIV status disclosure intentions and medical adherence intentions among Black women living with HIV in the Southern U.S.

The hypotheses guiding this research study included the following:

H_{1a-c}: Participants in the EE condition will report: a) lower levels of internalized stigma; b) higher levels of disclosure intentions; c) higher levels of medical adherence intentions.

Data Collection Plan

Participants will be recruited via two primary methods. Firstly, Facebook advertisements will be deployed to recruit participants who meet the inclusion criteria. Secondly, participants will be recruited via a Qualtrics panel.

Statistical Methods

An Analysis of Covariance (ANCOVA) will be used to control for the influence of age on the relationships of interest. This analysis will determine if there is a statistically significant difference between the treatment arm (90 DAYS film) and the control arm (Brochure) on the following primary variables: internalized stigma, intentions to disclose, and intentions for medical adherence. The analyses will be conducted using SPSS version 24.