Official Study Title: An Economic and Relationship-strengthening Intervention for HIV-affected Couples Who Drink Alcohol in Malawi

NCT #: NCT04906616

December 4, 2023

Study Protocol and Statistical Analysis Plan

Mlambe Protocol

For Aim 1, we will adapt and integrate two efficacious interventions (Suubi and Uthando Lwethu) into a combined intervention targeting alcohol use in HIV-affected couples. After developing a draft of the intervention manual, we will conduct 5 focus group discussions with key stakeholders (e.g., HIV care providers, village and religious authorities, traditional marriage counselors, microfinance and banking representatives) and couples from the target population. Findings will be analyzed and incorporated into the intervention.

For Aim 2, we will develop the materials to conduct a pilot RCT of the intervention in order to assess feasibility and acceptability. Materials to be developed include randomization procedures, intervention manuals, training procedures, study procedures, and study instruments.

For Aim 3, we will recruit 80 couples with at least one partner on ART who is a heavy alcohol user from two HIV clinics in Malawi to participate in the pilot RCT (40 couples per arm). Couples will be screened for inclusion in the study and will complete baseline surveys directly following consent and enrollment. Following the completion of baseline surveys, couples will be randomized to either the control or intervention arm in blocks of 20 couples each until the sample size is reached. A block randomization schema will be generated by the project statisticians using SAS. Couples will be given sealed envelopes containing their randomized assignment. Couples randomized to the control arm will privately receive brief alcohol advice (5-10 minutes) immediately following notification of their randomization assignment (see the Mlambe manual for details related the brief alcohol advice). The brief alcohol advice will include accurate alcohol and ARV risk reduction information and will serve as a basis for comparison to additional alcohol-related activities in the intervention arm. Couples randomized to the intervention arm will be scheduled for the first of ten sessions, held monthly, related to financial literacy and couple communication. Couples from both the control and intervention arms will complete surveys administered to both partners at baseline, ten months past baseline, and 15 months past baseline.

Couples will also be asked to provide a small sample of blood at ten months past baseline. If blood samples are lost by the lab or rendered unusable due to unforeseen issues, we will ask participants to return for an additional blood draw following the 10-month assessment visit. We will collect tracking data on feasibility and acceptability of the intervention. At the end of the study, we will conduct qualitative exit interviews with 20 couples. All data will be used to refine the intervention and prepare for a full-scale efficacy trial (future grant/study).

Mlambe Statistical Plan

The primary statistical analyses will include descriptive statistics of the feasibility and acceptability indicators, comparing each statistic (e.g., % retained) to the corresponding threshold. Above-threshold findings will suggest a reasonable level of feasibility and acceptability for the corresponding aspects of study procedures. Below-threshold findings would suggest that remedial modifications to study procedures and/or design would be required prior to moving forward with a full-scale trial; qualitative analyses of the exit interviews described below will be instructive under this circumstance.

For the outcomes assessed in the future trial, we will compute descriptive statistics to capture measures of central tendency for continuous variables and proportions for binary variables. We will also conduct a trial run of our planned analysis procedures for the future RCT to ensure that the requisite data are collected and to refine statistical methods for issues such as missing data and non-normally distributed variables.