We Prevent: A Dyadic Approach to HIV Prevention and Care Among Young Male Couples

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Phase III DATA ANALYSIS

We will examine differences between the treatment groups for the index participants using t-tests or Wilcoxon rank sum tests for continuous variables and chi-square tests for categorical variables. We will conduct analyses of our primary HIV and STI testing behavior outcome using regression analyses to compare each active treatment group to the control in pairwise comparison tests at an adjusted significance level of 0.017 to reduce Type-I errors in our 2-arm trial. The proportion of index participants who obtain at least 2 tests at least 3 months apart within the follow-up period will be calculated and presented with corresponding 95% exact binomial confidence intervals. The regression will be run with group assignment only in the model, as well as, controlling for participant characteristics, with a focus on understanding the role of reported relationship dynamics and mechanisms of change (i.e., information, motivation, and behavior) in mediating the outcome. The ability of the intervention to yield increase in PrEP knowledge and efficacy over time will be examined using two separate outcomes. Scores at baseline and all follow-ups will be analyzed using generalized linear models (GLM) with properly-chosen (based on the distribution of dependent variable) link functions to analyze longitudinal PrEP outcome data. The GLMs will be estimated using generalized estimating equations with robust standard error estimates (GEE), which provide an extension of regression analysis to the case of correlated or repeated observations with appropriate modeling of the covariance structure. Models will control for demographic characteristics and study arm and will explore interactions between treatment arm and individual characteristics. The incidence of sex acts will be calculated as an incidence density, with the numerator being number of individual at risk sex acts, and the denominator being person-years of follow time. Comparisons of the incidence of at-risk sex acts and incidence of STIs will be made by comparing incidence densities across the arms. Period incidence rates (3-monthly incidence density rates) of at-risk sex will be estimated by performing a generalized estimating equations (GEE) Poisson regression analysis of the 3 monthly counts, implemented using SAS PROC GENMOD/ GEE models will control for demographic characteristics, baseline HIV testing history and relationship dynamics and hypothesized mediators, and examine interactions between relationship dynamics and sexual risk-taking. Analysis will also consider differences in changes in information, motivation, and behavioral skills in accordance with the RELO-IMB model. Qualitative data from the exit interviews and will be conducted in collaboration with the ATN analytic cores, using framework analysis,38 which is systematic and dynamic in its approach to qualitative data, resulting in the ability to produce accessible analyses focused on specific research questions. The thematic framework will be refined for coding by reading and re-reading the data, identifying themes that emerge, and writing analytical memos about those themes. Next, specific sections will be identified that corresponded to particular themes. Finally, we will refine the relationship between indexed data and the original thematic framework, interpreting the resulting themes. Reliability amongst the coders will be checked by having each coder code a subset of transcripts with acceptable agreement be ≥90% reliability. Disagreements will be resolved through discussion. This analysis will involve identifying and summarizing patterns of experiences related to participation in the RCT. Analysis will involve identifying how to improve the intervention and provide recommendations for future studies. The study team will review analysis of qualitative data, and assess the strengths and weakness of the each of the components of the intervention based on the findings.