

NCT03751020

Title of Research Project: Development and preliminary trial of a
brief, portable health intervention for rural sexual minority
emerging adults

SAP Date 7.29.2019

Development and Preliminary Trial of a Brief, Portable Health Intervention for Rural Sexual Minority Emerging Adults

Statistical Analysis Plan

We will use hierarchical linear modeling to evaluate whether SA or EW demonstrate greater decreases from baseline in depressive symptoms, suicidality, substance use, and HIV risk behaviors, at post-intervention and 3-mo. follow-up relative to control participants. Level 1 will include time and the Level 2 variables will include intervention condition and possible covariates such as demographic and psychosocial variables. We will conduct “intent-to-treat” analyses in which all cases are analyzed and multiple imputation is used to estimate follow up data for treatment non-completers. Evidence for a significant main effect for improved outcomes will provide pilot data to justify a larger RCT examining the longer-term effectiveness (e.g., 6- and 12-month follow-ups) of one or both of our writing interventions. Analyses will also explore the degree to which social support, gender, baseline health risk, and identity centrality moderate intervention effects. Although we are likely not fully powered to detect mediation, our design and sample size allow us to estimate the size of the direct paths to and from the mediators—estimates that will determine the sample size for a future proposal. However, if the magnitude of the direct paths to and from the mediators are medium to large, as suggested by previous research, we would be sufficiently powered ($1 - \beta = .8$) to use a bias-corrected bootstrap approach to test mediation. Evidence for mediational effects will provide critical new information about mechanisms underlying SA and EW intervention efficacy.