Statistical Analysis Plan

A Trial of Online LGBTQ-affirmative Cognitive Behavioral Therapy to Reduce Depression and Associated Health Risks Among Young Adults
NCT04408469

01/18/2023

Intervention efficacy will be assessed using an intent-to-treat analysis and include all participants (n = 120). First, dependent variables and stigma moderators will be assessed for normality using skewness thresholds of ≥ 2 and kurtosis thresholds of ≥ 7 . If scales violate assumptions of normality, they will be square root transformed.

To examine the efficacy of LGBTQ-affirmative ICBT, we will use linear mixed models with maximum likelihood estimation and an unstructured covariance matrix to test the Condition × Time interaction effects between conditions over time for all continuous mental health outcomes (BSI, CESD, ODSIS, OASIS). For binary outcomes (suicidal thoughts, problematic drinking, SIDAS, sex-risk behavior), we will test intervention efficacy using a generalized linear mixed model with a logit link and a binomial distribution to test the Condition × Time effect predicting odds of each binary outcome between conditions over time. Primary efficacy analyses between conditions will include baseline (time = 0), immediate post-intervention (time =1), and 4-month follow-up (time = 2) to model the Condition × Time effect of receiving LGBTQ-affirmative ICBT (condition = 1) versus self-monitoring (condition = 0). Effect sizes (Cohen's d) for linear mixed models will be calculated as mean pre-post change (e.g., pre-intervention to post-intervention, pre-intervention to 4-month follow-up) in the LGBTQ-affirmative ICBT intervention minus the pre-post change in the self-monitoring condition, divided by the pooled baseline standard deviation.

To examine whether Condition × Time effects varied as a function of baseline levels of heterosexist stigma (i.e., internalized stigma, interpersonal stigma, and structural stigma), we will conduct moderation analyses using linear mixed models with maximum likelihood estimation, unstructured covariance matrix, and three-way interactions of Condition × Time × Stigma.

Moderation by internalized, interpersonal, and structural stigma will be entered together into

multivariable models for each outcome. Significant three-way interactions of Condition \times Time \times Stigma will be further probed and plotted to contrast high stigma (one standard deviation above the mean) with low stigma (one standard deviation below the mean). All results will be evaluated at p < .05.