NCT 03522948   updated January 24 2021

Alcohol and Implicit Process in Sexual Risk Behavior in MSM-Supplement

Study Procedures Protocol

Study Protocol Procedures NCT 03522948 updated January 21. 2021

The study was approved by the Boston University Institutional Review Board. Informed consent was obtained from all individuals before completion of the baseline assessment. Participants are recruited through various digital media outlets (e.g., Facebook, Grindr). Individuals between the age of 21-50 who report at least one heavy drinking episode in the past thirty-days (defined in screening as 5 or more drinks on a single occasion), one episode of CAI in the past ninety-days, and no involvement in an exclusive, monogamous relationship are recruited to participate in the study. Participants are screened by phone for eligibility which is confirmed at an in-person screening. Following baseline assessments, participants engage in a brief in-person intervention session regarding their alcohol use and sexual risk behaviors and are then enrolled in the mobile messaging component. Mobile messages are sent over the following four weeks to support intervention content. Five to six weeks after baseline, participants return to the lab to complete a follow up assessment and engage in a discussion regarding the acceptability of the mobile messages and satisfaction with the intervention approach. Measures of heavy drinking frequency, condomless anal intercourse (CAI) were collected as secondary outcomes at baseline and at follow-up. Cognitive- motivational processes related to condom use and reduction of drinking are also collected at each time point for descriptive purposes..

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Data Analytic Procedures

Data Analytic Strategy NCT 03522948

This is a small scale pilot study to assess the acceptability of the intervention. The primary outcome is descriptive, namely the mean and median score on the intervention satisfaction scale. Specifically, the index of acceptability for the mhealth approach consists of the mean and median scores of the Likert-scale CSQ satisfaction score at follow-up.

Frequency of heavy drinking days and condomless anal intercourse (CAI) are assessed at baseline and follow-up. For analyses, frequency of heavy drinking days was assessed with item #3 of the Alcohol Use Disorders Identification Test (AUDIT). This item has 5 response options ranging from "never" to "daily, almost daily" The baseline measure of past ninety-day CAI frequency will be divided by 3 to derive an average past thirty-day CAI frequency to parallel the time-period measured at follow up (past 30-day CAI). Secondary analyses consist of a series of paired sample t-tests which are used to measure differences in secondary outcomes between baseline and follow up. Given the small sample, effect size estimates are also provided to provide initial information about the potential impact of the intervention on outcomes. A series of self-regulation processes related to heavy drinking reduction and condom use are also assessed at these two time-points with the Goal Systems Assessment Battery. These ratings are used for descriptive purposes to identify potentially important mediators in subsequent work.