NCT 03755661   updated April 17, 2019

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

Study Procedures Protocol

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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 were men recruited through various digital media outlets (e.g., Facebook, Grindr). Individuals between the ages of 21-50 who reported at (1) at least one heavy drinking episode in the past thirty-days (defined in screening as 5 or more drinks on a single occasion) more than 14 drinks per week on average in the past month, (2) had one episode of condomless anal intercourse (CAI) with a man in the past ninety-days, and had a score of 3 or greater on the Kinsey scale were recruited to participate in the study. Those who were currently in an exclusive, monogamous relationship, had alcohol treatment in the past 3 years, or had treatment for schizophrenia or bipolar disorder were excluded. Participants were screened by phone for eligibility which was confirmed at an in-person screening. Following baseline assessments, participants were randomized to either the intervention or assessment only condition. Those assigned to the intervention condition engaged in a brief in-person intervention session (up to 50 minutes) regarding their alcohol use and sexual risk behaviors. They were then enrolled in the mobile application which supported the subsequent messaging component of the intervention. Mobile messages were sent over the following six- weeks to support the brief intervention content. Six weeks after baseline, participants completed the first follow up assessment, then again at 3-months, and finally at 6-months. Assessments were conducted by a research assistant who was blind to intervention condition. Measures of heavy drinking frequency in the past month, average drinks per week in the past month, and frequency of condomless anal intercourse (CAI) in the past 90-days assessed at the 3-month outcome were the primary outcomes of interest.

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Data Analytic Procedures

Data Analytic Strategy NCT 03755661

This is a small scale pilot study to provide preliminary effect sizes regarding intervention efficacy. The main outcome point was at the 3-month assessment. The three primary measures were as follows (1) frequency of heavy drinking days in the past 30, average number of drinks per week in the past 30 days, and number of condomless anal intercourse (CAI) episode in the past 90 days. Each of these outcomes were also are assessed at baseline.

All analyses were conducted using hierarchical multiple regression with the corresponding baseline value as a covariate entered in the first step. Condition (i.e., Intervention vs. Assessment) was dummy coded. The effect size value used in these analyses was f^2. For interpretation we used standard guidelines, of .02 as small effect, .15, medium effect, .35 large effect. We have also provided statistics for r-square change and the p-value for completeness. The primary outcome variable was f^2 at the 3-month outcome.

Secondary outcomes (i.e., alcohol-related consequences, 6-wk, CAI were analyzed using the same procedures).