

**Emotion Regulation Interventions for Alcohol-Related Sexual Aggression**

**NCT: STUDY00002103**

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## **Study Protocol and Statistical Analysis Plan**

### **Study Protocol**

The objective of this protocol was to evaluate the efficacy of two brief online emotion regulation interventions (compared to control) for reducing alcohol-related sexual aggression in heavy episodic drinking young men with a sexual aggression history. The study involved a proximal change experiment assessing the effects of two brief online interventions – cognitive restructuring and mindfulness – on men's sexual aggression during an sexual aggression-related analogue.

**Recruitment.** Participants were recruited from the community through advertisements placed in online classifieds, social networking websites, community newspapers, and local venues that target the young adult population. Ads stated that single men 21-30 years old were needed for a study of alcohol and male-female relationships. We also used flyers, brochures, and postcards in locations likely to reach young single men, such as local community colleges, coffee shops, and bars. All advertising materials included a URL for a website that provided information about the study. Interested participants then completed an initial online eligibility screening followed by an eligibility verification telephone call.

**Retention.** Participation involved a one-time visit to the study laboratory. Participants were enrolled into the study and completed the study in the same visit. As such, longitudinal retention efforts were not required.

**Study Design.** After providing informed consent, participants completed questionnaires assessing information about sexual risk behavior, drinking behavior, sexual aggression, and emotion regulation skills. They were then randomized to receive one of the three intervention arms (cognitive restructuring, mindfulness, or control). A randomized block design was used to assign participants to experimental conditions based on their sexual aggression history so that aggression backgrounds were evenly distributed across the cells. After the intervention, participants received either no alcohol (control beverage) or a high alcohol dose (target peak BAC = .08%), read a sexual aggression analogue, and rated their sexual aggression intentions.

### **Statistical Analysis Plan**

**Sexual Aggression Intentions.** For the sexual risk intentions outcome, we enrolled 209 subjects. The sexual aggression intentions variable includes scores from a scale on which participants rate their likelihood of continuing with sexual activity after a hypothetical woman refused further sexual contact. To test our hypotheses, a series of ANOVAs were conducted to examine the main and interactive effects of intervention condition and beverage condition on sexual aggression-related intentions with planned pairwise comparisons examined for both the cognitive restructuring and mindfulness conditions compared to the control condition using the Sidak procedure to control for alpha inflation and protect against Type 1 error. Similarly, with pairwise comparisons, we explored whether there are any differences between the cognitive restructuring and mindfulness conditions on intervention efficacy.

**Power and Sample Size.** The study was powered to detect the moderation of beverage condition (sober vs. alcohol) on the association between the interventions (cognitive

restructuring, mindfulness, control) and sexual aggression-related intentions. Using G\*Power 3.1, we used an alpha of .05 and power of .80. Based on a medium effect size  $f = .21$ , this would require a sample size of 222, whereas  $f = .22$  required 203 participants. As such, we obtained a sample of 209 participants.