Men's Sexual Risk Behaviors: Alcohol, Sexual Aggression, and Emotional Factors

NCT: Not Yet Assigned

Date: March 18, 2019

Study Protocol and Statistical Analysis Plan

Study Protocol

The objectives of the protocol are to examine men's sexual risk intentions and sexual risk behaviors, with a focus on the contributing roles of sexual aggression propensity, alcohol intoxication, and emotions. The study will involve 3 phases: 1) a baseline survey; 2) a 30-day daily diary assessment of emotions, drinking and sex coping motives, and drinking and sexual behavior; and 3) a laboratory experiment assessing the effects of alcohol intoxication and provocation on in-the-moment emotional state and sexual risk behavior/condom use resistance likelihood.

Recruitment. Participants will be 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 will state that single men 21-30 years old are needed for an Arizona State University study of alcohol and male-female relationships. We will also use flyers, brochures, and postcards in locations likely to reach young single men, such as local community colleges, coffee shops, and bars. All advertising materials will include a URL for a website that will provide limited information about the study with particular emphasis on information about the PI and research at Arizona State University. If they are interested in proceeding, potential participants will need to call our offices for more detailed information, screening, and scheduling.

Retention. We will take multiple steps to retain participants throughout the project. First, we will reduce the time span between the three study phases as much as possible during scheduling such that all three phases of the study will take less than 6 weeks total. Second, we will make participation as convenient as possible by using online data collection for the baseline and daily diary surveys. We will also offer transportation assistance (e.g., bus passes, taxi rides home) for the in-lab experiment. Third, we will give reminders to participants if more than 2 days have passed without completion of the baseline survey or if they miss more than 2 consecutive daily assessments. Finally, we will structure our payment and incentive schedule to encourage full completion. Similar procedures and incentives have yielded retention rates of 87-92% over 3-month periods in our prior studies.

Study Design. All participants will compete an online baseline survey that will assess information about sexual risk behavior, drinking behavior, sexual aggression, and emotion regulation skills. The online daily diary study will require participants to answer questions once a day during a 30-day period assessing their emotions, sexual risk behaviors, and drinking behaviors. During the in-lab experiment, two factors will be manipulated between subjects: alcohol intoxication and provocation condition. We will use a randomized block design to assign participants to experimental conditions based on their sexual aggression history so that aggression backgrounds are evenly distributed across the cells. Participants will receive either no alcohol (control beverage) or a high alcohol dose (target peak BAC = .08%), will experience a standard experimental provocation manipulation (high vs. none), and then will read a sexual risk analogue and rate their sexual risk intentions while on the ascending limb of the BAC curve.

Statistical Analysis Plan

Sexual Risk Behavior. For the sexual risk behavior outcome, we plan to enroll 420 subjects. Sexual risk behavior will be assessed in multiple ways: having unprotected vaginal or anal sex (yes/no), condom use resistance (yes/no), and partner type (casual vs. steady). GLMMs with a negative binomial distribution and log link function will be used to examine the daily influence of emotions on alcohol consumption, and a binomial distribution and logit link function will be used to examine the daily influence of emotions on the binary indicators of sexual risk behavior. Multilevel mediation (MLM) will be conducted to examine the potential mediating effects of drink- and sex-to-cope motives on the relation between emotions and subsequent alcohol use and sexual risk behavior. The moderating effects of sexual aggression propensity and emotion dysregulation will be examined by creating interaction terms with daily emotions and will be entered in the GLMM models described above.

Sexual Risk Intentions. For the sexual risk intentions outcome, we plan to enroll 420 subjects. The sexual risk intentions variables will include unprotected sex and CUR intentions, and the between-subjects factors will be intoxication and manipulated provocation. Direct and indirect effects of alcohol intoxication (.08% vs. control) and provocation (high v. none) will be tested utilizing path analysis within a structural equation modeling (SEM) framework, which provides significance tests and confidence intervals for total indirect effects and specific indirect effects. A path analysis will be conducted to test whether alcohol intoxication directly increases sexual risk intentions and whether emotional state mediates the effects of provocation and alcohol intoxication on sexual risk intentions. To test the hypothesis that the effects of intoxication and provocation on negative emotional states will be greater among those with stronger sexual aggression perpetration propensities, SEM analyses that include that interaction term will be conducted. Additional SEM analyses will be conducted to test the moderating effects of emotion dysregulation on the negative emotion-sexual risk intentions relationship.

Power and Sample Size. The study was powered to detect the mediational effects of negative emotional state and on the relationship between provocation and alcohol intoxication on unprotected sex likelihood, as this hypothesis serves as a test of the overarching conceptual model and requires participants be randomized to one of four experimental conditions, thereby decreasing power. Monte Carlo simulations indicate that a sample size of 350 yields power .79 - .96 to detect small to medium effects. Based on an estimated 20% attrition rate, the final sample recruited will comprise 420 men. This sample size also yields sufficient power to detect small to medium effects in the within-subject GLMM analyses examining men's daily sexual risk behavior.