

Study Protocol and Statistical Analysis Plan

Study Title: Men, Mood, and Attention Study: Examination of Alcohol, State Anger, and Emotion Regulation Sexual Aggression

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Study Protocol

Overview. The study utilized a 2x2 design in which participants are randomized to beverage condition [alcohol (target BAC= .08gm%) or control (no alcohol control)] and an emotion induction (anger induction or control) condition to investigate the effects of alcohol intoxication, emotion regulation, and state anger on sexual aggression intentions.

Recruitment. Cisgender men were recruited from the community and local university and community college through fliers and advertisements placed in alcohol-serving establishments (e.g., bars, restaurants), shops, community centers, coffee shops, and other local venues. Online advertisements were posted in online classified and social networking websites reaching individuals within a 50 mile radius of Morehead State University. Interested men were instructed to call the lab for telephone screening or complete an online web-screening survey. Ads stated that single men, 21-35 years old, who regularly consumed alcohol were needed for a study of alcohol and male-female relationships. Per IRB requirements, advertisements emphasized the voluntary nature of research. 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 a telephone call to verify eligibility. Eligible callers were asked COVID-19 screening questions and informed of COVID-19 safety procedures for the study (masks, canceling appointment if feeling ill or positive COVID-19 test for themselves or close contact in the last 10 days).

Inclusion and Exclusion. Participant requirements for this study were (see Figure 1): **1)** biologically male and identify their gender as male; **2)** must be between the ages of 21-35; **3)** must be interested in sexual activity with women; **4)** must have engaged in at least one instance of condomless sex in the last six months; **5)** must on average consume between 5 and 25 standard drinks per week; **6)** must have previously had an instance of heavy episodic drinking (HED; at least five alcoholic drinks in two hours) in the last six months; **7)** must have no history of alcohol problems (as determined by the Brief Michigan Alcoholism Screening Test); and **8)** must not have a medical condition or take medications which contraindicate alcohol consumption. Exclusion criteria were: **1)** being in a monogamous relationship of longer than six months or not having sexual intercourse at all within the past six months and **2)** (as required by administration) current enrolled as a student at Morehead State University.

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 (see Figure 2). After providing informed consent, participants completed questionnaires assessing information about past sexual aggression and emotion regulation skills. They were then randomized to one of two mood induction arms (Anger vs. Control) and one of two alcohol condition arms [Alcohol (.08%gm) vs. sober control (.00%gm)]. 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. Participants completed outcome measures while on the descending limb of the alcohol biphasic

curve; that is, participants' Breathe Alcohol Concentration (BrAC) was descending at the time they completed outcome measures. Participants waited during the absorption period, during which they were regularly breathalyzed, until their Breathe Alcohol Concentration peaked and then begin to descend. Once their BrAC was confirmed to be descending (reaching a BrAC of .08%gm followed by two BrACs lower than .08%gm, participants underwent a mood induction. While participants were aware of the alcohol condition to which they had been assigned, deception was utilized such that participants were not aware they were assigned to a mood induction arm. Following completion of the mood induction, participants read an eroticized sexual aggression scenario, and then rated their sexual aggression, physical aggression, and psychological aggression intentions. Following completion of outcome measures, participants in the alcohol arm remained in the laboratory and underwent detoxification procedures after which they were debriefed and provided an honorarium. Prior to each participant in the alcohol arm leaving the study, a Morehead State Campus Police officer examined the most recent Breathalyzer reading and documented the reading. Participants in the sober control arm were debriefed and provided an honorarium immediately upon completion of outcome measures.

Statistical Analysis Plan

Because only three participants were recruited, statistical analyses are notably limited. Values for the outcome variables for the three participants have been provided in the results section. Because there are not sufficient participants for an ANOVA, one-sided t-tests were conducted to ascertain any differences in primary and secondary outcome variables across alcohol and mood induction arms.

Sexual Aggression Intentions (primary). Only three participants were recruited due to barriers associated with the ongoing COVID-19 as well as procedural barriers that were requested by the institution. The sexual aggression intentions variable includes scores from a 22-item scale on which participants rate their likelihood of continuing sexual activity after a hypothetical woman refuses further sexual contact.

Physical Aggression Intentions (secondary). The physical aggression intentions variable includes scores from a 5-item scale on which participants rate their likelihood of engaging in physical aggress (e.g., twisting her arm, slapping her) after a hypothetical woman refuses further sexual contact.

Psychological Aggression Intentions (secondary). The psychological aggression intentions variable includes scores from a 3-item scale on which participants rate their likelihood of engaging in psychological aggression (e.g., calling her names, calling her a bad sexual partner) after a hypothetical woman refuses further sexual contact.

Power and Sample Size. The study planned to recruit 200 participant to ensure sufficient power to test hypotheses. Power was calculated using nQuery version 8.4.1 in the 2x2 design. It was concluded that with 50 subject per group (including a conservative 10% dropout) we will have 80% power to detect an effect size of 0.3 in both factors with no interaction, and greater power if there is an interaction effect. Additional significant covariates (ANCOVA) will further increase power.

Figure 1: Eligibility Flow Chart

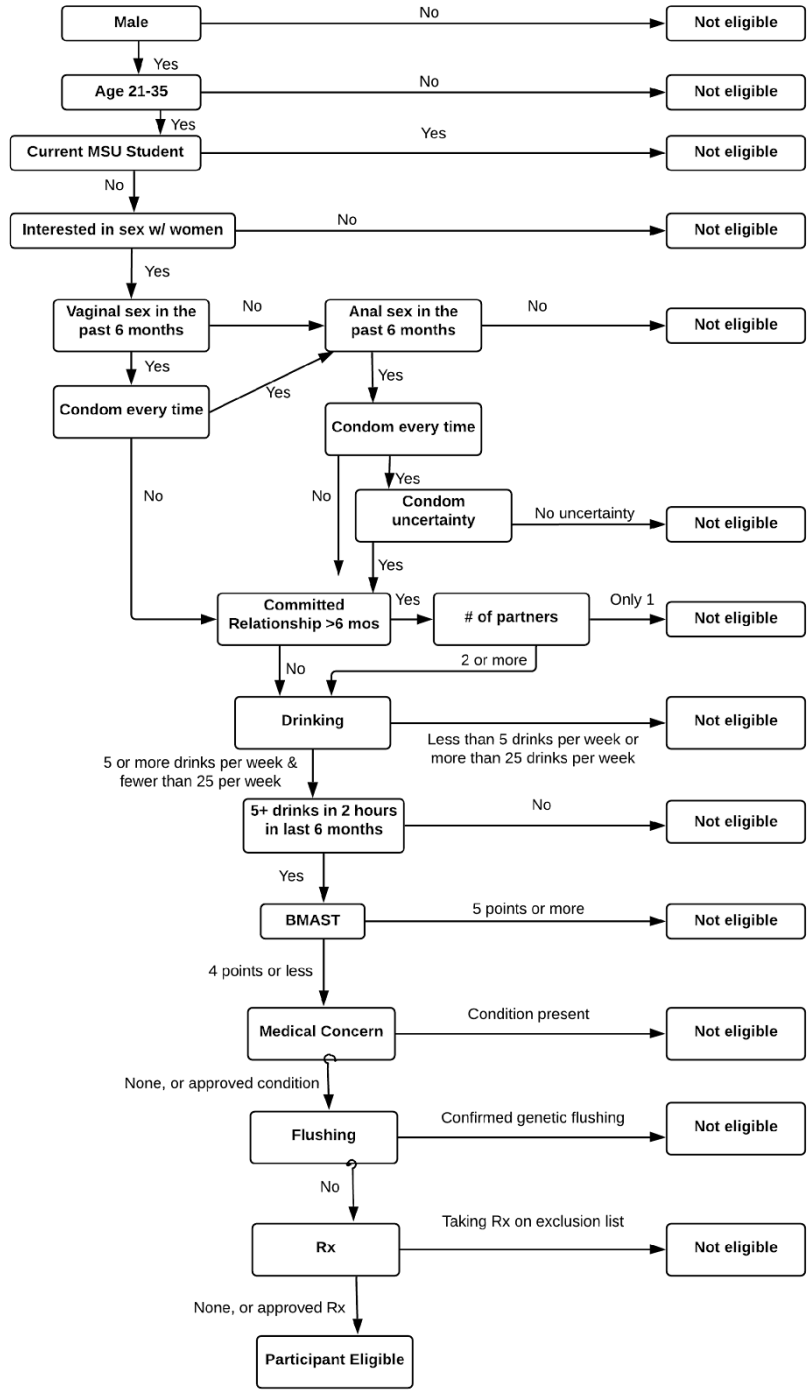


Figure 2: Study Procedures

