Developing a brief early cognitive intervention for PTSD and alcohol misuse

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Study Protocol

This study is a small pilot randomized controlled trial (RCT) to test initial efficacy of a one session + four coaching call cognitive intervention compared to symptom monitoring for the reduction of PTSD and alcohol use following a recent sexual assault (SA). Participants will be assessed at baseline, randomly assigned to receive the intervention plus weekly assessments vs. weekly assessments only (AO), and assessed again at 3-month follow-up.

Recruitment and Participants: Participants are recruited via community advertisements (flyers, online) and specific outreach targeted toward female identifying students enrolled at the first author's institution. We will collaborated with local community organizations to receive referrals.

Participants will be 76 (n = 38 intervention, n = 38 AO) women who are 2-10 weeks post SA and report alcohol misuse and PTSD symptoms. We will restrict our sample to women given that the majority of SA victims are female and the pilot nature of this study. For this research, SA will be defined as any non-consensual sexual activity ranging from forced penetration to unwanted contact. Participants will need a minimum of subthreshold PTSD symptoms related to recent SA (specifically criteria for two of the three PTSD symptom clusters; 1 reexperiencing, 3 avoidance, 2 hyperarousal) to ensure that they are experiencing SA related distress. Participants will endorse hazardous drinking over the past month, defined as exceeding NIAAA recommendations for low risk drinking for women (more than 3 drinks on one occasion) and at least two negative consequences of drinking. Additional inclusion criteria include: 1) female gender; 2) age ≥ 18 years, 3) capacity for informed consent, 4) English fluency, 5) no planned absences that would interfere with 5 weeks of participation, and 6) access to a telephone. Individuals will be excluded if they are 1) acutely suicidal with intent/plan or 2) exhibit current

psychosis.

Measures. Below is a description of measures for each time point. *Phone Screening.* To initially assess for SA exposure, we will include 2 questions on nature and timing of assault. We will also include a 20-item PTSD screen to assess that participants meet at minimum subthreshold PTSD symptoms. Finally, we will ask 2 items that assess quantity and frequency of drinking, and one to determine if alcohol has caused any problems in the previous week to ensure likelihood of hazardous drinking. *Interview Measures.* At baseline interviews are administered including the mood and psychotic disorder modules of the Structured Clinical Interview for DSM-IV (SCID) at baseline to assess for exclusion criteria of current psychosis or acute suicidality. At baseline and 3-month follow-up, we will administer the Timeline Followback (TLFB), a calendar based assessment of drinking with established reliability, to assess for quantity and frequency of alcohol use for the prior month. This will enable us to assess drinking at baseline and change in drinking following the intervention. Finally, at baseline and 3-month follow-up we will administer the Posttraumatic Stress Symptom Scale- Interview version (PSS-I) to assess for both DSM-IV diagnostic criteria of PTSD and severity of symptoms over the past two weeks. The PSS-I has excellent reliability and validity and will assess for change in PTSD symptoms with the intervention. *Self-report Measures.* We will administer self-report measures of drinking, assault history, and psychopathology at the in-person baseline and 3-month assessments and a briefer subset of these measures will be administered online at weekly intervals for four weeks following baseline. All self-report measures are widely used and have established reliability and validity. Constructs that are assessed include demographic information to describe the sample (e.g., age, race), history of unwanted sexual experiences, alcohol measures at baseline, weekly assessments, and 3-month follow-up to assess drinking behavior,

the Drinking Inventory of Consequences (DrInC) to assess interpersonal, physical, social, impulsive, and intrapersonal consequences of alcohol use, and the Daily Drinking Questionnaire (DDQ) to assess quantity/frequency of alcohol use over the previous week to look at self-report changes in drinking. Similarly, at baseline, weekly and follow-up we will administer the Posttraumatic Diagnostic Scale (PDS) to assess for ongoing PTSD symptoms and change in PTSD symptoms. Finally, at baseline and 3-months we will administer self-report measures to assess functioning and change in functioning including drug use, depression, and treatment received. Finally, a post-study reactions questionnaire will be given at the last weekly intervention session to assess participant reactions to the assessment and intervention strategies. This measure will be used to assess the feasibility and acceptability of the intervention.

Assessment and Intervention Training: Study assessors will be trained to administer interview assessments of PTSD and alcohol use and self-report measures, by receiving group didactics on interview measures and doing role plays of conducting interview assessments. They will complete at least one mock assessment before beginning assessments. The assessors will meet weekly as a group to discuss and make inclusion decisions and minimize rater drift and will receive as-needed supervision on assessment techniques. Interventionists will also be trained in the 90-minute in-person intervention and coaching calls. Intervention training will consist of group didactics, role plays, and mock interventions. Interventionists will participate in ongoing weekly group supervision. Fidelity to the intervention and reliability of assessments will be calculated for a subset of the sample once data collection is complete.

Procedures: Study procedures will begin with phone screening with the research coordinator (RC) to determine initial eligibility for SA exposure, PTSD symptoms, and alcohol use. Potentially eligible individuals will be scheduled for an in-person baseline session.

This study involves 7 assessment time-points: baseline, at intervention or post-randomization (for the AO group), 4 weekly assessments, and 3-month follow-up assessment. The baseline session will last 1.5-2 hours and will consist of interview (PSS-I, TLFB, SCID modules) and self-report measures on SA (SES), PTSD (PDS), depression/suicide (BDI), and substance use (DDQ, DrInC, DUDIT,). Baseline will be conducted by an assessor, and at the conclusion the RC will inform the participant of randomization condition (intervention vs. AO). Participants will be randomized with their condition known only to the RC and the PI, while the assessor who conducts baseline assessments will remain masked to condition. At baseline participants will be compensated at a rate of $20/hour. One week after baseline, individuals randomized to the intervention will return and meet with a interventionist for a 90 minute in-person intervention. At that time they will complete self-report measures on drinking and PTSD and will be compensated $10 for completing the questionnaires (PDS, DDQ, DrInC). One week following baseline AO participants will log on to a secure web server, complete these same measures of PTSD and drinking behavior, and be compensated $10. For the next 4 weeks, intervention participants will complete weekly 15-minute coaching calls with their assigned interventionist. Prior to each coaching call they will be prompted to complete on-line self-report measures of PTSD and alcohol use (PDS, DDQ, DrInC). AO participants will complete these same measures weekly without the coaching call. Participants will receive $10 for each on-line assessment they complete; those who complete all 4 will receive a $20 bonus. Finally, participants will be assessed at 3-month follow-up. They will meet with the same assessor from baseline and will re-complete interviews of PTSD and alcohol use, and self-report measures of alcohol and drug use, PTSD, depression, treatment satisfaction (reaction to treatment) and treatment received (Form 90). At 3-month follow-up participants will be paid $25/hour.

Participant Retention. We will use strategies including reminder calls/texts, weekly check in calls during active treatment for both groups, increasing incentives for follow-ups, and bonus payments for full completion to achieve an expected 80% retention rate.

Power and Data Analytic Plan.

Data analytic plan. Prior to inferential statistics, scale scores will be calculated for each of the variables following previously validated procedures. Univariate and bivariate descriptive statistics will be used to assess distributions and simple relationships among study variables. We will examine factors such as completion rate, number and length of coaching calls completed, and participants' reaction to treatment (reaction to treatment) to examine the feasibility of the intervention.

Preliminary Analyses

Stata 15.1 (StataCorp, 2017) was used for all analyses. Potential differences by treatment condition in demographics and background characteristics including age, race, ethnicity, sexual orientation, and treatment history were examined with *t*-tests or chi-square tests.

Primary Analyses

First, we will examine intervention satisfaction and acceptability by means and standard deviations of each satisfaction rating. Next, to evaluate differences between BRITE and the symptom monitoring control condition in PTSD and alcohol use outcomes between baseline and 3-month follow-up, we will conduct separate multilevel mixed-effects models for PTSD symptom severity, average drinks per drinking day, heavy episodic drinking frequency, and alcohol consequences. We will fit two-level random-intercept models with an independent covariance structure between the random effects controlling for treatment history testing for a condition x time interaction. We will conduct similar multilevel mixed-effects models examining

differences between BRITE and AO in PTSD symptom severity, average drinks per drinking day, and heavy episodic drinking frequency using self-reports at baseline, randomization (also intervention delivery session), each of the four weeks of coaching calls, and the 3-month follow-up controlling for treatment history. Pairwise comparisons for intervention x time effects were examined as described above.

Missing data. For missing data, we will examine both intent-to-treat and completer analyses to examine possible differences in the outcome as a result of drop out. For missing data due to a participant providing incomplete data, we will examine whether the missingness can be considered ignorable (e.g., missing completely at random or related to variables in the analyses [including earlier time points]). For any non-ignorable missing data, we will use multiple imputation procedures or employ analytic procedures that handle missing data in less biased ways such as maximum likelihood estimation.

Power analysis. The RCT was powered to examine the main hypothesis regarding the efficacy of the intervention compared to AO on PTSD and drinking. We expect a medium-to-large effect size for both alcohol and PTSD outcomes Using G*Power 3.1.7 with an ANOVA with 3 repeated measures, a sample size of 60 (30 per condition) is needed to identify medium-to-large effects with power of .80. To obtain this sample of treatment completers, we will recruit 76 women (38 per condition).