Protocol Synopsis

Grant number: 1R01AA027499-01A1

Date: September 22, 2019

Grant Title: Understanding and testing recovery processes for PTSD and alcohol use following sexual assault

NCT ID: Pending

Section 4. Protocol Synopsis

4.1 Brief Summary

This phased, doubly randomized clinical trial (N = 180) will test the efficacy of either a PTSD-focused brief intervention, imaginal exposure, or an alcohol-focused brief intervention, alcohol skills training, compared to supportive telehealth in preventing long-term mental health consequences in the early aftermath of sexual assault (1 month to 1 year after sexual assault). A novel phased study design will allow for exploration of efficacy of primary and secondary intervention approaches to test the questions of: 1) whether it is more efficacious to target PTSD or alcohol misuse first; and 2) whether it is necessary to target both PTSD and alcohol misuse processes to facilitate recovery or if targeting one is sufficient. This clinical trial will further test mechanisms of recovery following sexual assault exploring the role of both fear and reward processes to elucidate the most efficacious treatment targets. Employing well-established laboratory paradigms tasks, discriminant conditioning and probabilistic reward tasks, to capture baseline underlying vulnerabilities in fear and reward systems, respectively, will allow for exploration of how these processes impact recovery. This trial is significant in exploring transdiagnostic mechanisms, fear and reward, implicated in recovery following sexual assault and using a novel design to compare efficacy, ordering, and necessity of two distinct intervention approaches; imaginal exposure and alcohol skills training.

In Aim 1, we will evaluate imaginal exposure and alcohol skills training compared to supportive telehealth to determine relative efficacy of two primary intervention approaches in promoting recovery from PTSD and alcohol misuse at 1-month follow-up. Aim 2 will explore whether receiving both approaches (imaginal exposure and alcohol skills training) is more effective than receiving only one approach alone for decreasing PTSD and alcohol misuse at 2- and 6-month follow-up. Finally, Aim 3 evaluates a model of individual prediction of intervention response by exploring the effects of baseline fear and reward deficits and time since assault on response to each intervention; imaginal exposure and alcohol skills training. Key outcomes include PTSD symptoms and alcohol misuse (quantity, frequency). Taken together findings of this study will inform mechanisms of recovery and best practice intervention approaches following recent sexual assault.

4.2 Study Design

This study is designed as a phased, double randomization trial exploring comparative efficacy of two brief interventions delivered in the early recovery phase following sexual assault: imaginal exposure and alcohol skills training. In addition, we will explore fear and reward processes as transdiagnostic mechanisms that are implicated in recovery following sexual assault as predictors of individualized intervention response and recovery. Participants will be selected for recent sexual assault (1 month to 1 year), elevated PTSD symptoms, and alcohol misuse. They complete a baseline assessment to determine eligibility, baseline tasks to capture fear and reward functioning, and randomization to one of three primary intervention conditions: (1) imaginal exposure, (2) alcohol skills training, or (3) supportive telehealth (active control condition). Following the primary intervention phase, participants in the first two intervention groups (imaginal exposure, alcohol skills training) will be randomized again to one of two secondary intervention groups: (1) the alternate intervention from that received in the primary phase, or (2) no additional intervention. Participants in the supportive telehealth condition will continue with supportive calls and weekly symptom assessments. Assessments with interviewers blind to intervention assignment will assess PTSD symptoms and alcohol use at baseline, 1-month, 2-months, and 6-months follow-ups. All participants will complete self-report questionnaires at baseline and follow-ups and weekly on PTSD symptoms, alcohol use, and other constructs of interest (e.g., alcohol consequences, depression, fear and reward).

The Specific Aims are:

Specific Aim 1: Evaluate whether targeting PTSD via imaginal exposure or alcohol misuse via alcohol skills training is most efficient at promoting recovery.

Specific Aim 2: Evaluate whether targeting PTSD or alcohol misuse alone (imaginal exposure or alcohol skills training) or both is most efficient at promoting recovery.

Exploratory Aim 3: Evaluate individualized prediction of intervention response, examining baseline performance on fear and reward tasks and time since assault as differential intervention moderators (imaginal exposure vs alcohol skills training).

Participants and Recruitment:

Participants will be 180 individuals who identify as female, are ages 18-65, and report an experience of unwanted and distressing sexual contact (i.e., a sexual assault) in the previous 4 weeks. All participants will report clinically significant symptoms of PTSD and alcohol misuse (2+ heavy episodic drinking occasions [4+ drinks] in past month) at baseline. Exclusion criteria were established to ensure the safety and feasibility of delivering the interventions and include factors such as active suicidality or psychosis, medically unstable bipolar disorder, and an ongoing relationship with the perpetrator of the most recent sexual assault.

Randomization:

This study implements a phased randomization design. Following baseline assessments and fear and reward tasks, participants will be randomized to three conditions: imaginal exposure, alcohol skills training, supportive telehealth. After the primary intervention phase (3 weeks) participants in imaginal exposure and alcohol skills training will be randomized again to either the alternate intervention or no additional intervention. Participants in supportive telehealth will continue with supportive calls and symptom monitoring (weekly assessments) for the entire duration of the study. Randomization will be conducted via computerized, randomizer program. All team members will be blind prior to the assignment and only the study coordinator revealing the randomization to the participant will be aware. Block randomization will be done based on severity (PSS-I-5: 35 >: yes/no; TLFB: 5 drinking days/past 2 weeks >: yes/no). Participants will be informed of their randomized primary intervention condition (imaginal exposure, alcohol skills training, supportive telehealth). A second randomization, for those in the first two intervention conditions (imaginal exposure, alcohol skills training), randomization to the alternative or no additional intervention, will be conducted at 1-month follow-up using the same procedures.

Brief Interventions:

Alcohol Intervention: Alcohol Skills Training. Six 50 min, twice weekly sessions will be provided based on content from existing alcohol skills training and relapse prevention protocols [80]. Each session includes in session skill alcohol teaching and practice on increasing use of adaptive coping skills and attainment of positive rewarding activities (e.g., social support, positive thinking patterns).

PTSD Intervention: Brief Imaginal Exposure. Six 50 min, twice weekly sessions will be provided based on a published intervention for treatment for PTSD, which uses imaginal exposure to address PTSD. The protocol includes psychoeducation, information gathering, recounting of the trauma memory, and processing of relevant emotions and beliefs associated with the memory to promote extinction of fear and promote new, more adaptive meaning around the trauma memory [177].

Supportive Telehealth. Twelve, twice weekly sessions will be provided based on existing active control treatments provided for PTSD [212]. The protocol involves weekly online writing about daily non-trauma related concerns and hassles and weekly routine therapist phone calls. These calls include a brief check in, answering any questions, and progress on the online writing. The goal for therapists will be to be non-directive and supportive, focusing on non-trauma related present-day concerns. If needed, referrals for additional resources will be offered.

Assessments:

For Aims 1 and 2, assessments will include gold-standard clinician administered interviews delivered by independent evaluators blind to intervention condition and well-validated self-report measures. Information collected will include symptoms of PTSD, alcohol use, fear, reward, depression, and suicidality. Aim 3 will be based on these same interview and self-report measures as well as behavioral performance and psychophysiological responding to two well-validated laboratory tasks of fear (discriminant conditioning AX+/BX- paradigm) and reward (probabilistic reward task) processes.

Assessments with interviewers blind to intervention assignment will assess primary outcomes of PTSD symptoms [PTSD Symptom Scale-Interview (PSS-I-5); 186] and alcohol use quantity/frequency [Timeline Followback (TLFB); 188] at baseline, 2-months, 3-months, and 6-months post sexual assault, as well as related constructs of interest including other mental disorders [Structured Clinical Interview for DSM-5 (SCID-5); 190], depression [Quick Inventory of Depressive Symptomatology-C (QIDS-C); 191], suicidality [Columbia-Suicide Severity Rating Scale (C-SSRS); 192], and trauma history [Trauma History Questionnaire (THQ); 193].

All participants will complete self-report questionnaires at baseline, 2-, 3-, and 6month follow-ups and weekly. These measures will assess PTSD symptoms [PTSD Symptom Scale-Self-Report (PSS-SR-5); 194],

alcohol use [Daily Drinking Questionnaire (DDQ); 195], alcohol consequences [Short Inventory of Problems (SIP)], alcohol cravings [Penn Alcohol Craving Scale (PACS0; 199], depression [Quick Inventory of Depressive Symptomatology (QIDS-SR16); 201], reward [Snaith-Hamilton Pleasure Scale (SHAPS), 202], fear [Posttraumatic Avoidance Behavior Questionnaire (PABQ), 204], and functioning [Global Psychosocial Functioning (GPF) and Global Quality of Life (GQL); 205].