Resolving Psychological Stress

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Study Protocol

Overview:

We will perform a phone screen or have participants fill out an online eligibilty survey to determine eligibility for the study. Based on the answers to the screening questions, we will invite potentially eligible participants to attend an appointment at the San Francisco Veterans Affairs Medical Center to complete baseline assessments to include eligibility assessments and baseline testing. We may ask the questions from the eligibility screening in person if this is requested by the interested potential participant. The eligibility assessment will include the Clinician Administered PTSD Scale and the Structured Clinical Interview for the American Psychiatric Association's Diagnostic and Statistical Manual-V. For participants who are eligible after these assessments, we will complete baseline testing, which will include psychological and physiological tests. The eligibility and baseline assessments can take place over the course of one or two appointments. Following this, participants will be instructed on how to use the mobile app and how to complete the 15 days of training and assessments. Finally, after completing this program of training and assessments, they will return to the lab for follow-up assessments.

Inclusion Criteria:

To qualify for participation, participants will: 1) have current chronic PTSD (full- or sub-threshold) as defined by DSM-V criteria lasting at least 3 months and meeting at least one DSM-V criteria for threat sensitivity; 2) be aged 18-75; 3) have the ability to understand and comply with the training protocol and complete study assessments; 4) be either veterans or non-veterans; 5) have a DSM-V diagnosis of Alcohol Use Disorder.

Exclusion Criteria:

Exclusionary criteria include: 1) current ongoing trauma or trauma exposure within the past 3 months; 2) severe non-alcohol substance use disorder in the past 3 months (any level of alcohol use disorder is acceptable); 3) active suicidality; 4) lifetime history of schizophrenia or bipolar disorder I; 5) medical conditions including seizure disorders, neurological disorders, moderate or severe head injury (e.g., loss of consciousness greater than 30 minutes, severe traumatic brain injury), systemic illness affecting nervous system function, heart defect, or medically unstable injuries; 6) Recent change in psychotherapeutic treatment (e.g., psychotherapy, counseling) for PTSD or other psychiatric symptoms within the last 3 months, change in type of pharmacological treatment or a greater than 50% change in dose of pharmacological treatment within the last 3 months, or a planned change under one of these categories during the study period*; 7) subjects who, in the opinion of the investigator, are otherwise unsuitable for a study of this type. Individuals who are determined to require additional services, whether included or excluded from the study, will be referred to the VA or outside services if clinically appropriate. Additionally, individuals who report significant hearing difficulties but who are deemed eligible to participate in the study otherwise will be excluded from the fear-potentiated startle portion of the assessments at baseline and follow-up, as this task involves an acoustic startle.

15-Day Training and Assessment Phase:

The 15-day training and assessment phase will take place with the assistance of a mobile application called REPS (Resolving Psychological Stress). Eligible consenting participants will perform REPS training and assessments on the mobile application for 15 days. Participants will have up to three weeks to complete all the sessions. Participants will be instructed to complete a total of twelve days of training in conjunction with daily assessments of mood, stress, sleep and unusual events as well as three days of a more thorough assessment of mood, stress, depression, anxiety and PTSD symptoms once per week on the device. The training days involve approximately 15-minute long sessions of the REPS paradigm dot probe training and daily questions on the mobile app. Weekly assessment days should take 20 minutes on the mobile app. Participants may contact study personnel during office hours with questions or concerns via telephone or through email. We will contact participants by phone once per week to assess adherence to the protocol and to ensure that their device is functioning properly. We will assess adherence only by self-report. App-based follow-up assessments will take place at the end of 12 days of training. For participants who have not completed 12 days of training within 21 days of the start of training, we will push a follow-up assessment, which they will be asked to complete as soon as possible.

REPS Paradigm

Each training session with daily questions will last for approximately 15 minutes. At the beginning of the session, participants will be asked to report on their mood and emotions and stress exposure before beginning the REPS training session. During the training session, they will be exposed to threatening words in the ABM condition (e.g., death, crazy, worry) or neutral words in the control condition (e.g. hill, jersey, check). These are chosen based on their own ratings of 50 words. The ratings are entered into an algorithm which determines the most threatening words for that participant. On each trial, the participants will be exposed to a threatening (ABM) or neutral (control) word and a matched neutral word for a very brief period of time (500ms). The words will then disappear and one of them will be replaced by a probe in the form of either the letter E or F and the participant will be asked to indicate whether an E or an F appears. In the ABM training paradigm, the probe will replace the neutral stimulus all of the time, which is thought to train the participants to direct their attention towards a neutral stimulus in the context of a threatening stimulus. In the control condition, the probe will replace one set of neutral stimuli all of the time. There will be a brief inter-trial break (e.g., 500 - 1500 ms) between each trial. The participant will complete this training task for last approximately 10 minutes with an additional 5 minutes of daily questions.

Statistical Analysis Plan

Power analysis: This study is designed to yield estimates of effect size rather than to complete a definitive trial of ABM in PTSD.

Statistical Analyses: Descriptive analyses of behavioral and questionnaire data are used to assess feasibility and acceptability of REPS. Exploratory analyses examine the effects of intervention (attention bias modification versus control training) x time (baseline, follow up) on PCL-5 (PTSD Checklist-5) scores using mixed models. The PCL-5 was given via the mobile application immediately before participants starting their threat-related attention bias or neutral control attention training and at follow-up.