Studying the Modification of Attention Bias Remotely After Trauma (SMART)

Protocol Document

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Overview: This study is a Phase II 3 (Time) x 7 (Condition) randomized controlled trial of an intervention targeting threat-related attention biases, a purported mechanism of PTSS. Time is within subjects and includes a baseline pre-training assessment, a post-training assessment at 2-4 weeks, and a follow-up post-training assessment at 8 weeks. Condition is between subjects and includes seven conditions, listed below.

Group Randomization: Eligible participants were randomized to one of seven conditions:

- **Condition 1:** ABM with word stimuli
- **Condition 2:** ABM with face stimuli
- **Condition 3:** ACT with word stimuli
- **Condition 4:** ACT with face stimuli
- **Condition 5:** Placebo control training with word stimuli
- **Condition 6:** Placebo control training with face stimuli
- **Condition 7:** Assessment Only

The only difference between the conditions is (1) the placement of the probe , and (2) the type of stimuli presented (e.g. words, faces).

Placement of the probe varies by condition as follows:

> **Attention Bias Modification (ABM)** training involves a probe detection task as follows: (1) a fixation cross appears on the screen for 500ms; (2) the fixation cross is replaced by two target stimuli (e.g. one threat word and one neutral word for word stimuli condition; one threatening face and one neutral face for face stimuli) that are displayed at the top and the bottom of the screen for 500ms; (2) the stimuli disappear and a visual probe appears (the letter E or F), in the location of one of the two stimuli until the participant responds to indicate whether the letter was an E or an F using response buttons at the bottom of the phone screen. In the active ABM condition, the two target stimuli include one threat stimuli (i.e. word or face) and one neutral stimulus, and the probe replaces the neutral stimulus 100% of the time. The goal of the active ABM training is to encourage participants to redirect attention from threatening stimuli to neutral stimuli because this training has been shown in previous research to reduce anxiety and stress reactivity.
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> **Attention Control Training (ACT)** follows the exact same procedure as ABM; however, the probe replaces the neutral stimuli 50% of the time and replaces the threatening stimuli the other 50%. The goal of the ACT is to train control over attention in the context of threat.
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> **Placebo Control Training** also follows the exact procedures as ABM, however both target stimuli shown are neutral and the probe replaces one neutral stimulus. Since both stimuli are neutral, the condition acts as a placebo training paradigm as participants are not exposed to threatening stimuli.
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> **Assessment Only** participants receive no training at all and only complete the assessments for the study. The purpose of this condition is to examine if merely answering questions about PTSS and related phenomena reduces PTSS severity.

Participants in the active ABM, ACT, and placebo control conditions WERE subdivided into one of two levels: word or face stimuli. All words were taken from a validated set of threatening words. For participants in the face stimuli groups, all faces were pulled from the RADIATE (Racially Diverse Affective Expression) set of emotional faces.

Procedures: Participants will be provided with instructions via email on how to download the mobile app and will be provided with a log in ID and PIN and text instructions on how to use the app. Upon logging into the app for the first time, they will complete a battery of questionnaires.

All participants, regardless of condition completed training at the following timepoints:

- **Day 1:** Pre-intervention questionnaires and assessment in SMART app (20 minutes)
- **Day 2-8:** Training in the SMART app (5 minutes per day)
- **Day 9:** Assessment in SMART app (15 minutes)
- **Day 10-16:** Training in the SMART app (15 minutes per day)
- **Day 17:** Assessment in SMART app and post-intervention questionnaires (25 minutes)
- **Day 56:** Assessment in SMART app and follow-up questionnaires (20 minutes)

Assessment days are Day 1, 9, 17 and 56, while Training days are Day 2-8 and 10-16.The difference between the conditions occurs on the training days. Conditions 1-6 are dependent on two variants: the type of stimuli presented (i.e. words vs faces), and the placement of the probe (50% behind neutral stimulus, 100% behind neutral stimulus, both stimuli are neutral). Participants in these six conditions completed 128 trials of their assigned training; one trial is defined as presenting the fixation cross for 500 ms, two stimuli presented on the screen, then subsequent probe detection. Therefore, participants saw 128 pairs of stimuli in a daily training session.

On training days, participants answered sets of questions about PTSS symptoms and events over the past 24 hours (e.g. how stressful the day has been, how many nightmares they had, etc). Upon completing the questions, Conditions 1-6 then completed the training assignment they were randomized to. Condition 7 only answered the daily questions and did not complete any subsequent training.

On Assessment Days, participants in Conditions 1-6 completed the probe detection task using the same type of stimuli they use during the training days and the PCL. Condition 7 only completed the PCL and did not complete the probe detection task.