Study Protocol

Study Title: Neural Mechanisms of Enhancing Emotion Regulation in Bereaved Spouses
ClinicalTrial.gov Identifier: NCT04822194
Sponser: The National Institute on Aging
Intervention: Cognitive Emotion Regulation Training
Protocol Number: 1
Phase: Phase 1
May 21, 2025
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Objectives**:**

The objective of this research study is to examine the efficacy and behavioral and neural mechanisms of a cognitive emotion regulation training intervention aimed at improving psychological outcomes such as reducing depressive symptoms and grief rumination in bereaved spouses. Training efficacy will be assessed through psychological and neural indices of negative affect, and physiological indices including respiratory sinus arrhythmia (RSA), a measure of heart-rate variability. Cognitive reappraisal (i.e. the ability to modify the trajectory of an emotional response by thinking about and appraising emotional information in an alternative, more adaptive way) represents a highly promising target for psychological intervention in bereavement[1]. Reappraisal can be operationalized via two primary tactics: psychological distancing (i.e. appraising an emotional stimulus as an objective, impartial observer) and reinterpretation (i.e. imagining a better outcome than what initially seemed apparent). The project builds upon promising preliminary work to investigate the effectiveness and underlying neurobiological mechanisms of a novel, five-session cognitive reappraisal intervention in bereaved spouses. The study aims to mechanistically relate changes in psychological, psychophysiological, and neural function during a novel emotion regulation intervention never before implemented in this stressed, high risk group. The goal is to inform future interventions that can reduce negative psychological outcomes in bereaved spouses.

Design**:**

Recently-bereaved participants (i.e. approximately 6 months post-spousal loss) will be screened for eligibility, then randomly assigned to receive training in either distancing or reinterpretation, with five sessions occurring every 1-3 days, with longitudinal collection of affective, psychophysiological, and functional magnetic resonance imaging (fMRI) data. During the five sessions (T1-T5), participants will undergo cognitive emotion regulation training and an emotion regulation task in their respective training groups, complete questionnaires, and take a 5 minute RSA reading. Functional MRI scans will be acquired at T1 and T5. Follow-up questionnaire assessments of perceived stress, depressive symptoms and grief rumination will occur at one and two months post-intervention. We propose to recruit 84 participants in this study (i.e., 42 participants per intervention cell).

Methods**:**

Reappraisal Intervention Procedure. At sessions T1-T5, participants will complete a widely used image-based reappraisal task[2-5]. In the task, participants view non-violent images from the IAPS[6] with themes relevant to grief and loss in bereavement. Task images are distinct from training images but contain the same themes. Neutral images contain at least one person but are emotionally neutral. All images at every session will be unique, presented in a randomized order, and counterbalanced across sessions and negative trial types. In the task, images are preceded by a cue word (either "LOOK" or "DECREASE"). On LOOK trials, participants will be asked to look at the image to-follow and respond naturally to it. On DECREASE trials, participants will be instructed to apply the appropriate regulation strategy (i.e., either distancing or reinterpretation) to decrease their emotional response to the image. Participants trained in distancing will be asked to alter the way they think about a personal connection to situations by viewing the photos with a rational, impartial mindset or imaging the events happened a long time ago, whereas participants trained in reinterpretation will be asked to tell themselves a story about the photos that whatever is going on will soon be better than it is now or the pain the person is feeling will be easier to bear with time. The resulting three trial types are: LOOK paired with a neutral image ("Look Neutral"), LOOK paired with a negative image ("Look Negative"), and DECREASE paired with a negative image ("Reappraise Negative"). One hundred and eighty total negative and 90 total neutral images are used in the task, with 18 trials per trial type per session, distributed evenly among 3 task runs. Following the presentation of each image, participants will be asked to rate their negative affect on a scale of 1 (least negative) to 4 (most negative).

Self-report Questionnaires. Negative affect ratings will be assessed at T1 through T5. Perceived stress will be assessed using the Perceived Stress Scale (PSS)[7] at T1 through T5 and both follow-ups. Participants will complete additional self-report questionnaires at T1, T5, and both follow-ups measuring depressive symptoms using the Center for Epidemiologic Studies Scale (CES-D)[8], intensity and nature of grief-related cognitive processes using the Utrecht Grief Rumination Scale (UGRS)[9], and emotion regulation strategy use using the Emotion Regulation Questionnaire (ERQ)[10].

Functional Magnetic Resonance Imaging. Participants will complete the picture task at sessions T1 and T5, while undergoing functional magnetic resonance imaging (fMRI) using a simultaneous multislice (SMS)-accelerated (3x) EPI acquisition protocol (63 axial slices; TR=1.2 s; TE=27 ms, 2-mm cubic voxels). Participants will be scanned in a 3.0T Siemens Vida MRI scanner at the Houston Methodist Research Institute outfitted with an MR-compatible LCD display and an MR-compatible 4-response button box. Participants will be screened for metal and other MR-contraindications before entering the scanner.

RSA. RSA will be continuously measured during sessions T1 through T5 non-invasively using a Corsense heart rate variability monitor by Elite HRV. RSA will be measured during a 5-minute resting epoch while seated.

References

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