Evaluating the Impact of an Emotion Regulation Intervention on Emotion Perception

Purpose of the Study

Aim 1: To evaluate the short-term impacts of an emotion regulation intervention on emotion perception in the laboratory. In the laboratory training session, we will compare performance on behavioral emotion perception tasks between participants who receive the intervention, a training in an emotion regulation skill (i.e. mindful breathing), and participants in the control conditions (perspective-taking and worry inductions). Hypothesis 1: We predict that participants in the emotion regulation intervention condition will show less negative bias in their performance compared to participants in the control conditions. We also predict that intensity of emotional distress will be associated with negative biases.

Aim 2: To investigate the longitudinal effects of this intervention on emotion perception outside the lab using experience sampling. After the laboratory training session in aim 1, participants in both groups will receive an auditory reminder of the emotion regulation skill (a specific tone) three times a day through their mobile phones for one week and then will complete emotion perception tasks. Using our method of generalization, the participants in the intervention group have learned to associate the tones with reductions in emotional distress. For this aim, we will compare changes in performance on the emotion perception tasks over time between the three groups. Hypothesis 2: We predict that these cues will lead to greater decreases in negative biases in emotion perception over time compared to the control conditions. We will also test whether changes in emotional distress and regulation mediate the longitudinal changes in emotion perception performance.

Background & Significance

Emotion perception problems are a transdiagnostic problem in mental health. Dysfunctional social processes, such as problems with perceiving and understanding other people's emotional expressions, are some of the main targets of mental health treatment emphasized within the Research Domain Criteria (RDoC) of the National Institute of Mental Health. Recent efforts in the NIMH have included assessing and targeting deficits emotion perception, one of the core social cognition processes that are impaired in schizophrenia.(Pinkham et al., 2014) However, emerging evidence has revealed that problems with emotion perception are also associated with many affective and personality disorders that are characterized by emotion dysregulation, such as depression, anxiety disorders and borderline personality disorder (Daros, Zakzanis, & Ruocco, 2013; Lazarus, Cheavens, Festa, & Zachary Rosenthal, 2014; Plana, Lavoie, Battaglia, & Achim, 2014; Schreiter, Pijnenborg, & aan het Rot, 2013). These problems often manifest as negative biases in emotion perception, the tendency to judge other people's emotional expressions negatively (Bradley, Mogg, White, Groom, & Bono, 1999; Dyck et al., 2009; Joormann & Gotlib, 2006) that contribute to further emotional difficulties (Rapee & Heimberg, 1997) and serious psychosocial problems such as violent offending,(Jolliffe & Farrington, 2004) aggression(Dodge, 1993), poor relationship quality(Carton, Kessler, & Pape, 1999) and general psychiatric distress (Crick & Dodge, 1994). Negative biases in emotion perception may also be a vulnerability factor for psychopathology, as there is evidence that problems with perceiving emotions in facial expressions are associated persistence and relapse of depression (Bouhuys, Geerts, & Gordijn, 1999). Therefore, there is a need for effective interventions for problems with emotion perception across affective and personality disorders. As these disorders are often comorbid (Grant et al., 2004),

effective interventions should target and treat transdiagnostic processes associated with social dysfunction in these disorders.

Novel, targeted, and transdiagnostic interventions are needed for problems emotion perception in affective and personality disorders. There is recent interest in clinical psychology to move away from labor and time-intensive treatment packages and to develop brief, accessible interventions (or "micro-interventions") that target transdiagnostic processes underlying dysfunction across different psychiatric disorders. Because mental health providers often find that personality disorders and related interpersonal issues often do not respond to traditional psychotherapies (Beck, Davis, & Freeman, 2015), new approaches to interventions for social deficits are especially needed. An emerging, promising approach to improving social functioning is targeting psychology processes involved in social interaction (i.e. social cognition).(Penn, Sanna, & Roberts, 2008) Preliminary intervention efforts have demonstrated that remediation of problems perceiving emotional expressions are effective within schizophrenia (Kurtz & Richardson, 2012), and autism spectrum disorders (Roelofs et al., 2016). However, these interventions treat problems that are specific to these disorders (e.g. lack of knowledge of social cues) and do not target and treat the problems associated with affective and personality disorders (e.g. negative biases). In absence of effective emotion perception treatments for these populations, more research is needed to identify and target psychological processes that interfere with social processes within affective and personality disorders. To address this gap in the literature, I propose targeting specific psychological states that regularly interfere with emotion perception within these disorders.

Difficulties regulating emotional distress may lead to negative biases in emotion perception. Difficulty reducing intense, negative emotions is a potential target for treating negative biases in emotion perception. First, emotion perception deficits may be a serious issue within patients with affective and personality disorders characterized by emotion dysregulation, problems managing and reducing negative emotional experiences (Gross & Muñoz, 1995). Beyond the diagnoses, problems managing one's own negative emotional states interferes with many social cognitive processes, including perceiving and understanding other people's emotional expressions (Decety & Lamm, 2006; Eisenberg, Fabes, Guthrie, & Reiser, 2000). Specifically, research in healthy samples has demonstrated that increases in negative emotions lead to negative biases in emotion perception tasks (Chepenik, Cornew, & Farah, 2007; Niedenthal, Halberstadt, & Margolin, 2000; Schmid & Schmid Mast, 2010). These findings can be interpreted as a mood-congruence effect, in which a person's emotional state leads them to selectively attend to and encode stimuli in the environment that is consistent with that emotion (Forgas & Bower, 1987). Furthermore, some researchers have argued that this effect may be particularly common within individuals who have chronic emotion dysregulation (i.e. borderline personality disorder (Daros et al., 2013; Domes, Schulze, & Herpertz, 2009)), whose social behavior is particularly mood-dependent. In line with this argument, our previous research demonstrated that high activation of negative emotions decreases sensitivity to other people's emotional expressions across anxiety disorders, depressive disorders, and personality disorders (McMahon, Kim, Fang, Neacsiu, & Rosenthal, in press). Therefore, states of unregulated, intense negative emotions (i.e. distress) may often impair emotion perception abilities within people diagnosed with clinically significant emotional difficulties. We hypothesize that training patients to regulate their distress with emotion regulation skills will lead to less negative biases in emotion perception compared to patients who do not receive this training.

Mindfulness is a promising emotional regulation skill that could reduce negative biases in emotion perception. Identifying a brief intervention that effectively reduces negative emotions is necessary to investigate the impact of emotion regulation on emotion perception. Previous research has shown that mindfulness is a skill that is positively associated with both emotion perception ability and emotion regulation (Quaglia, Goodman, & Brown, 2015). First, mindfulness can be used to modulate experiences of negative emotions (Chambers, Gullone, & Allen, 2009; Roemer, Williston, & Rollins, 2015). For example, one study found that a 15-minute mindful breathing induction led to less negative emotional responses to negatively-valenced stimuli than control condition (a worry induction) (Arch & Craske, 2006a). Secondly, brief mindful breathing interventions can also lead to improvements in emotion perception.(Tan, Lo, & Macrae, 2014) Taken together, findings suggest that mindful breathing can be used as an emotion regulation skill that may have beneficial impacts on emotion perception. To our knowledge, these relationships have yet to be tested within clinical samples with emotion dysregulation. Given its established effect on emotion regulation, a mindful breathing skill will be taught to participants as an emotion regulation skill as a micro-intervention. A useful comparison condition would be a micro-intervention that targets perspective-taking (Jackson, Meltzoff, & Decety, 2005), another social cognitive process related to perceiving other people's emotions. Perspective-taking inductions may share similar mechanisms as mindfulness as another type of metacognitive intervention, but they do not address dysregulated emotions. Therefore, a perspective-taking micro-intervention will be used in this study as the active comparison condition.

Our team's intervention that generalizes emotion regulation skills is a novel approach to testing if reducing emotional distress reduces emotion perception biases. To study the longitudinal effects of emotion regulation skills on emotion perception, these skills must be applied over time in patients' daily lives. In almost all behavioral therapies, the learning process occurs inside a clinic setting, and patients are expected to transfer this learning outside the clinic setting to the natural environment. However, patients often find it extremely difficult to generalize newly learned adaptive responses from one context to another (Stokes & Osnes, 2016). A key principle that can be used to facilitate generalization of newly learned behavior across contexts is: stimuli that are paired with training and transported into relevant contexts in the natural environment can be used as functional mediators to promote generalization.(Stokes & Osnes, 2016) This has been tested in our lab within adults with a variety of psychiatric diagnoses all characterized by having high difficulties with emotion regulation. Preliminary findings from our NIMH-funded study with emotionally dysregulated adults, "Evaluating a Novel Method of Generalizing Emotion Regulation" (IRB #: Pro000035922), demonstrated that within the lab, auditory reminders of habituation (i.e. natural reductions in emotional arousal over time) reduced emotional distress ($F=6.75$, $p=.011$) and arousal ($F=7.05$, $p=.009$) significantly more than a control condition. Emotional distress and arousal were assessed with both self-report (e.g. Subjective Units of Distress) and physiological measures (e.g. galvanic skin conductance). Reminders delivered via mobile phones over one week also significantly reduced emotional distress compared to placebo sounds ($X2=11.54$, $p<.001$). These findings suggest promise for the use of novel reminders of learned emotion regulation skills to improve the ability to perceive other people's emotions in real social contexts. The next steps in this research program is to test the effects of this intervention on other psychological processes that are fundamental to daily functioning, such as emotion perception.

In sum, this study investigates the impact of a novel, generalizable emotion regulation micro-intervention on emotion perception biases in a transdiagnostic sample of adults. Negative biases in

emotion perception are present within a wide range of psychiatric populations characterized by emotional difficulties and may contribute to debilitating social dysfunction. These deficits call for brief, accessible and effective interventions that target transdiagnostic processes that lead to these emotion perception biases. Therefore, this study proposes to investigate if a brief, emotion regulation intervention reduces negative biases in emotion perception within a transdiagnostic clinical sample with emotion dysregulation. This study will leverage our lab's translational method of generalizing learned emotion regulation skills to real social contexts through mobile-phone technology. We will compare the effects of this emotion regulation intervention with two comparison conditions that involve inductions that have been shown to increase emotional distress in response to stressful experiences: a worry induction and a perspective-taking induction. The findings from this study will determine whether problems with emotion perception can be reduced by helping patients manage their own emotional experiences in adaptive ways. These findings will inform larger clinical trials in larger samples and over longer periods of time. Therefore, this proposed project could pave the way for a new approach to treating emotion perception and other social processes in a wide range of clinical populations.

Design & Procedures

This study is funded by Duke University Bass Connections Project Teams, through Duke Institute for Brain Sciences (DIBS). It is also funded by the Varela Award from the Mind & Life Institute.

Study Overview: This study will be a three-group study and will broadly follow the protocols of our team's previous study, "Evaluating a Novel Method of Generalizing Emotion Regulation" (Pro000035922). The study will be conducted over two sessions in the lab (intake and training sessions), followed by one week of receiving mobile phone prompts (testing phase). In the first intake session, all participants will be assessed for psychiatric diagnoses and complete the emotion perception tasks. Then, the participants will return one week later for the training session. Participants will be a randomized to one of three groups: 1. Mindful Breathing, 2. Habituation, or 3. Control condition. After the training session, all participants will receive mobile phone prompts during the one-week testing phase. At the end of testing phase, all participants will complete the self-report measures of psychological functioning and the emotion perception tasks through an online survey. Emotional distress will be measured repeatedly throughout the study. See figure for a summary of the main procedures in the study protocol, with measures that may be used in primary and exploratory analyses:

Recruitment and Assessment. Before being recruited into the study, potential participants will complete a phone screen—a pre-experiment screening questionnaire (see Phone Screen document) or complete an online survey done through Qualtrics to assess certain exclusion and inclusion criteria (see inclusion/exclusion criteria in section 5). As the phone screen collects PHI (e.g. name, email and/or telephone number, knowledge of psychological symptoms, etc) in order to determine eligibility for the study, we request the waiver of consent to collect this information prior to informed consent. Potentially eligible participants will come to the lab for their intake session to fully determine eligibility for the study (see Request for Waiver of Consent). Upon arrival, a Clinical Assessor (Kibby McMahon or Caitlin Fang) will review the consent form, answer any questions, and obtain written informed consent. The Clinical Assessor then will administer diagnostic interviews (i.e. Structured Clinical Interview for

DSM-5 (SCID-5)(First, Williams, Karg, & Spitzer, 2015)) and self-report instruments needed to assess all other inclusion/exclusion criteria (see section 5).

Measures and Tasks

Interviews: During the intake session, diagnostic exclusions and current/past prevalence of Axis I and II diagnoses will be determined by the Structured Clinical Interview for Mental Disorders-I and II (SCID-I and II for DSM-5), interviews with demonstrated reliability used in our lab. The Treatment History Interview, brief version (B-THI; Linehan & Heard, 1987) will also be used at the intake session to assess previous and ongoing psychiatric services received and the NART will assess reading ability. All interviews will be videotaped or audio recorded and Dr. Rosenthal will determine the reliability of every tenth interview. These video and/or audio recordings will be recorded directly onto the assessor's Duke computer, using a USB connected web camera that is connected to the hard drive of that computer. The recordings do contain PHI and thus the Duke lab computer used for recording has been encrypted with PGP. These video/audio files will be only temporarily stored on the local Duke computer and will be moved to Department of Psychiatry & Behavioral Sciences protected folder.

If the participant recently took part in another study at CBRTP, he or she may not be required to complete all portions of the SCID interviews. Specifically, if the participant completed a SCID-I diagnostic interview with one of our study assessors within the previous four weeks, he or she would only be required to complete any portions of the SCID-I not completed as part of the earlier study assessment. If the participant completed the SCID-II within the previous six months, he or she would not be required to complete the SCID-II. In those cases, data from the earlier assessments would be used for this study. These procedures reduce the burden on the participant by eliminating the need to duplicate lengthy interviews, while still ensuring that the data is current.

Emotion Perception: The main outcome measure of emotion perception will be assessed with behavioral tasks, described below.

(1) Emotion Perception Bias Task (EPBT). This behavioral assessment is adapted from other studies investigating the effects of mood on emotion perception biases (Dyck et al., 2008; Schmid & Mast, 2010). In this task, participants will view photographs of people's faces expressing either a negative emotion (e.g. angry), positive emotion (e.g. happy). These photos will be displayed to participants one at a time for a brief period, and then asked to judge the emotion in a multiple-choice format (e.g. "happy" or "angry"). At the end of this task, participants are asked to rate how confident they were in the accuracy of their responses on a 0-100 scale.

(3) The Bell Lysaker Emotion Recognition Task (BLERT) (Bell, Bryson & Lysaker, 1997) measures the ability to identify affect cues. It is an audio-visual task designed to elicit a person's ability to discriminate seven emotional states (i.e. happiness, sadness, fear, disgust, surprise, anger or no emotion) given facial, voice-tonal and upper-body movement cues. The BLERT consists of twenty-one, 10-second vignettes (using the same male actor) containing one of three monologues involving a work related topic. After each vignette, the tape is paused and the participant circles the corresponding emotional label on an answer sheet. After identifying the emotion for each video, participants are asked to rate how confident

they were in the accuracy of their response on a 0-100 scale. Performance is indexed as the total number of correctly identified emotions (ranging from 0 to 21). Test scores include the total number of correct responses, the number of correct positive affect responses (happy and surprise), the number of correct negative affect responses (sadness and fear), the number of correct difficult responses and number of correct easy responses.

(3) A phone-based assessment of emotion perception, adapted from procedures used in text-based emotion perception research in healthy populations (Cheshin, Rafaeli, & Bos, 2011). Participants receive standardized text messages that are previously rated for emotional valence on a 0 (very negative) to 9(very positive) scale by independent raters. To increase ecological validity, participants are told that these messages have been sent by the experimenter, who is expressing an emotion through the message (e.g. "I just got into an argument with a friend, so I'm not having a good day"). After participants receive the text message, they are instructed to rate the valence of the emotion of the message on the same 10-point scale. This phone-based emotion perception task will only be administered during the one-week testing phase. See the text message script document for the text message content participants would receive during testing phase.

Emotion: Emotional arousal will be measured through self-report and physiological measures: (1) Skin conductance will be measured using Ag-AgCl electrodes, which are connected to a Biopac MP150 device in an adjacent room. Amplified signals of analog data are converted to digital form and filtered using Biopac's Acqknowledge Software and are stored in a database on the computer. (2) Subjective units of general psychological distress (SUDS; visual analogue scale from 0-100); (3) the Sedation Scale (SS), a self-report measure of emotional and general levels of arousal, and (4) the PANAS-2 (Watson, Clark, & Tellegen, 1988), a measure of current emotional state.

Face-reader data collection. We have acquired new software (Facereader from Noldus) that can be used to analyze facial expressions from an inputted video and to output emotional experiences resultant from the facial analysis. This software complements the physiological data acquisition that we are doing and can add a new dimension to our data collection and analysis. We plan to video record participant's faces during the stressor and regulation periods of the study using a Microsoft webcam that is connected directly to a Duke approved laptop or computer. We will ask at consent for special permission for this procedure. We will only record participants' faces if consent is given. These recordings will be transferred right away at the end of the session on a secured server and deleted from the laptop (similar procedures as for assessment videos). The videos will be kept up to 6 years post study finish and deleted within that timeframe.

Psychological Functioning: Exploratory outcome variables will be changes in self-reported impairments in daily functioning and other psychiatric symptoms. These include:

1. Difficulties in Emotion Regulation Scale (DERS) (Gratz, 2004)

2. Interpersonal Reactivity Index (IRI),(Davis, 1980)

3. Toronto Mindfulness Scale (TMS) (Lau, et al., 2006),

4. Basic Empathy Scale (BES) (Carre et al., 2013)

5. Patient Health Questionnaire-depression module (PHQ-9) (Kroenke & Spitzer, 2002)

6. Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998)

7. NIH Toolbox Adult Social Relationship Scales (NIH SRS) (Cyranowski, 2013)

8. Ambiguous Intentions Hostility Questionnaire (AIHQ-A; Combs et al, 2007)

9. Early Memories Task (EMT; Mayman, 1968)

10. Psychological Flexibility Questionnaire (PFQ; Ben-Itzhak, 2014))

Personally-Relevant Emotional Stressor Task. Using the method used in our previous studies, we will create four negative emotional arousal scripts that will be used in a random order during the first lab session. The clinical assessor will ask the participant to describe three of the most recent stressful experiences in their lives within the past two weeks (a timeline that has shown to be feasible within our previous studies with emotionally dysregulated participants). Participants will write a description of each event, and the clinical assessor will work with the participant to establish a clear story for each event that can be recited in approximately 30 seconds. The clinical assessor will digitally record these scripts into .mp3 files, which will be used in random order as the emotional stressors. Each stressor is presented to the participant three times. Participants will be instructed to listen carefully to the recorded stressor via headphones (30s) and to imagine the stressful experience as vividly as possible. All participants will be given these instructions, but additional instructions are given according to the experimental condition.

Experimental Procedures

Intake Session: After determining eligibility, participants will complete measures of social and psychological functioning (DERS, IRI, PANAS-2, TMS, AIHQ-A, NIH SRS, PHQ-9, BES, EMT, SIAS, PFQ) and the two laboratory emotion perception tasks (BLERT, EPBT) through an online Qualtrics survey on a standard desktop computer in the laboratory. At this time, they will provide four recent stressful experiences for the personalized stressor task.

Training Session: All participants will come back to their lab for this session (ideally between 5-7 days after the intake session), which will take approximately 1.5 hours. First, all participants will be asked about: 1) current distress and suicidal urges (i.e. Suicide Risk Protocol), 2) any changes in medications since the previous visit, 3) nicotine, caffeine, and alcohol use that day, 4) subjective units of general psychological distress (SUDS; visual analogue scale from 1-9), 5) dissociation state, assessed using self-report (Dissociative-Tension States Scale 4 item version-DSS-4 from the DSS-acute), 6) levels of arousal with the Sedation Scale, and 7) current affect with the PANAS-2. Then, the experimenter will affix electrodes and will use Biopac MP150 hardware and AcKnowledge software for data acquisition. All participants will be assessed for baseline negative emotional arousal with psychophysiological (galvanic skin response) measures for five minutes. Then, participants will be randomized to one of three groups:

Condition 1: Mindful Breathing. Participants assigned to this condition will first receive an orientation to mindful breathing, an emotion regulation skill based on Mindfulness Based Stress Reduction (Kabat-Zinn, 1990). The experimenter will orient them to the concept of focusing attention on the breath while feeling intense emotions, explaining that it's an active skill that one can use to calm down when distressed. After the initial orientation, participants are instructed to participate in the stressor task to while practicing the mindful breathing skill. Reductions in emotional arousal will be continuously monitored using a real-time monitoring program that samples arousal through skin conductance every 500ms relative to the average baseline arousal. Emotional distress will also be assessed repeatedly throughout the task (SUDS). Once participants reduced their sympathetic arousal (returning to baseline in skin conductance) in the stressor task, a novel tone will be heard through the headphones. Through classical conditioning, participants learn to associate this specific sound with reductions in negative emotional arousal and distress.

Condition 2: Habituation. This comparison condition will most closely resemble the procedures of the previous study on generalizing emotion regulation (Pro00035922). Participants will hear each stressor for a minimum of 2 and a maximum of 4 times. Reductions in emotional arousal will be continuously monitored using a real-time monitoring program that samples arousal through skin conductance every 500ms relative to the average baseline arousal. Emotional distress will also be assessed repeatedly throughout the task (SUDS). Once participants reduced their sympathetic arousal (returning to baseline in skin conductance) in the stressor task, a novel tone will be heard through the headphones. Through classical conditioning, participants learn to associate this specific sound with reductions in negative emotional arousal and distress.

Condition 3: Control. This control condition will only present the stressor task without further instructions. Although emotional distress (SUDS) and sympathetic arousal (SCR) will be measured in this task as the first condition, participants in this condition will not hear the tones.

Immediately after the emotional stressor task, all participants will again report: 1) subjective units of general psychological distress (SUDS; visual analogue scale from 0-9), 2) dissociation state, assessed using self-report (Dissociative-Tension States Scale 4 item version-DSS-4 from the DSS-acute), 3) levels of arousal with the Sedation Scale, and 4) current affect with the PANAS-2. They will then complete the laboratory emotion perception bias task and a manipulation check. Afterward, they will be oriented to the mobile phone prompts they will receive during the testing phase.

Testing Phase: During the one-week testing phase, participants in both conditions will receive three text-message prompts through their own phones randomly each day. These prompts will function both as an EMA measurement of self-reported negative emotional distress, as well as the delivery method of the tones. We will have a specific application, processed and stored on Heroku, that will receive and send text messages to participants via Twilio. In each prompt, participants will be asked to report on their current negative emotional distress (SUDS). When participants report high distress (i.e., SUDS>2), they will automatically hear the tone by receiving a text message with an .mp3 file. The participants in the control conditions will also hear the tone despite having no previous associations with it, to control for potential placebo effects. After hearing this sound, participants will report again on

their distress, then complete the phone-based emotion perception task. As a manipulation check, the participants in the emotion regulation intervention condition will be asked if they actu ally used the mindful breathing skill. If the participant does not meet criterion for high distress, they will instead receive a text response on their phone thanking them for their response (see text message sample script document).

All participants will complete the laboratory emotion perception tasks and self-report measures of emotion and psychological functioning through an online Qualtrics survey at the end of this testing phase. They will also complete an exit questionnaire through this Qualtrics survey (see exit questionnaire document).

Selection of Subjects

Inclusion criteria include

(1) ages 18-55;

(2) have a smartphone and agree to receive text-messages;

(3) high emotion dysregulation, assessed with the Difficulties with Emotion Regulation Scale (DERS)(Gratz & Roemer, 2004). There is no single consensus definition of difficulties with emotion regulation. However, one influential contemporary model proposes a multi-dimensional approach to conceptualizing difficulties with emotion regulation, including difficulties with: emotional awareness, emotional clarity, achieving goals when upset, impulsivity when upset, unwillingness to accept negative affect when upset, and accessing strategies to regulate emotions when upset (Gratz & Roemer, 2004). In the present application, we utilize this model and accompanying measure, the Difficulties with Emotion Regulation Scale (DERS; Gratz & Roemer), when characterizing our sample as being individuals who have problems regulating emotions. The mean DERS total score across all published reports (n = 13) with adult psychiatric samples (n = 19) is 112.15 (SD = 22.38). Following the established protocols from previous studies, we will use a total score of 90 or higher in the DERS for inclusion. In our previous study (Pro000035922), the 208 eligible participants had a mean DERS score of 117.6 (SD=17.95) at intake. These participants met criteria for a variety of affective and personality disorders, including major depression (68.3%, 22.1% current), generalized anxiety disorder (40.4%), and borderline personality disorder (11.1%). Therefore, we are confident that this DERS threshold will ensure recruitment of a transdiagnostic, clinical sample with emotion dysregulation.

Exclusion criteria include

(1) Current mania;

(2) Meets criteria for any current psychotic disorder symptom;

(3) Currently/chronically homeless;

(4) Current suicidal ideation (see data & safety section for specific criteria);

(5) Psychiatric hospitalization within past 6 months;

(6) Unable to read, blind or deaf. Our previous study recruited only participants who were currently in treatment, but this study will include both participants who are currently in treatment, as well as those who are not in treatment. Intelligence Quotient (IQ) will be assessed with the North American Adult Reading Test (NART).21-22 Subjects with a NART calculated IQ score of <90 will be excluded from the study.

(7) high self-reported autistic traits, as assessed by the Autism Spectrum Quotient (Auyeung & Baron-Cohen, 2012). If participants score more than 6 out of 10 for the total score, they are considered at risk for autism.

Clinical Assessment. Individuals not excluded by the phone screen will come to the lab to determine eligibility for the study. Upon arrival, a Clinical Assessor will review the consent form, answer any questions, and obtain written informed consent. Next, the Clinical Assessor will administer diagnostic interviews (SCID I, II for DSM-5) and self-report instruments (i.e., demographics, DERS) needed to assess all other inclusion/exclusion criteria Ineligible participants will be debriefed and compensated ($10) for their partial participation. Eligible participants will complete remaining assessments. This approach helps to reduce unnecessary participant burden and increase project efficiency. After inclusion/exclusion criteria are assessed and eligibility is confirmed, participants will schedule their next appointment (ideally min 1 day and max 14 days post screening). Of note, the population being seen in this study can have many different problems currently and in their past and sometimes the interview assessments, along with assessing inclusion/exclusion criteria, can last longer than expected. At the subject's discretion, we may have to finish portions of the assessment interviews (non inclusion/exclusion portions) on a second day. If that is the case, the subject will finish the interviews or the self-report scales on a separate day or on Day 1 of the experiment, after the computer experiment.

Participants who are unable to return, unexpectedly for the training session within 14 days of the last day of the assessment (due to reasons such as sickness, holidays, weather related incidents, unexpected travel or transportation issues), but who remain in contact with the coordinator and are still willing and able to come in to complete the study, will be allowed to continue in the study. The assessor who collected their personalized scripts will check in with the subject prior to the training session to verify that the scripts are still valid stressors. If the training session visit occurs within one month of the screening assessment, all SCID-I & SCID-II data collected from assessment will still be valid (as per the SCID assessment standards). If the training session visit occurs more than one month after the assessment day, the subject will be rescreened (i.e. will sign another consent, redo DERS, all self-report, SCID-I, THI and scripts. We allow screen fail subjects who did not meet inclusion/exclusion criteria at the first visit to rescreen for the study, if it is deemed appropriate (examples include DERS<90).

Subject Recruitment and Compensation

Participants may be recruited using 1) flyers and posters at Duke University Medical Center (DUMC) campus and the surrounding Research Triangle area, 2) online advertisements used on DukeHealth.org, DukeList, Craigslist, the UNC Psychiatry webpage http://www.med.unc.edu/psych/research, UNC's research site, Join the Conquest https://jointheconquest.org/index.php/en/, and facebook 3) direct referrals from local healthcare providers, Duke/UNC outpatient clinics, and other studies of depression 5) Our IRB-approved participant registry (IRB# Pro00000853) in the CBRTP, 6) Duke Clinical Research

Unit (DCRU) volunteer registry, 7) ResearchMatch.org, (see below for description of the CBRTP registry, DCRU volunteer registry, ResearchMatch.org).

The content of recruitment materials will be based on flyers, brochures and email/website scripts (see recruitment materials).

Prospective participants will either 1) contact the study coordinator's office at Duke or be called for a telephone screening interview, administered by a Study Coordinator/approved study team member, or 2) they may visit the websites ClinicalTrials.gov or Dukehealth.org and see the study description or posting. The telephone-screening instrument (see telephone script) is designed to rule out individuals who clearly meet certain exclusion criteria. The Duke study coordinator or approved study staff member will go through the telephone script document within Qualtrics & will be directly entering potential participant's responses to the telephone script electronically-thus no paper copies of the telephone script will exist. Because this study includes individuals with a range of psychiatric diagnoses, we expect most individuals will qualify at the phone screen for a face-to-face diagnostic assessment with the study Clinical Assessor to assess inclusion/exclusion criteria. If potential participants are ruled out via the phone script, their contact information will not be collected but all previous data collected prior to them ruling out will be kept in Qualtrics under a record number.

As an aid to shorten the recruitment prescreening process, prospective participants will be directed by all Duke flyers & brochures to the online screen survey within Duke's Qualtrics platform. Once on the Qualtrics online screen, they will read a description of the study (a modified version of the IRB approved phone screen) and if interested, will continue with answering the online screen questions (see online screen script for Qualtrics). The Qualtrics survey begins with an information statement designed to describe the study, risks and benefits in the absence of informed consent. If they agree to continue, they will then be asked their current age & if their age meets the study inclusion/exclusion criteria, they will continue on with the rest of the Qualtrics online screen as per Qualtrics online script. If they do not meet the age requirement, they will receive a message in Qualtrics indicating that they are not eligible and the survey will end. The results from the Qualtrics online survey will be monitored by the study coordinator and other study staff who will have access via a username and password. The data from the online survey can be imported to a SPSS or an excel .csv file which can only be accessed by the approved study team. Each day, study staff can check results of the online survey to see if any new potential participants have completed the survey and contact those people to either set up their first appointment or inform them that they don't qualify for the study per inclusion/exclusion criteria. Upon download of the prescreening information from Qualtrics by the study coordinator or designated study staff, if it is noted that the subject did not complete all of the online screen questions, the plan is for the study coordinator/staff to contact the subject. They would thank them for starting the screen and prompt them to complete the online screen again or by phone (if easier, using the phone script) if they are still possibly interested in the study.

If the potential participant is indeed ineligible for in-person screening, the study coordinator/approved study team member will log in to Qualtrics and remove their contact information from the study record by the end of the study enrollment period. After removing the contact information, the record number will continue to exist in Qualtrics with only the subject's research information. We estimate that across both study phases, approximately 150 online/phone screen interviews will be needed to enroll 90 subjects to get 72 who complete the study.

CBRTP Database Registry: Subjects who have previously agreed to be in our database registry (IRB# Pro00000853) to be considered for research studies would be contacted either to do a phone screen or directed to the Qualtrics online screen after reading through the phone script information to introduce the study and see if the individual is interested in being screened. Those interested participants will be given information from CBRTP staff about the study and scheduled for an appointment.

DCRU Volunteer Registry: This is a registry that the DCRU has that contains a list of potential study volunteers who have participated in research within the DCRU, who have said they would be interested in participating in other research. In exchange for a fee from our study team, a member of the DCRU team will identify potential research volunteers based on our study specific inclusion/exclusion that we give them and they will send out an email with a blurb about our study (this content is first approved by the IRB) and our contact information. Interested participants would then contact our study coordinator and complete a phone screen or go directly to the Qualtrics online screen for the study.

ResearchMatch.org: ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University. There is no cost for researchers at participating institutions in the ResearchMatch Network to use ResearchMatch for the purposes of conducting recruitment feasibility analysis or participant recruitment. The Vanderbilt IRB provides oversight for ResearchMatch as a recruitment tool and this has been documented within the ResearchMatch IRB Letter of Understanding (available upon request). We would be sending a study recruitment message to potential study volunteers through ResearchMatch.org. ResearchMatch requires us to confirm that the recruitment language has been IRB approved and that our direct study contact information has been removed (email/phone/website) before sending our study announcement through ResearchMatch to volunteers that appear to be a good match for our study. The study PI, Dr. Rosenthal, will seek approval from the institutional liaison to have ResearchMatch recruitment access where he is able to search for appropriate matches amongst the non-identifiable ResearchMatch Volunteer profiles in the system. Our study's recruitment content will be inserted into the standard ResearchMatch electronic notification that informs possible matched Volunteers that we have identified them as a potential match for our study. The secure ResearchMatch clearinghouse will route this standard ResearchMatch notification that includes the IRB approved study content that we enter on "Contacting Volunteers" steps available through ResearchMatch (i.e. similar to the content available on a flyer or poster) to each of these ResearchMatch volunteers. These potential matching volunteers will have the option of replying yes, no, or not respond through a set of quick links available in this notification to our study announcement. By responding yes, the volunteer has

authorized ResearchMatch to release their contact information to us. This contact information of the Yes responding ResearchMatch Volunteers will be made available on our "Managing my Study" dashboard. Once we receive the contact information for those volunteers who respond yes, a member of our study staff would contact them to do a phone screen or direct them to our Qualtrics online screen after reading through the phone script information to introduce the study and see if the individual is interested in being screened.

Social Media: We plan to post ads for the study on social media websites such as Facebook. We will create a study facebook profile and place adds using the study page profile. The language in the ads will follow the language approved by the IRB for internet content. We may forward the link to the online adds from study staff personal Facebook accounts also.

Compensation. Compensation is as follows:

$60 for individuals who are eligible and complete the full assessment

$10 for those who are ruled out on the assessment day and complete only a partial assessment (approx 30 minutes)

$75 after completion of assessment and training session

$85 after completion of full study

Subject's Capacity to Give Legally Effective Consent

To be eligible, subjects must be able to give legal effective consent.

Risk/Benefit Assessment

Risks in this study may arise from 1) the assessment interviews and questionnaires, and 2) discussing and hearing recent personally distressing events.

The assessment interviews and questionnaires may be stressful for some people. Some individuals may experience increased emotional discomfort as they discuss past or present problems during the assessments. During each in-person assessment, a trained professional will be available for consultation should discomfort become extreme.

Minimizing Risks

All participants will be asked to read, discuss, and sign written consent forms that describe the study procedures. Assessors will first give a narrative of the consent, and then have the subjects read it themselves. Following this, assessors will summarize the consent and answer any questions the subjects may have. The written document will not be signed until all questions and study concerns have been addressed. All participants will be told that they are free to withdraw from the study without penalty at

any time. Every effort will be made to make the environment comfortable and supportive during assessment procedures: snacks and beverages may be offered, breaks will be taken, and the assessment will be stopped if the subject wishes or if stress is too high. All assessment sessions will be video recorded and will be supervised via regular weekly study meetings with Dr. Rosenthal and other study staff. However, subjects will be afforded the option during the informed written consent process to opt out of being audio or video recorded and still remain in the study.

As a necessary aspect of participation in this study about emotion regulation, participants will be asked to describe and subsequently hear personally upsetting stories. This aspect of the study will be clearly delineated in the consent form and the study staff member obtaining consent will verbally describe this aspect of the study to each prospective participant. Participants are also free to discontinue the study at any time. Should a participant's discomfort become extreme and includes strong thoughts of suicide, a trained professional will be available on-site during all active study hours. Because suicidal ideation is an exclusion criterion, we do not expect this to be likely risk. We will be using the Suicide Risk/Distress Protocol along with the SCID-I to assess suicidal ideation, intent, self-harm, and date of most recent attempt at the beginning of the assessment day and at the end. In the rare event that a high rating of ideation or distress occurs, the trained study staff will work with Dr. Rosenthal and the participant to address these suicidal thoughts and if they are deemed to be at imminent risk of suicide after the conversation, we will call 911 or obtain a commitment from the participant to go to the nearest hospital emergency room, (e.g. Duke ER). We will also use the Suicide Risk/Distress Protocol to assess ideation, intent and self-harm at pre and post the intake and laboratory sessions.

Study-related adverse and serious events are not expected but will be closely monitored and will be reported to the proper authorities according to established FDA guidelines. All information gathered in this study will be maintained in the research record.

Potential Benefits

Participants will be contributing to our understanding of the way that mindful breathing may improve the ability to perceive other people's emotions. As part of the study design, the participants randomized to receive the mindful breathing intervention and the perspective-taking induction (the active comparison group) will learn useful skills to help regulate their emotions or improve their relationships, as hypothesized. Participants randomized to the control condition (the worry induction) may benefit from monitoring their emotional state repeatedly throughout the study, which may increase emotional awareness.

Costs to the Subject

Participants will incur no costs for participating in any phase of this study.

Data Analysis & Statistical Considerations

For the primary outcome of biases in emotion perception, the estimates were derived from a mean difference between conditions. With a Type-I error rate of 5% and 72 participants (24 per group), we will have at least 80% power to detect a medium to large effect size (Cohen's f = 0.38), based on previous research demonstrating negative biases in emotion perception using similar behavioral measures.(Schmid & Schmid Mast, 2010) Because we anticipate a 10% to 15% rate of dropout, 30 participants will be randomized to each group. Therefore, this study will recruit 90 adult participants over the age of 18 who have high emotion dysregulation and interpersonal problems.

Since 2004, the CBRTP has recruited a range of adult psychiatric samples all characterized by problems with emotion regulation. Across studies of emotional functioning, it is estimated that our lab has run over 980 participants since 2004, at a rate of roughly 90 per year. In our previous NIMH project, over 33 months we have screened 1154 individuals and enrolled 169 participants, at a rate of 5.12 per month. We project enrolling 90 participants over 14 months, at a rate of 6.43 per month. Given our demonstrated track record of success meeting the required recruitment target in the present application, we expect to meet recruitment targets in the proposed project.

Specific Aim 1: Aim 1 will determine if the emotion regulation intervention leads to fewer negative biases in emotion perception during the laboratory training session. For this aim, we will conduct ANCOVA analyses to study group differences in performance on the emotion perception laboratory tasks, controlling for their baseline scores assessed in the intake session. To compare the conditions' impacts on negative biases, we will analyze group differences in 1) number of trials with neutral facial expressions are misclassified as negative emotions; 2) accuracy for positive emotions and negative emotional expressions. We will also examine the relationship between emotional distress and emotion perception. Hypothesis 1: Participants in our emotion regulation condition will have less negative bias in emotion perception (e.g. fewer neutral faces misclassified as negative, lower accuracy for negative emotions, higher accuracy for positive emotions) compared to participants in both the control conditions. Even though the perspective-taking and mindful breathing conditions may have similar effects (e.g. increasing attention to social cues (Olsson et al., 2016; Quaglia, Goodman, & Brown, 2016)), perspective-taking inductions may still lead to mood-congruent biases by increasing negative emotional responses (Lamm, Batson, & Decety, 2007). Therefore, we predict that the emotion regulation intervention would reduce this bias significantly more than both the worry and perspective-taking conditions. We also predict that intensity of emotional distress will be related to negative biases in emotion perception.

Specific Aim 2: Aim 2 will compare the changes in emotion perception over time between the emotion regulation breathing condition and the control conditions. For this aim, Multilevel modeling (MLM) will be used because it permits evaluation of longitudinal data on participants over time with trajectories for each participant examined as random effects. We will conduct MLM analyses to study group differences in changes in the laboratory emotion perception tasks assessed during intake (time 1), the training session (time 2) and after the testing phase (time 3). For the phone-based behavioral task, we will first examine the psychometric properties of this measure in this clinical sample. Then, we will analyze group

differences in the valence of emotion perception ratings over the one-week testing phase. We will also examine whether changes in emotion dysregulation and distress mediate changes in negative biases over time. Finally, we will also explore the effects of the intervention on self-reported psychological and social functioning. Hypothesis 2: One week of hearing the tones via mobile phones will lead to greater long-term changes in negative biases emotion perception for participants in the emotion regulation condition compared to the participants in the control conditions. Changes in emotional regulation and distress over time will mediate changes in negative biases in emotion perception over time.

If our hypotheses are not supported and the conditions do not have significantly different effects on emotion perception, these findings would be indicative of trait-like deficits in emotion perception beyond the momentary effects of mood or perspective-taking. We would then use moderation analyses to explore the role of other stable factors within emotion perception performance, such as trait empathy (measured by the IRI) or psychiatric diagnoses.

Data & Safety Monitoring

The subjects will be fully informed of the nature of the study requirements prior to enrollment and periodically throughout the study. The subject's well-being will be continuously monitored by the study team and the Principal Investigator will report all serious adverse events in an expedited manner to the Duke University Health System (DUHS) Institutional Review Board (IRB) office and all applicable regulatory authorities in accordance with the Center's standard operating procedures.

Quality assurance. Dr. Rosenthal will meet weekly with the Study Coordinator, assessors, and any research assistant to review any research issues that may have arisen during the past week as well as to monitor progress on subject recruitment and other research-related matters. Additional meetings are conducted on an as-needed basis.

Reporting mechanisms of AEs & SAEs to the IRB. In this study we will use the FDA's definition of adverse events (AEs) and serious adverse events (SAEs). It is not expected that any such AEs or SAEs will occur in this experiment. However, AEs and SAEs will be assessed by a trained study coordinator and discussed at the weekly research staff meetings. Any SAE will be brought to the attention of the PI as soon as possible and not longer than 24 hrs. Any SAE, will be reported to the Duke University Medical Center Institutional Review Board using the appropriate documentation within 5 days of the event. This will be the responsibility of the PI. The Duke University Medical Center Institutional Review Board will make a determination as to whether additional reporting requirements are needed.

Suicide Ideation & Risk. During the assessment day, clinical assessors will assess suicidal ideation at two points during the interview:

Time One: During the Suicide Risk and Distress Protocol (pre and post assessment)

Time Two: While assessing Major Depressive Disorder, current and past (if the subject endorses Major Depressive symptoms)

Subjects who endorse suicidal ideation but deny intent and plan will be included in the study. Subjects who are at high risk for self-harm, endorsing intent and plan, will be excluded from the study. Subjects who report a suicide attempt within the past 6 months, will also be excluded. For the subjects who are at current high risk for self-harm (i.e., intent to kill oneself is rated higher than a 4 on a 7-point scale while the assessor is going through the Suicide Risk and Distress Protocol or subject states that s/he is uncertain about being able to control suicidal impulses), assessors will complete the Suicide Assessment Worksheet and follow the instructions outlined in the Suicide Risk and Distress Protocol. This is also discussed under the minimizing risks section of this document.

Protocol violations that could represent serious or continuing noncompliance will be brought to the attention of the PI as soon as possible and not longer than 24 hrs. These violations will be reported to the Duke University Medical Center Institutional Review Board using the appropriate documentation within 5 days of notification of the PIs.

Reporting of non-study related, non-serious AEs are not reported to the IRB, and not entered on the study AE tracking log.

Non-serious AEs that are deemed study related will be reported to the PI with annual reporting and entered into the study AE tracking log. These will be reported to the IRB as needed.

Protocol deviations around study visit windows, skipped questions on self-report measures, missed therapy sessions, etc. will not be reported to the Duke IRB. Other protocol deviations will be reported to the PIs upon discovery and will then be reported to the Duke IRB within 2 weeks.

In this study, if a subject experiences an SAE or study related, non-serious AE and they are not resolved at their final study visit, because it is a minimal risk study, we do not plan to continue to follow the event past their final study visit.

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