Study Protocol

Title: Primary Care Based Mindfulness Intervention for Chronically Traumatized Individuals

NCT Number: NCT03922581

Protocol date: January 21, 2022

Scientific Protocol

Research Study: Primary Care Based Mindfulness Intervention for Chronically Traumatized Individuals

Principal Investigator:
Abigail Powers Lott, PhD,
Assistant Professor
Department of Psychiatry and Behavioral Sciences

Version: 12
Version Date: January 21, 2022

External Collaborators:
Nicole Nugent, PhD, Associate Professor, Department of Psychiatry and Human Behavior

- De-identified Data Analysis/Statistics

Abstract

There is significant public health burden of chronic trauma exposure in low income, predominantly ethnic minority, urban communities, which is reflected in the extraordinarily high levels of trauma-related psychiatric disorders, particularly posttraumatic stress disorder (PTSD) and major depressive disorder (MDD). Despite this, limited access to behavioral health treatment and significant barriers to treatment engagement and success remain[1] and integrating mind-body approaches in medical settings could be a critical next step in treating chronically traumatized individuals in these urban settings. This study will utilize a randomized controlled trial design along with a multi-method assessment approach to ascertain the feasibility, acceptability, and preliminary mechanisms of action and outcomes of mindfulness-based cognitive therapy versus wait-list control in 80 African Americans with chronic trauma exposure and comorbid PTSD and MDD symptoms. Subjects will be recruited from primary care waiting rooms at Grady Memorial Hospital. Individuals must screen positive for depression and PTSD in order to be eligible for the study through the Patient Health Questionnaire-9 and Primary Care PTSD Screen. Once enrolled, subjects will be randomized to an 8 session (90 minutes each) group intervention or wait-list control. We will examine retention and follow-up rates, subjects' report of acceptability and interest in the intervention, and examine barriers to treatment engagement through self-report measures and exit interviews. We will also investigate preliminary mechanisms of action and outcomes of the mindfulness intervention in targeting emotion regulation and autonomic processes by measuring self-report of emotion dysregulation using the Difficulties in Emotion Regulation Scale and autonomic arousal to trauma cues using Esense technology to assess skin conductance during administration of Standardized Trauma Interview. Latent growth modeling will assess relative changes in emotion dysregulation and autonomic function over time through intervention and 1 month follow-up.

Introduction and Background

More than half of individuals in the United States experience at least one traumatic event in their lifetime.[2, 3] Exposure to multiple traumatic events increases risk for psychiatric disorders in a dose-response manner; as the number of traumas experienced increases, comorbid PTSD and MDD symptoms also increase.[4, 5] In the general population, the lifetime prevalence of PTSD and MDD have been estimated to be 5-10%[6] and 8-16%[7-9] respectively, but rates as high as 30-50% for these disorders are observed among civilians living in areas with high violence, with up to half of those individuals meeting criteria for both disorders.[10-12] Low socioeconomic status is strongly associated with increased exposure to multiple traumatic events, and as a result exhibit elevated rates of PTSD and MDD.[1, 13-16] Furthermore, economically disadvantaged African Americans living within urban environments experience particularly high levels of trauma, often beginning early in life.[13-18] Because chronic trauma exposure substantially increases the risk of PTSD and MDD,[6, 19] it is critical to intervene with at-risk, underserved populations where chronic trauma is highly likely to occur.

While individuals exposed to chronic trauma often have high levels of psychiatric symptom severity, they may be less likely than individuals with a discrete trauma exposure to engage in or improve from standard PTSD treatment.[20] Historically, trauma-based cognitive behavior therapies, such as Prolonged Exposure and Cognitive Processing Therapy, have been considered first-line treatments for PTSD.[21, 22] However, there are a number of limitations with these treatments related to low tolerability for patients with chronic trauma exposure, high rates of drop out, and continued presence of PTSD diagnosis.[22, 23] In addition, both treatments involve significant writing and worksheet-based homework. The target population in this study

includes individuals with limited literacy[24, 25] and requiring written homework may not be appropriate. Even those who are literate often have low levels of education, making the idea of written homework a barrier to treatment.[26] Furthermore, limited access to behavioral health care and stigma against such treatment reduces the chances that individuals from low-income environments seek care or are willing to engage in direct exposure-based trauma treatment.[26-28] Finally, despite the high co-occurrence of PTSD and MDD and the fact that PTSD interventions can also reduce some depressive symptoms, PTSD interventions directly target symptoms that do not overlap as clearly with MDD (e.g. re-experiencing, avoidance) and although PTSD interventions can also reduce some depressive symptoms, it is important to consider alternative treatment approaches among those with comorbid PTSD and MDD following chronic trauma exposure. Thus, turning toward complementary and integrative mind-body approaches may be critical for improving treatment success for a low-income traumatized population with comorbid PTSD and MDD.

One potential contender is mindfulness-based approaches, such as mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT, a variant of MBSR), as these are associated with improvements in physical and behavioral health conditions broadly,[29-35] medical resource utilization,[36-38] and ability to cope with physical health problems in most,[29, 32] but not all[39, 40] studies. Recently, both MBSR and MBCT approaches have been used with combat PTSD and childhood sexual abuse and studies show initial efficacy in reducing PTSD symptoms, particularly avoidance and numbing.[41-46] In addition, mindfulness approaches - particularly MBCT - are also effective in treating MDD[47, 48] and reducing risk of relapse.[49] Further, mindfulness approaches have shown promise in low-income African American populations. For example, recent studies reveal that another variant of a mindfulness-based intervention, compassion-based cognitive therapy, is associated with reductions in self-criticism and compassion, which in turn predict improvements in MDD symptoms among suicidal low-income African Americans.[50, 51] In addition, two studies have shown initial feasibility and acceptability in implementing an 8-week MBSR training with African American women with chronic trauma exposure.[52, 53] While examination of mind-body approaches in urban traumatized populations remains limited, the above studies indicating feasibility, acceptability, and symptom reduction suggest further research into these approaches is warranted.

Given significant barriers to behavioral healthcare among chronically traumatized, low-income African Americans[24, 25], bringing complementary and integrative behavioral health treatment to primary care locations where this population is already using resources may increase access and reduce stigma.[54] Evidence supports the use of mindfulness interventions in primary care settings.[37] For example, a recent study examining a brief MBSR protocol for use with combat veterans in primary care found preliminary evidence that the intervention was feasible, acceptable to the veterans, and effective in reducing both PTSD and MDD symptoms[46] and in enhancing physiological functioning.[55] The use of a mindfulness intervention in primary care may reduce the risk of drop outs and lower the burden on patients. Additionally, the mindfulness intervention will be fully experiential and therefore may reduce difficulty with engagement in treatment due to components like written homework. Such a complementary and integrative mind-body intervention may prove particularly efficacious if it targets ED and autonomic processes that characterize chronically traumatized individuals with PTSD and MDD.

Identifying and targeting underlying mechanisms that contribute to PTSD and MDD in low-income, chronically traumatized, African Americans is imperative. Emotion dysregulation (ED), or deficits in the ability to adaptively respond to emotional distress, is particularly prominent in individuals with chronic trauma exposure and may be a critical mechanism to consider.[56, 57]

There are many components of adaptive emotion regulation, including awareness and acceptance of emotional experience, adequate strategies to manage emotional responses, and the ability to control behavioral responses in the presence of strong emotions;[58] individuals with chronic trauma exposure show deficits across all areas of emotion regulation. Dysregulation of the autonomic nervous system is seen as one key objective marker of ED. Dysfunction of autonomic processes is associated with child abuse exposure,[59-61] often an indicator of more chronic trauma exposure,[62] although direct associations with chronic trauma exposure remain unclear.

ED is a transdiagnostic *process* that contributes to many types of psychiatric conditions related to trauma, including PTSD and MDD.[63-65] Poor emotion regulation predicts greater PTSD symptom severity and therefore may be a mechanism that accentuates or perpetuates PTSD symptoms.[66] Impaired autonomic function also correlates with PTSD and MDD and is another proposed mechanism of risk for the development of these disorders.[67] PTSD is associated with heightened physiological reactivity[68, 69] while MDD is associated with heightened baseline sympathetic arousal and blunted sympathetic response to stress.[70] In fact, research in our lab[68] has shown that enhanced reactivity to fearful stimuli is a biomarker of PTSD, but not depression among trauma-exposed individuals. Importantly, not all individuals with PTSD exhibit this autonomic pattern; some individuals also show a blunted physiological response. Research suggests there may in fact be two distinct subtypes of PTSD reflecting emotional undermodulation (hyperarousal and enhanced sympathetic activation) and emotional overmodulation (dissociation and emotional numbing with blunted sympathetic activation).[71] Enhanced reactivity relates most strongly to hyperarousal symptoms[68] and treatment studies using Prolonged Exposure have shown that greater physiological reactivity prior to treatment predicts better treatment success.[72] However, since not all individuals with PTSD exhibit strong physiological reactivity, and chronic trauma exposure increases the likelihood of the presence of emotional overmodulation (i.e., dissociation, numbing), choosing a mind-body treatment that can target ED, regardless of the type, may be very beneficial in populations with high rates of chronic trauma exposure across the lifespan. Furthermore, emotional numbing is a core component of PTSD that strongly overlaps with depression and may help maintain PTSD symptoms[48, 73], and so using a treatment that may target such symptoms is warranted.

In considering mechanisms of action for our mind-body intervention, multiple studies have shown the benefits of mindfulness-based approaches in enhancing emotion regulation and autonomic function.[44, 74-76] Mindfulness acts to increase attentional control, enhance awareness of emotional experience, and provide a space for experiential exposure to internal emotional responses through nonjudgment and acceptance.[77, 78] A common element in evidence-based treatments for PTSD is exposure.[79] While mindfulness does not directly target exposure to trauma memories, the treatment does provide interoceptive exposure to emotions, which is a critical part of healthy emotion regulation and enhancing emotion regulation may result in reductions in PTSD and MDD symptoms in turn. Furthermore, focus on enhancing autonomic function through mindfulness may be associated with marked improvement in symptoms related to hypoarousal (such as emotional numbing)[80-82], which are often the PTSD symptoms hardest to treat.[73] Additionally, MBCT's focus on decoupling from negative cognitions may help to reduce the frequency of negative cognitions and resulting negative emotional reactions[83] which could aid in reducing cognitive symptoms present across both PTSD and MDD.

While there is substantially less empirical evidence to demonstrate the effectiveness of mind-body approaches like mindfulness in treating trauma patients at present, for the reasons described above, our mindfulness intervention may in fact be more acceptable than currently

employed cognitive-behavioral approaches for this underserved population of chronically traumatized adults. This study will utilize MBCT, an 8-week complementary and integrative behavioral health protocol in a primary care setting, determine its feasibility and acceptability, and gather preliminary evidence for its ability to effectively target ED and autonomic function among chronically traumatized African Americans. It is hoped that results will advance our understanding of the psychological and physiological mechanisms of action that drive PTSD and MDD symptom change through mindfulness interventions in chronically traumatized low-income African Americans.

Objectives

Specific Aim 1: Evaluate feasibility and acceptability of mindfulness intervention in a high-risk, underserved population. *Aim 1a: Examine retention and follow-up rates in the intervention and control groups.* Completion of assessments and intervention session attendance will be tracked. *Aim 1b: Examine subjects' report of acceptability of and interest in the intervention*. Satisfaction with intervention will be assessed with a self-report measure and through an exit interview post-intervention. Descriptive statistics and frequency distributions will be evaluated. *Aim 1c: Examine barriers to treatment engagement in the intervention.* Barriers to treatment will be assessed with a self-report measure and through descriptions provided by subjects post-intervention. Descriptive statistics and frequency distributions will be evaluated.

Specific Aim 2: Investigate preliminary mechanisms of action and outcomes of mindfulness intervention in targeting emotion regulation and autonomic processes. *Aim2a: Evaluate if intervention results in greater reductions in ED than wait-list control.* Self-report ED (emotional awareness, acceptance, strategy use, behavioral control) data will be collected at four time-points (pre-intervention, half-way through intervention, post-intervention, 1m follow-up). *Aim 2b: Evaluate if intervention results in greater normalization of autonomic function than wait-list control.* Autonomic arousal to trauma cues (using skin conductance; pre- and post-intervention, 3 month follow-up) will be measured. Latent growth modeling (LGM) will assess relative changes in ED and autonomic function through intervention and follow-up.

Study design and methods

Procedure: Initial screening for eligibility will occur in the medical clinics of Grady Memorial Hospital or through phone-based screening through a parent project, the Grady Trauma Project (IRB00078593). After initial screening through the Grady Trauma Project to determine eligibility for the study associated with this study and appropriate informed consent procedures, subjects will participate in a pre-intervention assessment. These may be in person or virtually depending on safety-related challenges due to the COVID-19 pandemic. Virtual assessments will either occur via phone or Zoom (HIPAA-compliant platform). Following the pre-intervention assessment, they will be randomly assigned using a random number generator to either the MBCT intervention or wait-list control group condition. We will use block stratified randomization (in blocks of 20) to ensure variability in PTSD and MDD diagnosis in the two groups. We will also use allocation concealment by placing the treatment allocation information in opaque envelopes so the study staff that are enrolling subjects do not know in advance which treatment condition will be assigned next. I will generate the allocation sequence and will not be in charge of recruiting subjects. I will also not be blind to assignment and will not collect dependent variables. In the case of virtual assignment to condition, 2 independent staff members not engaged in active recruitment or assessment will have the allocation sequence and will provide it to the staff member doing the pre-assessment following the completion of the interview. The

staff members who will conduct the CAPS and MINI (to assess other Axis I disorders) will be blind to group assignment. The time requirement for the MBCT intervention group will be eight 90-minute sessions. Groups will be offered virtually. Subjects will be compensated $10 for their time at each intervention session. Upon the completion of the 8 sessions (MBCT group) or 8 weeks after the pre-intervention assessment (assessment-only wait-list group), a post-intervention assessment will be conducted. Again, this may occur in person or virtually depending on COVID-19 conditions. One month later, a follow-up assessment will be conducted by phone or Zoom. The time requirement for the pre and post assessment will be ~3 hours and subjects will be compensated $60 for these assessments. The follow up assessment will take approximately one hour and subjects will be compensated $20 for that assessment.

Measures			**Intervention (8 weeks)**									
	Screen	Pre	1	2	3	4	5*	6	7	8	Post	FU
Traumatic Events Inventory	X											
Alcohol Use Disorders Identification Test	X											
Drug Abuse Screening Test	X											
Primary Care PTSD Screen	X										X	X
Patient Health Questionnaire-9	X										X	X
PTSD Checklist for DSM-5	X										X	X
Beck Depression Inventory, II	X										X	X
Standardized Trauma Interview *(+ SC)*		X									X	X
Difficulties in Emotion Regulation Scale		X			X		X		X		X	X
Clinician Administered PTSD Scale		X									X	
MINI International Neuropsychiatric Interview		X									X	
Five Facet Mindfulness Questionnaire		X									X	X
Self Compassion Scale, Short Form		X									X	X
PANAS		X									X	X
Client Satisfaction Questionnaire											X	
Perceived Barriers to Psychological Treatments											X	
Post-group Follow-up Questionnaire**											X	

*****Assessment-only subjects will also fill out measures for intervention week 5.
**For group intervention participants only

Psychological Measures: As part of the parent study, subjects will be administered five baseline measures to determine eligibility for proposed study: 1) The *Traumatic Events Inventory*[11] will detail frequency and type of Criterion A trauma exposure during childhood and adulthood; 2) The *Alcohol Use Disorders Identification Test*[84, 85] is a screening measure for alcohol misuse (≥8 will serve as our cutoff for potential alcohol use disorder); 3) The *Drug Abuse Screening Test, 10 item version*[86, 87] is a screening measure for drug abuse (≥6 will serve as our cutoff for potential substance use disorder); 4) The *Primary Care PTSD Screen* (PC-PTSD)[88] is a 4-item screen designed for use in primary care will assess for presence of PTSD symptoms and serve as PTSD screener; and 5) The *Patient Health Questionnaire-9* (PHQ-9)[89] will assess for presence of depressive symptoms and serve as MDD screener; Classification of PTSD+ will include scores ≥3 on PC-PTSD and MDD+ will include scores ≥5 on PHQ-9. Other measures

that will be used in the proposed study include: 1) *Standardized Trauma Interview*[90] , a 41-item clinician-administered interview that gathers information on relevant aspects of the trauma and demographic information at baseline; 2) *Difficulties in Emotion Regulation Scale*[58] , which measures ED and includes six subscales (non-acceptance of emotions, difficulty with goal-directed behavior in the presence of negative emotions, difficulty controlling impulses in the presence of negative emotions, lack of awareness of emotions, limited use of effective emotion regulation strategies, and lack of understanding of emotions); 3) *Five Facet Mindfulness Questionnaire*[91] will assess mindfulness; it includes five facets (observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience); 4) Self Compassion Scale, Short Form[92] will assess self compassion. 5) *The PTSD Checklist for DSM-5*[93] will be used as another self-report measure of PTSD. 6) *The Beck Depression Inventory, II*[94] will be used as another self-report measure of depression symptoms. Diagnoses at pre- and post-assessments also will be assessed by the *MINI International Neuropsychiatric Interview*[95] (for MDD) and the *Clinician Administered PTSD Scale*[96] (for PTSD), both of which are semi-structured interviews. 7) The *Positive and Negative Affect Scale*[97] will be used to assess trait level positive and negative affect.

Physiological Response to Trauma: Skin conductance (SC) response will be measured using a mobile SC device, eSense (Mindfield Biosystems). Continuous recording of SC is measured with electrodes on hands and data is transmitted through the eSense app. Using the PhenX Toolkit protocol (#630901), a two minute baseline measure of SC will be obtained and then SC levels will be measured during administration of the Standardized Trauma Interview immediately following to determine physiological reactivity to trauma stimuli. SC response is calculated by subtracting SC level at the end of baseline recording (average of last 30 seconds) from the maximum SC level value during the trauma interview. This has been previously tested and found feasible for use in this population.[98] eSense will only be collected if it is deemed safe for participants to come to the laboratory for this portion of the assessment. If not, all other psychological measures will be gathered virtually and this portion of the assessment will be skipped.

Study Design: Following random assignment to assessment-only or intervention group, subjects will participate in either assessment only or 8-visit group intervention. Groups will vary in size depending on participant recruitment but will not exceed 8. **Intervention:** The group intervention will be an adapted version for our population from the MBCT for the prevention of depression relapse intervention. The main adaptations include 1) substitution of psychoeducation about MDD alone with psychoeducation geared toward trauma and stress physiology and discussion of MDD and PTSD symptoms and 2) no written homework or monitoring, although formal and informal practice during the week and in times of distress will be encouraged. The adapted MBCT will consist of eight, weekly 90-minute group sessions that will involve skills training and in-class practice in: 1) mindfulness techniques including 20-minute meditation exercises; 2) psychoeducation; and 3) feedback and supportive group discussion of exercises. Specific in-class mindfulness exercises will include: a) ‘mindful eating’, b) brief ‘body-scan’, c) ‘mindful stretching’, d) ‘mindful walking’, e) sitting mindfulness meditation exercises with various objects (breath, sounds, emotional states, thoughts). We are using this adapted version to reduce length of sessions and burden on subjects and enhance feasibility for use in primary care settings. The manualized intervention will be delivered by trained and closely supervised therapists who are overseen by the PI. Group sessions will occur via Zoom. Group guidelines and safety considerations for telehealth group sessions will be reviewed at the start of every group. Participants will be asked to find a private space to participate to protect the confidentiality of other group members. If all group members agree, all group sessions will be

video recorded to evaluate fidelity and aid in supervision of therapists. At weeks 3, 5, and 7 ED will be assessed given its role as a mechanism of change. **Wait-list Control:** Subjects in the assessment-only group will engage in the pre, post, and follow-up assessments, and an additional brief assessment mid-way between the pre-and post- assessment that will include the same measure of ED that is administered to the intervention group at Week 5. No active treatment will be given to subjects randomized to this condition since the question of clinical interest and practical import at this stage is whether MBCT is more effective than treatment as usual; however subjects will be given the option to participate in the group following participation in the assessments.

Training: All research study therapists will be experienced practicum students in doctoral clinical psychology graduate programs with training in empirically-supported treatment for psychiatric conditions or postdoctoral fellows that have already received a PhD in clinical psychology. These research personnel will be under the supervision of licensed clinical psychologists on the study team who will oversee all treatment and provide weekly supervision on every participant. The study therapists will be trained in all measures being used in the study and will fully understand the goals and purpose of the research proposed.

Risks to Participation: One potential risk is that the participant may be asked to talk about prior experiences and events that may be emotionally difficult to discuss and may bring up distressing feelings. The intervention is not focused on purposefully discussing past traumas; however, mindfulness therapy can increase individuals' awareness of negative thoughts and emotions. Additionally, if at any point during any session, the participant feels uncomfortable, they will always be given the option to stop engagement in group session. Therapists will monitor participants' subjective symptom and distress level at every therapy session and will conduct a risk assessment if symptoms appear to have increased.

In addition to monitoring participants within the sessions, therapists will provide information at the first session of treatment for what the participant should do if they experience a significant increase in symptoms or have any emotional problems outside of their study visit. This information will include the therapist's work phone number where they can be reached during business hours (8:00am - 5:00pm), as well as the phone number for the Georgia Crisis and Access Line, which is a 24-hour hotline with licensed psychologists and social workers who can take crisis calls and provide immediate assistance should the participant need it. Throughout the study, participants will be reminded of these resources.

Benefits to Subject: One potential benefit is that the participants will see a decrease in depression and/or PTSD symptoms and will be better able to function day-to-day. Additionally, this study may provide insight into how treatment can affect emotion regulation, depression, and PTSD and may inform treatment options particularly in low-income populations in the future.

Participant selection

Population: Participants will be men and women between the ages of 18 and 65, recruited from Grady Memorial Hospital medical clinics. Grady Memorial Hospital is an inner-city hospital in downtown Atlanta, GA (Target N=80).

Subject Inclusion/Exclusion Criteria and Rationale: **Inclusion criteria.** 1) Ability to provide informed consent, 2) Willingness to participate in study, 3) Self-identity as African American, 4) 18-65 years old, 5) History of childhood and/or adult trauma exposure (3 total criterion A traumas) 6) positive PTSD screen (PC-PTSD ≥ 3), and 7) positive MDD screen (PHQ-9 ≥ 5). **Exclusion criteria.** 1) Presence of intellectual disability, bipolar, or psychotic disorder; and 2)

Presence of current substance use disorder (past 1 month; see cut off scores in psychological measures below), and 3) active suicidality (for scores ≥1 on suicide item from the Patient Health Questionnaire (PHQ-9), a suicide risk assessment will be conducted by a study clinician to determine if active suicidality is present and safety procedures as outlined in Protection of Human Subjects will be initiated). **Rationale for inclusion criteria in subjects:** To ensure consistent presence of chronic trauma exposure across subjects, we will require individuals to report exposure to at least 3 traumatic events in their lifetime. We will also require the presence of PTSD and at least mild levels of depression based on screening measures, as comorbidity among these disorders is more common in chronically traumatized populations and will allow for examination of whether the intervention is helpful in targeting the underlying mechanisms that are predicted to cut across these two disorders. Preliminary data from a subsample of subjects (n=988) that were recruited from the Grady Trauma Project in the primary care setting show feasibility of this approach. Using only the items that are found on the screener measures from PTSD and depression proposed for this study, and the proposed inclusion criteria (i.e., scores ≥3 on PC-PTSD and scores ≥10 on PHQ-9), indicated that 76.5% (n=756) of subjects met inclusion criteria for both PTSD and depression symptoms. However, due to challenges in recruitment since the study began, we have lowered the requirements for depressive symptoms to include mild levels of depression (PHQ-9 ≥ 5).

Setting: Data collection for pre-, post-, and follow up assessments will take place at the Glenn Building on Grady Hospital Campus. The Glenn Building is an Emory building where all of our research offices are located on the basement level. We have five interview rooms that will be used for both clinical interviews. These rooms are private. Group therapy sessions will take place in large group rooms located in the primary care clinics at Grady Memorial Hospital.

Recruitment: Participant identification and recruitment will follow several steps. First, participants will be screened from active recruiting efforts through the Grady Trauma Project (IRB00078593) which focuses on screening active patients in medical clinics at Grady Memorial Hospital. If the participant is consented and participates in the Grady Trauma Project and during the course of his or her participation is found to meet inclusion criteria for this study, our study will be briefly described, and participants will be given the option of whether or not to allow a study coordinator to contact them. We will also recruit through direct provider referral from medical providers in Grady Memorial Hospital clinics if the patient agrees to have the provider give us their information. Agreeing to be contacted does not require agreeing to participate in the study. If a participant expresses interest in this study, agrees to be contacted, and provides contact information, a study co-investigator will contact him or her by phone to assess whether the participant is still interested and to set up an initial clinical interview to determine appropriateness for the study.

If a subject wishes to withdraw from the study and sends the revocation of authorization letter or reaches out the study team and expresses their desire to withdraw they will be considered discontinued from the study at that point. The subject will be given the opportunity to also remove all of their previous data from the analysis at this point as well. Since subjects are compensated on time and travel per visit completed, there will be no change in the payment schedule

Informed Consent

Participants will complete informed consent electronically using the redcap e-consent format.

A study co-investigator or research fellow will verbally describe the contents of the document and answer any questions. If the participant agrees to be in the study, he or she will indicate consent by e-signing the consent form. Only participants who can give full authorized self-consent will be included in the study. We will not enroll any individual for whom consent needs to be obtained by a legally authorized individual. Consent will be obtained in a private office room with both the participant and a study co-investigator or research fellow present. Consent will be obtained during the initial interview for the study, at least 24 hours prior to the first session of treatment. Consent for videotaping will be separately reviewed with the study participant following consent to participate in the study and explanation that consent to videotape is voluntary and not necessary to participate in the study will be provided. Consent will be obtained by co-investigators or research fellows that have been fully trained in obtaining informed consent.

If during the course of the study, it is deemed helpful for continuity of care for the study clinician to discuss psychiatric symptoms or progress in group intervention with a current provider (physician, psychiatrist, or therapist), a consent for release of subject information will be reviewed with the participant and if the participant agrees to the release of subject information, he or she will indicate consent by signing the consent form.

Statistical analysis

Overall analytic approach: Analyses will be conducted using a combination of R[99], SAS and MPlus 6.1.[100] Proposed models capitalize on the benefits (power, minimization of measurement error, minimization of multiple testing) of latent modeling. Interpretation of results will adjust for number of tests performed using the step-down procedure.[101, 102] MPlus, used to test composite models, permits the use of both frequentist and Bayesian analysis estimation for handling missing data. Bayesian estimation procedures allow multiple imputation of multiple datasets, subsequently used for maximum likelihood estimation with parameter estimates averaged across imputed datasets. Consistent with Kraemer's recommendations for design of intervention development research[103], the proposed research is focused on evaluating feasibility and acceptability (Aim 1) and preliminary examination of mechanisms of action of the intervention (Aim 2). We expect to meet all Feasibility and Acceptability criteria as demonstrated by acceptable recruitment, retention, and adherence to the intervention and subjects will report that the intervention protocol is acceptable and easy. **Preparing/defining variables:** Data will be examined for assumptions, with estimation procedures applied as a function of data characteristics (Poisson distribution, zero-inflation, etc). Analyses will not impose artificial cutoffs but examine naturally-existing continua, which enhance power and permit the potential identification of nonlinear relationships in which small, cumulative, changes in predictor variables result in large, discontinuous changes in outcomes as predicted by "cusp catastrophe"; we have previously reported such nonlinear influences of early life stress.[104] Measurement models will be formally tested to assess constructs. If analyses do not support the presence of the expected unitary constructs, subsequent analyses will examine aims as defined by observed variables. Model invariance tests will also be used to assess appropriate statistical treatment of sex;[105-107] if measurement invariance is not observed, analyses will stratify by sex. Pending model invariance testing, time invariant and time varying covariates will be included in composite models. Analyses will adjust for relevant time varying and time invariant covariates. ***Aim 1a: Examine retention and follow-up rates in the intervention and control groups.*** Retention rates will be assessed using session attendance. Previous MBSR interventions among low-income minority populations have yielded completion rates of 53-80%.[52, 53, 108] Based on 80% completion rates of MBSR in primary care[46] and 75% completion rates of

MBCT[45] both in combat vet samples and our anticipated improved accessibility through primary care, I expect that subjects in the intervention group will evidence at least 75% retention and follow-up rates.

Aim 1b: Examine subjects' report of acceptability of and interest in the intervention. Feasibility and acceptability will be assessed using the Client Satisfaction Questionnaire. We will compare the descriptive statistics and frequency distributions to an established threshold of an average of at least a 3 (mostly satisfied) on subjects' responses. We expect to find that the intervention will meet or exceed expectations.

Aim 1c: Examine barriers to treatment engagement. Barriers to treatment will be assessed using the Perceived Barriers to Psychological Treatment. We will compare our descriptive statistics and frequency distributions to our established threshold of at least one "substantial" barrier (items endorsed as making it extremely difficult or impossible to attend intervention session) on the measure. We expect similar rates of "substantial" barriers in assessment-only and intervention groups, but higher rates of barriers to be related to higher symptom severity of PTSD and MDD.

Aim 2a: Evaluate if MBCT results in greater reductions in ED than wait-list control. In order to examine the impact of intervention on ED, we will conduct LGM with intervention predicting a reduction in ED over the course of the intervention. Specifically, intervention will be regressed on slope and time will be parameterized such that baseline is the intercept and follow-ups are modeled as weeks post baseline.

Aim 2b: Evaluate if MBCT results in greater normalization of autonomic function than wait-list control. The benefits of LGM will also be applied to our assessment of the effects of intervention on autonomic function, with intervention subjects expected to evidence reduced autonomic arousal to trauma cues at post-intervention and follow-up relative to controls. Specifically, we will conduct an LGM of autonomic arousal to trauma cues, with intervention group regressed on slope such that MBCT subjects are expected to show reduced autonomic arousal to cues (negative slope) relative to control subjects who are expected to show little to no change over time in arousal.

C.4) Power Analysis. Statistical power was calculated using G-Power 3.1.2. As described above, proposed analyses are tailored to each aim and are designed, in part, to maximize power and minimize multiple-testing errors through the use of LGM. However, it is difficult to provide *a priori* estimates of power for full models given that power depends on multiple parameters that are difficult to specify prior to the analyses. Accordingly, both for space constraints and conservative minimization of assumptions regarding power gains, we estimate power using a multiple regression framework. Please note that building on published latent factor and latent growth simulations,[109] we did conduct a few Monte Carlo simulations and were able to confirm that our power is enhanced (with most simulations showing power of .99, assuming expected medium sized effects) using the proposed analyses. We also summarize across aims, to conserve space as well as minimize assumptions. Defined by Cohen,[110] conventions for describing effect sizes for multiple regression (f^2) are .02 for a small effect, .15 for a moderate effect, and .35 for a large

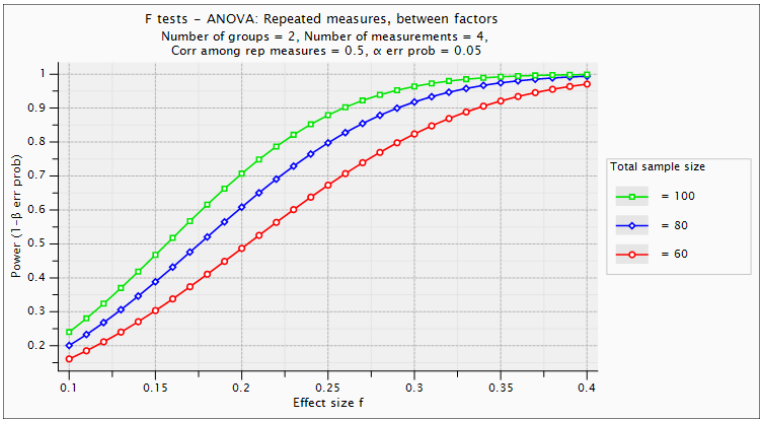

Figure 1. Effect size justification for proposed sample.

effect. Shown in Figure 1, the proposed sample should be adequate (power=.80) to detect a moderate small effect of f^2=.25. Also shown in Figure 1, although larger samples would of course improve power to detect very small effects, the proposed sample of 80 evidences notable gains in power over a sample of 60. Given criticisms about the clinical value of very small effects, we are most interested in effects sizes that fall in the moderate range. Accordingly, the current sample should be well powered to detect effects that are clinically meaningful. Similar treatment studies of MBSR and MBCT with veterans and civilians support medium to large effect sizes for reduction in PTSD and depression symptoms (d=0.59-0.99).[35, 42, 45, 46] Extrapolating from the effects indicated in these investigations, we should be well powered to detect significant effects across aims.

Data and Safety Monitoring Plan

The PI and study personnel have completed and passed the Human Subjects Protection Education Program provided by Emory University. Certification letters will be provided upon request. The present study is an intervention study and therefore we will complete a data safety monitoring plan to ensure oversight and monitoring of the study to ensure the safety of participants and the validity and integrity of the data. The PI will monitor safety issues throughout the study. Specifically, study progress and safety will be reviewed weekly (and more frequently if needed). The PI will work closely with Dr. Nadine Kaslow to monitor for potential adverse reactions of subjects to mindfulness exercises and if significant exacerbation of symptoms or safety concerns emerge, the subject will be offered immediate psychological services through the Grady Health System and NIA project. Progress reports, including subject recruitment, retention/attrition, and adverse events (AE) will be provided to an Independent Monitor (IM) semi-annually. The IM for this study will be the Data Safety Monitoring Board in the Department of Psychiatry and Behavioral Sciences. An Annual Report will be compiled and will include a list and summary of AEs. In addition, the Annual Report will address (1) whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The Annual Report will be sent to the IM and will be forwarded to the IRB.

Confidentiality

Confidentiality will be protected throughout the study and following completion of the study. This will be done in a number of ways. First, all participants will be assigned a subject ID and all data gathered and session notes will only contain de-identified information and their subject ID. Also, participants will be informed of the confidential nature of the study and informed of the limitations of confidentiality. Also, all participant information will be kept in a locked desk drawer in a locked office or stored on a password protected and secured electronic network.

The only linkage between identifiable information about participants and their subject IDs will be kept on the informed consent forms, which will be separated from all other data and study materials and kept in a locked drawer in a locked office.

Finally, at the beginning of the group intervention, the importance of confidentiality among group members outside of session will be emphasized.

References

1. Fiscella, K., et al., *Inequality in quality: addressing socioeconomic, racial, and ethnic disparities in health care.* Jama, 2000. **283**(19): p. 2579-2584.

2. Kessler, R.C., et al., *Posttraumatic stress disorder in the National Comorbidity Survey.* Archives of general psychiatry, 1995. **52**(12): p. 1048-1060.
3. Resnick, H.S., et al., *Prevalence of civilian trauma and posttraumatic stress disorder in a representative national sample of women.* Journal of consulting and clinical psychology, 1993. **61**(6): p. 984.
4. Green, B.L., et al., *Outcomes of single versus multiple trauma exposure in a screening sample.* Journal of traumatic stress, 2000. **13**(2): p. 271-286.
5. Follette, V.M., et al., *Cumulative trauma: The impact of child sexual abuse, adult sexual assault, and spouse abuse.* Journal of traumatic stress, 1996. **9**(1): p. 25-35.
6. Kessler, R.C., et al., *Posttraumatic stress disorder in the National Comorbidity Survey.* Archives of General Psychiatry, 1995. **52**(12): p. 1048-1060.
7. Kessler, R.C., et al., *The epidemiology of major depressive disorder: Results from the national comorbidity survey replication (ncs-r).* JAMA, 2003. **289**(23): p. 3095-3105.
8. Tara W. Strine , M.P.H., et al., *Depression and Anxiety in the United States: Findings From the 2006 Behavioral Risk Factor Surveillance System.* Psychiatric Services, 2008. **59**(12): p. 1383-1390.
9. Hasin, D.S., et al., *Epidemiology of major depressive disorder: Results from the national epidemiologic survey on alcoholism and related conditions.* Archives of General Psychiatry, 2005. **62**(10): p. 1097-1106.
10. Alim, T.N., et al., *Trauma exposure, posttraumatic stress disorder and depression in an African-American primary care population.* J Natl Med Assoc, 2006. **98**(10): p. 1630-6.
11. Gillespie, C., et al., *Trauma exposure and stress-related disorders in inner city primary care patients.* General Hospital Psychiatry, 2009. **31**: p. 505-514.
12. Franklin, C.L. and M. Zimmerman, *Posttraumatic stress disorder and major depressive disorder: Investigating the role of overlapping symptoms in diagnostic comorbidity.* Journal of Nervous and Mental Disease, 2001. **189**: p. 548-551.
13. Breslau, N., et al., *Trauma and posttraumatic stress disorder in the community: the 1996 Detroit Area Survey of Trauma.* Arch Gen Psychiatry, 1998. **55**(7): p. 626-32.
14. Breslau, N., et al., *Traumatic events and posttraumatic stress disorder in an urban population of young adults.* Arch Gen Psychiatry, 1991. **48**(3): p. 216-22.
15. Fitzpatrick, K.M. and J.P. Boldizar, *The prevalence and consequences of exposure to violence among African-American youth.* J Am Acad Child Adolesc Psychiatry, 1993. **32**(2): p. 424-30.
16. Selner-O'Hagan, M.B., et al., *Assessing exposure to violence in urban youth.* J Child Psychol Psychiatry, 1998. **39**(2): p. 215-24.
17. Shakoor, B.H. and D. Chalmers, *Co-victimization of African-American children who witness violence: effects on cognitive, emotional, and behavioral development.* J Natl Med Assoc, 1991. **83**(3): p. 233-8.
18. Gillespie, C.F., et al., *Trauma exposure and stress-related disorders in inner city primary care patients.* Gen Hosp Psychiatry, 2009. **31**(6): p. 505-14.
19. Chiu, S., et al., *Evaluating risk factors and possible mediation effects in posttraumatic depression and posttraumatic stress disorder comorbidity.* Public Health Rep, 2011. **126**(2): p. 201-9.
20. Cloitre, M., et al., *Patient characteristics as a moderator of post-traumatic stress disorder treatment outcome: combining symptom burden and strengths.* British Journal of Psychiatry Open, 2016. **2**(2): p. 101-106.
21. Rauch, S., A. Eftekhari, and J.I. Ruzek, *Review of exposure therapy: a gold standard for PTSD treatment.* Journal of rehabilitation research and development, 2012. **49**(5): p. 679-688.

22. Resick, P.A., et al., *A comparison of cognitive-processing therapy with prolonged exposure and a waiting condition for the treatment of chronic posttraumatic stress disorder in female rape victims.* Journal of consulting and clinical psychology, 2002. **70**(4): p. 867.
23. Orsillo, S.M. and S.V. Batten, *Acceptance and commitment therapy in the treatment of posttraumatic stress disorder.* Behavior Modification, 2005. **29**(1): p. 95-129.
24. Williams, M.V., et al., *Inadequate functional health literacy among patients at two public hospitals.* Jama, 1995. **274**(21): p. 1677-1682.
25. Kaslow, N.J., et al., *Risk and protective factors for suicidal behavior in abused African American women.* Journal of consulting and clinical psychology, 2002. **70**(2): p. 311.
26. Davis, R.G., et al., *Treatment barriers for low-income, urban African Americans with undiagnosed posttraumatic stress disorder.* Journal of traumatic stress, 2008. **21**(2): p. 218-222.
27. Roeloffs, C., et al., *Stigma and depression among primary care patients.* General hospital psychiatry, 2003. **25**(5): p. 311-315.
28. Brown, C., et al., *Depression stigma, race, and treatment seeking behavior and attitudes.* Journal of community psychology, 2010. **38**(3): p. 350-368.
29. Grossman, P., et al., *Mindfulness-based stress reduction and health benefits: A meta-analysis.* Journal of psychosomatic research, 2004. **57**(1): p. 35-43.
30. Arias, A.J., et al., *Systematic review of the efficacy of meditation techniques as treatments for medical illness.* Journal of Alternative & Complementary Medicine, 2006. **12**(8): p. 817-832.
31. Baer, R.A., *Mindfulness training as a clinical intervention: A conceptual and empirical review.* Clinical psychology: Science and practice, 2003. **10**(2): p. 125-143.
32. Greeson, J.M., *Mindfulness research update: 2008.* Complementary health practice review, 2009.
33. Ludwig, D.S. and J. Kabat-Zinn, *Mindfulness in medicine.* Jama, 2008. **300**(11): p. 1350-1352.
34. Demarzo, M.M., et al., *The efficacy of mindfulness-based interventions in primary care: a meta-analytic review.* The Annals of Family Medicine, 2015. **13**(6): p. 573-582.
35. Radford, S.R., et al., *The feasibility and effectiveness of mindfulness-based cognitive therapy for mixed diagnosis patients in primary care: a pilot study.* Mental health in family medicine, 2012. **9**(3): p. 191.
36. Kurdyak, P., A. Newman, and Z. Segal, *Impact of mindfulness-based cognitive therapy on health care utilization: a population-based controlled comparison.* Journal of psychosomatic research, 2014. **77**(2): p. 85-89.
37. Roth, B. and T.-W. Stanley, *Mindfulness-based stress reduction and healthcare utilization in the inner city: preliminary findings.* Alternative therapies in health and medicine, 2002. **8**(1): p. 60.
38. Roth, B. and D. Robbins, *Mindfulness-based stress reduction and health-related quality of life: Findings from a bilingual inner-city patient population.* Psychosomatic Medicine, 2004. **66**(1): p. 113-123.
39. Kearney, D.J., et al., *Effects of participation in a mindfulness program for veterans with posttraumatic stress disorder: A randomized controlled pilot study.* Journal of Clinical Psychology, 2013. **69**(1): p. 14-27.
40. Wahbeh, H., et al., *Mechanistic Pathways of Mindfulness Meditation in Combat Veterans With Posttraumatic Stress Disorder.* Journal of clinical psychology, 2016.
41. Kimbrough, E., et al., *Mindfulness intervention for child abuse survivors.* Journal of clinical psychology, 2010. **66**(1): p. 17-33.
42. Kearney, D.J., et al., *Association of participation in a mindfulness program with measures of PTSD, depression and quality of life in a veteran sample.* Journal of clinical psychology, 2012. **68**(1): p. 101-116.

43. Earley, M.D., et al., *Mindfulness Intervention for Child Abuse Survivors: A 2.5-Year Follow-Up.* Journal of clinical psychology, 2014. **70**(10): p. 933-941.
44. Bhatnagar, R., et al., *The effects of mindfulness training on post-traumatic stress disorder symptoms and heart rate variability in combat veterans.* The Journal of Alternative and Complementary Medicine, 2013. **19**(11): p. 860-861.
45. King, A.P., et al., *A pilot study of group mindfulness-based cognitive therapy (MBCT) for combat veterans with posttraumatic stress disorder (PTSD).* Depression and anxiety, 2013. **30**(7): p. 638-645.
46. Possemato, K., et al., *A Randomized Clinical Trial of Primary Care Brief Mindfulness Training for Veterans With PTSD.* Journal of clinical psychology, 2016. **72**(3): p. 179-193.
47. Finucane, A. and S.W. Mercer, *An exploratory mixed methods study of the acceptability and effectiveness of mindfulness-based cognitive therapy for patients with active depression and anxiety in primary care.* BMC psychiatry, 2006. **6**(1): p. 1.
48. Hofmann, S.G., et al., *The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review.* Journal of consulting and clinical psychology, 2010. **78**(2): p. 169.
49. Ma, S.H. and J.D. Teasdale, *Mindfulness-based cognitive therapy for depression: replication and exploration of differential relapse prevention effects.* Journal of consulting and clinical psychology, 2004. **72**(1): p. 31.
50. Johnson, S., et al., *Compassion-based meditation among African Americans: Self-criticism mediates changes in depression.* Suicide and Life-threatening Behavior, in press.
51. Loparo, D., et al., *The efficacy of cognitively-based compassion training for African American suicide attempters.* Mindfulness, in press.
52. Dutton, M.A., et al., *Mindfulness-based stress reduction for low-income, predominantly African American women with PTSD and a history of intimate partner violence.* Cognitive and behavioral practice, 2013. **20**(1): p. 23-32.
53. Vallejo, Z. and H. Amaro, *Adaptation of mindfulness-based stress reduction program for addiction relapse prevention.* The Humanistic Psychologist, 2009. **37**(2): p. 192-206.
54. Farber, E.W., et al., *Psychology in patient-centered medical homes: Reducing health disparities and promoting health equity.* American Psychologist, 2017. **72**(1): p. 28.
55. Bergen-Cico, D., K. Possemato, and W. Pigeon, *Reductions in cortisol associated with primary care brief mindfulness program for veterans with PTSD.* Medical care, 2014. **52**: p. S25-S31.
56. Briere, J. and S. Rickards, *Self-awareness, affect regulation, and relatedness: Differential sequels of childhood versus adult victimization experiences.* The Journal of nervous and mental disease, 2007. **195**(6): p. 497-503.
57. Lanius, R., R. Bluhm, and P. Frewen, *How understanding the neurobiology of complex post-traumatic stress disorder can inform clinical practice: a social cognitive and affective neuroscience approach.* Acta Psychiatrica Scandinavica, 2011. **124**(5): p. 331-348.
58. Gratz, K.L. and L. Roemer, *Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the difficulties in emotion regulation scale.* Journal of Psychopathology and Behavioral Assessment, 2004. **26**(1): p. 41-54.
59. Ford, J.D., et al., *Child abuse and autonomic nervous system hyporesponsivity among psychiatrically impaired children.* Child Abuse & Neglect, 2010. **34**(7): p. 507-515.
60. Neigh, G.N., C.F. Gillespie, and C.B. Nemeroff, *The neurobiological toll of child abuse and neglect.* Trauma, Violence, & Abuse, 2009. **10**(4): p. 389-410.
61. Gutman, D.A. and C.B. Nemeroff, *Persistent central nervous system effects of an adverse early environment: clinical and preclinical studies.* Physiology & behavior, 2003. **79**(3): p. 471-478.
62. Widom, C.S., S.J. Czaja, and M.A. Dutton, *Childhood victimization and lifetime revictimization.* Child abuse & neglect, 2008. **32**(8): p. 785-796.

63. Berenbaum, H., et al., *A taxonomy of emotional disturbances.* Science and Practice, 2003. **10**(2): p. 206-226.
64. Bradley, B., et al., *Emotion dysregulation and negative affect: Association with psychiatric symptoms.* Journal of Clinical Psychiatry, 2011. **72**: p. 685-691.
65. Aldao, A., S. Nolen-Hoeksema, and S. Schweizer, *Emotion-regulation strategies across psychopathology: A meta-analytic review.* Clinical Psychology Review, 2010. **30**: p. 217-237.
66. Tull, M.T., et al., *A preliminary investigation of the relationship between emotion regulation difficulties and posttraumatic stress symptoms.* Behavior Therapy, 2007. **38**(3): p. 303-313.
67. Hopper, J.W., et al., *Preliminary evidence of parasympathetic influence on basal heart rate in posttraumatic stress disorder.* Journal of Psychosomatic Research, 2006. **60**(1): p. 83-90.
68. Jovanovic, T., et al., *Impaired fear inhibition is a biomarker of PTSD but not depression.* Depression and anxiety, 2010. **27**(3): p. 244-251.
69. Jovanovic, T., et al., *Altered resting psychophysiology and startle response in Croatian combat veterans with PTSD.* International Journal of Psychophysiology, 2009. **71**(3): p. 264-268.
70. Rottenberg, J., *Cardiac vagal control in depression: a critical analysis.* Biological psychology, 2007. **74**(2): p. 200-211.
71. Lanius, R.A., et al., *Emotion modulation in PTSD: Clinical and neurobiological evidence for a dissociative subtype.* The American journal of psychiatry, 2010.
72. Wangelin, B.C. and P.W. Tuerk, *Taking the pulse of prolonged exposure therapy: Physiological reactivity to trauma imagery as an objective measure of treatment response.* Depression and anxiety, 2015. **32**(12): p. 927-934.
73. Feeny, N.C., et al., *Exploring the roles of emotional numbing, depression, and dissociation in PTSD.* Journal of traumatic stress, 2000. **13**(3): p. 489-498.
74. Tull, M.T., et al., *Development and initial examination of a brief intervention for heightened anxiety sensitivity among heroin users.* Behavior Modification, 2007. **31**(2): p. 220-242.
75. Gratz, K.L. and M.T. Tull, *Emotion regulation as a mechanism of change in acceptance-and mindfulness-based treatments.* Assessing mindfulness and acceptance processes in clients: Illuminating the theory and practice of change, 2010: p. 107-133.
76. Krygier, J.R., et al., *Mindfulness meditation, well-being, and heart rate variability: a preliminary investigation into the impact of intensive Vipassana meditation.* International Journal of Psychophysiology, 2013. **89**(3): p. 305-313.
77. Vujanovic, A.A., et al., *Mindfulness in the treatment of posttraumatic stress disorder among military veterans.* 2013.
78. Lang, A.J., et al., *The theoretical and empirical basis for meditation as an intervention for PTSD.* Behavior modification, 2012: p. 0145445512441200.
79. Foa, E.B., et al., *Effective treatments for PTSD: practice guidelines from the International Society for Traumatic Stress Studies*. 2008: Guilford Press.
80. Hauschildt, M., et al., *Heart rate variability in response to affective scenes in posttraumatic stress disorder.* Biological Psychology, 2011. **88**(2): p. 215-222.
81. Lehrer, P.M., E. Vaschillo, and B. Vaschillo, *Resonant frequency biofeedback training to increase cardiac variability: Rationale and manual for training.* Applied psychophysiology and biofeedback, 2000. **25**(3): p. 177-191.
82. Stephenson, K.R., et al., *Changes in Mindfulness and Posttraumatic Stress Disorder Symptoms Among Veterans Enrolled in Mindfulness-Based Stress Reduction.* Journal of clinical psychology, 2016.
83. Hayes, S., et al., *Open, aware, and active: Contextual approaches as an emerging trend in the behavioral and cognitive therapies.* Annual Review of Clinical Psychology, 2011. **7**: p. 141-168.

84. Hays, R.D., J.F. Merz, and R. Nicholas, *Response burden, reliability, and validity of the CAGE, Short MAST, and AUDIT alcohol screening measures.* Behavior Research Methods, Instruments, & Computers, 1995. **27**(2): p. 277-280.
85. Bohn, M.J., T.F. Babor, and H.R. Kranzler, *The Alcohol Use Disorders Identification Test (AUDIT): validation of a screening instrument for use in medical settings.* Journal of Studies on Alcohol, 1995. **56**(4): p. 423-432.
86. Yudko, E., O. Lozhkina, and A. Fouts, *A comprehensive review of the psychometric properties of the Drug Abuse Screening Test.* Journal of Substance Abuse Treatment, 2007. **32**(2): p. 189-198.
87. Maisto, S.A., et al., *Use of the AUDIT and the DAST-10 to identify alcohol and drug use disorders among adults with a severe and persistent mental illness.* Psychological Assessment, 2000. **12**(2): p. 186-192.
88. Cameron, R.P. and D. Gusman, *The primary care PTSD screen (PC-PTSD): development and operating characteristics.* Primary Care Psychiatry, 2003. **9**(1): p. 9-14.
89. Kroencke, K., R. Spitzer, and J. Williams, *The PHQ-9: validity of a brief depression severity measure [Electronic version].* Journal of General Internal Medicine, 2001. **16**(9): p. 606-13.
90. Foa, E.B. and B.O. Rothbaum, *Treating the trauma of rape: Cognitive-behavioral therapy for PTSD*. 2001: Guilford Press.
91. Baer, R.A., et al., *Using self-report assessment methods to explore facets of mindfulness.* Assessment, 2006. **13**(1): p. 27-45.
92. Raes, F., et al., *Construction and factorial validation of a short form of the self-compassion scale.* Clinical psychology & psychotherapy, 2011. **18**(3): p. 250-255.
93. Blevins, C.A., et al., *The posttraumatic stress disorder checklist for DSM-5 (PCL-5): Development and initial psychometric evaluation.* Journal of Traumatic Stress, 2015. **28**(6): p. 489-498.
94. Beck, A., R. Steer, and G. Brown, *Manual for the Beck Depression Inventory-II*. 1996, San Antonio, TX: Psychological Corporation.
95. Sheehan, D.V., et al., *The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10.* Journal of clinical psychiatry, 1998.
96. Blake, D.D., et al., *Clinician-administered PTSD scale for DSM-IV.* Boston: National Center for Posttraumatic Stress Disorder, 1998.
97. Watson, D., L.A. Clark, and A. Tellegen, *Development and validation of brief measures of positive and negative affect: the PANAS scales.* Journal of personality and social psychology, 1988. **54**(6): p. 1063.
98. Hinrichs, R., et al., *Mobile assessment of heightened skin conductance in posttraumatic stress disorder.* Depression and Anxiety, 2017. **0**: p. 1-6.
99. R, et al., *R: A language and environment for statistical computing, reference index version 2.2.1. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org.* 2005: Vienna, Austria.
100. Muthen, L.K. and B.O. Muthen, *Mplus User's Guide. Seventh Edition.* . 1998-2012, Muthen & Muthen: Los Angeles, CA.
101. Benjamini, Y. and Y. Hochberg, *Controlling the false discovery rate-a new and powerful approach to multiple testing.* Journal of the Royal Statistical Society B, 1995. **57**: p. 289-300.
102. Benjamini, Y. and D. Yekuteli, *The control of the false discovery rate in multiple testing under dependency.* Ann. Statist, 2001. **29**: p. 1165-1188.
103. Kraemer, H.C., et al., *Caution regarding the use of pilot studies to guide power calculations for study proposals.* Archives of General Psychiatry, 2006. **63**(5): p. 484-489.

104. Armey, M.A., N.R. Nugent, and J.H. Crowther, *An exploratory analysis of situational affect, early life stress, and non-suicidal self-injury in college students.* Journal of Child and Adolescent Trauma, in press.
105. Meredith, W. and J. Horn, *The role of factorial invariance in modeling growth and change*, in *New Methods for the Analysis of Change*, L.M. Collins and A.G. Sayer, Editors. 2001, American Psychological Association: Washington, DC.
106. Meredith, W., *Measurement invariance, factor analysis, and factorial invariance.* Psychometrika, 1993. **58**: p. 525-543.
107. Vandenberg, R. and E. Lance, *A review and synthesis of the measurement invariance literature: Suggestions, practices, and recommendations for organizational research.* Organizational Research Methods, 2000. **3**: p. 4-69.
108. Burnett-Zeigler, I.E., et al., *Mindfulness based stress reduction adapted for depressed disadvantaged women in an urban Federally Qualified Health Center.* Complementary therapies in clinical practice, 2016. **25**: p. 59-67.
109. Muthen, L.K. and B.O. Muthen, *How to use a Monte Carlo study to decide on sample size and determine power.* Structural Equation Modeling: A Multidisciplinary Journal, 2002. **9**(4): p. 599-620.
110. Cohen, J., *Statistical power analysis for the behavioral sciences Lawrence Earlbaum Associates.* Hillsdale, NJ, 1988: p. 20-26.