Intensive Mindfulness-based Resilience Training in First Responders: A Pilot Study

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Describe Your Project (2000 character limit)

First responders (law enforcement, firefighters, and emergency medical system personnel) are subjected to daily pressures from their duties with resultant compassion fatigue, burnout, anger, poor mental and physical health, maladaptive behavior, and sleep disturbance. The unprecedented heroin and opioid epidemic in West Virginia has accelerated the stresses as these first responders witness overdoses and overdose death on a frequent basis. The plight and suffering of children of the overdose victims is an additional overlooked element in the stress on the first responder community. The proposed project will deliver mindfulness-based resilience training to improve the mental and physical wellbeing of first responders in the Charleston and Huntington areas and measure the effects of this training on this population using validated questionnaires and saliva cortisol before and after the training.

Location of the Research

Cabell, Kanawha, and Putnam Counties, West Virginia

Lay Summary of the Study (written at the 6th grade reading level)

West Virginia is in the midst of an unprecedented opioid and heroin epidemic with profound social, health, and economic consequences. West Virginia is experiencing the highest rate of overdose mortality in the United States in 2015 (41 per 100,000). In 2014 Hepatitis B rates were highest in the nation (10.1 per 100,000) and tied for second in Hepatitis C (3.4 per 100,000) due in large part to injection drug use. The first responders, Police, Fire, and Emergency Medical Services (EMS), are being pushed beyond their limits, leading to compassion fatigue, burnout, and high attrition rates from the additional stress and real risks from potential exposure to Hepatitis B, C, and HIV through needle sticks. These occupations are already commonly considered to be among the most stressful occupations, wherein organizational and operational stressors put police, firefighters, and EMS at physical and mental health risk. This stress, especially among law enforcement officials (LEOs), is often experienced within a context of excessive anger, which decreases wellbeing and has the potential to negatively impact public wellbeing as well. These public safety personnel are often left to manage stress and anger in a cultural context that does not support help-seeking behavior and that encourages maladaptive coping mechanisms. Mindfulness-Based Resilience Training (MBRT) has demonstrated significant improvement in self-reported mindfulness, resilience, perceived operational and administrative stress, burnout, emotional intelligence, emotion regulation, mental and physical health, anger, fatigue, and sleep disturbance in Oregon LEOs[1]. This study will aim to replicate and expand upon this effort to teach MBRT not only to police, but also fire, and EMS personnel in Charleston and Huntington, West Virginia. These cities are especially affected by the opioid and heroin epidemic where their first responders are at high risk for compassion fatigue and burnout. We will measure improvements in resilience through self-assessed health outcomes and correlate the results with salivary cortisol, a marker of stress.

Specific Research Question and Specific Aims

Research Question: Can MBRT lead to improved physical and mental wellbeing as measured by validated self-assessments and salivary cortisol?

Specific aim #1: The overall goal of this research project is to deliver mindfulness-based resilience training (MBRT) and demonstrate improved mental and physical wellbeing among first

responders involved in the opioid and heroin epidemic (law enforcement, firefighters, and emergency medical system personnel) compared to baseline measures and reduced stress as measured by salivary cortisol.

Specific aim #2: Determine delivery and acceptability among first responders in Appalachia. MBRT is relatively novel in this population and to our knowledge has never been applied to a broader first responder community outside law enforcement and not to our knowledge in Appalachia.

Specific aim #3: Evaluate the delivery of MBRT in an intensive 2.5 day setting with follow up remotely with an online communication method such as Skype, FaceTime, or Zoom.

Hypotheses: We hypothesize the following based on previous research:

1. MBRT will improve self-reported measures over the 2.5-day intensive intervention with a remote, virtual booster intervention 4 weeks after the 2.5-day initial intervention relative to baseline: a) Mindfulness and resilience, b) Physical and mental health, c) Stress and burnout, d) Emotional functioning, and e) Family functioning, f) Sense-making and decision-making.
2. Pre- to post-MBRT changes in mindfulness, physical health, mental health, and stress would predict post-MBRT salivary cortisol, while controlling for pre-MBRT salivary cortisol

Design

1. **Fully describe all procedures to be performed in sequential order in outline format.**

The impetus of the proposed research project came from meetings of the Great Rivers Harm Reduction Coalition, which includes public health and first responders from Cabell, Kanawha, and Putnam Counties. It was clear from discussions about the breadth and depth of the opioid and heroin epidemic that first responders are an overlooked vulnerable population in this public health crisis. Law enforcement, fire, and EMS personnel stated they need a means to cope with the daily onslaught of overdoses and interdiction efforts in addition to their daily calls and would be amenable to a resilience-building and stress-reducing intervention involving research into the effectiveness of the intervention. Subjects for the proposed research would be first responders from the three-county area, but primarily from the cities of Charleston and Huntington. Subjects will be recruited from volunteers targeting leadership and thought leaders at the frontline. Each 2.5-day intensive immersion into MBRT would be coordinated with each agency to ensure maximum participation without disrupting work schedules. Up to 35 participants will participate in each cohort. This study aims to recruit 2 cohorts from the pool of first responders in the Cabell, Kanawha, and Putnam Counties area for a minimum of 50 participants. Self-report measures will be conducted at time 0 (before the intervention), time 1 (after the 2.5-day intensive training), time 2 (4 weeks after the 2.5-day intensive training and after the week 4 remote/virtual booster training) and at time 3 (90 days after the initial intensive training). The self-report questionnaires will include the Five Facet Mindfulness Questionnaire (FFMQ), a 39-item questionnaire assessing individuals' daily tendency to be mindful.[2] The Mindfulness Process Questionnaire (MPQ) is a 7 question self-report measure that assesses the degree how mindfulness is intentionally practiced or attempted and the ability to bring compassionate awareness to the present moment after observing the attention has drifted off or become

judgmental.[3] The Brief Resilience Scale is a 6-item scale designed to assess the ability to recover from stress using a 5 point Likert scale.[4] To measure health outcomes, the Patient Reported Outcomes Measurement Information System (PROMIS®) designed to improve self-reported In this study, we plan to use short form versions of several PROMIS domains to assess health outcomes. The Global Health Short-Form is a 10-item instrument representing multiple domains that can be scored into a Global Physical Health (GPH) component and Global Mental Health (GMH) component. Additionally, we assessed Anger (8 items), Fatigue (4 items), Sleep Disturbance (4 items), and Pain Interference (4 items). All items are rated on a 5-point Likert-type scale using various endpoints.[5] Stress and burnout will be measured with the 4-item Perceived Stress Scale-4 (PSS-4) to assess perceived stress in life situations.[6] The Police Stress Questionnaire (PSQ) is a 40-item questionnaire consisting of two subscales measuring operational stressors (20 job content items) and organizational stressors (20 job context items) on a seven-point Likert-type scale, ranging from 1 (no stress at all) to 7 (a lot of stress), and higher scores indicate greater stress. Nearly all the questions could be applicable to all first responder groups.[7] The Oldenburg Burnout Inventory (OLBI) is a 16-item measure of burnout with two dimensions: exhaustion and disengagement.8 The Emotional Intelligence Scale (EIS; Schutte et al. 1998) is a 33-item scale of emotional intelligence. Items are rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), and three items are reverse scored. All items are summed to create a total score, and higher scores indicate greater emotional intelligence.[9] The Difficulties in Emotion Regulation Scale (DERS) is a 36-item measure that assesses clinically relevant difficulties in emotion regulation. Items are scored on six scales: lack of emotional awareness (6 items), lack of emotional clarity (5 items), difficulties controlling impulsive behaviors when distressed (6 items), difficulties engaging in goal-directed behavior when distressed (5 items), non-acceptance of negative emotional responses (6 items), and limited access to effective emotion regulation strategies (8 items).10 Family functioning will be measured through the Family Assessment Device (FAD), a 60-item measure.11 The FAD consists of six subscales and a seventh subscale (general family functioning: GFF) incorporates items from the six subscales. In this study we plan to use the 12-item GFF scale, which can be used as an indicator reflecting global family functioning.[12] Salivary cortisol is a biologic marker for stress and is a measure of the hypothalamic-pituitary-adrenal axis (HPA axis). One of the characteristics of the HPA axis is the strong circadian rhythm and the cortisol awakening response (CAR). Salivary cortisol levels are highest in the morning after awakening, and decline throughout the day and lowest around midnight, to rise again in the early morning hours. A distinct characteristic of the HPA axis is the cortisol awakening response (CAR).[13] The CAR is characterized by a sharp rise (between 50 and 75%) of cortisol levels within the first 30 minutes after awakening.[14] Repeated measurement of free cortisol levels within the 60 minutes after awakening in the morning is considered a stable and reliable biological marker of adrenocortical activity.15 We plan to collect approximately 2-3 ml of saliva at 0, 30, and 45 minutes after awakening in the morning at times 0,1,2, and 3 as described above. To examine changes in our measures during the course of MBRT, we plan to use a multilevel modeling approach with restricted maximum likelihood estimation (REML) to examine linear change over time as a fixed effect. We used REML because our data collection resulted in varying sample sizes for our measures, allowing for more accurate estimates with small sample sizes and missing data that are missing at random or completely at random [16,17] To test whether changes in mindfulness, emotional intelligence, and difficulties with emotion regulation (i.e., process variables) preceded changes in mental health, physical health, stress, pain interference, anger, fatigue, sleep disturbance, burnout, resilience, and family functioning (i.e., outcome variables), using the

multilevel modeling approach, we plan to examine which variables significantly change from time 0 to time 1, from time 1 to time 2, from time 2 to time 3, and from time 0 to time 2 and time 3. To analyze the CAR, plan to use multilevel modeling with REML examining the main effects of phase of measurement (pre, post as above) and time after waking (0, 30, 45 minutes), as well as the interaction between the main effects. We also plan to investigate the association between the cortisol response patterns and change in mindfulness (FFMQ), stress (PSS-4), physical health, and mental health. For that purpose, we plan to analyze the area under the curve with respect to increase (AUCI) to analyze the linear relationship between each independent variable and cortisol awakening levels. Cortisol levels will be transformed into a single value by calculating the AUCI for each assessment day (1 pre and 1 post). These variables will be used in a hierarchical linear regression with pre-AUCI entered in step 1, and change in stress, physical health, mental health, and mindfulness entered in step 2, to predict post-AUCI. Alpha will be set at .05 for all analyses. The PI will be responsible for recruitment of subjects and coordinating with researchers and staff at WVU for analysis and will help oversee the implementation of the intervention. The co-PI will also assist with overseeing the intervention as well as scheduling follow-up, particularly in the Huntington community and will assist in analysis and in evaluation of difficulties. Such difficulties may include scheduling difficulties for follow-up after the intensive intervention, subject drop-out, and sustaining local resources to assist the subjects.

2. **Discuss probability of group assignment to experimental and control groups.**

   Participants will serve as their own controls so they will participate in both the control group and the interventional group.

3. **Inclusionary Criteria**

   Participants must meet the following inclusionary criteria to be eligible for the study: Be employed as a law enforcement official, firefighter, or emergency medical services technician or supervisor from Cabell, Kanawha, or Putnam Counties.

4. **Exclusionary Criteria**

   Exclusionary criteria include 1) at high risk for suicide, 2) a current psychotic disorder or significant co-morbid diagnosis (e.g., Schizophrenia, Schizoaffective Disorder, etc.), 3) high score on of 3 screening tools (PSS-4, PSQ, and DERS) with follow-on questioning which would indicate referral to a mental health practitioner, 4) primary substance use disorder.

   If a patient becomes suicidal during the course of their participation in the study they will be evaluated and provided immediate intervention to ensure their safety and stabilization.

5. **Does the research involve more than minimal risk to participants?**
   No.

6. **Describe the provisions to monitor the data to ensure the safety of participants**

(data and safety monitoring plan).

a. **Who will monitor the data?**
   All survey data will be monitored by the Principal Investigators.

b. **What "data" will be monitored?**
   The study is composed of three general sets measures that will be monitored: primary outcome measures, secondary outcome measures, and mediating measures.

   Primary Outcome Measures

   The following self-assessment tools will be used:

The Brief Resilience Scale is a 6-item scale designed to assess the ability to recover from stress using a 5-point Likert scale.[4]

To measure health outcomes, the Patient Reported Outcomes Measurement Information System (PROMIS®) designed to improve self-reported in this study, we plan to use short form versions of several PROMIS domains to assess health outcomes. The Global Health Short-Form is a 10-item instrument representing multiple domains that can be scored into a Global Physical Health (GPH) component and Global Mental Health (GMH) component. Additionally, we will assess Anger (8 items), Fatigue (4 items), Sleep Disturbance (4 items), and Pain Interference (4 items). All items are rated on a 5-point Likert-type scale using various endpoints.[5]

Stress and burnout will be measured with the 4-item Perceived Stress Scale-4 (PSS-4) to assess perceived stress in life situations.[6]

The Police Stress Questionnaire (PSQ) is a 40-item questionnaire consisting of two subscales measuring operational stressors (20 job content items) and organizational stressors (20 job context items) on a seven-point Likert-type scale, ranging from 1 (no stress at all) to 7 (a lot of stress), and higher scores indicate greater stress. Nearly all the questions could be applicable to all first responder groups.[7]

The Oldenburg Burnout Inventory (OLBI) is a 16-item measure of burnout with two dimensions: exhaustion and disengagement.8

The Emotional Intelligence Scale (EIS; Schutte et al. 1998) is a 33-item scale of emotional intelligence. Items are rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), and three items are reverse scored. All items are summed to create a total score, and higher scores indicate greater emotional intelligence.[9]

The Difficulties in Emotion Regulation Scale (DERS) is a 36-item measure that assesses clinically relevant difficulties in emotion regulation. Items are scored on six scales: lack of emotional awareness (6 items), lack of emotional clarity (5 items), difficulties controlling impulsive behaviors when distressed (6 items), difficulties engaging in goal-directed behavior when distressed (5 items), non-acceptance of negative emotional responses (6 items), and limited access to effective emotion regulation strategies (8 items).10

Family functioning will be measured through the Family Assessment Device (FAD), a 60-item measure.11 The FAD consists of six subscales and a seventh subscale (general family functioning: GFF) incorporates items from the six subscales. In this study we plan to use the 12-item GFF scale, which can be used as an indicator reflecting global family functioning.[12]

Secondary Outcome Measures

Salivary cortisol is a biologic marker for stress and is a measure of the hypothalamic-pituitary-adrenal axis (HPA axis). One of the characteristics of the HPA axis is the strong circadian rhythm and the cortisol awakening response (CAR). Salivary cortisol levels are highest in the morning after awakening, and decline throughout the day and lowest around midnight, to rise again in the early morning hours. A distinct characteristic of the HPA axis is the cortisol awakening response (CAR).[13] The CAR is characterized by a sharp rise (between 50 and 75%) of cortisol levels within the first 30 minutes after awakening.[14] Repeated measurement of free cortisol levels within the 60 minutes after awakening in the morning is considered a stable and reliable biological marker of adrenocortical activity.15 We plan to collect approximately 2-3 ml of saliva at 0, 30, and 45 minutes after awakening in the morning.

Mediating Measures

Five Facet Mindfulness Questionnaire (FFMQ), a 39-item questionnaire assessing individuals' daily tendency to be mindful.[2]

The Mindfulness Process Questionnaire (MPQ) is a 7 question self-report measure that assesses the degree how mindfulness is intentionally practiced or attempted and the ability to bring compassionate awareness to the present moment after observing the attention has drifted off or become judgmental.[3]

c. How frequently will data be monitored?

Self-report measures will be conducted at time 0 (before the intervention), time 1 (after the 2.5-day intensive training), time 2 (4 weeks after the 2.5-day intensive training and after the week 4 remote/virtual booster training) and at time 3 (90 days after the initial intensive training). Data will be monitored during each of these times.

d. What analyses will be performed on the data?

Data completeness will be assessed for missing data field at all times. The analysis after time 1 and each subsequent time will include changes in mindfulness, emotional intelligence, and difficulties with emotion regulation (i.e., process variables) preceded changes in mental health, physical health, stress, pain interference, anger, fatigue, sleep disturbance, burnout, resilience, and family functioning (i.e., outcome variables), using the multilevel modeling approach, we plan to examine which variables significantly change from time 0 to time 1, from time 1 to time 2, from time 2 to time 3, and from time 0 to time 2 and time 3.

Aim 1 Analyses

Descriptive statistics such as frequencies and proportions will be computed for each of the quantitative measures described in the sections above. To examine changes in our measures during the course of MBRT, we plan to use a multilevel

modeling approach with restricted maximum likelihood estimation (REML) to examine linear change over time as a fixed effect. We used REML because our data collection resulted in varying sample sizes for our measures, allowing for more accurate estimates with small sample sizes and missing data that are missing at random or completely at random [16,17] To test whether changes in mindfulness, emotional intelligence, and difficulties with emotion regulation (i.e., process variables) preceded changes in mental health, physical health, stress, pain interference, anger, fatigue, sleep disturbance, burnout, resilience, and family functioning (i.e., outcome variables), using the multilevel modeling approach, we plan to examine which variables significantly change from time 0 to time 1, from time 1 to time 2, from time 2 to time 3, and from time 0 to time 2 and time 3.

Aim 2 Analyses

To analyze the CAR, plan to use multilevel modeling with REML examining the main effects of phase of measurement (pre, post as above) and time after waking (0, 30, 45 minutes), as well as the interaction between the main effects. We also plan to investigate the association between the cortisol response patterns and change in mindfulness (FFMQ), stress (PSS-4), physical health, and mental health. For that purpose, we plan to analyze the area under the curve with respect to increase (AUCI) to analyze the linear relationship between each independent variable and cortisol awakening levels. Cortisol levels will be transformed into a single value by calculating the AUCI for each assessment day (1 pre and 1 post). These variables will be used in a hierarchical linear regression with pre-AUCI entered in step 1, and change in stress, physical health, mental health, and mindfulness entered in step 2, to predict post-AUCI. Alpha will be set at .05 for all analyses.

Process Evaluation

The overall goal of this research project is to deliver mindfulness-based resilience training (MBRT) and demonstrate improved mental and physical wellbeing among first responders involved in the opioid and heroin epidemic (law enforcement, firefighters, and emergency medical system personnel) compared to baseline measures and reduced stress as measured by salivary cortisol. Process evaluation provides a description of the acceptability of MBRT in a first responder population in Appalachia as well as the delivery of MBRT in an intensive 2.5 day setting with follow up remotely with an online communication method such as Skype, FaceTime, or Zoom.

e. What decision rules (e.g., stopping rules) will be considered?

Participants will be monitored weekly by the mindfulness instructor and if they report significant discomfort with the mindfulness intervention, they can decide

stop the study based on physical or psychological discomfort.

f. **Will unexpected harms be detected promptly?**

The mindfulness instructor will meet with participants in the mindfulness intervention group weekly and unexpected harm will be assessed at this time.

g. **Will an increased frequency or severity of unexpected harms be detected promptly?**

The mindfulness instructor will meet with participants in the intervention group weekly and unexpected harm will be assessed at this time.

h. **Will the protocol be stopped once benefits are proven to outweigh harms?**

We do not anticipate being able to fully assess the effectiveness of the mindfulness intervention until after the 2.5-day intensive intervention concludes.

i. **Will the protocol be stopped once harms are proven to outweigh benefits?** In the extremely unlikely event that harms outweigh any benefits, the trial will be stopped.

7. **For more than minimal risk describe how data will ensure the safety of participants.**

We do not anticipate more than minimal risk with this pilot project.

8. **Does the research involve surveys or questionnaires?**

Yes.

a. **Will you be asking questions that might distress your subjects (i.e., questions about abuse, trauma, etc.)?**

No.

9. **Does the research involve interviews?**

Yes. Interviewing (called inquiry in mindfulness instruction) is integral to almost all mindfulness-based programs, including MBRT.

a. **Will you be asking questions that might distress your subjects (i.e., questions about abuse, trauma, etc.)?**

No.

10. **Does the research involve data analysis?**

    Yes.

11. **Is the research a clinical trial?**

    Yes.

12. **Include a literature review and explain the scientific rationale for the study.**

Mindfulness-based resilience training (MBRT) is based on mindfulness-based stress reduction (MBSR) first introduced at the University of Massachusetts School of Medicine in 1979 by Jon Kabat-Zinn. The original 8-week program was designed to teach participants to use their innate inner resources to enhance awareness to the present moment experience, primarily through experiential, non-cognitive learning about the mind's capacity to create stories which may or may not correlate with what is really happening in the present. This program has been described in detail and studied rigorously in many contexts of physical and mental health.[18] MBRT builds on the original 8-week course structure of MBSR and is designed to train participants in a number of experiential exercises evoking qualities of mindfulness: mental focus, sustained attention and personal and situational awareness. These exercises include versions of the body scan (body awareness exercise), sitting meditation, mindful movement, walking meditation, eating meditation, mindful martial arts exercises and other elements of MBSR. These studies demonstrated effectiveness across a wide range of measures of physical and mental health.[1,19] Our plan is to use identical measures as the original pilot study[1] but modify the delivery after empiric unpublished observations by one of the authors, Richard Goerling, that a shorter but intensive intervention was more likely to be effective than an 8-week course with a 4-week post-intervention follow-up. This study therefore builds on the demonstrated success of prior MBRT interventions with three changes: Cultural venue (Appalachia as opposed to the Pacific Northwest), includes fire and EMS in addition to law enforcement, and is presented in a 2.5-day intensive intervention with a 4-week remote follow-up (booster) and a 3-month post-intensive intervention evaluation.

HIPAA

1. **Does the research involve Protected Health Information (PHI) in any way?**

   The only PHI we will be collecting is the participant's name and phone number. This information will only be on the consenting forms which will be kept in a locked cabinet. Participant names will be in the Redcap database which is password protected.

Subjects

1. **Describe in detail what will be done to identify and recruit participants?**

   The impetus of the proposed research project came from meetings of the Great Rivers Harm Reduction Coalition, which includes public health and first responders from Cabell,

Kanawha, and Putnam Counties. It was clear from discussions about the breadth and depth of the opioid and heroin epidemic that first responders are an overlooked vulnerable population in this public health crisis. Law enforcement, fire, and EMS personnel stated they need a means to cope with the daily onslaught of overdoses and interdiction efforts in addition to their daily calls and would be amenable to a resilience-building and stress-reducing intervention involving research into the effectiveness of the intervention. Subjects for the proposed research would be first responders from the three-county area, but primarily from the cities of Charleston and Huntington.

2. **Are subjects less than 18 years old?**

   No.

3. **Will assent be obtained from all children?**

   N/A - there will be no children recruited for the study.

4. **Will parental/guardian consent be obtained for the children to participate in the study?**

   N/A - there will be no children recruited for the study.

5. **If subjects are under the age of 18 will be enrolled, will they be re-consented at 18 years of age?**

   N/A - there will be no children recruited for the study.

6. **Will subjects include any of the vulnerable populations (cognitively impaired, WVU/UHA/WVUH employees, pregnant women, prisoners, or WVU students?**

   No.

7. **Describe steps that will be taken to protect the rights and welfare of included vulnerable populations (i.e. informed consent, protecting confidentiality, undue coercion, etc.).**

   N/A.

Sample Size

1. **Indicate the approximate number of subjects to be enrolled?**

   We anticipate enrolling 70 participants starting in August 2017 and continuing through

December 2017.

2. **Describe why the proposed sample size was chosen for this study?**

The sample size was chosen to be the size of 2 cohorts of first responders in a class size of 35 participants per class. 70 is the number of participants we expect to be able to recruit for this study from the Cabell, Kanawha, and Putnam County areas.

3. **Describe how information relevant to the protection of participants will be managed. Address unanticipated problems involving risks to participants or others, interim results, and protocol modifications.**

   Study data will be collected and managed using REDCap (Research Electronic Data Capture). REDCap is a secure web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The REDCap software was developed by Vanderbilt University and has been obtained and installed for usage at West Virginia University.

   Participant data for this study will be stored electronically in the REDCap platform. The REDCap platform is managed by the West Virginia Clinical and Translational Science Institute (WVCTSI). Only project investigators listed on this protocol will have access to the REDCap data platform. Each investigator will be granted access to the REDCap data system through a secure login. The REDCap server at WVU is secured and physically resides in WVU Healthcare's clinical data center. Data backups are secured in a remote data center along with the organization's clinical data. Disaster recovery is routinely tested.

4. **Describe the plan for data analysis. Address how the proposed analysis relates to the primary purpose of the study.**
   See section 6d above.

Potential Risks/Discomforts

1. **Describe and assess any potential possibilities for risk or harm to the subjects as a result of their participation in the research, including discomforts, hazards, or inconveniences to the subject.**

   Risk posed to the participants is minimal, considering that the primary intervention is mindfulness meditation. The completion of surveys presents minimal risk other an infringement on the patient's time.

   Should any participants require mental health care, their medical insurance will be billed for their clinic treatment. There will be no cost to the subject for mindfulness component of the study.

2. **Describe how and where researchers will interact with participants. How will these interactions be kept private?**

   Researchers and instructors will interact with participants at the 2.5-day intensive site and at their worksites where they will complete the self-assessment. All interactions will take place in a secure room behind closed doors. The setting will be closed for the self-assessments and the salivary cortisol collections away from public thoroughfares.

Potential Benefits

1. **Describe potential benefit(s) to be gained by the individual subject as a result of participating in the research. Payments to subjects should be included in this section but rather addressed in the Payments/Reimbursements section.**

   All participants will be able to participate in the MBRT and will receive the benefits of mindfulness training, which has been linked to improved mental and physical health outcomes in other populations and among law enforcement officials.

2. **Describe the potential benefit(s) to society and scientific/medical knowledge of the planned work.**
   Should the hypothesis be confirmed, first responders in West Virginia will have an effective intervention to improve resilience, address perceived stress and burnout, and lead to greater mental and physical wellbeing in the face of unprecedented stresses associated with the opioid and heroin epidemic. The delivery of the intervention in an intensive 2.5 days setting with MBRT experts and remote follow-up would enable this intervention to be scaled across the state among other populations of first responders. To our knowledge, never has MBRT or any similar mindfulness-based or other contemplative approach been used to managing stress, improving resilience, or addressing compassion fatigue and burnout in first responders in West Virginia and no specific program has been applied to address the unique stresses imposed by the opioid and heroin epidemic.

Consent Procedures

1. **Will the PI and/or Co-I consent subjects for this study? If not, explain why someone other than the PI or Co-I will consent subjects.**

   Yes.

Confidentiality

1. **Is there any way the PI or the research team can identify subjects using the data?**

   Yes, project investigators will be able to identify participants in order to track treatment outcomes in both the treatment and control groups. However, we do not believe we are tracking any sensitive data.

2. **How long will data be kept?**

   Data will be de-identified at the conclusion of the intervention and used publishing purposes, so they will be retained indefinitely because participants will not be able to be identified.

3. **Where will data be securely located?**

   Participant data will be stored electronically in the REDCap platform. The REDCap platform is managed by the West Virginia Clinical and Translational Science Institute (WVCTSI). Only project investigators listed on this protocol will have access to the REDCap data platform. Each investigator will be granted access to the REDCap data system through a secure login. The REDCap server at WVU is secured and physically resides in WVU Healthcare's clinical data center. Data backups are secured in a remote data center along with the organization's clinical data. Disaster recovery is routinely tested. Any paper copies of research material will be kept in a locked cabinet.

4. **Besides the PI, the study staff, and the IRB, identify anyone who will have access to identifiable research data.**

   No.

5. **Describe all steps that will be taken to maintain confidentiality of data and privacy of subjects.**

   In addition to the use of REDCap, in order to protect confidentiality and PHI, participation in this pilot intervention will not be disclosed to other treaters or collateral contacts for which they sign a clinical release. Participants will not be contacted by study staff unless indicated as part of the research protocol or specifically requested by the subject.

Payments/Reimbursements

1. **Will subjects be paid or reimbursed to participate in this research project (gift cards included)?**

   No.

2. **Indicate the dollar amount, or dollar amount value, of the payment.**

N/A

3. **Describe the payment distribution plan.**

N/A

References

1. Christopher MS, Goerling RJ, Rogers BS, Hunsinger M, Baron G, Bergman AL, Zava DT. A Pilot Study Evaluating the Effectiveness of a Mindfulness-Based Intervention on Cortisol Awakening Response and Health Outcomes among Law Enforcement Officers. J Police Crim Psych. 2016; 31(1): 15-28.
2. Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. Assessment. 2006;13(1):27–45.
3. Erisman SM, Roemer L. A preliminary investigation of the process of mindfulness. Mindfulness. 2012; 3(1):30–43.
4. Smith BW, Dalen J, Wiggins K, Tooley E, Christopher P, Bernard J. (2008) The brief resilience scale: assessing the ability to bounce back. Int J Behav Med. 2008; 15(3):194–200.
5. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, Rose M. The Patient-Reported Outcomes Measurement Information System(PROMIS): progress of an NIH Roadmap cooperative group during its first two years. Med Care. 2007;45(5 Suppl 1):S3.
6. Cohen S, Williamson G. Perceived stress in a probability sample of the United States. In: Spacapan S, Oskamp S (eds) The social psychology of health. The Claremont Symposium on Applied Social Psychology. 1988; Sage Publications, Thousand Oaks, pp 31–67.
7. McCreary DR, Thompson MM. Development of two reliable and valid measures of stressors in policing: the operational and J Police Crim Psych organizational police stress questionnaires. Int J Stress Manag. 2006 13(4):494.
8. Demerouti E, Bakker AB, Vardakou I, Kantas A (2003) The convergent validity of two burnout instruments: a multitrait-multimethod analysis. Eur J Psychol Assess. 2003; 19(1):12.
9. Schutte NS, Malouff JM, Hall LE, Haggerty DJ, Cooper JT, Golden CJ, Dornheim L. Development and validation of a measure of emotional intelligence. Personal Individ Differ.1998; 25(2):167–177.
10. Gratz KL, Roemer L. Multidimensional assessment of emotion regulation and dysregulation: development, factor structure, and initial validation of the difficulties in emotion regulation scale. J
Psychopathol Behav Assess. 2004;26(1):41–54
11. Epstein NB, Baldwin L, Bishop DS. The McMaster family assessment device. J Marital Fam Ther.1983; 9:171–180.
12. Kabacoff RI, Miller IW, Bishop DS, Epstein NB, Keitner GI (1990) A psychometric study of the McMaster Family Assessment Device in psychiatric, medical and nonclinical samples. J Fam Psychol. 1990; 3:431–439.
13. Matousek RH, Pruessner JC, Dobkin PL. Changes in the cortisol awakening response (CAR) following participation in mindfulness based stress reduction in women who completed treatment for breast cancer. Complement Ther Clin Pract. 2011; 17(2):65–70.
14. Clow A, Hucklebridge F, Thorn L. The cortisol awakening response in context. Int Rev Neurobiol. 2010;93:153–175.
15. Pruessner JC, Wolf OT, Hellhammer DH, Buske-Kirschbaum A, Von Auer K, Jobst S,

Kaspers F, Kirschbaum C. Free cortisol levels after awakening: a reliable biological marker for the assessment of adrenocortical activity. Life Sci.1997;61(26):2539–2549.
16. Maas CJ, Hox JJ. Sufficient sample sizes for multilevel modeling. Methodol Eur J Res Methods Behav Soc Sci. 2005;1(3):86.
17. Snijders TA, Bosker RJ. Standard errors and sample sizes for two level research. J Educ Behav Stat. 1993;18(3):237–259.
18. Kabat-Zinn J. Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness. Delta Publishing, 1990; New York.
19. Bergman AL, Christopher MS, Bowen S. Changes in Facets of Mindfulness Predict Stress and Anger Outcomes for Police Officers. Mindfulness. 2016;7:851-858.
20. Shonin E, Van Gordon W, Griffiths MD. The emerging role of Buddhism in clinical psychology: towards effective integration. Psychol. Relig. Spiritual. 2014;6, 123–137.
21. Dobkin PL, Irving JA, Amar S. For whom may participation in a mindfulness-based stress reduction program be contraindicated? Mindfulness. 2012; 3, 44–50.
22. Shonin E, Van Gordon W, Griffiths MD. Do mindfulness-based therapies have a role in the treatment of psychosis? Aust. NZ J. Psychiatr. 2014;48, 124–127.