

FULL PROTOCOL TITLE

Mindfulness-Based Resilience Training for Aggression, Stress and Health in Law Enforcement Officers: A 3-arm multisite randomized feasibility trial

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December 8, 2020

Supported by:

**The National Center for Complementary and Integrative Health. Grant
Number U01AT009841**

Tool Revision History

Version Number: 1

Version Date: 11/13/2018

Summary of Revisions Made:

Version Number: 2

Version Date: 12/21/2018

Summary of Revisions Made:

Version Number: 3

Version Date: 1/14/2019

Summary of Revisions Made:

Version Number: 4

Version Date: 2/20/2019

Summary of Revisions Made: Timing of cortisol collection, revised lab stress task and addition of attention task (SART), added description of Portland research space, adjusted SME and MBRT session length, blood pressure monitor equipment change.

Version Number: 5

Version Date: 3/6/2019

Summary of Revisions Made: Added stressor task to assessment flowchart and revised SME and MBRT session language.

Version Number: 6

Version Date: 3/12/2019

Summary of Revisions Made: Corrected typos to content added in Version 5.

Version Number: 7

Version Date: 6/3/2019

Summary of Revisions Made: Updated study locations, removed cortisol awakening response, added two new assessments (MAIA II and PASA), updated procedures for stress challenge including repeating measure at 3-month follow-up visit. Added Project Coordinator, Janae Taylor to study roster.

Version Number: 8

Version Date: 6/18/2019

Summary of Revisions Made: removed “informed” from verbal consent for phone screening, and removed “with saliva collection aid” from description of cortisol measurement.

Version Number: 9

Version Date: 7/15/2019

Summary of Revisions Made: Updated list of self-report measures and schedule of evaluations, added “Screen” box to participant flow diagram, added website, removed full-time and active status eligibility requirements (part-time LEOs may be eligible and “active status” is redundant with being and LEO), added description of the Social Evaluative Cold Pressor Task and saliva collection procedures, revised focus group question about saliva collection procedures.

Version Number: 10

Version Date: 8/27/2019

Summary of Revisions Made: Revised inclusion criteria to add “...at the rank of Sergeant or below,” extended assessment windows from 2 weeks to 3 weeks (for pre-, post-, 3-month followup, and 6-month followup), added Omron HEM-907XL to calibrate blood pressure at all assessment visits.

Version Number: 11

Version Date: 11/5/2019

Summary of Revisions Made: Added statement that if needed, we will recruit officers from Greater Portland and Albuquerque Metro areas in addition to Albuquerque Police Department and Portland Police Bureau; revised randomization allocation ratio from 1.5:1:1 to 2:1.5:1 for MBRT, SME, and NIC conditions, respectively; updated saliva collection timeframes.

Version Number: 12

Version Date: 7/1/2020

Summary of Revisions Made:

Due to COVID-19-related restrictions, screening, informed consent, and enrollment will all be via phone, REDCap and/or email. Assessment sessions and focus group procedures will be administered remotely to avoid in-person contact with participants. If state, local and university policies allow, intervention MBRT sessions 1 and 7 will be delivered in person at the respective study sites. If not, these sessions will also be conducted using the online Zoom platform. All SME sessions will be conducted online. Physiological lab-based assessments (HR, BR, sAA and cortisol) and stress induction (SECPT) will no longer be administered. A home-administered dried blood spot analyses assessing inflammatory cytokines was added at baseline, postcourse and 3-month assessment periods. Previous random sampling of participants to invite to participate in focus groups changed to inclusion of all participants in individual feedback phone interviews. Previously separate site-based intervention teams shifted to using the same pairs of interventionists at both sites. iMINDr software will be replaced with Illumivu software. Audio recording of sessions is now audio and video recording of sessions.

Version Number: 13

Version Date: 12/8/2020

Summary of Revisions Made: Added Madison Police Department as a recruitment site and Dan Grupe, PhD (University of Wisconsin Madison) as a co-investigator.

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PRÉCIS

Mindfulness-Based Resilience Training for Aggression, Stress and Health in Law Enforcement Officers

Objectives

The primary objective of the study is to identify, optimize and refine best clinical and research practices to ensure success in a future multisite efficacy trial assessing effects of Mindfulness-Based Resilience Training (MBRT) versus attention control, Stress Management Education (SME), and a no intervention control on physiological, behavioral, and psychological outcomes among LEOs. The study's specific primary objectives are to ensure efficiency, optimization and fidelity of all procedures across all study sites.

1: Enhance efficiency of recruitment, engagement, and retention across sites

- 1.1 Refine recruitment methods used in our recent R21 trial to maximize inclusion of female and ethnic minority LEOs
- 1.2 Enhance previous R21 procedures to ensure $\geq 80\%$ LEO retention throughout intervention and follow-up phases
- 1.3 Enhance participant treatment engagement and compliance to treatment protocol
- 1.4 Identify recruitment and retention barriers, and appropriately refine procedures

2: Ensure fidelity and equivalence of lab, assessment, and data management procedures across sites

- 2.1 Assess and improve efficiency of data collection and procedures for on-the-job LEO excessive use of force (e.g., aggressive drawing and discharge of weapons, vehicle rams, and illegal takedowns)
- 2.2 Confirm acceptability of self-report (resilience, aggression, burnout, depression, suicidal ideation, trauma, and alcohol misuse) and stress-related proinflammatory biomarkers (C-reactive protein [C-RP], interleukin 6 [IL-6], interleukin 10 [IL-10], tumor necrosis factor-alpha [TNF- α]) data collection
- 2.3 Train relevant study staff in REDCap and confirm compliance with Good Clinical Practice procedures

3: Optimize intervention training procedures and ensure fidelity to intervention protocols across sites

- 3.1 Refine training and supervision procedures for clinical interventionists to enhance intervention fidelity
- 3.2 Hone session coding procedures and adapt the Adherence and Competence Scale for use with both MBRT and SME to ensure fidelity and equivalence across sites and the two active interventions

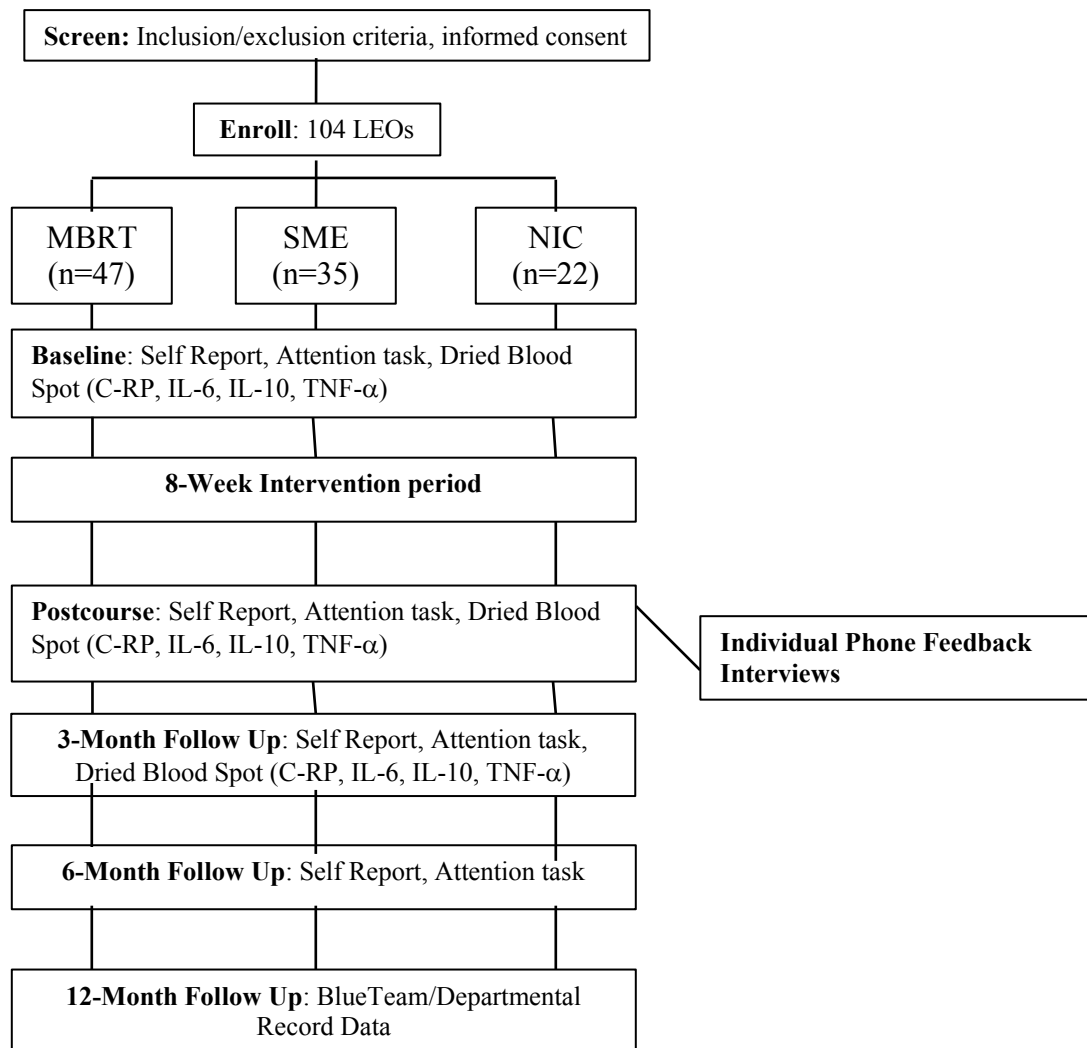
4: Assess participant experience and optimize outcome measures across sites

- 4.1 Qualitatively evaluate feasibility, acceptability, and impact of assessments, protocol, and interventions
- 4.2 Confirm sensitivity, responsiveness to change, and psychometric soundness of outcome measures

Design and Outcomes

The study will use a randomized multi-site (Portland, Albuquerque, Madison) clinical trial assessing feasibility and across-site equivalence of all study procedures. Three study arms include MBRT, an attention control (SME), and a no-intervention control (NIC). Outcomes include physiological, behavioral, and psychological indices of officer wellbeing, resilience, and excessive use of force in law enforcement officers.

Participants will complete baseline, post-intervention, and 3- and 6-month follow-up assessments. Assessments include self-report measures, a computerized attention task, and a self-administered dried blood spot test. Participants will be invited to participate in a post-intervention telephone feedback interview. Twelve-month departmental excessive use of force data will be collected from police department databases, and will involve neither direct participant interaction nor compensation.



Interventions and Duration

Participants in all 3 arms will be involved in the study for baseline data collection, collected within the 14 days prior to the intervention period, followed by an 8-week intervention period

during which participants randomized to MBRT or SME will receive an active intervention. Participants in the NIC condition will not receive any intervention. There will then be a 6-month follow-up period (± 7 days), totaling 7.75 - 8.25 months total of study involvement. Although 12-month data are collected via police department (e.g., BlueTeam) databases, participant involvement ends after the 6-month follow-up assessment point.

Sample Size and Population

We will recruit 104 law enforcement officers (52 at Albuquerque, 26 at Portland, and 26 at Madison). Using a 2:1.5:1 randomization allocation ratio for MBRT, SME, and NIC conditions, respectively, across three sites, 47 participants will be randomized to MBRT; 35 to SME; and 22 to NIC. Participants will be stratified by gender to ensure equivalent gender representation across conditions.

All participants will be invited to participate in individual feedback interviews via phone after the post-course assessment.

1. STUDY OBJECTIVES

1.1 Primary Objective

Objective 1: Enhance efficiency of recruitment, engagement, and retention across sites.

We will successfully enroll 52 LEOs at Albuquerque, 26 at Portland, and 26 at Madison, with an *across-site average* of 20% female and 35% racial/ethnic minority participants; 85% of participants will attend ≥ 6 MBRT or SME sessions (i.e., treatment completer), and complete 75% of assigned homework. Based on 80% retention at 3 *months* in the recent R21, enhanced retention efforts will result in $\geq 80\%$ at 6 *months*.

Per NCCIH SARP guidelines, we will gauge accrual and retention by accrual of $\geq 80\%$ but no higher than 150% of benchmark number at a given time point, study initiation delay of ≤ 1 accrual reporting period (~ 4 months), and actual loss to follow-up rate $\leq 20\%$.

Objective 2: Ensure fidelity and equivalence of lab, assessment, and data management procedures across sites.

100% of staff will complete trainings in research ethics, an NIH Good Lab Practice course, and all assessment and lab procedures. Throughout the study, there will be $\leq 5\%$ rate data procedural errors, tracked in REDCap (same procedure used in R21 study). Based on the R21 study, we expect $\leq 15\%$ missing data due to omitted or refused completion of measures from active participants. Collection of self-report measures will be acceptable to LEOs at all sites, i.e., all assessments will be completed in the allotted time, assessment burden will be acceptable, and questionnaire items will be relevant and acceptable ($\geq 75\%$ of LEOs rate assessment protocol as “reasonable” or “very reasonable” in content, clarity and time burden). We will obtain departmental excessive use of force (i.e., BlueTeam or other departmental data) for 100% of participants at all sites in designated period (1 month to assemble pre-baseline, and 1 month to assemble at 12-month follow-up). Biweekly reviews will yield 100% adherence to data management protocol at both data collection sites.

Objective 3: Optimize intervention training procedures and ensure fidelity to intervention protocols across sites. All study MBRT and SME interventionists will complete intensive clinical trainings, demonstrate 90% fidelity on Adherence and Competence scales, and

subsequently maintain $\geq 85\%$ overall fidelity (including session content coverage, presence of main themes, and global skills). Interrater reliability between all coders will be $\geq .75$, which is an established criterion for excellent reliability.

Objective 4: Assess participant experience and optimize outcome measures across sites.

Well-developed content themes with data saturation emerging from feedback interviews will provide information on acceptability, impact of assessments, protocol and intervention fidelity, and equivalence of these markers across sites. Benchmark sensitivity and responsiveness values will determine the most sensitive and responsive measures relative to all study outcomes, versus a significance testing approach in which standardized/conventional threshold values are used to make decisions regarding significance. Sensitivity and responsiveness information will determine which outcomes are most impacted by MBRT for retention in a future full-scale multi-site efficacy trial. Benchmarks for equivalence across sites will be evidenced by: a) qualitative themes that suggest experiential continuity across sites, and b) equivalence in outcome measure response distributions, reliability estimates, and intraclass correlations.

1.2 Secondary Objectives

Our primary objectives include assessing sensitivity and responsiveness of all study procedures and assessments. We will thus not consider any objectives to be primary or secondary.

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Policing is one of the most highly stressful occupations.^{3, 4} Unpredictable exposures to violence, chronic stress, job dissatisfaction, and expectations for optimal performance lead to an intensive work environment.⁵ Stress-impaired law enforcement officers (LEOs) are more likely to be aggressive toward suspects and use excessive force.^{6, 7} LEO occupational stress has also been linked to disproportionately high rates of depression and suicide,⁸ PTSD,⁹ burnout,¹⁰ and alcohol misuse.¹¹ Collectively, stress inherent to policing exacts enormous personal, financial, and societal costs.

Bureau of Justice Statistics (<https://www.bjs.gov>) estimates 59.4 million U.S. residents age 16 or older had one or more face-to-face contacts with police in 2011 (most recent year data were available). Among them, an estimated 2.3 million experienced threat or use of force by police, and nearly 75% of those described it as excessive. Appropriate use of force in acutely stressful situations is an essential component to safe and successful policing. However, physiological stress responses to acute LEO critical incidents can influence behavior and impact the outcome of the incident.

Studies on human responses to stressful events demonstrate neuroendocrine markers play an important role in physiological reactivity to stress.^{12, 13} Stress responsiveness is primarily regulated by two neuroendocrine axes: the sympathetic adrenomedullary (SAM) and hypothalamic-pituitary-adrenocortical (HPA) systems - distinct but interrelated systems designed to help the body mobilize resources to deal with psychosocial and physical challenges that can be measured across different time points (e.g., acute, awakening profiles, chronic). Acute psychological stress quickly activates the SAM axis, eliciting release of catecholamines such as

noradrenaline and adrenaline, resulting in elevation of heart rate (HR), blood pressure (BP) and salivary alpha amylase (sAA). Dysfunction within the SAM and HPA systems among distressed and/or chronically stressed populations is thoroughly documented, including in LEOs,^{17, 18} and is indicated by exaggerated or blunted reactivity to stressors and/or prolonged recovery time.^{19, 20}

Regular exposure to acute and chronic stressors, such as organizational challenges, and exposure to violence and potential harm, contribute to elevated rates of LEO mental illness. LEOs experience, on average, over three traumatic events for every six months of service,²¹ with annual PTSD prevalence rates as high as 19%,²² compared to an estimated 3.5% prevalence in U.S. adults. High trauma-exposed LEOs are more likely to discharge their firearm during critical incidents,^{23, 24} report higher rates of job dissatisfaction and burnout than most other occupations,²⁵ and burnout is associated with aggression and excessive use of force.^{26, 27} LEOs have high rates of alcohol consumption and binge drinking,²⁸ and deaths due to alcohol-related liver disease are twice that of the general population.²⁹ LEOs who engage in hazardous drinking are four times more likely to commit physical violence against others.³⁰ Rates of depression and suicide are up to three times higher than the general public, even with probable underreporting of LEO suicide.³¹

2.2 Study Rationale

Programs targeting LEO stress often lack effectiveness, with a focus on post-incident intervention instead of prevention. Despite elevated rates of PTSD, burnout, alcohol consumption, alcohol-related death, and suicide, and the significant implications of compromised officers to the safety of the public, effective LEO trainings and interventions are still lacking. The majority of intervention research among LEOs has examined Critical Incident Stress Debriefing (CISD),^{32, 33} described as, “a structured group story-telling process combined with practical information to normalize group member reactions to a critical incident...only used in the aftermath of a significant traumatic event.” (p. 36) However, authors of a Cochrane Review³⁴ concluded, “there is no evidence that single session individual psychological debriefing is a useful treatment for the prevention of post-traumatic stress disorder after traumatic incidents.” (p. 2) Although some individual studies report positive effects on specific indices of LEO mental health, RCTs, systematic reviews, and meta-analyses have concluded CISD is ineffective and can have iatrogenic effects, exacerbating acute stress reactions among LEOs and other first responders.³⁵⁻³⁷ A recent meta-analysis³⁸ examining effectiveness of stress reduction programs among LEOs found small effect sizes, and concluded that, “insufficient evidence exists to demonstrate the effectiveness of stress management interventions for reducing negative physiological, psychological or behavioral outcomes among police officers and recruits.” (p. 508)

Mindfulness-Based Resilience Training is an 8-week program combining training in standardized mindfulness practices targeting factors that facilitate resilience, CBT, and psychoeducation. It contains experiential and didactic exercises including body scan, sitting and walking meditation, mindful movement and discussions. To supplement in-session content and support practice between sessions, MBRT participants will use the Ilumivu app, which is programmed with exercises and monitoring software.

Preliminary evidence suggests mindfulness training (MT) is a promising approach for the specific risks, challenges and outcome patterns present in the LEO population. MT has strong empirical support in lab-based, clinical, and community-based research, evincing outcomes such as reduced violence and aggression,³⁹⁻⁴¹ and improved biomarkers of SAM and HPA stress reactivity, including HR, BP, cortisol, and sAA.⁴²⁻⁴⁶ In a recent study,⁴⁷ authors concluded salutary effects of MT may be *most* likely in high-stress populations, in which stress is known to affect onset or aggravation of poor mental and physical health outcomes. Authors hypothesized that MT might “reduce SAM- or HPA-axis reactivity (or normalize dysregulated stress signaling in these systems), and subsequently impact stress-related disease-specific biological processes.” (p. 405).

MT may regulate how the individual appraises stress, and increase secondary appraisals of approach-oriented coping resources, thus reducing stress reactivity. Recent meta-analyses support this theory, indicating MT improves common LEO health and risk factors, including stress,^{48, 49} depression and suicidal ideation,^{49, 50} alcohol misuse,^{51, 52} trauma,^{49, 53} and burnout,^{54, 55} and increases psychological resilience.^{56, 57} MT has been shown to be feasible and to lead to improved health outcomes among several high-stress populations, such as military personnel,^{58, 59} physicians,^{60, 61} firefighters,⁶² and inner-city teachers.⁶³ Resilience training has also been shown to improve the capacity to adapt to stress and improve outcomes in high-stress populations.^{60, 64} These approaches often focus on skills training to buffer against ongoing acute and chronic stressors.^{65, 66} Several pilot studies have shown LEO resilience-enhancing programs improve HR, BP, sAA and behavioral performance in live or simulated critical incident simulation tasks.⁶⁷⁻⁷⁰ Based on work with military and first-responder populations, Jha and colleagues⁷¹ recently proposed a conceptual model of risk reduction among high-stress professions, in which mindfulness and resilience synergistically impact health and risk factors, such as those common among LEOs.

Stress Management Education (SME) was designed as an active control condition for other Mindfulness-Based Intervention trials. SME uses a group-based didactic approach with modules on physiological and dietary effects of stress, time management, sleep physiology and insomnia, nutrition, exercise, stress hardiness, and factors mitigating impacts of stress. To supplement in-session content, and to match amount and format of assigned homework in the MBRT condition, SME participants will also use the Iumivu app, programmed with audio content and monitoring software.

3. STUDY DESIGN

The study will use an Individually-Randomized Group Treatment (IRGT) design, which will entail randomizing individuals, not groups, to an intervention that will be delivered to groups of Law Enforcement Officers (LEOs). An IRGT design is typically used when examining an intervention that is intended to be delivered to individuals or implemented at an individual level versus a Group/Cluster-randomized (GR) design that is used when the intervention is intended to be delivered and implemented at a group level.⁷² MBRT is delivered as a group, but the meditation practice is implemented at an individual level. Therefore, an IRGT design is preferable over a GR design, which is consistent with the use of an IGRT design in randomized controlled trials (RCTs) examining the efficacy of mindfulness-based interventions in the extant literature.^{73, 74} An IRGT design will allow us to assess the impact of MBRT on individual LEOs.

The units of assignment and observation in the proposed study will be at the individual level since MBRT randomization and measurement will occur at an individual LEO level. Given that our primary objectives include assessing the sensitivity and responsiveness of all self-report, physiological, and behavioral outcomes, we will not consider any of our outcome measures to be primary or secondary measures. Our goal is to identify which outcomes are most impacted by MBRT, which will guide us in choosing primary and secondary outcomes in a future fully-powered efficacy RCT.

The target population for our study is LEOs working in urban settings in the United States. LEOs will be recruited from Portland Police Bureau (PPB), Albuquerque Police Bureau (APB), and Madison Police Department (MPD). PPB employs 966 full-time, active duty officers, serving approximately 603,106 citizens in the Greater Portland Metropolitan Area; women and racial/ethnic minorities represent 16% and 16%, respectively. APD employs 921 full-time, active duty officers, serving approximately 907,301 citizens in the Greater Albuquerque Metropolitan Area; women and racial/ethnic minorities represent 16% and 47%, respectively. MPD employs 486 full-time, active duty officers, serving approximately 258,054 citizens in the Greater Madison Metropolitan Area; women and racial/ethnic minorities represent 28% and 21%, respectively. We will make concerted efforts to recruit a target final sample comprising $\geq 16\%$ women and $\geq 16\%$ racial/ethnic minorities in Portland, $\geq 16\%$ women and $\geq 35\%$ racial/ethnic minorities in Albuquerque, $\geq 25\%$ women and $\geq 20\%$ racial/ethnic minorities in Madison.

We will recruit 104 participants. Using a 2:1.5:1 randomization allocation ratio for MBRT, SME, and NIC conditions, respectively, across the three study sites, 47 participants will be randomized to MBRT; 35 to SME; and 22 to NIC. Our sample size is based on feasibility trial recommendations suggesting 12-25 participants per arm to optimize estimation of group means and variability without oversampling in terms of diminishing returns in parameter estimation, and to provide reasonably precise information in terms of confidence intervals around retention rates.

If we do not get an adequate response from either of the two departments, we will expand recruitment to neighboring police departments in the Greater Portland Metro and/or Albuquerque Metro areas.

All data collection will happen remotely, either online or via home-based collection and mail (for dried blood spot samples).

The MBRT and SME interventions will remain time-matched, each totaling 17 hours over the 8-week delivery. However, the SME intervention sessions will be administered entirely online, aligned with standard usual care format for similar officer trainings. A preferred hybrid in-person/online format for MBRT will be implemented if safety guidelines permit, in which the 2 extended sessions (weeks 1 and 7) will be conducted in person, while other sessions will remain online. In-person sessions will take the following precautions:

- PPE face covering required by participants and research staff
- Only 50% room occupancy
- Temperature checks at the door, confirmation participant has no symptoms and is not part of a vulnerable population

If respective COVID-19-related state, local, or university policies prohibit or strongly recommend against in-person contact, all MBRT sessions will be administered entirely online. The hybrid vs. fully online format will be determined prior to engaging officers in the screening process, and will remain in place for the duration of that cohort. If state, local or university COVID-19-related recommendations or policies change during the course of a hybrid model, and session 1 has already been conducted in-person, session 7 may shift to an online format. The material and structure of the MBRT course allows for this flexibility.

At the Oregon study site, in-person MBRT intervention sessions would take place in the Pacific University Health and Resilience Center (PU-HRC) in Portland, OR. The building has four individual offices, two psychophysiology assessment rooms, a large conference/intervention room, and a space for secure storage of data. Drs. Christopher and Bowen, and study coordinator Taylor each have dedicated individual offices in this building and their Research Assistants have continuous and protected access to these offices along with dedicated student space.

At the New Mexico study site, in-person intervention sessions would take place at The Department of Psychology at the University of New Mexico (UNM).

Intervention locations at both study sites were carefully chosen, in collaboration with the corresponding police departments, to ensure low threshold accessibility. Per police department-recommended criteria, locations are central, accessible via public transportation, have parking options, and do not have signage that indicates mental health or addiction services, which can be a barrier for law enforcement participation. Space allows for compliance with social distancing recommendations.

Enrollment for the study will take place during Year Two of the grant from Month 2 through Month 8. The first phase of baseline data collection will occur during Month 4 of Year 2, directly preceding the beginning of MBRT and SME training for the first cohort of participants in Months 4 and 5. The second phase of baseline data collection is delayed due to COVID-19 restrictions. It will now occur during Year Three in Month 1, directly preceding the beginning of MBRT and SME training for the second cohort of participants in Months 2 and 3.

The first phase of post-intervention data collection will occur during Year 2, Month 8, directly following the end of the scheduled MBRT and SME training for the first cohort of participants; the second phase of post-intervention data collection will occur in Year 3, Months 3-4, directly following completion of MBRT and SME training for the second cohort of participants. Qualitative data collection (i.e., individual feedback interviews) for each training cohort will occur during the same months as post-intervention data collection.

The first phase of 3-month follow-up data collection (first training cohort) will occur during Year 2 Month 10; the second phase of 3-month follow-up data collection (second training cohort) will occur during Year 3, Month 6. The first phase of 6-month follow-up data collection (first training cohort) will occur during the Year 3, Month 2; the second phase of 6-month follow-up data

collection (second training cohort) will occur during the Year 3, Month 9. The first phase of 12-month follow-up data collection (first training cohort) will occur during Year 3, Month 8; the second phase of 12-month follow-up data collection (second training cohort) will occur during the Year 4, Month 1.

MBRT will be delivered in 8 weekly 1-hour sessions with an extended 7-hour class in week 1, and 4-hour class in week 7. MBRT contains experiential and didactic exercises including body scan, sitting and walking meditation, mindful movement and discussions. We have developed and refined MBRT based on focus group data from pilot research and feedback from our R21 trial (R21AT008854); content and language has been altered to be more relevant to LEOs, and there is greater emphasis on managing stressors inherent to police work, including critical incidents, job dissatisfaction, public scrutiny, and interpersonal, affective, and behavioral challenges. To supplement in-session content and support practice between sessions, MBRT participants will use Illumivu mobile software, which is programmed with exercises and monitoring software. MPI Bowen will co-lead the MBRT intervention with Co-I Lt. Richard Goerling (ret.) for all study sites. Co-Is Goerling and Witkiewitz will collaborate with Bowen to prepare for the training at the Oregon study site; Goerling, Witkiewitz, and Bowen will oversee MBRT interventionist training at the New Mexico study site. Goerling co-developed MBRT, and is an expert in MBIs with first responders; Bowen and Witkiewitz have facilitated, trained and supervised MBIs, and have collaborated on multiple MBI-related NIH trials.

Our active control group will be a Stress Management Education (SME) training, which is designed as an active control condition for MBSR trials.⁷⁶ SME uses a group-based didactic approach with modules on physiological and dietary effects of stress, time management, sleep physiology and insomnia, nutrition, exercise, stress hardiness, and factors mitigating impacts of stress. It is an 8-week, 1.5-hour class with weekly homework (amount matched to MBRT), with 2 extended 4-hour sessions, and gentle movement exercises. Dr. Hoge (SME developer) will provide input and support to ensure interventionists are trained to fidelity. Training will be conducted by trainers approved by Dr. Hoge, who has experience conducting SME and training interventionists. MPI Christopher, a licensed clinical psychologist with experience facilitating stress management groups, will oversee SME training with support from Dr. Hoge.

MBRT and SME groups will be led by separate interventionists, with at least masters level training in mental health or a related field, and matched for level of education and experience. MBRT interventionists will have previous training in and experience with MBRT or related interventions (e.g., MBSR, MBCT or MBRP), and will undergo intensive training, weekly clinical supervision, and regular meetings with MPIs to discuss fidelity and other clinical issues. Drs. Christopher, Bowen, and Witkiewitz are clinical psychologists with combined knowledge of psychoeducational protocols, MBIs, first responder populations, trauma, substance abuse, and other psychosocial outcomes. Given the importance of internal validity of interventions in RCT research, careful attention will be given to intervention adherence and consistency across sites, with all sessions being audio and video recorded. Under the supervision of Dr. Christopher, Dr. Witkiewitz, and consultant Hoge, advanced graduate students at both study sites will review four randomly selected sessions from each MBRT cohort to assess intervention fidelity, adapting the MBRP Adherence and Competence measure used in previous trials.⁷⁷ Drs. Christopher, Bowen, and Witkiewitz, as well as consultant Hoge, will do the same for each SME cohort. Drs.

Christopher, Bowen and Witkiewitz will provide weekly supervision to all interventionists to ensure fidelity and minimize drift. Participants in the NIC condition will not engage in a training; therefore, the administration of this group will only entail scheduling and meeting NIC participants for data collection.

Following baseline assessment, study staff not involved in data collection will randomly assign participants to a condition using SPSS and REDCap, stratifying for gender and using a permuted-block randomization procedure frequently used in mindfulness-based treatment trials^{78, 79} to ensure balance within strata and across arms. The study statistician will create an allocation table using SPSS and upload it to REDCap, which study staff will use to implement the randomization procedure. Participants will be randomly assigned using a 2:1.5:1 ratio respectively (MBRT = 47; SME = 35; NIC = 22). Randomization will occur separately at each site to ensure equal ratios at all sites across the three trial arms. Since we are randomizing at each study site and stratifying for gender, study site and gender will become non-ignorable clusters. Therefore, we will adjust for study site and gender in our statistical models to avoid a deviation in our type I error rate from .05.⁸⁰ We will include study site as a covariate in our statistical models. In addition, since including gender and study site as covariates in our statistical models will effectively decrease the sample size even further, we will conduct sensitivity and responsiveness to change analyses with and without covariates to ensure all inferential analyses can be conducted, and will compare the results between models with and without covariates to identify potential Type II Errors in models with covariates included.

Blinding will not be able to occur for participants since they will know their group assignment upon completing baseline assessment. We will, however, compartmentalize study staff to particular tasks and blind them to all other study components. Study staff will be involved in one of the following categories of activities and will not be involved in activities in any other category: design and analysis (i.e., designing the trial, overseeing design implementation, and analyzing trial data), intervention implementation (i.e., interventionist training, intervention implementation, and intervention fidelity monitoring), enrollment and randomization (using REDCap to randomize participants to trial arms and informing participants of their group assignment), recruitment (implementing recruitment, tracking participant enrollment and demographic information, maintaining contact with participants to schedule data collection appointments), and data collection (quantitative and qualitative data collection). Only study staff involved in enrollment and randomization activities will have access to both participant names and unique ID codes. This compartmentalization will create blinding for study staff in that those designing the trial and analyzing data will not be interacting with participants, involved in trial interventions, or have access to participant names; study staff interacting with participants in the interventions will not be involved in collecting or analyzing outcome data and will not have access to unique ID codes; study staff involved in data collection will be blinded to participant group assignment; study staff involved in collecting quantitative data will be blinded to participant group assignment as well as participant names (study staff involved in quantitative data collection will have access to unique ID codes); and study staff involved in qualitative data collection will be blinded to unique ID codes. (Due to the need to obtain qualitative information about participants' experiences in the SME and MBRT arms, we are unable to blind study staff involved in qualitative data collection to group assignment).

The study procedures (training, recruiting, randomization, etc.) will be overseen by the PU and UNM study sites. Overall design and direction of the protocol will reside in Oregon, and dried blood spot samples will be assayed at the Laboratory for Human Biology Research at Northwestern University under the direction of Thomas McDade, PhD.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

LEOs will be recruited from PPB, APD, and MPD. We will over recruit for a target final sample across sites of 20% women and 35% racial/ethnic minorities.

Eligible participants must: 1) be 21-65 years old (age limitations for both police departments); 2) demonstrate English fluency; 3) be a sworn LEO at the rank of Sergeant or below; 4) agree to random assignment to condition; and 5) be willing to complete assessments at multiple time points and participate in intervention groups.

4.2 Exclusion Criteria

Individuals will be excluded from participation if they: 1) have participated in MBSR, MBRT or a similar mindfulness course, 2) score in the severe range on brief screening measures of depression, suicidal ideation, alcohol use, or PTSD, or 3) are unable or unwilling to give written informed consent.

4.3 Study Enrollment Procedures

Recruitment. LEOs will be recruited from PPB, APD, and MPD. PPB employs 966 full-time, active duty officers, serving approximately 603,106 citizens in the Greater Portland Metropolitan Area; women and racial/ethnic minorities represent 16% and 16%, respectively. APD employs 921 full-time, active duty officers, serving approximately 907,301 citizens in the Greater Albuquerque Metropolitan Area; women and racial/ethnic minorities represent 16% and 47%, respectively. MPD employs 486 full-time, active duty officers, serving approximately 258,054 citizens in the Greater Madison Metropolitan Area; women and racial/ethnic minorities represent 28% and 21%, respectively. We will over recruit for a target final sample across sites of 20% women and 35% racial/ethnic minorities (see Inclusion Enrollment Report).

In collaboration with human resources staff at PPB, APD, and MPD, we will recruit 104 LEOs for study participation, conducted via: 1) emailed invitations sent to all eligible LEOs, 2) informational website and flyers posted at PPB, APD, and MPD facilities, and 3) community-based police organization leadership. We used similar recruitment methods for our R21 study and met recruitment goals. Co-I's Goerling, Rosenbaum, and Grupe will oversee recruitment at PPB, APD, and MPD, respectively. Recruitment will include information about interventions, assessed outcomes, concordance between community and investigator goals, and research team contact information. Interested individuals will voluntarily contact the research team by phone for eligibility screening. They will be informed of study purpose, eligibility criteria and randomization process. If the officers are interested in participation and believe the study may be

a good fit for them, they will provide informed consent via REDCap, then screen for eligibility criteria. Eligible LEOs will be mailed a dried blood spot collection kit immediately after the consenting process, and will make a remote (via Zoom) appointment for baseline assessment.

Screening Log. Interested individuals will be tracked using REDCap. Data collected will include reasons for ineligibility and for non-participation of eligible candidates.

Informed Consent. Study staff will obtain informed consent via REDCap from all participants prior to screening and baseline data collection. The consent form will include information about randomization, release of information (including data from PPB and APD databases), researchers' responsibilities regarding records collected, DHHS certificate of confidentiality, registration with clinicaltrials.gov, and permission to audio and video record sessions.

Randomization. Study staff not involved in data collection will randomly assign participants to condition using SPSS and REDCap, stratifying for gender, using a permuted-block randomization procedure frequently used in MT trials to ensure balance within strata and across groups. The study statistician will create an allocation table using SPSS, and upload it to REDCap, which will be used to implement the randomization procedure.

Following completion of the baseline online survey and confirmed completion of the dried blood spot sample, participants will be assigned using a 2:1.5:1 ratio (MBRT = 47; SME = 35; NIC = 22), allowing more robust evaluation of measure sensitivity and responsiveness as well as more accurate parameter estimation for the MBRT group. Randomization will occur separately at each site to ensure equal ratios at all sites across the three arms.

Participants will be notified of group assignment via phone call by a study team member. Participants assigned to MBRT and SME conditions will receive emailed information regarding course structure, dates/times, and class format. All participants will be provided information on assessment timeline, reminder calls they will receive, and contact information for the research team. Participants assigned to SME or NIC will be offered an opportunity to attend an MBRT course after the final 12-month follow-up collection of departmental excessive use of force data.

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Both MBRT and SME will include psychoeducation, gentle movement exercises focused on stress reduction and fitness, and weekly homework assignments, and will be matched for time and assigned homework.

MBRT will be delivered in groups of 10 to 13 law enforcement officers, in 8 weekly sessions of 1 hour each, with the exception of weeks 1 and 7 which are extended 7- and 4-hour classes, respectively, for a total of 17 intervention hours. The extended session, modeled after MBSR, is intended to provide an immersive training experience. The session will contain a series of mindfulness practices, including body scan, mindful movement, and walking and breath-focused

meditations. The session will focus primarily on formal mindfulness practices, in contrast to inclusion of discussion and psychoeducational components contained in other MBRT sessions.

If state, local and university allow Sessions 1 and 7 to be in-person, they will be conducted at the study sites. If not, they will be conducted using the online Zoom platform. Any MBRT in-person intervention sessions will be held in reserved rooms able to accommodate up to 25 people, and large enough to comply with social distancing guidelines - specifically, the Psychology Research Lab in Portland, and at UNM Department of Psychology in Albuquerque. All MPD groups will be conducted remotely. Online groups will be facilitated via Zoom. MPI Bowen and Co-Is Goerling and Witkiewitz will oversee MBRT interventionist training. Goerling co-developed MBRT, and is an expert in MBIs with first responders; Bowen and Witkiewitz have facilitated, trained and supervised MBIs, and have collaborated on multiple MBI-related NIH trials.

SME will be delivered as a weekly, 8-week, 1.5 hour class, except for weeks 1 and 7 which are extended to 4-hour classes, for a total of 17 intervention hours, with weekly homework (amount matched to MBRT), and gentle movement exercises. The content focuses on psychological, physiological, and dietary effects of stress, time management techniques, fitness, sleep hygiene, nutrition, and factors mitigating effects of stress. Dr. Hoge (SME developer) will provide input and support to ensure interventionists are trained to fidelity. Training will be conducted by trainers approved by Dr. Hoge, with experience conducting SME and training interventionists. MPI Christopher, a licensed clinical psychologist with experience facilitating stress management groups, will oversee SME training with support from Dr. Hoge. Potential adverse effects include: minor aches or strains from mindful movement practices, and mild emotional distress completing self-report measures or exposure to the socially evaluative cold pressor task challenge procedures.

MBRT and SME groups will be led by separate interventionists, with at least masters level training in mental health or a related field, and matched for level of education and experience. MBRT interventionists will have previous training in and experience with MBRT or related interventions (e.g., MBSR, MBCT or MBRP), and will undergo intensive training, weekly clinical supervision, and regular meetings with MPIs to discuss fidelity and other clinical issues. Drs. Christopher, Bowen, and Witkiewitz are clinical psychologists with combined knowledge of psychoeducational protocols, MBIs, first responder populations, trauma, substance abuse, and other psychosocial outcomes. They each have extensive experience developing, implementing, supervising, and assessing similar interventions.

Given the importance of internal validity of interventions in RCT research, careful attention will be given to intervention adherence and consistency across sites, with all sessions audio and video recorded. Under supervision of Drs. Christopher, Bowen, Witkiewitz and consultant Hoge, advanced graduate students at both study sites will review four randomly selected sessions from each MBRT and SME cohort, adapting the MBRP Adherence and Competence measure used in previous trials. Drs. Christopher, Bowen and Witkiewitz will provide weekly supervision to all interventionists to ensure fidelity and minimize drift.

Participants randomized to the NIC condition will not receive any intervention, but will participate in the same assessments as the two active intervention conditions (i.e., at baseline, post-intervention, 3- and 6-month follow-up). Assessment times will be yoked to those of the two active intervention conditions.

5.2 Handling of Study Interventions

Both the MBRT and SME interventions will follow a session-by-session protocol. They will both be delivered in 8 weekly sessions with a total training time of 17 hours. Both groups include psychoeducation, gentle movement exercises, and weekly homework assignments.

5.3 Concomitant Interventions

5.3.1 Allowed Interventions

Any prescribed medications are allowed during the course of the study.

5.3.2 Required Interventions

There are no required additional interventions.

5.3.3 Prohibited Interventions

There are no prohibited interventions in this study.

5.4 Adherence Assessment

Participant adherence to intervention will be measured by attendance (completer ≥ 6 out of 8 sessions^{1, 2}), and 50% completion of assigned audio recorded home practice, tracked using Ilumivu software.

6. STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessmen		Phone Screen	Baseline, Enrollment, Randomization: Visit 1	Post-intervention: Visit 2	3 Month Follow-Up: Visit 3	6 Month Follow-Up: Visit 4
Verbal Consent		X				
Inclusion/Exclusion Criteria		X				
Informed Consent		X				
Alcohol Misuse		X	X	X	X	X
Depression		X	X	X	X	X
Suicidal Ideation		X	X	X	X	X
Trauma Symptoms		X	X	X	X	X
Medication Use			X	X	X	X

Assessmen		Phone Screen	Baseline, Enrollment, Randomization: Visit 1	Post-intervention: Visit 2	3 Month Follow-Up: Visit 3	6 Month Follow-Up: Visit 4
Current Psychological Treatment			X	X	X	X
Tobacco Use			X	X	X	X
Adverse Childhood Experiences			X			
C-reactive protein			X	X	X	
IL-6			X	X	X	
IL-10			X	X	X	
TNF- α			X	X	X	
Aggression			X	X	X	X
Psychological Resilience			X	X	X	X
Sleep Disturbance			X	X	X	X
Mindfulness			X	X	X	X
Self-Compassion			X	X	X	X
Burnout			X	X	X	X
Sustained Attention to Response Task			X	X	X	X
Interoceptive Awareness			X	X	X	X
Perceived Stress			X	X	X	X
Treatment Expectancy/Credibility (MBRT and SME)			X			
Global Impression of Change (MBRT and SME)				X		
Acceptability (procedures)				X		
Acceptability (MBRT and SME)				X		
Compliance (MBRT and SME)				X		

6.2 Description of Evaluations

6.2.1 Screening Evaluation

Consenting Procedure

Informed consent will be attained prior to screening and study enrollment (telephone administered by Research Assistant or Project Coordinator). Study staff administering consent will have minimum bachelors level education, and will have completed the human subjects protection trainings. They will be trained and supervised by Drs. Bowen, Christopher, or Witkiewitz. Interested individuals will call PU (PPB or MPD) or UNM (APD) research offices and be given information about the study. If interested, they will provide consent via REDCap, then complete a phone eligibility screen (see below).

The consent form will include information about randomization, release of information (including data from PPB and APD databases), researchers' responsibilities regarding records collected, DHHS certificate of confidentiality, registration with clinicaltrials.gov, and permission to audio and video record sessions. The signing of this form indicates the study enrollment date.

All signed informed consent forms will be stored in REDCap and printed and stored in a locking file cabinet within study coordinator Taylor's locked research office (PU) or Co-I Witkiewitz's (UNM) locked research lab. Members of the research team will complete a form documenting the informed consent process, which will be stored electronically on the secure REDCap system.

Screening Procedure

Prior to beginning the phone eligibility screen, administered by a Research Assistant or the Project Coordinator, participants will be informed of the study purpose, procedures, and the randomization process and eligibility criteria. They will provide verbal consent for a phone screening where they will be asked non-sensitive questions (age, employment status, previous mindfulness training and willingness to be randomized and attend study visits and trainings) and told the eligibility criteria. If they are likely eligible and interested, they will be invited to continue with informed consent and screening for eligibility.

Eligible participants must: 1) be 21-65 years old (age limitations for both police departments); 2) demonstrate English fluency; 3) be a sworn LEO at the rank of Sergeant or below; 4) agree to random assignment to condition; and 5) be willing to complete assessments at multiple time points and participate in intervention groups. Individuals will be excluded from participation if they: 1) have participated in MBSR, MBRT or a similar mindfulness course, or 2) score in the severe range on brief screening measures of depression,⁸¹ suicidal ideation,⁸² alcohol use,⁸³ or PTSD.⁸⁴

- Depression: Patient Health Questionnaire (PHQ-9; Score 20 or more = Severe)
- Suicidal Ideation: Concise Health Risk Tracking (CHRT; Agree or Strongly Agree on one or more "active suicidal ideation or plans" items #10, #11 and/or #12)
- Alcohol Use: Alcohol Use Disorders Identification Test (AUDIT; Score of 20 or more indicate high risk or almost certain dependence.)
- PTSD: The Primary Care PTSD Screen for *DSM-5* (PC-PTSD-5; Score of 5 or more)

Immediately following the screening, participants will be informed whether they are eligible for study participation. Those not meeting criteria or not interested will be offered a list of mental health and stress management community resources. Eligible and consenting individuals will make an individual appointment for a remote (via Zoom) baseline assessment.

We estimate screening will take approximately 20 minutes, based on experience with similar procedures. Research staff will enter de-identified screening data into a spreadsheet, which will be stored on a secure server.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

Consent for study enrollment:

The study enrollment date is the day an individual who has met all the screening criteria signs (via REDCap) the informed consent form. A Randomization and Enrollment Form, documenting enrollment and allowable window between the enrollment date and randomization, will be entered into REDCap, a secure internet-based survey and data management software system housed on a secure server.

Randomization, immediately following completion of the baseline assessment procedure, must occur within 60 days of screening.

Baseline Assessments

- Adverse Childhood Events
 - Childhood Trauma Questionnaire⁸⁵
- Treatment Expectancy and Credibility
 - Expectancy/Credibility Questionnaire⁸⁶
- Proinflammatory Cytokines (C-RP, IL-6, IL-10, TNF- α)
 - Dried Blood Spot Collection Kit
- Psychological Resilience
 - Brief Resilience Scale⁸⁹
- Alcohol Misuse
 - PROMIS Alcohol Use⁹⁰
 - PROMIS Alcohol Use Negative Consequences⁹⁰
- Depression
 - PROMIS Depression⁹¹
- Sleep Disturbance
 - PROMIS Sleep Disturbance¹³⁷
- Mindfulness
 - Five Facet Mindfulness Questionnaire – Short Form¹³⁸

- Self-Compassion
 - Self-Compassion Scale – Short Form¹³⁹
- Aggression
 - Buss Perry Aggression Questionnaire – Short Form¹⁴⁰
- Suicidal Ideation
 - Concise Health Risk Tracking - Self-Report⁸²
- Trauma Symptoms
 - PTSD Checklist for DSM5⁹²
- Burnout
 - Oldenburg Burnout Inventory⁹³
- Sustained Attention to Response Task¹³⁴
- Interoceptive Awareness
 - Multidimensional Assessment of Interoceptive Awareness-II¹³⁵
- Perceived Stress
 - Perceived Stress Scale-10¹³⁶

Randomization

Immediately following completion of the Zoom-facilitated baseline assessment session, and confirmed completion of the dried blood spot sample, study staff not involved in data collection will randomly assign participants to condition using SPSS and REDCap. The study statistician will create an allocation table using SPSS, and upload it to REDCap, which will be used to implement the randomization procedure for all sites. All trial randomization codes will be stored within REDCap, which is a secure (HIPAA-complaint) internet-based survey and data management software system housed on a secure server at Oregon Health and Science University.

Participants will then be notified via phone of group assignment by a study team member. Participants assigned to MBRT and SME conditions will receive emailed information regarding course structure, dates/times, and class format. All participants will be provided information on assessment timeline, reminder calls they will receive, and contact information for the research team. Initiation of study intervention will be between 1 and 21 days. Participants assigned to SME or NIC will be offered an opportunity to participate in an MBRT course after the final 12-month follow-up collection of departmental excessive use of force data. Participants in all conditions will have access to resources provided by PPB, APD or MPD, including counseling services.

6.2.3 Blinding

Throughout the study, all assessors will be blind to study condition. Interventionists and participants will not be blinded. No one will be authorized to break that blind, and at no point in

the study will assessors be unblinded.

6.2.4 Followup Visits

Postcourse followup (must occur within 21 days of end of 8-week intervention period).

- Proinflammatory Cytokines (C-RP, IL-6, IL-10, TNF- α)
 - Dried Blood Spot Collection Kit
- Psychological Resilience
 - Brief Resilience Scale
- Alcohol Misuse
 - PROMIS Alcohol Use
 - PROMIS Alcohol Use Negative Consequences
- Depression
 - PROMIS Depression
- Sleep Disturbance
 - PROMIS Sleep Disturbance
- Mindfulness
 - Five Facet Mindfulness Questionnaire – Short Form
- Self-Compassion
 - Self-Compassion Scale – Short Form
- Aggression
 - Buss Perry Aggression Questionnaire – Short Form
- Suicidal Ideation
 - Concise Health Risk Tracking - Self-Report
- Trauma Symptoms
 - PTSD Checklist for DSM-5
- Burnout
 - Oldenburg Burnout Inventory
- Sustained Attention to Response Task
- Interoceptive Awareness
 - Multidimensional Assessment of Interoceptive Awareness-II
- Perceived Stress
 - Perceived Stress Scale-10
- Global Impression of Change¹⁴¹

- Acceptability
 - Acceptability of Assessment Procedures
 - Postcourse Satisfaction Survey (MBRT and SME)
- Intervention Compliance
 - Meditation Practice Questionnaire (MBRT)
 - Ilumivu (MBRT and SME)

3- and 6-month follow-up (must occur within ± 10 days of target date. Target date is relative to end of the intervention period, i.e., 90 days for 3-month followup, and 180 days for 6-month followup):

Note: 6-month follow-up is final study visit.

- Proinflammatory Cytokines (C-RP, IL-6, IL-10, TNF- α) (**Only at 3-month follow-up**)
 - Dried Blood Spot Collection Kit
- Psychological Resilience
 - Brief Resilience Scale
- Alcohol Misuse
 - PROMIS Alcohol Use
 - PROMIS Alcohol Use Negative Consequences
- Depression
 - PROMIS Depression
- Sleep Disturbance
 - PROMIS Sleep Disturbance
- Mindfulness
 - Five Facet Mindfulness Questionnaire – Short Form
- Self-Compassion
 - Self-Compassion Scale – Short Form
- Aggression
 - Buss Perry Aggression Questionnaire – Short Form
- Suicidal Ideation
 - Concise Health Risk Tracking - Self-Report
- Trauma Symptoms
 - PTSD Checklist for DSM-5
- Burnout
 - Oldenburg Burnout Inventory

- Sustained Attention to Response Task
- Interoceptive Awareness
 - Multidimensional Assessment of Interoceptive Awareness-II
- Perceived Stress
 - Perceived Stress Scale-10
- Intervention Compliance
 - Meditation Practice Questionnaire (MBRT)
 - Ilumivu (MBRT and SME)

12-month Followup (must occur on target date, which is 360 days from the end of the intervention period):

- Excessive Use of Force (Individual-level LEO excessive use of force (i.e., aggressive drawing and discharge of weapons, vehicle rams, illegal takedowns, administrative and citizen complaints)
 - BlueTeam⁹⁶ Database and/or other departmental data

6.2.5 Completion/Final Evaluation

The final evaluation is the 6-month followup. See above for assessments.

Study coordinator will contact any participants who discontinue the intervention to identify reason for early termination (e.g., illness, not finding the intervention beneficial, schedule change). In the event a participant discontinues due to an intervention-related adverse event, study staff will continue to follow-up with the participant until the issue is resolved.

7. SAFETY ASSESSMENTS

Minimal risks will exist for all participants involved in this project. Participants will be informed that MBRT and SME are considered to have very low risk for adverse events. These risks are considered to be minimal and are addressed in the consent forms.

In this study, the expected minimal risks to the subject are as follows:

- Minor **aches or strains** from mindful movement practices.
- Mild **emotional distress** completing self-report measures

To minimize risk during the mindful movement practices, participants will be instructed to recognize their physical limitations and to not exceed them. Given that this is an able-bodied population, and movement practices are very mild (e.g., gentle stretching) it is unlikely that injury will occur. To minimize risk related to completing the measures or procedures, participants will be notified during consent that participation is voluntary and that they can withdraw at any time.

7.1 Specification of Safety Parameters

At screening, individuals will be excluded from participation if they score in the severe range on brief screening measures of depression, suicidal ideation, alcohol use, or PTSD. Therefore, potential participants with severe mental illness and related safety issues will be excluded from the study and will be offered a list of mental health and stress management community resources.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

The interventions in this study are low risk.^{97, 98} Therefore we do not anticipate intervention-related risk to participant safety. In addition to screening, suicidal ideation will also be assessed at baseline, post-intervention, 3- and 6-month follow-up. Dr. Christopher (Portland and Madison) or Dr. Witkiewitz (Albuquerque) will contact any participant who endorses suicide risk as evidenced by Concise Health Risk Tracking (CHRT) endorsement of suicidal ideation (i.e., Agree or Strongly Agree on one or more “active suicidal ideation or plans” items #10, #11 and/or #12). Drs. Christopher or Witkiewitz will gather more information and make an appropriate referral for mental health services.

7.3 Adverse Events and Serious Adverse Events

An **adverse event (AE)** is defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recording regardless of their relationship to the study intervention.

A **serious adverse event (SAE)** is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly.

Dr. Christopher (Portland and Madison) or Dr. Witkiewitz (Albuquerque) will contact any participant who endorses suicide risk as evidenced by Concise Health Risk Tracking (CHRT) endorsement of suicidal ideation (i.e., Agree or Strongly Agree on one or more “active suicidal ideation or plans” items #10, #11 and/or #12). Drs. Christopher or Witkiewitz will gather more information and make an appropriate referral for mental health services.

Research staff will be trained to identify potential for risk and adverse events. All student research assistants will be advanced doctoral students in clinical psychology, both of the MPIs (Christopher and Bowen) and Co-I (Witkiewitz) are licensed clinical psychologists. Thus, the research team has an attunement to potential adverse events that will be augmented with training and preparation. Together, the training team will focus on preparing all team members to identify potential risks for adverse events and what steps to take if such risk occurs. Collection of AE's and SAE's will be unsolicited. If an AE of SAE occurs, trained study staff will adhere to the Report Procedures outlined in section 7.4.

7.4 Reporting Procedures

All AEs will be documented using the Adverse Event Form and stored in REDCap. Drs. Christopher (Portland and Madison) and Witkiewitz (Albuquerque) will be responsible for completing Adverse Event Forms. AEs will be classified by severity level and relatedness to the study. Minimally, the MPI's will be contacted in the event of any AE. The MPI's will review the list of AEs with the Independent Monitoring Committee (IMC) on a semi-annual basis. SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IMC, IRB, and NCCIH in accordance with requirements.

- Unexpected fatal or life-threatening SAEs related to the intervention will be reported to the NCCIH Program Officer within 72 hours. Other serious and unexpected SAEs related to the intervention will be reported to the NCCIH Program Official within 15 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the IMC, IRB, NCCIH, and other oversight organizations in accordance with their requirements. In the annual AE summary, the IMC Report will state that they have reviewed all AE reports.

7.5 Followup for Adverse Events

AEs will be tracked by Drs. Christopher (Portland and Madison) and Witkiewitz (Albuquerque) until resolved or stable. The Adverse Event Forms will be used to document actions taken and outcomes of all AEs.

7.6 Safety Monitoring

Per the NICCIH Program Official (Dr. Lanay Mudd), this study will be monitored by an Independent Monitoring Committee. IMC details are in section 9.4 (Interim Analyses and Stopping Rules)

8. INTERVENTION DISCONTINUATION

If a participant endorses suicidal ideation at any point during the study, they will be referred for psychological treatment and evaluated by Drs. Christopher (Portland and Madison) or Witkiewitz (Albuquerque) using the CHRT for suitability to continue in the study.

9. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

Our analytic aim is to obtain information to estimate group means, variability, and confidence intervals, identify primary and secondary outcomes, and conduct an a priori power calculation for sample size estimation for a future fully-powered efficacy RCT. Our study aims to optimize measurement by empirically assessing the sensitivity and responsiveness of conceptually well-justified candidate measures for the future trial. Since this is not an efficacy study, no primary or secondary hypotheses have been proposed to test the impact of MBRT on outcomes; however, results from this study will be used to determine primary and secondary outcome categories for the future trial.

All of the self-report measures in this study have been validated and found to be reliable in past research. The physiological measures in this study have been validated and found to be reliable methods of assessing relevant biomarkers in past research. The behavioral measure that will be used in this study is a standardized tracking system that integrates officer, administrator, and citizen data and is considered the current “gold standard” for assessing LEO use of force.⁹⁹⁻¹⁰¹ An important objective of this study is to demonstrate the potential utility of this behavioral measure as a research outcome. Preliminary review of these data suggest there is sufficient variability in departments at all study sites; however, to our knowledge, the sensitivity to between-group differences and responsiveness to changes during an intervention have not yet been assessed.

Our design is an individually-randomized group treatment trial with three arms (MBRT, SME, and NIC). This design was chosen in order to assess the sensitivity of outcome measures to between-group differences at the end of MBRT and responsiveness to changes in individual LEOs during the course of MBRT. Inclusion of three arms will document the willingness of LEOs to accept randomization to these treatment options, and enable our study staff to assess and optimize the implementation of all study procedures across a no-treatment control group, an active control group, and a treatment group at multiple study sites. This information will allow us to identify primary and secondary outcomes as well as detect and correct any procedural flaws in order to optimize procedures for a future fully-powered, multi-centered efficacy RCT.

9.2 Sample Size and Randomization

Our sample size estimate is derived from a recent conceptual framework and systematic analysis for conducting a feasibility trial in preparation for a future fully-powered efficacy RCT,¹⁰² as well as best practices¹⁰³⁻¹⁰⁵ and suggestions for extending CONSORT guidelines to feasibility trials.¹⁰⁶ Sample sizes of 12-25 participants per arm are recommended to optimize estimation of group means and variability without oversampling in terms of diminishing returns in parameter estimation,^{107, 108} and to provide reasonably precise information in terms of confidence intervals around retention rates.¹⁰⁹ This range is consistent with the median treatment arm size of 18 found in a systematic review of feasibility trials,¹¹⁰ and is sufficient to assess our primary goals of optimizing study procedures and obtaining data for parameter estimation, measure sensitivity, and measure responsiveness. Given the optimization aim of our study, we did not conduct an a priori power analysis based on effect sizes and a variance inflation factor to estimate the needed sample size. Our study will provide estimates of means and variability (including intraclass correlations) that we will use for an a priori power calculation for sample size estimation in a future fully-powered efficacy RCT. Consistent with guidelines on the NIH Research Methods Resources Webpage, the proposal for the future fully-powered efficacy RCT will include a sensitivity analysis that reflects the impact of potential differences between the estimate and realized value of the intraclass correlation, the number of clusters per arm, and size and variability of those clusters, based on the data we obtain in this study.

Measure sensitivity to our study arms will be assessed by examining relative efficiency; more specifically, by dividing the *F*-value for each behavioral, physiological, and self-report outcome by the largest *F*-value among the outcomes.^{111, 112} To generate the *F*-values for relative efficiency comparisons, we will conduct a one-way between-subjects Analysis of Variance for each outcome for MBRT vs. SME and MBRT vs. NIC. To adjust for non-ignorable clustering in order

to obtain more accurate (i.e., unbiased) F -values, we will include study site and gender, as covariates in all ANOVA analyses (i.e., perform a one-way between-subjects Analysis of Covariance for each outcome). Assessing relative efficiency entails generating F -values for comparison purposes and does not require determining whether the group differences are significant; however, adjusting for non-ignorable clustering will allow us to avoid deviation from a type I error rate of .05 and calculate F -values that most precisely reflect group differences for each outcome. Responsiveness to change will be assessed, in part, by comparing standardized mean responses, which will not require conducting an inferential test and therefore will not be impacted by type I or type II error rates. To assess responsiveness to change, we will also calculate partial correlations with a global impression of change measure and residualized change scores for each self-reported outcome,¹¹³ adjusting for variability due to gender and study site. Just as for our relative efficiency assessment, examination of partial correlations will not entail significance testing, but instead generating correlation coefficients for comparative purposes; however, we will partial out variability due to gender and study site to obtain precise (i.e., unbiased) estimates of covariance between a global impression of change measure and self-report outcomes.

Based on our recent R21 study (R21AT008854), in which we had an overall attrition rate of 20% across all study arms, we predict an overall attrition rate of 20% across our three study arms.

When a participant drops out, we will attempt to obtain information from that LEO regarding the reason for withdrawal. This information will allow us to determine the nature of the missing data (i.e., missing completely at random, missing at random, missing not at random) for analytic purposes; assess whether the withdrawal is due to a protocol violation and if the LEO experienced an AE due to the intervention (if the LEO is in the MBRT or SME arm); and obtain information that could inform future program modifications (e.g., increase the flexibility of program delivery, reduce participant burden, etc.). All protocol violations will be handled by having the Co-PIs meet with relevant study staff to identify the nature of the violation, the reason for the violation, and potential remediations; the Co-PIs will then work with all relevant study staff to implement a remediation plan and decide on a timeframe for re-assessing the procedure to ensure the violation is not re-occurring.

9.2.1 Treatment Assignment Procedures

Randomization will be stratified first by study site, and then within study site by gender. We will employ a permuted-block randomization procedure, stratifying by gender, to assign participants to study arms. We will employ this randomization procedure to: 1) be able to optimize the study procedures we plan to use in a future fully-powered efficacy RCT, 2) obtain parameter estimates that reflect the causal impact of MBRT on outcomes, 3) assess measure sensitivity and responsiveness in a way that reflects the causal impact of MBRT on participants, and 4) ensure balance within strata and across study arms.

Using procedures piloted in our R21 (R21AT008854), following baseline assessment, study staff not involved in data collection will randomly assign participants to condition using SPSS and REDCap. The study statistician will create an allocation table using SPSS, and upload it to REDCap, which will be used to implement the randomization procedure at each site. All trial randomization codes will be stored within REDCap, which is a secure (HIPAA-complaint) internet-based survey and data management software system housed on a secure server at Oregon Health and Science University.

This study does not meet criteria for a double- or triple-blinded RCT, as the study participants will be aware of their intervention assignment. To limit possible bias, the participants will be asked to not reveal their treatment assignment to data collection staff. Masking will be maintained by compartmentalizing study staff to a certain category of tasks that will prevent the study staff analyzing data from interacting with study participants and knowing participant names or any other personally identifying information, the study staff involved in implementing the intervention from being involved in data collection and analysis, the study staff involved in randomizing study participants and informing them of their study arm assignment from being involved in intervention implementation and data collection, and the study staff involved in data collection from knowing study arm assignment. Only study staff involved in recruitment activities will have access to both participant names and unique ID codes. The study statistician will monitor protocol fidelity around masking by maintaining contact with study staff involved in intervention implementation, data collection, and randomization to ensure that masking is maintained and identify any protocol violations. If a protocol violation occurs around masking, the study statistician will consult with the MPIs to identify the nature of the violation, the reason for the violation, and potential remediation plans. The study statistician will then implement the remediation plan by working with relevant study staff. Our study protocol does not require unblinding at any point during the study phase; however, if an unforeseen situation requires that unblinding becomes necessary, the study statistician, in consultation with the MPIs, would coordinate and implement the unblinding. If additional study staff beyond the statistician and MPIs are necessary to implement the unblinding, the statistician will only enlist the help of study staff who are absolutely necessary to implement the unblinding. If the unblinding compromises a study staff's ability to engage in his/her/their assigned task, we will replace that study staff member.

9.3 Definition of Populations

Our sensitivity and responsiveness analyses will utilize an ITT approach. If attrition occurs, the study statistician will review the reasons for withdrawal to determine if missing data are missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR). If data are MCAR, then we will use a complete-case approach to estimate parameters and conduct sensitivity and responsiveness analyses. If missing data are MAR or MNAR, we will employ a multiple imputation approach to impute data before estimating parameters and conducting sensitivity and responsiveness analyses. We will also estimate parameters and conduct sensitivity and responsiveness analyses using a complete-case approach for comparison purposes.

9.4 Interim Analyses and Stopping Rules

Interim analyses are not included in our protocol and will not be necessary to assess our study aims.

The study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints (in this case, the trial will be suspended versus stopped completely to allow assessment and modification of recruitment procedures); (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping

the trial. MPI Christopher will include an assessment of external information that might impact the viability of the trial in the annual progress report to NIH and will consult with the IMC to assess the impact of significant data loss due to problems in recruitment, retention, or data collection.

The IMC members are Dr. Scott Mist, Dr. Art Blume, and Dr. Seema Clifasefi. Dr. Mist is a biostatistician, Drs. Blume and Clifasefi are clinical psychologists with combined experience with clinical trials, mindfulness-based interventions, and adaptations of clinical protocols for underserved and high stress populations. The IMC is composed to ensure that the safety of study subjects is protected while the scientific goals of the study are being met.

The IMC members will not be associated with this research project, are not part of the key personnel involved in this grant, and have not collaborated with the two MPIs, Drs. Christopher and Bowen, within the past 3 years. Written documentation attesting to absence of conflict of interest will be collected at least annually, and each time there is a change in site investigators and/or institutions involved in the study. Thus, the IMC will be able to work independently of the MPIs. The members of the IMC will be qualified to review the patient safety data generated by this study.

The IMC will serve in accordance with the guidelines set forth in a charter provided to each member. IMC members will review and agree to the charter at the initial meeting. If changes to the charter are necessary, the IMC will review and affirm their agreement with the changes. Their concurrence will be noted in the IMC meeting summary. The IMC will typically meet twice a year, or as deemed necessary. A quorum of more than half of the IMC members is required to convene a meeting of the IMC. The IMC will approve the final protocol of the study before the study begins enrolling participants. In monitoring the data and safety throughout the trial, the IMC may recommend continuation of the trial, modifications to the trial, or termination of the trial in the event of overwhelmingly significant efficacy difference between groups or unacceptable adverse events.

Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports, including participant recruitment, retention/attrition, and AEs will be provided to the IMC members following each of the quarterly reviews. 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 IMC and will be forwarded to the IRB and NCCIH. The IRB and other applicable recipients will review progress of this study on an annual basis.

The study team will generate annual Study Reports for the IMC and will provide information on the following study parameters: recruitment, retention, enrollment by month, demographics, subject status, treatment duration, and AE status. Study Report tables will be generated only from aggregate (not by group assignment) baseline and aggregate safety data for the study population. A separate Closed Safety Report, with unmasked group baseline and safety data, will be generated for the IMC by a designated unmasked member of the team, but

will not be reviewed by the study team. As noted above, we will also review quarterly with the IMC subject accrual, subject status, adherence data, AEs and SAEs.

During the funding of this study, any action by the IRB or one of the study investigators that results in a temporary or permanent suspension of the study will be reported to the NCCIH Program Official within one business day of notification.

9.5 Outcomes

Outcomes will be analyzed using quantitative analyses (sensitivity and responsiveness) after creating composite scores for self-report measures and physiological outcomes. For behavioral data, we will analyze individual behavioral items as well as a composite score.

Committee oversight of outcome analyses and results is not included in our protocol (oversight of AE information is discussed above in section 9.4). However, Drs. Christopher (Portland) and Witkiewitz (Albuquerque) will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. The primary source of research materials will be a combination of self-report (i.e., psychological resilience, trauma, alcohol misuse, depression, suicidality, burnout, and aggression), physiological (C-RP, IL-6, IL-10, TNF- α), and behavioral (use of force reports, e.g. BlueTeam database) outcomes. Self-report measures will be collected via Qualtrics; psychophysiological data will be collected via a dried blood spot kit; and audio homework assignment data will be collected via Ilumivu; and study forms will be entered by the research team and stored electronically on REDCap. Behavioral data will be obtained from the database with the assistance of police department staff. Drs. Christopher (Portland) and Witkiewitz (Albuquerque) will oversee data downloads from Qualtrics, REDCap, and Ilumivu as well as psychophysiological and behavioral data collection; a second research team member will verify that data downloads and collection were done correctly. The project manager will manage data storage.

9.5.1 Primary Outcome

Given that our goal is to optimize study procedures and outcome measurement through sensitivity and responsiveness analyses, we will not be grouping outcome measures into primary and secondary categories. The data we obtain through this trial will be used to identify primary and secondary outcomes for a future fully-powered efficacy RCT.

9.5.2 Secondary Outcomes

Given that our goal is to optimize study procedures and outcome measurement through sensitivity and responsiveness analyses, we will not be grouping outcome measures into primary and secondary categories. The data we obtain through this trial will be used to identify primary and secondary outcomes for a future fully-powered efficacy RCT.

9.6 Data Analyses

Quantitative:

Following best practice guidelines¹¹⁴⁻¹¹⁶ including CONSORT feasibility guidelines¹⁰⁶ and past research,^{111, 117} we will measure sensitivity (using a relative efficiency approach) and

responsiveness to change (examining within-group change over time). Relative efficiency analyses will be used to establish that our outcome measures are sensitive to differences between our treatment arm of focus (MBRT) and our other two arms - an active control arm (SME) and a no-treatment control arm (NIC). Therefore, sensitivity analyses will focus on assessing the degree to which outcomes are sensitive to study arms and not whether change is significant. Sensitivity to differences for MBRT compared to SME and NIC will be assessed by examining the relative efficiency of each outcome variable for MBRT versus SME and NIC separately. We will calculate the relative efficiency for MBRT versus SME by conducting one-way, between-subjects Analysis of Covariance (ANCOVA) analyses with MBRT versus SME as the independent variable and each outcome variable at post-training as the dependent variable; we will include study site and gender as covariates. We will also conduct ANOVAs using the same independent and dependent variables to ensure that all inferential tests are conducted and identify any potential Type II Errors among the ANCOVAs. We will then divide the *F*-statistic for each behavioral (BlueTeam/departmental use of force; individual indicators of use of force as well as a composite score of use of force using the individual indicators), physiological (C-RP, IL-6, IL-10, TNF- α), and self-report (aggression, alcohol misuse, depression, suicidal ideation, trauma symptoms, burnout, and psychological resilience) outcome by the largest *F*-statistic among these analyses, such that the larger the number, the more sensitive that outcome is to the impact of MBRT relative to the active control group.¹¹²

To calculate the relative efficiency of MBRT versus NIC, we will conduct one-way, between-subject ANCOVAs with MBRT vs. NIC as the independent variable, each outcome variable at post-training as the dependent variable, and gender and study site as covariates. Again, we will also conduct ANOVAs using the same independent and dependent variables to ensure all inferential tests are conducted and identify any potential Type II Errors among the ANCOVAs. We will then divide the *F*-statistic for each behavioral, physiological, and self-report outcome by the largest *F*-statistic among these analyses; again, the larger the number, the more sensitive the outcome is to MBRT relative to the no-treatment control group. These sensitivity analyses will allow assessment of which behavioral, physiological, and self-report outcomes are most sensitive to MBRT.

Responsiveness to change across time will be assessed in the MBRT arm for behavioral, physiological, and self-report outcomes by: 1) calculating and comparing standardized mean responses (SMR) for outcomes by subtracting the baseline mean response for each outcome from the post-intervention mean response for that outcome, and dividing by the standard deviation of change for that outcome;^{121, 122} 2) calculating and comparing partial correlation coefficients (adjusting for study site and gender) between a global impression of change measure that captures the subjective experience of changes in stress, job performance, and resilience at post-intervention and residualized change scores (baseline to post-intervention) for each self-report outcome.¹²³⁻¹²⁵ For both SMR values and correlation coefficients, the higher the absolute value, the more responsive the outcome is to change across time in the MBRT arm. We will conduct additional correlation analyses using the same variables without adjusting for study site and gender to identify any potential Type II Errors among the partial correlations.

In addition, we will examine data for any indications of systematic site differences. Using baseline data (where sample size will be greatest) and pooling arms, since no treatment differences are expected at baseline, distributions of standardized responses on outcome measures will be summarized, graphed, and compared across sites. Key parameters, reliability

estimates (i.e., Cronbach's alpha), and intraclass correlations will be estimated and checked for discrepancies between sites. Identified discrepancies will be investigated to determine site-specific issues that would undermine assumptions of conceptual and structural equivalence of measurement.

Given the optimization aim of our study, our analyses will not adjust for intraclass correlations across study arms (and any heterogeneity in those correlations). Our study will allow us to obtain information about the magnitude of intraclass correlations and the degree to which they are heterogeneous across study arms, which we will use for our data analysis plan in a future fully-powered efficacy RCT.

Qualitative:

In the proposed study, individual feedback phone interviews will be conducted following post-intervention assessment to qualitatively assess participants' experience of all procedures. All interviews will be conducted within two weeks of the end of the intervention period to maximize internal consistency. It is anticipated that each interview will last approximately 15-20 minutes.

MPIs Bowen and Christopher have developed draft questions for the feedback interview guide. Consistent with the timeline submitted in the proposal, the study team will finalize the feedback interview guide and protocol by month 4 of study year 1. Per recently published guidelines for maximizing impact of qualitative research in feasibility studies to inform an RCT,¹²⁶ broad feedback interview question categories include: 1) intervention content and delivery; 2) trial design, conduct, and process; 3) treatment outcomes; and 4) measures and assessment burden. Sample questions include:

Intervention Content and Delivery (MBRT and SME groups)

- If you invited a friend to participate in the training, what would you tell them?
- What aspects of the training were *most* helpful for you?
- What aspects of the training were *less* helpful for you?
- What were the biggest obstacles to fully engaging in or completing the training?

Trial Design, Conduct, and Process (all groups)

- What was your reaction to being randomized to the _____ group?
- Were reminder calls/contact with coordinator helpful (too much/ too little)?
- What feedback do you have to help improve the experience of future officers who will take part in the same study?

Outcomes (MBRT and SME groups)

- What changes, if any, did you notice in your resilience after completing the training?
- Did the training affect your ability to cope with stress?
- Has the training impacted your day-to-day work?

Measures and Assessment Burden (all groups)

- What was your experience with the computerized measures (i.e., assessment burden, clarity of questions, ease of administration process)?

- What was your experience with the dried blood spot collection (i.e., burden, clarity of instructions)?

Individual phone feedback interviews will be conducted using standardized methods, as described by Flick¹²⁷. Each interview will be conducted by a trained research assistant, and will be audio recorded and transcribed. LEOs will be instructed to refrain from disclosing unnecessary personal information. Informed consent procedures will clearly state that participation in feedback interviews is voluntary, and participants will be instructed to share only what they choose to. They will be reminded that all content will be de-identified to protect their anonymity.

A thematic analysis approach¹²⁸⁻¹³⁰ will be used to explore participant experiences with the goal of understanding feasibility, acceptability and impact of the assessments, protocol, and intervention. Analyses will consist of: 1) familiarization, 2) initial coding, 3) creating themes, 4) reviewing themes, 5) defining and naming themes, and 6) data interpretation. MPI Christopher and two trained research team members will initially independently review feedback interview data. Emerging themes will be used to develop a coding scheme and the team will then independently apply the codes from the finalized code structure. The coding team will meet regularly to review coding and resolve differences by in-depth discussion and negotiated consensus to ensure inter-rater reliability. A dynamic approach will be used by analyzing the first wave of feedback interview data following initial MBRT and SME groups, which may result in changes to intervention or trial procedures, then reassessing the impact of these changes on participants' experience of assessments, protocol, and/or intervention.^{131, 132} We will also assess the equivalence of experience across sites, and confirm self-report measurement sensitivity based on the relationship between qualitative reports of change and quantitative results on outcome measures.¹³³

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Self-report data will be collected using Qualtrics, a data collection software platform that operates on a secure server. A dried blood spot kit will be used to collect blood spots. Each participant will be identified by a unique ID code and data will be linked to unique ID. Personal identifying information (i.e., names and phone numbers) will only be used on forms such as the informed consent or telephone contact logs, where they are essential. Any forms with identifying information will be kept secure and separate from data. Tracking forms linking names and unique study ID codes will be stored on Box, a secure, HIPAA-compliant data storage system, accessible only to IRB-authorized research staff.

10.2 Data Management

Data will be stored in REDCap and Qualtrics. REDCap is a secure (HIPAA-complaint) internet-based survey and data management software system housed on a secure server at Oregon Health and Science University. Qualtrics is a data collection software platform supported by Pacific University that operates on a secure server.

10.3 Quality Assurance

10.3.1 Training

Goals and Strategies: All study staff will be trained in NIH Good Clinical Practice. Interventionists will undergo intensive MBRT or SME training. Ongoing oversight and supervision of all intervention procedures will occur throughout the trial, including weekly review of MBRT and SME sessions and clinical supervision. We will hone intervention protocols and session coding procedures, train coders, and adapt the Adherence and Competence Scale⁷⁷ for use with both MBRT and SME to ensure parallel domains are assessed, and that fidelity is equivalent, both across sites and between MBRT and SME interventions. Specifically, four of the eight sessions (50%) will be randomly selected from each MBRT and SME group to be rated by two independent coders, who will be randomly assigned to session. Raters will be trained until they meet $\geq .75$ interrater reliability, then meet for periodic calibration meetings to prevent rater drift.

10.3.2 Quality Control Committee

Our Steering Committee will oversee quality control.

10.3.3 Metrics

Senior study staff will visit both study sites to ensure equivalent equipment, training in lab-based protocols, and access to oversight and supervision. All study staff will train in NIH Good Clinical Lab practices. Corrective feedback will be given on all procedures by MPIs and Co-Is throughout the trial. Study coordinators at each study site will spot check self-report and meditation practice outcomes at all time points to assess for out of range values and excessive missing data.

10.3.4 Protocol Deviations

The Steering Committee will meet monthly to advise MPIs on study coordination and management, and the IMC will meet regularly to review procedures and any deviations that occur. Deviations will be documented in a study log maintained by the MPI's at Pacific and the site PI at UNM.

10.3.5 Monitoring

There will be ongoing oversight and supervision of all procedures throughout the trial, including weekly contact between study investigators, weekly site team meetings, and bi-weekly multi-site full staff meetings to review lab and data collection protocols. Investigators will review a checklist of all procedures to ensure completion and fidelity to each stage, and take corrective action as needed. To ensure equivalence of data management, appropriate study staff at both study sites will be trained in: 1) Ilumivu (homework adherence data); 2) Microsoft Excel (to which Ilumivu data will be uploaded at post, 3- and 6-months); 3) NVivo (analyze qualitative feedback interview data); 4) SPSS (analyze quantitative data), 5) Qualtrics (collect and store self-report data); Inquisit (for Sustained Attention Response Task) and 6) REDCap (used for project management and completion tasks such as form completion, tracking randomization assignment, and attendance). Procedures for data collection, tracking, and management will be identical across sites.

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRB responsible for oversight of the study.

11.2 Informed Consent Forms

REDCap consent forms will be obtained from each participant. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be emailed to each participant and this fact will be documented in the participant's record. Signed informed consent forms will be printed and stored in a locking file cabinet within Project Coordinator Taylor's (Portland) or Co-I Witkiewitz's (Albuquerque) locked research office. Members of the research team will complete a form documenting the informed consent process, which will be stored electronically on the secure REDCap system. No special classes or vulnerable participants will be involved in the study. All participants are LEOs, and thus fluent English speakers, literate, and ≥ 21 years of age. All participants will thus be able to complete informed consent.

11.3 Participant Confidentiality

Any data, specimens, forms, reports, audio and video recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All study data will be stored on Box, a secure, HIPAA-compliant data storage system housed and supported by Pacific University and University of New Mexico. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NCCIH, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NCCIH, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

12. COMMITTEES

Steering Committee: Drs. Bowen, Christopher, Witkiewitz, and NCCIH staff.

13. PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures developed by the Steering Committee.

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15. SUPPLEMENTS/APPENDICES

15.1 Procedures Schedule

