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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Principal Investigators:

Michael Christopher, PhD, Professor, Pacific University

Sarah Bowen, PhD, Associate Professor, Pacific University

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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.

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STUDY TEAM ROSTER

Pacific University

Michael Christopher, PhD, 503-327-1563, mchristopher@pacificu.edu

Sarah Bowen, PhD, 206-778-7080, bowen@pacificu.edu

Matthew Hunsinger, PhD, 503-352-3612, matthewh@pacificu.edu

Lt. Richard Goerling, 503-501-0662, rgoerling@pacificu.edu

Janae Taylor, 503-352-2408, janae.taylor@pacificu.edu

University of New Mexico

Katie Witkiewitz, PhD, 505-277-5953, katiew@unm.edu

Oregon Health & Science University

Barry Oken, PhD, 503-494-7772, oken@ohsu.edu

Albuquerque Police Department/University of New Mexico

Nils Rosenbaum, MD, 505-924-6018, nrosenbaum@cabq.gov

PARTICIPATING STUDY SITES

Pacific University

MPI: Michael Christopher, PhD, 503-327-1563, mchristopher@pacificu.edu

MPI: Sarah Bowen, PhD, 206-778-7080, bowen@pacificu.edu

University of New Mexico

Co-I: Katie Witkiewitz, PhD, 505-277-5953, katiew@unm.edu

Oregon Health & Science University

Co-I: Barry Oken, PhD, 503-494-7772, oken@ohsu.edu

Portland Police Bureau

Liaison/Co-I: Lt. Rich Goerling, 503-501-0662, rgoerling@pacificu.edu

Albuquerque Police Department/University of New Mexico

Co-I: Nils Rosenbaum, MD, 505-924-6018, nrosenbaum@cabq.gov

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 two 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 ≥ 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 biomarker (HR, BP, Cortisol and sAA) data collection
2.3 Hone critical incidents stress challenge procedures to ensure physiological biomarker responsiveness
2.4 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

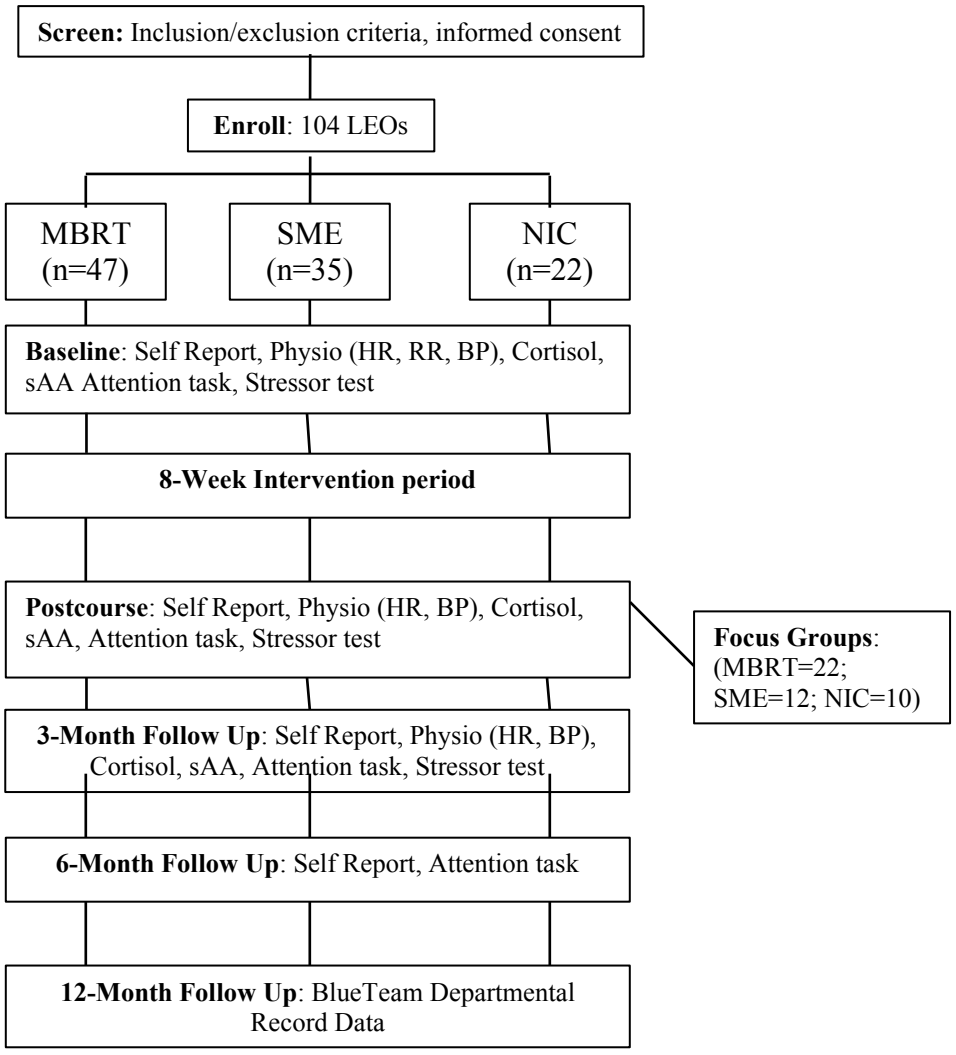
4*:* Assess participant experience and optimize outcome measures across sites

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) 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, saliva cortisol collection, physiological measures (heart rate, respiration rate, and blood pressure), a computerized attention task, and a stressor test. A subsample of participants will participate in a post-intervention focus group. 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 14 days of the start of 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 (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 each study site). Using a 2:1.5:1 randomization allocation ratio for MBRT, SME, and NIC conditions, respectively, across two sites, 47 participants will be randomized to MBRT (~24 at each site); 35 to SME (~17 at each site); and 22 to NIC (11 at each site). Participants will be stratified by gender to ensure equivalent gender representation across conditions.

Using an approximate 2:1:1 ratio, a random sample of 15, 8, and 7 MBRT, SME, and NIC participants, respectively, will be invited to participate in focus groups at each site after the post-course assessment. Purposeful sampling will be used to ensure adequate gender representation in all conditions. We anticipate approximately 11 MBRT, 6 SME, and 5 NIC participants will agree to attend for a total of 44 (22 MBRT, 12 SME, 10 NIC).

1. STUDY OBJECTIVES

1.1 Primary Objective

Objective 1: Enhance efficiency of recruitment, engagement, and retention across sites. We will successfully enroll 52 LEOs per site, 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 ≥80% at *6 months*.
Per NCCIH SARP guidelines, we will gauge accrual and retention by accrual of ≥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 ≤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 ≤5% rate data procedural errors, tracked in REDCap (same procedure used in R21 study). Based on the R21 study, we expect ≤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 both 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 (≥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 (BlueTeam) data for 100% of participants at both 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 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 ≥85% overall fidelity (including session content coverage, presence of main themes, and global skills). Interrater reliability between all coders will be ≥.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 focus groups 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, awaking 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 Review[34] 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-analysis[38] 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 iMINDr app, which is programmed with exercises and monitoring software, and worksheets to track daily experiences and behaviors such as triggers and stress reactions.

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 colleagues[71] 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 iMINDr 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) and Albuquerque Police Bureau (APB). 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. We will make concerted efforts to recruit a target final sample comprising ≥ 16% women and ≥ 16% racial/ethnic minorities in Portland, and ≥ 16% women and ≥ 35% racial/ethnic minorities in Albuquerque.

We will recruit 104 participants (52 participants at each site). Using a 2:1.5:1 randomization allocation ratio for MBRT, SME, and NIC conditions, respectively, across the two study sites, 47 participants will be randomized to MBRT (~24 at each site); 35 to SME (~17 at each site); and 22 to NIC (11 at each site). 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.

At the Oregon study site, training and data collection will 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, training and data collection will take place at The Department of Psychology at the University of New Mexico (UNM).

Assessment and 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.

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 will occur during Year Two in Month 8, directly preceding the beginning of MBRT and SME training for the second cohort of participants in Months 8 and 9.

The first phase of post-intervention data collection will occur during Year 2, Month 8, directly following the end of MBRT and SME training for the first cohort of participants; the second phase of post-intervention data collection will occur in Year 2, Month 12, directly following completion of MBRT and SME training for the second cohort of participants. Qualitative data collection (i.e., focus groups) 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 2. 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 6. 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 3, Month 12.

MBRT will be delivered in 8 weekly 2-hour sessions with an extended 6-hour class in weeks 1 and 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 the iMINDr app, which is programmed with exercises and monitoring software, and worksheets adapted from Mindfulness-Based Relapse Prevention[75] to track daily experiences and behaviors such as triggers and stress reactions. MPI Bowen will co-lead the MBRT intervention at the Oregon study site with an advanced graduate student; a different interventionist will lead the MBRT intervention at the New Mexico study site with the assistance of an advanced graduate student. Co-Is Goerling and Witkiewitz will collaborate with Bowen to prepare for the training at the Oregon study site; Goerling, Witkiewtiz, 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, 2.5-hour class with weekly homework (amount matched to MBRT), one extended 6-hour session, 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-recorded. Under the supervision of Dr. Christopher, Dr. Witkiewitz, and consultant Hoge, advanced graduate students at both sites will review four randomly selected audio-recorded 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 both 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. In addition, participants in the MBRT groups will receive the training from different interventionists across sites; the same will be the case for SME participants. 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] Given that there will be covariance between study site and interventionist, and considering the size of our sample, we will include study site but not interventionist 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 setting up data collection appointments 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 will be implemented at both sites – with all training, recruiting, randomization, etc. completed in parallel at both sites. Overall design and direction of the protocol will reside in Oregon, and processing of cortisol will be centralized at Salimetrics (State College, PA).

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

LEOs will be recruited from PPB and APD. 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 attend 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 and APD. 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. 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 and APD, we will recruit 104 LEOs (52 per site) for study participation, conducted via: 1) 10-15 minute recruitment sessions, 2) emailed invitations sent to all eligible LEOs, 3) informational website and flyers posted at PPB and APD facilities, and 4) community-based police organization leadership. We used similar recruitment methods for our R21 study and met recruitment goals. Co-I's Goerling and Rosenbaum will oversee recruitment at PPB and APD, 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, and will provide verbal consent for a brief phone screening. If the officers and research staff believe the study may be a good fit, the officers will be scheduled for an in-person screening visit where they will provide written informed consent and screen for eligibility criteria. Eligible LEOs will complete the individual baseline assessments immediately after the in-person screening and consenting process. The screening and baseline visits will be completed at the PU-HRC (Portland) or UNM (Albuquerque).

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 written informed consent from all participants prior to 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-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.

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 both sites across the three arms.

Participants will be notified of group assignment by a study team member. Participants assigned to MBRT and SME conditions will receive information regarding course structure, dates/times, and class format, and 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 2 hours each, with the exception of weeks 1 and 7 which are extended 6-hour classes, for a total of 24 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.

MBRT and SME intervention groups will be held in reserved rooms able to accommodate up to 25 people - specifically, the Psychology Research Lab in Portland, and at UNM Department of Psychology in Albuquerque. 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, 2.5 hour class, except for weeks 1 and 7 which are extended to 4.5-hour classes, for a total of 24 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 recorded. Under supervision of Drs. Christopher, Bowen, Witkiewitz and consultant Hoge, advanced graduate students at both sites will review four randomly selected audio-recorded 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 NCI 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 24 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 iMINDr software.

6. STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessment	Phone Screen	In Person 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	X				
Written 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
Current Psychological Treatment			X	X	X	X
Tobacco Use			X	X	X	X
Adverse Childhood Experiences			X			
Blood Pressure			X	X	X	
Heart Rate			X	X	X	
Respiration Rate			X	X	X	
Salivary Alpha Amylase			X	X	X	
Salivary Cortisol			X	X	X	
State Distress			X	X	X	

Assessment	Phone Screen	In Person Screen	Baseline, Enrollment, Randomization: Visit 1	Post-intervention: Visit 2	3 Month Follow-Up: Visit 3	6 Month Follow-Up: Visit 4
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

There will be two consenting processes: one prior to screening (telephone administered by Research Assistant or Project Coordinator), and one prior to study enrollment (administered in person 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 or UNM research offices and be read a form asking them to provide verbal consent to complete a phone eligibility screen, which will request contact, employment, and demographic information.

For those eligible, Research Assistants will obtain written informed consent from all participants prior to 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-record sessions. The signing of this form indicates the study enrollment date.

All signed informed consent forms will be 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 to help determine if it is appropriate to schedule a screening visit. If they are likely eligible and interested, they will be invited to come to the PU-HRC or UNM research offices for a screening visit to complete the informed consent and screen 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 attend 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 in-person screening visit, 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 immediately complete the individual baseline assessments.

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 the second 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 baseline assessment, must occur within 60 days of screening.

Baseline Assessments

- Adverse Childhood Events
  - Childhood Trauma Questionnaire[85]
- Treatment Expectancy and Credibility
  - Expectancy/Credibility Questionnaire[86]
- Heart Rate, Respiration Rate, and Blood Pressure
  - Omron HEM-907XL
  - Caretaker4 cNIBP
- Salivary Alpha Amylase*
  - SalivaBio oral swab
- Salivary Cortisol*
  - SalivaBio oral swab
- State Distress**
  - Visual Analogue Scale[87]

- Primary Appraisal Secondary Appraisal[88]

- Psychological Resilience
  - Brief Resilience Scale[89]
- Alcohol Misuse
  - PROMIS Alcohol Use[90]
  - PROMIS Alcohol Use Negative Consequences[90]
- Depression
  - PROMIS Depression[91]
- Sleep Disturbance
  - PROMIS Sleep Disturbance[137]
- Mindfulness
  - Five Facet Mindfulness Questionnaire – Short Form[138]
- Self-Compassion
  - Self-Compassion Scale – Short Form[139]
- Aggression
  - Buss Perry Aggression Questionnaire – Short Form[140]
- Suicidal Ideation
  - Concise Health Risk Tracking - Self-Report[82]
- Trauma Symptoms
  - PTSD Checklist for DSM5[92]
- Burnout
  - Oldenburg Burnout Inventory[93]
- Sustained Attention to Response Task[134]
- Interoceptive Awareness
  - Multidimensional Assessment of Interoceptive Awareness-II[135]
- Perceived Stress
  - Perceived Stress Scale-10[136]

* To determine salivary alpha amylase (sAA) and cortisol stress reactivity and recovery, saliva samples will be collected 5 minutes before, immediately after, and 15, 25, 35, and 45 minutes after the SECPT using the SalivaBio swab method (Salimetrics, State College, PA). For each sample,

participants will be asked to place the swab under their tongue on the floor of their mouth for 90 seconds.

**The state distress evaluations will take place during a socially evaluated cold-pressor task (SECPT). The SECPT is a validated standardized protocol for experimental stress induction in humans. As part of the task, participants will be informed that they will be videotaped and that these video recordings will be analyzed for facial expression. Participants will then be asked to insert their right hand up to and including the wrist into ice water (2º C). It will be made clear that the procedure can be uncomfortable and that participants can remove their hand from the ice-cold water at their own discretion without consequences. Participants who keep their hand in the water for 3 minutes will be instructed at that point to remove their hand. After the SECPT, all participants will watch a neutral 60-minute video (Planet Earth II or Blue Planet II) during the recovery period.

Randomization

Immediately 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.

Participants will then be notified of group assignment by a study team member. Participants assigned to MBRT and SME conditions will receive information regarding course structure, dates/times, and class format, and 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 attend 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 or APD, 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):

- Heart Rate, Respiration Rate, and Blood Pressure
  - Caretaker4 cNIBP
  - Omron HEM-907XL
- Salivary Alpha Amylase
  - SalivaBio oral swab
- Salivary Cortisol

    - SalivaBio oral swab
- State Distress
    - Visual Analogue Scale
    - Primary Appraisal Secondary Appraisal
- 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 Change[141]
- Acceptability

- Acceptability of Assessment Procedures
- Postcourse Satisfaction Survey (MBRT and SME)

- Intervention Compliance
  - Meditation Practice Questionnaire (MBRT)
  - iMINDr[95] (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.

- Heart Rate, Respiration Rate, and Blood Pressure (3 month only)
  - Caretaker4 cNIBP
  - Omron HEM-907XL
- Salivary Alpha Amylase (3 month only)
  - SalivaBio oral swab
- Salivary Cortisol (3 month only)
  - SalivaBio oral swab
- State Distress (3 month only)
  - Visual Analogue Scale
  - Primary Appraisal Secondary Appraisal
- 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)
  - iMINDr[95] (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)
  - BlueTeam[96] Database

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 or exposure to the video stress

challenge procedures.

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) 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) 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 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 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 visit, they will be referred for psychological treatment and evaluated by Drs. Christopher (Portland) 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 both 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 practices[103-105] 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, gender, and interventionist 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, study site, and interventionist. 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, study site, and interventionist 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 calculating mean responses across time or area of the curve for 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 (HR, BP, sAA, cortisol), and behavioral (use of force reports in the BlueTeam database) outcomes. Self-report measures will be collected via Qualtrics; psychophysiological data will be collected via saliva, HR, RR, and BP; and audio homework assignment data will be collected via iMINDr; 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 iMINDr 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 guidelines[114-116] including CONSORT feasibility guidelines[106] 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 use of force; individual indicators of use of force as well as a composite score of use of force using the individual indicators), physiological (HR, BP, sAA, and cortisol), 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. When examining sAA and cortisol, AUCi will be used as the dependent variable.

To optimize measurement of stress reactivity, we will assess HR and BP during the three phases (baseline, reactivity, and recovery) of the stress induction task as separate dependent variables. Lastly, we will examine the speed of return to baseline during the recovery phase of the stress

induction task for sAA, cortisol, HR, and BP as additional dependent variables.[118-120] 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 heterogenous across study arms, which we will use for our data analysis plan in a future fully-powered efficacy RCT.

Qualitative:

In the proposed study, focus groups will be conducted following post-intervention assessment to qualitatively assess participants' experience of all procedures. Using an approximate 2:1:1 ratio, a random sample of 15, 8, and 7 MBRT, SME, and NIC participants, respectively, will be invited to participate in 2 MBRT, 1 SME, and 1 NIC focus groups at each site, for a total of 8 focus groups. Each participant will attend only one focus group. We anticipate approximately 11 MBRT, 6 SME, and 5 NIC participants will agree to attend, for an anticipated total focus group sample of 44 (22 MBRT, 12 SME, 10 NIC) across sites. All focus groups will be conducted within two-weeks of the end of the intervention period to maximize internal consistency. It is anticipated that each focus group will last approximately 60-90 minutes.

MPIs Bowen and Christopher have developed draft questions for the focus group guide. Consistent with the timeline submitted in the proposal, the study team will finalize the focus group 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 focus group 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 of coming to the lab for testing?
- 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 saliva collection (i.e., burden, clarity of instructions)?

Focus group discussions will be conducted using standardized methods, as described by Krueger and Casey[127]. Each group will be co-led by a trained moderator and an assistant, and will be audio recorded and transcribed. The moderator will introduce the study and guide discussion, and the assistant will handle logistics, note preliminary themes, and assist in summarizing the discussion, sharing the summary with participants at the end of the group (Krueger & Casey)[127]. LEOs will be instructed to refrain from disclosing unnecessary personal information. Informed consent procedures will clearly state that participation in focus groups 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 approach[128-130] 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 focus group 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 focus group 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

Trained graduate research assistants will collect participant data. Assessors will be blinded to condition. Self-report data will be collected using Qualtrics, a data collection software platform that operates on a secure server. Psychophysiological equipment will be used to assess heart rate, respiration rate, and blood pressure (Caretaker4 cNIBP). The SalivaBio oral swab method will be used to collect saliva. 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 REDCap, a secure internet-based survey and data management software system housed on a secure server, 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 audio-recorded MBRT and SME sessions and clinical supervision. We will hone intervention protocols and session coding procedures, train coders, and adapt the Adherence and Competence Scale[77] 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 ≥.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. Spot checks on saliva procedures will be performed twice monthly at both sites by study coordinators. Corrective feedback will be given on all procedures by MPIs and Co-Is throughout the trial. Study coordinators at each 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 lab and assessment 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 sites will be trained in: 1) iMINDr (homework adherence data); 2) Microsoft Excel (to which iMINDr data will be uploaded at post, 3- and 6-months); 3) NVivo (analyze qualitative focus group 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

A signed consent form 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 given to each participant and this fact will be documented in the participant's record. Signed informed consent forms will be 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 $\geq$ 21 years of age. All participants will thus be able to complete informed consent.

11.3 Participant Confidentiality

Any data, specimens, forms, reports, audio 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.

14. REFERENCES

1. Eisendrath S, Gillung E, Delucchi K, Chartier M, Mathalon D, Sullivan J, Segal Z, Feldman M. Mindfulness-based cognitive therapy (MBCT) versus the health-enhancement program (HEP) for adults with treatment-resistant depression: a randomized control trial study protocol. *BMC Complementary and Alternative Medicine.* 2014;14(1):95.
2. Vollestad J, Sivertsen B, Nielsen GH. Mindfulness-based stress reduction for patients with anxiety disorders: evaluation in a randomized controlled trial. *Behav Res Ther.* 2011;49(4):281-288.
3. Violanti JM, Andrew ME, Mnatsakanova A, Hartley TA, Fekedulegn D, Burchfiel CM. Correlates of hopelessness in the high suicide risk police occupation. *Police Practice and Research.* 2016;17(5):408-419.
4. Violanti JM, Fekedulegn D, Andrew ME, Charles LE, Hartley TA, Burchfiel CM. Adiposity in policing: mental health consequences. *Int J Emerg Ment Health.* 2011;13(4):257-266.
5. Avdija AS. Stress and law enforcers: testing the relationship between law enforcement work stressors and health-related issues. *Health Psychology and Behavioral Medicine.* 2014;2(1):100-110.
6. Kop N, Euwema M, Schaufeli W. Burnout, job stress and violent behaviour among Dutch police officers. *Work & Stress.* 1999;13(4):326-340.
7. Kurtz DL, Zavala E, Melander LA. The Influence of Early Strain on Later Strain, Stress Responses, and Aggression by Police Officers. *Criminal Justice Review.* 2015;40(2):190-208.

8. Wang Z, Inslicht SS, Metzler TJ, Henn-Haase C, McCaslin SE, Tong H, Neylan TC, Marmar CR. A prospective study of predictors of depression symptoms in police. *Psychiatry Res.* 2010;175(3):211-216.
9. Faust KL, Ven TV. Policing Disaster: An Analytical Review of the Literature on Policing, Disaster, and Post-traumatic Stress Disorder. *Sociology Compass.* 2014;8(6):614-626.
10. McCarty WP, Skogan WG. Job-Related Burnout Among Civilian and Sworn Police Personnel. *Police Quarterly.* 2013;16(1):66-84.
11. Yun I, Lee C-H. Hazardous alcohol use among South Korean police officers: Examining predictions from general strain theory. *International Journal of Law, Crime and Justice.* 2015;43(2):194-213.
12. Bibbey A, Carroll D, Roseboom TJ, Phillips AC, de Rooij SR. Personality and physiological reactions to acute psychological stress. *International Journal of Psychophysiology.* 2013;90(1):28-36.
13. Nater UM, Skoluda N, Strahler J. Biomarkers of stress in behavioural medicine. *Curr Opin Psychiatry.* 2013;26(5):440-445.
14. Stalder T, Kirschbaum C, Kudielka BM, Adam EK, Pruessner JC, Wust S, Dockray S, Smyth N, Evans P, Hellhammer DH, Miller R, Wetherell MA, Lupien SJ, Clow A. Assessment of the cortisol awakening response: Expert consensus guidelines. *Psychoneuroendocrinology.* 2016;63:414-432.
15. Inslicht SS, Otte C, McCaslin SE, Apfel BA, Henn-Haase C, Metzler T, Yehuda R, Neylan TC, Marmar CR. Cortisol awakening response prospectively predicts peritraumatic and acute stress reactions in police officers. *Biol Psychiatry.* 2011;70(11):1055-1062.
16. Pineles SL, Rasmusson AM, Yehuda R, Lasko NB, Macklin ML, Pitman RK, Orr SP. Predicting emotional responses to potentially traumatic events from pre-exposure waking cortisol levels: a longitudinal study of police and firefighters. *Anxiety, Stress, & Coping.* 2013;26(3):241-253.
17. Violanti JM, Fekedulegn D, Andrew ME, Hartley TA, Charles LE, Miller DB, Burchfiel CM. The impact of perceived intensity and frequency of police work occupational stressors on the cortisol awakening response (CAR): Findings from the BCOPS study. *Psychoneuroendocrinology.* 2017;75:124-131.
18. Galatzer-Levy IR, Steenkamp MM, Brown AD, Qian M, Inslicht S, Henn-Haase C, Otte C, Yehuda R, Neylan T, C., Marmar CR. Cortisol response to an experimental stress paradigm prospectively predicts long-term distress trajectories in response to active police service. *Journal of Psychiatric Research.* 2014;56:36-42.
19. Groer M, Murphy R, Bunnell W, Salomon K, Van Eepoel J, Rankin B, White K, Bykowski C. Salivary measures of stress and immunity in police officers engaged in simulated critical incident scenarios. *J Occup Environ Med.* 2010;52(6):595-602.
20. Andersen JP, Dorai M, Papazoglou K, Arnetz BB. Diurnal and Reactivity Measures of Cortisol in Response to Intensive Resilience and Tactical Training Among Special Forces Police. *Journal of Occupational and Environmental Medicine.* 2016;58(7):e242-e248.
21. Patterson GT. The Relationship Between Demographic Variables and Exposure to Traumatic Incidents Among Police Officers. *The Australasian Journal of Disaster and Trauma Studies.* 2001;2(1):1-9.

22. Hartley TA, Violanti JM, Sarkisian K, Andrew ME, Burchfiel CM. PTSD symptoms among police officers: associations with frequency, recency, and types of traumatic events. *Int J Emerg Ment Health.* 2013;15(4):241-253.
23. Gersons BPR. Patterns of PTSD among police officers following shooting incidents: A two-dimensional model and treatment implications. *Journal of Traumatic Stress.* 1989;2(3):247-257.
24. Montgomerie JZ, Lawrence AE, Lamotte AD, Taft CT. The link between posttraumatic stress disorder and firearm violence: A review. *Aggression and violent behavior.* 2015;21:39-44.
25. Backteman-Erlanson S, Padyab M, Brulin C. Prevalence of burnout and associations with psychosocial work environment, physical strain, and stress of conscience among Swedish female and male police personnel. *Police Practice and Research.* 2013;14(6):491-505.
26. Queirós C, Kaiseler M, da Silva AL. Burnout as predictor of aggressivity among police officers. *Journal of Police Studies/Cahiers Politiestudies.* 2013;1(2).
27. Sack III RE. *Rethinking use of force: A correlational study of burnout and aggression in patrol officers*: Alliant International University, Fresno; 2009.
28. Ballenger JF, Best SR, Metzler TJ, Wasserman DA, Mohr DC, Liberman A, Delucchi K, Weiss DS, Fagan JA, Waldrop AE, Marmar CR. Patterns and predictors of alcohol use in male and female urban police officers. *Am J Addict.* 2011;20(1):21-29.
29. McNeill M. *Alcohol and the police workplace: Factors associated with excessive intake*: National Police Research Unit Payneham; 1996.
30. Oehme K, Donnelly EA, Martin A. Alcohol Abuse, PTSD, and Officer-Committed Domestic Violence. *Policing.* 2012;6(4):418-430.
31. Violanti JM. Suicide or undetermined? A national assessment of police suicide death classification. *Int J Emerg Ment Health.* 2010;12(2):89-94.
32. Everly GS, Flannery RB, Mitchell JT. Critical incident stress management (CISM): A review of the literature. *Aggression and Violent Behavior.* 2000;5(1):23-40.
33. Mitchell JT, Everly G. Critical incident stress management and critical incident stress debriefings: Evolutions, effects and outcomes. *Psychological debriefing: Theory, practice, and evidence.* 2000:71-90.
34. Rose S, Bisson J, Churchill R, Wessely S. Psychological debriefing for preventing post traumatic stress disorder (PTSD). *Cochrane Database Syst Rev.* 2002;2(2).
35. Adler AB, Litz BT, Castro CA, Suvak M, Thomas JL, Burrell L, McGurk D, Wright KM, Bliese PD. A group randomized trial of critical incident stress debriefing provided to US peacekeepers. *Journal of traumatic stress.* 2008;21(3):253.
36. Jacobs J, Horne-Moyer HL, Jones R. The effectiveness of critical incident stress debriefing with primary and secondary trauma victims. *International journal of emergency mental health.* 2004;6(1):5-14.
37. Kenardy J. The current status of psychological debriefing : It may do more harm than good. *BMJ : British Medical Journal.* 2000;321(7268):1032-1033.
38. Patterson GT, Chung IW, Swan PW. Stress management interventions for police officers and recruits: a meta-analysis. *Journal of Experimental Criminology.* 2014;10(4):487-513.

39. Wongtongkam N, Day A, Ward PR, Winefield AH. The influence of mindfulness meditation on angry emotions and violent behavior on Thai technical college students. *European Journal of Integrative Medicine.* 2015;7(2):124-130.
40. Wongtongkam N, Ward PR, Day A, Winefield AH. A Trial of Mindfulness Meditation to Reduce Anger and Violence in Thai Youth. *International Journal of Mental Health and Addiction.* 2014;12(2):169-180.
41. Fix RL, Fix ST. The effects of mindfulness-based treatments for aggression: A critical review. *Aggression and Violent Behavior.* 2013;18(2):219-227.
42. Gao J, Fan J, Wu BWY, Zhang Z, Chang C, Hung Y-S, Fung PCW, Sik Hh. Entrainment of chaotic activities in brain and heart during MBSR mindfulness training. *Neuroscience Letters.* 2016;616:218-223.
43. Hughes JW, Fresco DM, Myerscough R, van Dulmen MH, Carlson LE, Josephson R. Randomized controlled trial of mindfulness-based stress reduction for prehypertension. *Psychosom Med.* 2013;75(8):721-728.
44. Nyklíček I, Mommersteeg PMC, Van Beugen S, Ramakers C, Van Boxtel GJ. Mindfulness-based stress reduction and physiological activity during acute stress: A randomized controlled trial. *Health Psychology.* 2013;32(10):1110-1113.
45. Matousek RH, Pruessner JC, Dobkin PL. Changes in the cortisol awakening response (CAR) following participation in mindfulness-based stress reduction in women who completed treatment for breast cancer. *Complement Ther Clin Pract.* 2011;17(2):65-70.
46. Duchemin A-M, Steinberg BA, Marks DR, Vanover K, Klatt M. A small randomized pilot study of a workplace mindfulness-based intervention for surgical intensive care unit personnel: effects on salivary α-amylase levels. *Journal of occupational and environmental medicine.* 2015;57(4):393-399.
47. Creswell JD, Lindsay EK. How Does Mindfulness Training Affect Health? A Mindfulness Stress Buffering Account. *Current Directions in Psychological Science.* 2014;23(6):401-407.
48. Khoury B, Sharma M, Rush SE, Fournier C. Mindfulness-based stress reduction for healthy individuals: A meta-analysis. *Journal of Psychosomatic Research.* 2015;78(6):519-528.
49. Khoury B, Lecomte T, Fortin G, Masse M, Therien P, Bouchard V, Chapleau MA, Paquin K, Hofmann SG. Mindfulness-based therapy: a comprehensive meta-analysis. *Clin Psychol Rev.* 2013;33(6):763-771.
50. Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. *J Consult Clin Psychol.* 2010;78(2):169-183.
51. Goyal M, Singh S, Sibinga ES, et al. Meditation programs for psychological stress and well-being: A systematic review and meta-analysis. *JAMA Internal Medicine.* 2014;174(3):357-368.
52. Chiesa A, Serretti A. Are mindfulness-based interventions effective for substance use disorders? A systematic review of the evidence. *Subst Use Misuse.* 2014;49(5):492-512.
53. Polusny MA, Erbes CR, Thuras P, et al. Mindfulness-based stress reduction for posttraumatic stress disorder among veterans: A randomized clinical trial. *JAMA.* 2015;314(5):456-465.

54. Luken M, Sammons A. Systematic Review of Mindfulness Practice for Reducing Job Burnout. *The American Journal of Occupational Therapy.* 2016;70(2):7002250020p7002250021-7002250020p7002250010.
55. Regehr C, Glancy D, Pitts A, LeBlanc VR. Interventions to reduce the consequences of stress in physicians: a review and meta-analysis. *J Nerv Ment Dis.* 2014;202(5):353-359.
56. Zenner C, Herrnleben-Kurz S, Walach H. Mindfulness-based interventions in schools—a systematic review and meta-analysis. *Frontiers in Psychology.* 2014;5:603.
57. Kallapiran K, Koo S, Kirubakaran R, Hancock K. Review: Effectiveness of mindfulness in improving mental health symptoms of children and adolescents: a meta-analysis. *Child and Adolescent Mental Health.* 2015;20(4):182-194.
58. Johnson DC, Thom NJ, Stanley EA, Haase L, Simmons AN, Shih PA, Thompson WK, Potterat EG, Minor TR, Paulus MP. Modifying resilience mechanisms in at-risk individuals: a controlled study of mindfulness training in Marines preparing for deployment. *Am J Psychiatry.* 2014;171(8):844-853.
59. Stanley EA, Schaldach JM, Kiyonaga A, Jha AP. Mindfulness-based mind fitness training: A case study of a high-stress predeployment military cohort. *Cognitive and Behavioral Practice.* 2011;18(4):566-576.
60. Epstein RM, Krasner MS. Physician resilience: what it means, why it matters, and how to promote it. *Academic Medicine.* 2013;88(3):301-303.
61. Schroeder DA, Stephens E, Colgan D, Hunsinger M, Rubin D, Christopher MS. A Brief Mindfulness-Based Intervention for Primary Care Physicians: A Pilot Randomized Controlled Trial. *American Journal of Lifestyle Medicine.* 2016.
62. Kaplan JB, Bergman AL, Christopher M, Bowen S, Hunsinger M. Role of Resilience in Mindfulness Training for First Responders. *Mindfulness.* 2017;8(5):1373-1380.
63. Meiklejohn J, Phillips C, Freedman ML, Griffin ML, Biegel G, Roach A, Frank J, Burke C, Pinger L, Soloway G. Integrating mindfulness training into K-12 education: Fostering the resilience of teachers and students. *Mindfulness.* 2012;3(4):291-307.
64. Leppin AL, Bora PR, Tilburt JC, Gionfriddo MR, Zeballos-Palacios C, Dulohery MM, Sood A, Erwin PJ, Brito JP, Boehmer KR, Montori VM. The Efficacy of Resiliency Training Programs: A Systematic Review and Meta-Analysis of Randomized Trials. *PLoS ONE.* 2014;9(10):e111420.
65. Masten AS. Resilience in developing systems: Progress and promise as the fourth wave rises. *Development and psychopathology.* 2007;19(03):921-930.
66. Meredith LS, Sherbourne CD, Gaillot SJ. *Promoting psychological resilience in the US military*: Rand Corporation; 2011.
67. Arnetz BB, Nevedal DC, Lumley MA, Backman L, Lublin A. Trauma resilience training for police: Psychophysiological and performance effects. *Journal of Police and Criminal Psychology.* 2009;24(1):1-9.
68. Andersen J, Dorai M, Papazoglou K, Arnetz B. Diurnal and reactivity measures of cortisol in response to intensive resilience and tactical training among special forces police. *Journal of Occupational and Environmental Medicine.* 2016;58(7):242-248.
69. Arnetz BB, Arble E, Backman L, Lynch A, Lublin A. Assessment of a prevention program for work-related stress among urban police officers. *International archives of occupational and environmental health.* 2013;86(1):79-88.

70. Andersen JP, Papazoglou K, Koskelainen M, Nyman M, Gustafsberg H, Arnetz BB. Applying Resilience Promotion Training Among Special Forces Police Officers. *SAGE Open.* 2015;5(2):2158244015590446.
71. Jha AP, Rogers SL, Morrison AB. Mindfulness training in high stress professions: Strengthening attention and resilience. *Mindfulness-Based Treatment Approaches: Clinician's Guide to Evidence Base and Applications*. 2014;347.
72. Pals SL, Murray DM, Alfano CM, Shadish WR, Hannan PJ, Baker WL. Individually randomized group treatment trials: a critical appraisal of frequently used design and analytic approaches. *American journal of public health.* 2008;98(8):1418-1424.
73. Fjorback LO, Arendt M, Ornbol E, Fink P, Walach H. Mindfulness-based stress reduction and mindfulness-based cognitive therapy: a systematic review of randomized controlled trials. *Acta Psychiatr Scand.* 2011;124(2):102-119.
74. Eberth J, Sedlmeier PJM. The Effects of Mindfulness Meditation: A Meta-Analysis. 2012;3(3):174-189.
75. Bowen S, Chawla N, Marlatt GA. *Mindfulness-based relapse prevention for addictive behaviors: A clinician's guide*: Guilford Press; 2010.
76. Hoge EA, Bui E, Marques L, Metcalf CA, Morris LK, Robinaugh DJ, Worthington JJ, Pollack MH, Simon NM. Randomized controlled trial of mindfulness meditation for generalized anxiety disorder: Effects on anxiety and stress reactivity. *Journal of Clinical Psychiatry.* 2013;74(8):786-792.
77. Chawla N, Collin S, Bowen S, Hsu S, Grow J, Douglass A, Marlatt GA. The mindfulness-based relapse prevention adherence and competence scale: development, interrater reliability, and validity. *Psychother Res.* 2010;20(4):388-397.
78. Malboeuf-Hurtubise C, Achille M, Sultan S, Vadnais M. Mindfulness-based intervention for teenagers with cancer: study protocol for a randomized controlled trial. *Trials.* 2013;14(1):135.
79. Wells RE, Kerr CE, Wolkin J, Dossett M, Davis RB, Walsh J, Wall RB, Kong J, Kaptchuk T, Press D, Phillips RS, Yeh G. Meditation for Adults with Mild Cognitive Impairment: A Pilot Randomized Trial. *Journal of the American Geriatrics Society.* 2013;61(4):642-645.
80. Kahan BC, Morris TP. Assessing potential sources of clustering in individually randomised trials. *BMC Med Res Methodol.* 2013;13:58.
81. Kroenke K, Spitzer RL. The PHQ-9: A new depression diagnostic and severity measure. *Psychiatric Annals.* 2002;32(9):509-515.
82. Trivedi MH, Wisniewski SR, Morris DW, Fava M, Gollan JK, Warden D, Nierenberg AA, Gaynes BN, Husain MM, Luther JF. Concise Health Risk Tracking scale: a brief self-report and clinician rating of suicidal risk. *The Journal of clinical psychiatry.* 2011;72(6):757-764.
83. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. *Addiction.* 1993;88(6):791-804.
84. Prins A, Ouimette P, Kimerling R, Cameron RP, Hugelshofer DS, Shaw-Hegwer J, Thrailkill A, Gusman FD, Sheikh JI. The primary care PTSD screen (PC-PTSD): Development and operating characteristics. *Primary Care Psychiatry.* 2003;9(1):9-14.

85. Scher CD, Stein MB, Asmundson GJG, McCreary DR, Forde DR. The Childhood Trauma Questionnaire in a Community Sample: Psychometric Properties and Normative Data. *Journal of Traumatic Stress.* 2001;14(4):843-857.
86. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry.* 2000;31(2):73-86.
87. Lesage FX, Berjot S, Deschamps F. Clinical stress assessment using a visual analogue scale. *Occup Med (Lond).* 2012;62(8):600-605.
88. Gaab, J. PASA – Primary Appraisal Secondary Appraisal. *Verhaltenstherapie*. 2009;19: 114-115.
89. Smith BW, Dalen J, Wiggins K, Tooley E, Christopher P, Bernard J. The brief resilience scale: assessing the ability to bounce back. *Int J Behav Med.* 2008;15(3):194-200.
90. Pilkonis PA, Yu L, Dodds NE, Johnston KL, Lawrence SM, Daley DC. Validation of the alcohol use item banks from the Patient-Reported Outcomes Measurement Information System (PROMIS). *Drug Alcohol Depend.* 2016;161:316-322.
91. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D, Group PC. Item Banks for Measuring Emotional Distress From the Patient-Reported Outcomes Measurement Information System (PROMIS®): Depression, Anxiety, and Anger. *Assessment.* 2011;18(3):263-283.
92. Weathers, F. W., Litz, B. T., Keane, T. M., Palmieri, P. A., Marx, B. P., & Schnurr, P. P. (2013). *The PTSD Checklist for DSM-5 (PCL-5) – Standard* [Measurement instrument]. Available from https://www.ptsd.va.gov/
93. Demerouti, Mostert K, Bakker AB. Burnout and work engagement: a thorough investigation of the independency of both constructs. *J Occup Health Psychol.* 2010;15(3):209-222.
94. Bowen S, Witkiewitz K, Clifasefi SL, Grow J, Chawla N, Hsu SH, Carroll HA, Harrop E, Collins SE, Lustyk MK, Larimer ME. Relative efficacy of mindfulness-based relapse prevention, standard relapse prevention, and treatment as usual for substance use disorders: a randomized clinical trial. *JAMA Psychiatry.* 2014;71(5):547-556.
95. Wahbeh H, Zwickey H, Oken B. One method for objective adherence measurement in mind-body medicine. *J Altern Complement Med.* 2011;17(2):175-177.
96. IAPRO. BlueTeam: Frontline Software for IAPRO. http://www.iapro.com/products/blueteam/.
97. Christopher Michael S, Hunsinger M, Goerling LRichard J, Bowen S, Rogers Brant S, Gross Cynthia R, Dapolonia E, Pruessner Jens C. Mindfulness-based resilience training to reduce health risk, stress reactivity, and aggression among law enforcement officers: A feasibility and preliminary efficacy trial. *Psychiatry Research.* 2018;264:104-115.
98. Hoge EA, Bui E, Marques L, Metcalf CA, Morris LK, Robinaugh DJ, Worthington JJ, Pollack MH, Simon NM. Randomized controlled trial of mindfulness meditation for generalized anxiety disorder: effects on anxiety and stress reactivity. *The Journal of clinical psychiatry.* 2013;74(8):786-792.
99. Ariel B, Farrar WA, Sutherland AJJoQC. The Effect of Police Body-Worn Cameras on Use of Force and Citizens' Complaints Against the Police: A Randomized Controlled Trial. 2015;31(3):509-535.
100. Jetelina KK, Jennings WG, Bishopp SA, Piquero AR, Reingle Gonzalez JM. Dissecting the Complexities of the Relationship Between Police Officer-Civilian Race/Ethnicity

Dyads and Less-Than-Lethal Use of Force. *Am J Public Health.* 2017;107(7):1164-1170.
101. Jetelina KK, Reingle Gonzalez JM, Bishopp SA. Gradual escalation of use-of-force reduces police officer injury. *Inj Prev.* 2018;24(1):35-40.
102. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, Bond CM. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. *PloS one.* 2016;11(3):e0150205-e0150205.
103. Tickle-Degnen L. Nuts and bolts of conducting feasibility studies. *Am J Occup Ther.* 2013;67(2):171-176.
104. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, Fernandez M. How we design feasibility studies. *Am J Prev Med.* 2009;36(5):452-457.
105. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res.* 2016;25(3):1057-1073.
106. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. 2016;355.
107. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol.* 2012;65(3):301-308.
108. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. 2005;4(4):287-291.
109. Hertzog MA. Considerations in determining sample size for pilot studies. *Res Nurs Health.* 2008;31(2):180-191.
110. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Med Res Methodol.* 2013;13:104.
111. Rush AJ, Trivedi MH, Carmody TJ, Ibrahim HM, Markowitz JC, Keitner GI, Kornstein SG, Arnow B, Klein DN, Manber R, Dunner DL, Gelenberg AJ, Kocsis JH, Nemeroff CB, Fawcett J, Thase ME, Russell JM, Jody DN, Borian FE, Keller MB. Self-reported depressive symptom measures: sensitivity to detecting change in a randomized, controlled trial of chronically depressed, nonpsychotic outpatients. *Neuropsychopharmacology.* 2005;30(2):405-416.
112. Hays R, Anderson R, Revicki D. Psychometric considerations in evaluating health-related quality of life measures. *Quality of life research.* 1993;2(6):441-449.
113. Fayers PM, Machin D. *Quality of life: the assessment, analysis and reporting of patient-reported outcomes*: John Wiley & Sons; 2015.
114. Deyo RA, Diehr P, Patrick DL. Reproducibility and responsiveness of health status measures statistics and strategies for evaluation. *Controlled Clinical Trials.* 1991;12(4):S142-S158.
115. Hevey D, McGee HM. The effect size statistic: useful in health outcomes research ? *J Health Psychol.* 1998;3(2):163-170.

116. Stratford PW, Riddle DL. Assessing sensitivity to change: choosing the appropriate change coefficient. *Health and Quality of Life Outcomes.* 2005;3:23-23.
117. Lowe B, Kroenke K, Herzog W, Grafe K. Measuring depression outcome with a brief self-report instrument: sensitivity to change of the Patient Health Questionnaire (PHQ-9). *J Affect Disord.* 2004;81(1):61-66.
118. Oken BS, Chamine I, Wakeland W. A systems approach to stress, stressors and resilience in humans. *Behavioural Brain Research.* 2015;282:144-154.
119. Szivak TK, Kraemer WJ. Physiological Readiness and Resilience: Pillars of Military Preparedness. *J Strength Cond Res.* 2015;29 Suppl 11:S34-39.
120. Ali N, Pruessner JC. The salivary alpha amylase over cortisol ratio as a marker to assess dysregulations of the stress systems. *Physiology & Behavior.* 2012;106(1):65-72.
121. Middel B, van Sonderen E. Statistical significant change versus relevant or important change in (quasi) experimental design: some conceptual and methodological problems in estimating magnitude of intervention-related change in health services research. *International Journal of Integrated Care.* 2002;2:e15.
122. Sivan M. Interpreting Effect Size to Estimate Responsiveness of Outcome Measures. *Stroke.* 2009;40(12):e709-e709.
123. Fok CC, Henry D. Increasing the Sensitivity of Measures to Change. *Prev Sci.* 2015;16(7):978-986.
124. Lee AC, Driban JB, Price LL, Harvey WF, Rodday AM, Wang C. Responsiveness and Minimally Important Differences for Four Patient-Reported Outcomes Measurement Information System (PROMIS) Short Forms: Physical Function, Pain Interference, Depression, and Anxiety in Knee Osteoarthritis. *J Pain.* 2017.
125. Revicki D, Hays RD, Cella D, Sloan J. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *J Clin Epidemiol.* 2008;61(2):102-109.
126. O'Cathain A, Hoddinott P, Lewin S, Thomas KJ, Young B, Adamson J, Jansen YJ, Mills N, Moore G, Donovan JLJP, Studies F. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. 2015;1(1):32.
127. Krueger RA. *Focus groups: A practical guide for applied research*: Sage publications; 2014.
128. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology.* 2006;3(2):77-101.
129. Braun V, Clarke V. What can "thematic analysis" offer health and wellbeing researchers? *International journal of qualitative studies on health and well-being.* 2014;9:26152-26152.
130. Taylor JA, Hall DA, Walker D-M, McMurran M, Casey A, Stockdale D, Featherstone D, Thompson DM, MacDonald C, Hoare DJJP, Studies F. A psychologically informed, audiologist-delivered, manualised intervention for tinnitus: protocol for a randomised controlled feasibility trial (Tin Man study). 2017;3(1):24.
131. O'Cathain A, Goode J, Drabble SJ, Thomas KJ, Rudolph A, Hewison J. Getting added value from using qualitative research with randomized controlled trials: a qualitative interview study. *Trials.* 2014;15:215-215.
132. Donovan J, Mills N, Smith M, Brindle L, Jacoby A, Peters T, Frankel S, Neal D, Hamdy F. Quality improvement report: Improving design and conduct of randomised

trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. Commentary: presenting unbiased information to patients can be difficult. *Bmj.* 2002;325(7367):766-770.

133. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR. Methods to explain the clinical significance of health status measures. *Mayo Clin Proc.* 2002;77(4):371-383.

134. Robertson IH, Manly T, Andrade J, Baddeley BT, Yiend J. "Oops!": Performance correlates of everyday attentional failures in traumatic brain injured and normal subjects. *Neuropsychologia*. 1997; 35: 747–758.

135. Mehling WE, Price C, Daubenmier JJ, Acree M, Bartmess E, Stewart A. (The Multidimensional Assessment of Interoceptive Awareness (MAIA). *PLoS ONE*. 2012; 7(11): e48230.

136. Cohen S, Williamson G. Perceived stress in a probability sample of the United States. In S. Spacapan & S. Oskamp (Eds.), *The social psychology of health: Claremont Symposium on applied social psychology*. 1988. Newbury Park, CA: Sage.

137. Yu L, Buysse DJ, Germain A, Moul DE, Stover A, Dodds NE, Johnston KL, Pilkonis PA. Development of short forms from the PROMIS™ sleep disturbance and Sleep-Related Impairment item banks. *Behavioral sleep medicine.* 2011;10(1):6-24.

138. Baer R, Smith, G., Hopkins, J., Krietemeyer, J., Toney, L. Using self-report assessment methods to explore facets of mindfulness. *Assessment.* 2006;13(1):27-45.

139. Raes F, Pommier E, Neff KD, Van Gucht D. Construction and factorial validation of a short form of the Self-Compassion Scale. *Clinical Psychology & Psychotherapy.* 2011;18(3):250-255.

140. Diamond PM, Magaletta PR. The short-form Buss-Perry Aggression Questionnaire (BPAQ-SF): a validation study with federal offenders. *Assessment.* 2006;13(3):227-240.

141. Fischer D, Stewart AL, Bloch DA, Lorig K, Laurent D, Holman H. Capturing the patient's view of change as a clinical outcome measure. *JAMA.* 1999;282(12):1157-1162.

15. SUPPLEMENTS/APPENDICES

15.1 Procedures Schedule