Pacific University Institutional Review Board

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Informed Consent

Study Title

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

Study Personnel

Pacific University, University of New Mexico & University of Wisconsin - Madison Study Investigators			
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Study Invitation | Purpose | Location | Dates

You are invited to participate in a research study assessing the impact of different stress management programs among law enforcement officers. Mindfulness-Based Resilience Training (MBRT) and Stress Management Education (SME) training will be compared to each other and to participation in neither course. Our goal is to develop evidence-based training models that will reduce the negative consequences of stress and increase resilience among officers.

This study has been approved by the Pacific University, University of New Mexico and University of Wisconsin-Madison Institutional Review Boards. It will be conducted at Pacific University, the University of New Mexico and the University of Wisconsin – Madison from September, 2018 to August, 2022. It is anticipated that the results of this study will be presented at relevant conferences and in research publications. A description of the clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. These presentations and this website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

Participant Characteristics and Exclusionary Criteria

Participants must be between 21 and 65 years of age and be sworn law enforcement officers at the rank of Sergeant or below. Participants must agree to random assignment to one of three conditions and be willing to participate in assessments and in training courses. Participants must not have prior experience with mindfulness-based stress reduction or similar training, or have current severe depression, severe trauma/PTSD, severe alcohol misuse or suicidal ideation.

Study Materials and Procedures

Study Screening
If you choose to participate in this study, you will be asked screening questions today to determine if you are eligible. This will include questions about depression, alcohol use, trauma/PTSD and suicidal ideation. The screening should last about 20 minutes including time to review this Informed Consent form.

Online Assessments
If you are eligible, you will complete 4 online assessment visits over the course of about 9 months. Each of the 4 study assessment visits will be completed remotely through Zoom and will last about 1 hour each. Your first Baseline study visit will be scheduled today and should be completed during the next month. Once the training courses are complete you will complete a Post training assessment visit. You will also complete assessment study visits 3 months and 6 months after the training courses have ended.

Study visits will involve the following procedures:

- *Attention Task and Questionnaires:* We will ask you to complete a number of computer-administered questionnaires and an online basic attention task during the 4 assessment visits. We prefer you use a computer and be in a private place where you will not be distracted if possible. You will be asked to download a player app to be able to complete the online attention task, and can delete the player immediately after the task is complete. If you do not wish to download the player app onto your device, a laptop computer can be provided to your department for use during the study assessments.

- *Blood Spot Collection:* You will be asked to use a finger prick and place 5 drops of blood on a blood-spot card during 3 of the 4 assessment visits. You will be mailed a dry-blood spot collection kit and instructions prior to each visit. Once the blood is dry on the blood spot card, you will mail the card back to our offices so your blood can be analyzed for indicators of stress and inflammation.

Training Courses and Random Assignment:

After the Baseline study visit you will be randomly assigned to one of three conditions:

Stress Management Education (SME) course focuses on the effects of stress on the body and ways to reduce the impacts of stress. This course includes modules on sleep, time management, immune system, brain, nutrition, exercise, and habit modification.

Mindfulness-Based Resilience Training (MBRT) provides trainable awareness skills allowing for a more objective assessment of situations and a more skillful response, especially in the face of difficulty.

Non-Intervention Control Group (NIC) will not receive training during the course of the study, but will be offered the opportunity to receive training after the study ends.

Random assignment is similar to a coin toss and allows research studies to better assess the impacts of their training programs being studied. The study coordinator will let you know what group you are randomly assigned to and the exact dates and times the training courses will take place. You should only join the study if you can be available to attend the training courses during the dates and times offered.

If you are randomly assigned to the SME or MBRT groups, you will meet on Zoom once a week for 8 weeks. Six of the classes will be 1-1 ½ hours long, and two long classes will be either 4 or 7 hours long. Both training groups include education, gentle movement exercises, and weekly home practices to help integrate course material into daily life. The training courses will be recorded to assure instructors are providing the sessions in a consistent way and to allow supervision and feedback to the instructors. You will also be asked to listen to audio recordings outside of the training sessions. Software to access the audio content can be downloaded to your phone or tablet or

you can use a study device during the training course. The audio software will track the amount of time you listen to the recordings. It will also ask a few brief questions each week about your stress level and integration of course material into your daily life. This Ilumivu player app will be free, and can be downloaded to your phone or tablet.

If you are randomly assigned to the NIC group, you will not attend training during the course of the study. At the end of your participation in the study, no matter which group you were randomly assigned to, you will have the opportunity to attend either training course.

Individual Feedback Phone Interviews:
After the training courses and first post-training assessment are completed, you will be invited to participate in a 15-20 minute phone interview. We will ask you to provide feedback about your experiences during the study visits and training course, and how they could be improved in the future. These interviews will take place via Zoom and will be audio recorded and transcribed for analysis.

Time Requirements:
If you agree to take part in this study, you will be asked to complete four 60-minute study assessment visits over about 9 months. These will all be via Zoom. You will also complete a 15-20 minute phone interview to provide study feedback. If you are randomly assigned to the SME or MBRT groups, you will also attend 8 days of training for a total of 17 training hours, and asked to listen to 8 hours of audio recordings. The total time for these study activities are about 29 hours for participants of the SME and MBRT groups and 4 ½ hours for participants of the NIC group.

One year following the training groups, researchers may collect anonymous publicly available departmental data from your precinct for groups of officers who have and have not participated in the study.

Risks | Risk Reduction Steps | Clinical Alternatives

1. Anticipated Risks and Strategies to Minimize or Avoid Risk

Participation in this study will pose minimal risk. You will engage in an 8-week stress education course, mindfulness-based training program, or in a no-intervention control group. The safety of the SME and MBRT courses has been examined in numerous studies. You may experience minor physical or emotional discomfort during training related meditation or movement exercises. You may experience some pain and bruising at the site of the finger prick and may feel faint when blood drops are being collected. In very rare cases, infection at the site can occur. It is possible you may experience distress when engaging in the attention task or answering questionnaire items related to sensitive information. There is minimal psychological risk associated with answering questions about how you are feeling and functioning, and exposure to traumatic work and life events that could affect your mood. However, these risks are considered minimal to the extent that they are no greater than those ordinarily encountered in daily life. When providing information for study purposes, there is a risk that this information will not remain confidential. The investigators take this issue very seriously and every effort will be made to remove identifiers and keep your information in a secure environment.

2. Unknown Risks

It is possible that participation in this study may expose you (or an embryo or fetus, if you are or become pregnant) to currently unforeseeable risks.

3. Advantageous Clinical Alternatives

The alternative to participating in this research study is to not participate and to seek treatment or a similar training in the community.

Adverse Event Handling and Reporting Plan

In the event that you become sick, injured, distressed, or otherwise uncomfortable as a result of your involvement in the research study, you may stop your participation immediately. If such an event occurs, promptly notify the principal investigator or the Pacific University Institutional Review Board.

If the investigator(s) become aware of an adverse event, the IRB office will be notified by the next normal business day for minor events (e.g., emotional distress triggered by study questions about emotionally charged life events) and within 24 hours for major events (e.g., physical injury).

If you experience or are directly affected by an adverse event, you will be given the opportunity to withdraw any data collected from you during the study up to publication of the study results.

Direct Benefits and/or Payment to Participants

a. **Benefit(s) —**It is not known if there are any direct benefits to you as a study participant. The information gained from this study may contribute to scientific knowledge about how the training programs being studied affects well-being in law enforcement officers and other first responders.

b. **Payment(s) or Reward(s) —** N/A

Promise of Privacy

We will take several steps to ensure your privacy. Data will be kept in a confidential manner. Electronic records will be stored on secure encrypted servers and available only to authorized personnel with a password. The Informed Consent form will be signed prior to data collection and will be collected and stored using an internet-based program called Qualtrics that operates on a secure server. Questionnaire data will also be collected and stored using Qualtrics and securely stored on the company's server. Attention task data will be collected and stored using an internet-based program called Inquisit and securely stored on Millisecond Software's server. Audio recording tracking data collected from mobile apps are encrypted and stored on Ilumivu's cloud-based storage database. Electronic data without any identifying information will be stored in REDCap, a secure internet-based data management software system housed on a secure server hosted by Oregon Health and Science University. Once downloaded all data will be stored in HIPAA compliant Box files on Pacific University's secure encrypted servers.

The data collected from you during this study will be identified only by a unique ID number that will be generated prior to the study. Your name and other directly identifiable information will be stored separately from your study data. Only authorized study team members will be able to link your identifiable information with your ID number.

The university uses a Protected Zoom account that provides extra security. You will have the option to change your screen name in Zoom if you choose. Your study assessment visits held on Zoom will not be recorded. The SME and MBRT training courses will be recorded. Audio recordings will be immediately uploaded to secure HIPAA-protected files and the original audio and video recording will be deleted. Study staff who transcribe and code the recordings will not be involved in the trainings and therefore and will not be able to identify participants from the recordings. All recordings will be destroyed at the completion of the study.

The blood spot cards will be identified using the same unique ID number. The blood spot samples will be securely stored until we send them to the Laboratory for Human Biology Research at Northwestern University for analysis. The lab will not test, retain, or share the results and samples will be destroyed after analysis.

Results of this study will only be presented as average responses that are grouped together with other study participants. We will not present individual responses or any personally identifiable information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that researchers cannot disclose information, documents, or biospecimens to anyone who is not connected with this research. It also means they cannot release information that may identify you in any action or suit unless you say it is okay. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, such as court subpoena. The Certificate cannot be used to stop a sponsoring United States Government agency from checking records for auditing or evaluating federally-funded programs. The researchers will use the Certificate to resist any demands for information that would identify you except as explained below.

The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, and threats to harm yourself or others. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research.

Medical Care and Compensation in the Event of Accidental Injury

During your participation in this research study, it is important to understand that you are not a Pacific University or University of New Mexico clinic patient or client. You will not be receiving medical care (e.g., eye care, mental health care, physical therapy, etc.) as a result of your participation in this study. If you are injured during your participation in this study and it is not due to negligence by Pacific University, University of New Mexico, the University of Wisconsin – Madison, the investigator(s), or any organization associated with the research, you should not expect to receive compensation or medical care from the university(s), the investigator(s), or any organization associated with the study. If you are injured and it directly is related to your participation in this study as a research subject, please contact the Pacific University Institutional Review Board at 503-352-1478.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate will not affect your relationship with the university or your police department. You may choose to skip any question you would prefer not to answer or withdraw from the study at any time without negative consequences. If you choose to withdraw after beginning the study, the data you have already provided will be retained. If significant new findings are discovered during the course of this research that could impact your decision to continue participation, such findings will be shared with you and you will be given the opportunity to withdraw from the study.

Contacts and Questions

The investigator(s) will be happy to answer any questions you may have at any time during the course of the study. If you are not satisfied with the answers you receive, please call the Pacific University Institutional Review Board at 503-352-1478 to discuss your questions or concerns further. If you have questions about your rights as a research subject, or if you experience a research-related injury of any kind, please contact the investigator(s) and/or the IRB office. All concerns and questions will be kept in confidence.

Statement of Consent

	Yes	No
I am 18 years of age or over.	○	○
All my questions have been answered.	○	○
I have read and understand the description of my participation duties.	○	○
I have been offered a copy of this form to keep for my records.	○	○
I voluntarily agree to participate in this study and understand that I may withdraw at any time without consequence.	○	○

Please indicate whether you provide your consent to participate in this study by selecting an option below.

- ○ Yes, I agree to participate
- ○ No, I do not wish to participate

First Name	Last Name	
		Participant
Signature	Date	Study Role