Title: Data-driven Approaches to Healthcare Provider Resilience & Burnout During COVID-19

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Duke University Health System

Consent To Participate In A Research Study
ADULT
Data-driven Approaches to Healthcare Provider Resilience & Burnout during COVID-19

CONCISE SUMMARY

The purpose of the study is to assess the effectiveness of two non-pharmacologic methodologies, Experience Resolution Methodology (ERM) coaching, and Transcendental Meditation (TM) in comparison to treatment as usual (TAU) for developing resilience and alleviating burnout in health care providers, as measured by self-report (survey), physiologic studies, blood biomarkers, and neuro-functional imaging studies.

You will be randomly assigned (like drawing numbers out of a hat) to either to the TM group, ERM coaching (ERM) group, TM + ERM or the control group (treatment as usual.) You will be asked to attend 8 initial meditation instruction or group coaching sessions with periodic follow-up sessions for up to two years. You will be asked to fill out questionnaires, you will be provided with an Apple Watch or Empatica device to assess changes which may include heart rate, steps, sleep, blood tests and voice biomarkers. Some participants may be eligible to undergo a fMRI.

There are risks that are described in this document. The greatest risk of this study includes the loss of confidentiality.

You are being asked to take part in this research study because you are a healthcare provider (HCP) working in some capacity with patients during or immediately following the COVID-19 pandemic. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.
We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Sangeeta Joshi will conduct the study, and it is funded by the U.S. Department of Defense (DoD) and the Division of Pulmonary Medicine at the Duke University Health System (DUHS). The sponsor of this study, the U.S. Department of Defense, will pay Duke University to perform this research, and these funds may reimburse part of the research team's salary.

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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Sangeeta Joshi, will be your doctor for study-related issues. Continue care with your primary care and specialty providers for your personal healthcare needs.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if HCPs who learn and practice Transcendental Meditation (TM, a mind-body meditation intervention designed to reduce sympathetic arousal and promote a state of relaxation and calm), or who participate in Experience Resolution Methodology (ERM) Coaching (a systematic coaching methodology designed to reduce stress associated with specific experiences), or those who do both modalities, will demonstrate significantly higher levels of resilience and lower levels of burnout than the TAU (Treatment As Usual) control group, as measured by self-reporting (survey), physiologic measures, and neuro-imaging studies.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 280 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form.

You will then complete a ***baseline visit*** with the study team. At this visit, the following will occur:

- You will be asked about your medical history (such as treatment received for any illness, surgery, medications taken for illnesses or physical problems, and use of caffeine, alcohol, and cigarettes).
- You will be asked demographic information (such as your age, race, ethnic origin, marital status, and education, living arrangements, number of children, religious affiliation, and employment status).
- If you agree, you will have a blood sample drawn (36.5 mL or about 2.5 tablespoons) for immunological biomarkers to understand changes in your biological markers over time with or without interventions.
  Please initial below to indicate your choice:
  _____ Yes, I agree to have blood samples collected
  _____ No, I do not agree to have blood samples collected
- You will be randomized (like flipping a coin) to 1 of 4 arms:
  - Transcendental Meditation (TM)
  - Experience Resolution Methodology (ERM)
  - Transcendental Meditation (TM) and Experience Resolution Methodology (ERM)

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    - Treatment As Usual (TAU)
- Regardless of which arm you are assigned to, you will be asked to download the Pattern Health app on your personal device. Using this device, you will complete a series of questionnaires to help the study doctors know how you are doing and to facilitate in being compliant with your study procedures.
- If you are randomized to one of the TM arms, you may be asked to download an app called TM at Home. This app will enable you to practice TM remotely if needed.
- Using an app called Clairity, the study team will collect voice biomarkers from you. You do not need to download this app. The Clairity web app will use voice prompts intended to elicit responses when asked about 1) Hope, 2) Secrets, 3) Anger, 4) Fear, and 5) Emotional Pain. This will take approximately 6 minutes to complete.
- You will be asked to wear an Apple Watch (if you have an Apple device) or a wearable Empatica device. Only the Apple watch users will be allowed to take their device home.
- You may receive an eSense device to measure your Galvanic Skin Response (GSR). GSR refers to the changes in sweat gland activity that result from changes in emotional state.
    - If you are randomized to the TM+ERM or ERM groups and opt to participate in individual ERM coaching, you will be asked to use an eSense device before and after your sessions during a process called scripting.
    - Scripting is a process that asks you as series of questions about your emotional and mental state of being so as to more effectively attempt to target areas of burnout during your sessions.
    - You will be recorded during these individual ERM sessions for audio and visual biomarkers.
- Additionally, if you are randomized to either the TM, TAU or ERM group and you are willing to undergo an fMRI, you will then be scheduled for your baseline fMRI. If you are a woman of child-bearing potential, you will have a urine pregnancy test prior to the fMRI and will be excluded if pregnant.

After the completion of your baseline visit, depending on the treatment arm you were assigned, you will be asked to undergo a series of practices, teaching, or coaching sessions.

They are described on the following page:

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TM Arm: Training requirements

Training Type & General Information	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Week 1.5 to 2**	**Week 4**	**Week 8**	**Week 12**
Location of Training	In person or at selected site.	In person, at selected site, or remote.	In person, at selected site, or remote.	In person, at selected site, or remote.	Remote	Remote	Remote	Remote
Personal 1:1 Instruction	X							
Small Group Session		X	X	X				
Instructor Follow-up					X	X	X	X

a) Personal and small group sessions must be conducted in-person
b) Booster sessions, offered post 3 months (months 4-24), may be conducted in-person or remotely. Remote sessions may be conducted via zoom/WebEx or using the TM at Home app.
c) All sessions last between 60 to 75 minutes
d) After 12 weeks (3 months), participants are offered 60-minute booster sessions.

ERM Arm: Training requirements

Training Type & General Information	**Weeks 1-8 (once weekly)**	**Month 3 (once monthly)**
Location of Training	Remote	Remote
Group Coaching	X	X

a) Remote coaching will be conducted via Zoom/WebEx.
b) Group coaching sessions will last approximately 90 minutes each. During weeks 1-8 the participant will meet with the ERM coach once a week. Attendance will be taken. Beginning at month 3, sessions will be completed once monthly.
c) Monthly sessions will continue month 4 through month 12. Monthly drop-in sessions will be available to all participants assigned to this arm for months 13 through 24.

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TM + ERM Arm: Training requirements
A combination of TM and ERM visits will be conducted as described in the tables above. If you are randomized to this arm, your ERM coaching will begin 2-3 weeks after you initiate TM.

If you are randomized to either the TM or TM+ERM arm, you will have the opportunity to choose to participate in the National TM database. Your study coordinator will present you with an additional informed consent to read and review should this occur.

TAU Arm: Visit requirements
If you are randomized to the TAU arm, you will receive routine reminders via the Pattern Health app to complete your study surveys.

You will receive monthly reminders during your study participation informing you of available resources such as, but not limited to, treatments related to acupuncture, integrative health coaching, integrative nutrition and weight management, personal exercise training, massage therapy, yoga therapy, mindfulness-based stress reduction (MBSR), experiencing mindfulness, group fitness classes, gentle yoga, or chair yoga.

Additionally, you may be eligible to learn TM or ERM at the end of the study at no additional cost to you.

You will return to the study site at 3 months to complete the ***3-month study visit***. The following will occur:

- You will be asked to complete questionnaires that will help the study doctors know how your assigned treatment arm may be affecting you using the Pattern Health app.
- If you agree, you will have a blood sample drawn (36.5 mL or about 2.5 tablespoons) for immunological biomarkers to understand changes in your biological markers over time with or without interventions
  Please initial below to indicate your choice:
  ___ Yes, I agree to have blood samples collected
  ___ No, I do not agree to have blood samples collected
- Information collected on the Apple Watch or the Empatica device from your baseline visit to this visit will be downloaded and stored securely by the study team.
- A portable Galvanic Skin Response (GSR) device will be used to obtain your GSR.
- The Clairity app recording will be obtained for voice biomarkers.
- If you were selected to undergo the fMRI, you will have another fMRI at this visit. If you are a woman of childbearing potential, you will have a urine pregnancy test prior to the fMRI.

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The remaining visits, not including your treatment arm visits, are to be completed at ***6 months, 12 months, 18 months,*** and ***24 months.*** These visits are completed remotely and require that you complete questionnaires via the Pattern Health app. It is anticipated that the completion of each of these visits will take 20 minutes or less of your time.

Contact for Future Studies
We may want to contact you in the future to ask if you would like to participate in other research studies. If you agree, we would like to keep your contact information on file at the Duke site. This information will be kept confidential and will not be shared with other research groups. If you agree to be contacted for future studies, you will be asked to sign a separate consent form before you participate in those studies. Your decision regarding contact for future studies will not affect your participation in this study.

PLEASE INITIAL to indicate your willingness to be contacted about future research studies (indicate only ONE option):

_____ YES, you may keep my information on file and contact me about participation in future studies.
_____ NO, you may not contact me about future studies.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study will last for a total of 24 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your Dr. Joshi first.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Risks of confidentiality
There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be absolutely guaranteed. If you are completing this document in an e-consent format, you will receive a signed copy of the consent via the e-mail address that you provide. E-mail is not a secure means of communication, so this is a risk of loss of confidentiality. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study. You may stop your participation in this study at any time.

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Risks specific to mobile apps:
Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Unencrypted Communication:
Because e-mail/text does not provide a completely secure and confidential means of communication, please do not use email/text if you wish to keep your communication private. Instead, please call the study coordinator at 919-479-0743. Alternately, please let us know and we will communicate with you only through regular channels like the telephone.

Use of Duke Loaned Devices:
You will be loaned a Duke Apple Watch or Empatica device for use during this study, and if you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. The device will be pre-set with security settings. Please

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do not alter these during the course of the study. Participants who complete the study, will be allowed to keep the Apple watch for their personal use. If you do not complete study participation you will be asked to return the device when you leave the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately.

Risks of FMRI
Functional Magnetic resonance imaging (fMRI) uses a magnet and radio waves to make diagnostic medical images of the body, in this study – the brain. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in tattoos. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner.

If there is any question about potentially hazardous metal within your body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a flat, padded narrow bed and then slid into a small tunnel-like space approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

Risks of Drawing Blood:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Unknown Risks
There may be risks, discomforts, drug interactions or side effects that are not yet known. There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there will be no direct medical benefit to you. However, you may benefit from better stress management and improved resilience.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people

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including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to the U.S. Department of Defense and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board, and others as appropriate. Additionally, as part of this study, Duke University is partnering with the David Lynch Foundation and the Soferman and Lonsdorf, LLC. These entities specialize in the interventions, Transcendental Meditation (TM) and Experience Resolution Methodology (ERM), respectively. As a result, your protected health information, such as name, contact information including your phone number, email address and home address, as well as date of birth, and other sociodemographic and medication information, will be shared with them if you choose to participate and are randomized to their respective treatment. They will use this information for the sole purpose of contacting you to schedule your TM or ERM sessions. Your information will not be kept or maintained by either of these entities unless otherwise consented for and will only be used for this research study's purposes.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

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The study sponsor the U.S. Department of Defense has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the Dr. Joshi/the study team about the specific services and procedures (including the device, if applicable) that the sponsor will pay for, and the ones for which you or your insurance will be responsible

WHAT ABOUT COMPENSATION?
As noted above, each eligible iPhone user will receive an Apple watch to use during their study participation, which is worth approximately $600. Apple users who complete the 24-month study will be allowed to keep the watches as a form of compensation for their time and travel. For those individuals who do not receive an Apple watch for study use (i.e., Android users), they will each receive an Apple watch for equal compensation at the end of their study participation.
In addition you will be reimbursed as follows:

- **Baseline visit**: $40; if you give blood samples you will be reimbursed an additional $30; if you additionally participate in the fMRI you will be reimbursed an additional $100
- **3-month visit:** $40; if you give blood samples you will be reimbursed an additional $30; if you additionally participate in the fMRI you will be reimbursed an additional $100
- **Six-, Twelve-, Eighteen- and Twenty-four-Month Remote Follow-Up Visits:** $20 per visit

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Joshi at 919-681-3394 during regular business hours. After hours and on weekends and holidays please call the Duke Hospital operator at 919-684-8111 and ask to have Dr. Joshi paged.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

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Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, will not affect your access to health care at Duke and will not affect your job status if you are a Duke employee. If you do decide to withdraw, we ask that you contact Dr. Joshi in writing and let her know that you are withdrawing from the study. Her mailing address is 1821 Hillandale Rd, Suite 25A, Durham, NC 27705. You will be asked to return the Apple Watch or Empatica device. If you stay in the study, you will be able to keep your Apple watch upon completion of the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Joshi at 919-681-3394 during regular business hours. After hours and on weekends and holidays please call the Duke Hospital operator at 919-684-8111 and ask to have Dr. Joshi paged.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time