# First Responder Resiliency Program for Health Care Professionals During a Pandemic

## Study Protocol

## NCT04536376

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## General Study Information

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Study Title: First Responder Resiliency Program for Health Care Professionals During a Pandemic

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## Research Question and Aims

### Hypothesis

Healthcare professionals on the frontline of care can experience work-related environmental factors that lead to likely increased moral injury and staff turnover. We postulate that an integrative resiliency training program (i.e. First Responder Resiliency Program) will improve physical and mental health parameters in frontline healthcare professionals.

### Aims, purpose or objectives

The purpose of this study is to evaluate the feasibility of a resiliency program to provide an effective and sustainable solution to medical professionals experiencing high levels of stress while delivering frontline healthcare. With an emphasis on integration of mental and physical health management, the phase-based program delivers individualized, data-driven and quantifiable solutions that directly address pain points impacting healthcare professionals and organizations. We plan to study 10 healthcare professionals using a specifically designed resiliency program where data is passively captured from a finger-worn sensor that the participant wears nightly during sleep.

1. To study the feasibility of an individualized First Responder Resiliency Program in providing performance breathing interventions and stress inoculations to healthcare professionals.

The primary outcomes will be:

1) The quantifiable improvements in Perceived Stress, and Resilience Scale in frontline healthcare providers at specific time points during their participation in the First Responder Resiliency Program

### Objective

Through an integrative approach that addresses physical and mental health parameters through rapid and sustainable interventions, the First Responders Resiliency Program will deliver objective and quantifiable improvements in the areas of stress resilience, sleep efficiency, and immune function. Work productively, engagement and reduced physician turnover are key performance indicators of program success, our objective is to deliver results that improve employee joy in their work and personal lives.

### Background

Stress, exposure to infectious agents and inadequate sleep are inevitable components of daily life for frontline healthcare professionals. While these individuals dedicate their time and effort towards providing care to others, they often experience negative outcomes in their own physical and mental health leading to a high prevalence of moral injury and staff turnover. In addition to the approximately $4.6B annual cost to the US healthcare system[1], staff turnover rate is associated with the high prevalence of suicide among healthcare workers in the US, compared to other countries[2].

With the recent COVID-19 pandemic, these work-related environmental factors will likely lead to increased moral injury and staff turnover for healthcare professionals. In the population of healthcare professionals where exposure can be

difficult to avoid, it is important to focus on proactive, sustainable and validated physical and mental health solutions that address stress resilience and recovery with an emphasis on early detection and intervention.

## Study Design and Methods

### Methods

This is an open intervention clinical trial. Study participants will participate in an individualized program through an integrative approach that addresses physical and mental health parameters through rapid and sustainable interventions. Study involvement will last approximately 4 weeks.

We will assess the following:

- Comprehensive sleep analysis, heart rate, heart rate variability, respiratory rate, and temperature through the use of the Oura Ring finger-worn sensor worn nightly during sleep sessions.
- Assess changes in Sleep Quality Assessment, Perceived Stress, and Resilience Scale, measured at baseline and end of study.

### Data Collection

- Subjects will complete study surveys/questionnaires through REDCap. The coordinator can provide the Ipad digital or paper copy version of the survey/questionnaire to the subject for the in-person visits and by email link or phone interview for the remote visits.
- Survey data collection in this study will utilize REDCap[3]. The only anticipated paper source documents will be if subject chooses to complete surveys via paper copy or phone collection, which will then have select variables entered directly into the REDCap data entry system. All other data collection will be entered directly into this password protected system.
- Intervention data will be collected through the developer, (PN Medical and Oura) with use of the Oura Ring finger-worn sensor device and the phone application that the subject has the option to use. Data sharing between Mayo Clinic, PN Medical and Oura. Adherence to the Respiratory Muscle Training (RMT) interventions will be collected through a daily diary.

### Visit Flow and Timeline

| | **Consent** | **Baseline** | **Intervention Phase** | | | **End of Study** |
|---|---|---|---|---|---|---|
| **Visit Number** | V0 | V1 | | | | V2 |
| **Visit Week** | 0 | 1 | 2 | 3 | 4 | End of Week 4 |
| Informed Consent | X[1] | | | | | |
| Inclusion/Exclusion | X | | | | | |
| Oura ring (Measure size & Video) | X[2] | | | | | |
| Create study email | | X | | | | |
| Oura App registry by Subject | | X | | | | |
| Receive intervention tools | | X[3] | | | | |
| Cardiorespiratory Fitness | | X[8] | | | | X[8] |
| Questionnaires[4]: | | | | | | |
| Sleep Quality Assessment (PSQI) | X | | | | | X |
| Perceived Stress Scale (PSS) | X | | | | | X |
| Brief Resilience Scale (BRS) | X | | | | | X |

| | | | | | | |
|---|---|---|---|---|---|---|
| Depression (PHQ2) | X | | | | | X |
| Demographics Form | X | | | | | |
| Satisfaction Survey (WIWI) | | | | | | X |
| Education: | | | | | | |
| 90 minute intro session | | X[9] | | | | |
| Intervention: | | | | | | |
| Oura[5] | | X | X | X | X | |
| Breather Fit Device[6] | | | X | X | X | |
| Breather Fit Use Diary (RMT) | | | X | X | X | |
| Stress Inoculation[7] | | | X | X | X | |
| Optional Group Collaboration | | | X | X | X | |
| Weekly Scorecard | | | X | X | X | |
| Continuous monitoring, insights & adjustments by PNMedical | | X | X | X | X | |

[1] Consent can be completed digitally in person or through remote consenting.
[2] Subject will contact study team member with ring size that they would like request ordered. Rings will be shipped to study team for dispensing to subject at baseline visit.
[3] Subject receive items and introduction on care and use.
[4] Surveys can be completed digitally through an Ipad, in person, or a link sent to the subject's chosen email address.
[5] Oura Ring to be worn on subject's finger on nightly basis during rest or sleep.
[6] Use as directed for Respiratory Resilience Program.
[7] Performance Breathing Interventions, mobility exercises, and muscle activation.
[8] Subject will self-report distance walked and steps taken for this fitness test.
[9] Intro session will be scheduled with PN Medical collaborators, approximately 1 week after receiving study supplies (a minimum of 5 days of wearing device for baseline data).

**Assessments**

*Outcomes:*

- Demographics Form: This form collects demographic and other lifestyle history of the research subject.
- Stress: Will be evaluated through the Perceived Stress Scale (PSS)[4,5]. The PSS is a 10-item Likert scale scoring system that measures global life stress by assessing the degree to which experiences are appraised as uncontrollable or unpredictable. Scores can range from 0 to 40, with higher scores indicating greater perceived stress. Reliability is reported as 0.85, with Cronbach alphas ranging from 0.75-0.86.
- Resilience: Will be evaluated through the Brief Resilience Scale (BRS) Scale[6]. This is a 6-item Likert scale validated scoring system. The BRS is a reliable means of assessing resilience as the ability to bounce back or recover from stress.
- Sleep Quality: The Pittsburgh Sleep Quality Index (PSQI)[7] is an effective instrument used to measure the quality and patterns of sleep in adults. This is a 9-item Likert scale validated scoring system. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.
- Depression: For this measure we will use the PRIME-MD Questionnaire[8,9] which is a validated and frequently used self-report measure of depressive symptoms comprising of 2 questions, which was derived from the PHQ[10,11].
- Satisfaction with the program: Was it Worth it Questionnaire (WIWI)[12]: This satisfaction survey will be administered to the participants prior to completing intervention at the end of the study, probing their satisfaction with the research study. These data could be used to assess the feasibility of the intervention by asking the patient if the entire research experience was worth it for them.
- Biometrics: Trend analysis of comprehensive de-identified sleep data, heart rate, heart rate variability, and respiratory rate will be collected through the use of the Oura Ring device and provided by PN Medical.

*Adherence to Intervention:*

- Adherence to the Oura device will be assessed by de-identified data available from Oura and PN Medical.
- Adherence to Breather Fit device will be assessed by de-identified data available from Oura and PN Medical and subject self-report diary

| Recorded during sleep | Recorded during the day |
|---|---|
| • Resting heart rate (RHR)<br>• Heart rate variability (HRV)<br>• Respiratory rate<br>• Body temperature deviation<br>• In-depth sleep data<br>  ○ Automatic sleep tracking for sleep stages (Awake, Light, Deep, REM)<br>  ○ Sleep timing, duration, and quality<br>  ○ Restless movement detection<br>  ○ Ideal bedtime guidance | • Activity levels (intensity, timing, duration)<br>• Calories<br>• Steps<br>• Inactivity time and alerts<br>• Automatic detection of restful moments, such as naps<br><br>Note: Oura does not currently enable the ability to record continuous, on-demand data for RHR and HRV during the day. This data is available only when stationary, utilizing the Moment feature. |

*Intervention:*

- *Breather Fit Device*: This device is used for activation and build-up of the pulmonary system for optimization and strengthening of the respiratory muscle system for better pulmonary hygiene and improved cardiopulmonary function. Stress has a direct impact on immune and inflammatory responses, reducing the body's ability to fight infections. Furthermore, the pulmonary system is an important contributor as the upper airway serves as an entry passage for respiratory pathogens including viral and bacterial infectious agents. Therefore, optimizing airway clearance of secretions/pulmonary hygiene may offer an additional defense against unwanted microorganisms, mitigating their potential impact on the respiratory tract microbiome and risk for lower respiratory tract infections.

  
  

  The Breather Fit is a respiratory device made of medical grade plastic and is for oral use. It has to be cleaned ac-cording to the instructions (https://www.pnmedical.com/lessons/breather-fit-cleaning/) after every use to avoid contamination. In addition, hands should be washed for 30 seconds before use of the device. To avoid spreading of saliva droplets, the device should be used at a distance of 12 feet of other device users or persons.

- *Oura Ring:* The Oura device with Application collects and summarizes health data into three meaningful scores (Readiness, Sleep, Activity) that help harness the body's potential every day. Using infrared LEDs, NTC temperature sensors, an accelerometer, and a gyroscope, the Oura ring captures distinct parameters during the day and night, respectively.

- *Cardiovascular Assessment:* The 6 and 12 minute performance test created by KH Cooper is an objective measure of physical fitness and reflects oxygen uptake efficiency and cardiovascular status (https://erj.ersjournals.com/content/37/1/150, https://jamanetwork.com/journals/jama/article-abstract/337382). Study participants will perform a test to assess the distance covered by walking or running in 6 minutes. Results can be converted into estimates of VO2 max, and can be compared to reference values. The cardiovascular assessment will be performed before and after the RMT intervention.

- *Optional Group Collaboration:* Participants have the option of sharing their biometric data with colleagues in a confidential de-identified daily or weekly posting of scores for ongoing motivation, competition and education of best practices.

**Subject Retention**
Participants will be offered all the intervention materials (i.e. Oura Ring finger-worn sensor, Breather Fit device and continued use of the app) utilized at the end of the study, so that they may continue use post study evaluation, if they so wish.

**Study Design**
We will use standardized procedures to ensure uniform instructions and support for all subjects for the recruitment, screening, and study entry.

**Recruitment**
Subjects will be recruited from Mayo Clinic healthcare professionals assisting in frontline care of patients. We propose to recruit, consent and screen 15 participants through IRB approved contact materials in order to enroll 10 to study. All participants who respond to the recruitment message will be pre-screened for inclusion and exclusion criteria via a telephone pre-screen. Those who meet criteria will be invited to a consent visit followed by a study screening visit. After consent and screening has taken place, subjects who meet all study entry criteria will be invited to participate in the study.

**Consent and Screen**
Study coordinator will discuss with the potential subject who has expressed an interest in participating in the study. The study coordinator will begin by introducing the study details, and after determining that the subject has continued interest in study participation, will move on to the study consent. If the subject chooses to consent, the study coordinator will screen the participant for study entry inclusion/exclusion criteria. If study entry criteria are met, the subject will begin their study participation. They will be asked to complete the study surveys/questionnaires, and be given the Oura ring sizer. The ring sizer is used to assist in measuring a finger size, and the participant would ideally wear the sizer on the finger that they choose to wear the Oura ring on for the study for 24 hours. Participants will be offered a short video explaining use and maintenance of the Oura ring, and a short overview of what the device measures (heart rate, heart rate variability, sleep phases, activity). The participant will self-report to a study team member the ring size they would like ordered for them. The study team member will order and receive the ring for delivery to subject at Baseline.

**Baseline Phase (week 1):**
A study coordinator will meet in person with the subject to begin the Baseline phase of the study. The subject will be instructed on how to sign up for the Oura intervention application and given the study intervention materials, such as their Oura Ring, and Breather Fit device, and daily diary. They will be instructed on the care and cleaning of these devices.

Subjects will also be walked through the process of signing up for an email address to use for this study.

Please note, the participant will sign up for the Resiliency Program (APP) on their own since the program is external to Mayo Clinic. De-identified data collected by the program from the study subjects will be shared with Mayo study team for analysis.

In order to develop an individualized approach, it is important to assess beyond physical parameters and into the root cause of population-specific dysfunction, often related to the nervous systems. The Physician Resiliency Program begins with a minimum five-day baseline utilizing clinically reliable biometric collection in a natural environment to ensure data integrity.

The study subjects will be scheduled to participate in a 90 minute kick-off meeting to receive an educational overview of the First Responder Resiliency Program.

Study participants will be asked to undergo a cardiorespiratory fitness test for VO2 Max assessment utilizing the Oura app by walking for 6-12 minutes while walking on a treadmill or wearing a pedometer, and then self-reporting the distance or steps covered during this time.

Study participants will be requested to not modify any existing lifestyle habits to gain an accurate understanding of biometric trends during the baseline phase.

Subjects will be asked to wear the Oura Ring device during rest and sleep time.

**Run In Phase (week 1):**
Participants will then be instructed to use the Oura ring (Run-In Phase 5 days minimum) prior to initiating the Educational Phase.

**Education Phase (end of week 1, beginning of week 2):**
The Kickoff educational virtual meeting will be scheduled individually with each study participant. This meeting will begin with a short live introduction from PN Medical representative, then participants will view pre-recorded discussions about varying topics (background, user instructions, and training protocol for using the Breather Fit device; situational breathing strategies (SBS) for stress inoculation), and end with a live Q & A session where subjects can discuss the intervention and ask questions. Various topics will include the following:

- PN Medical- Paul DiTuro will discuss an overview of specific stress resilience tools and interventions, and review demonstration and practical application of muscle activation techniques utilized in Special Force Operators, professional athletes and corporate executives to prepare for stressful situations.
- PN Medical Chief Scientist Dr. Nina Bausek will cover the comprehensive review of organization-level biometric trends and introduction of validated interventions related to cardiorespiratory fitness and nervous system management, and will give an introduction to proactive approaches to optimize stress resilience and immune function through conscious breathing, respiratory muscle training, and pulmonary hygiene.
- PN Medical David Jack will discuss feature a series of videos explaining and demonstrating the situational breathing interventions, as well as a very short introduction to the video series. (This material is available on the pnmedical.com website.)

All pre-recorded video material will be available on a single landing site throughout the study. The url will be shared with the participants at the kickoff educational meeting. Participants will be encouraged to revisit the video material to refresh content and technique.

**Intervention Phase (weeks 2-4):**
To create an individualized approach for each subject an integrative program developed to provide validated, non-invasive & integrative solutions. Integrative programs may include:

- Respiratory Muscle Training (RMT) using Breather Fit device
- Sleep & Intervention(s)
- Stressor Inoculations (Situational Breathing Strategies, SBS)

Subjects will begin their interactive program and that will be based on a participant's weekly scorecard with an emphasis on functional improvements and positive reinforcement. The weekly scorecard will be sent as an email to the participant's study email address as well as the PI for review. Subjects will be asked to check this email weekly. Subjects will continue to wear their Oura Ring device during their rest and sleep times.

Participants will also be asked to begin the respiratory resilience program to activate and build-up their pulmonary system, and document their use of the Breather Fit device in a diary daily.

Respiratory Resiliency Program is the optimization and strengthening of the respiratory muscle system for better pulmonary hygiene and improved cardiopulmonary function. Short effective respiratory high intensity training

interventions provide rapid increase in respiratory and core muscle efficacy. Integration of high intensity training sessions with the biometric monitoring platform is provided to optimize compliance and adherence.

**End of Study (end of week 4):**
Study participants will again be requested to complete the cardiorespiratory fitness test assessment by walking for 6-12 minutes. The participant may choose to complete this test on a treadmill or using a pedometer, and they will need to self-report the distance or steps and time walked for this test.

Patients will be asked to return to the clinic for an in-person visit if possible (telephone and online will be an alternative). At this visit, subjects will be asked to complete end of study surveys, and return their completed Breather Fit device diary. Subjects will be able to keep the study intervention tools for continued personal use.

## Subject Information

Target accrual: 10 Mayo Clinic frontline healthcare professionals

Inclusion Criteria:

1. 18 years of age or older at the time of consent
2. Frontline healthcare professional
3. Have access to an Apple or Android device
4. Not pregnant by subject self-report at time of consent
5. Have the ability to provide informed consent
6. Have no contraindicating comorbid health condition as determined by the clinical investigators

Exclusion Criteria:

1. Currently (within the past 3 weeks) been practicing mindfulness training on a weekly/regular basis
2. Currently (within the past 3 weeks) been undergoing an additional program (e.g. CAM) to improve quality of life or sleep
3. Currently (within 3 weeks) been enrolled in another clinical or research program (e.g. CAM) which intervenes on the patients' QOL, stress or sleep
4. An unstable medical or mental health condition as determined by the physician investigator

## Review of medical records, images, specimens

☒ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.
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## Data Analysis

**Power Statement:** The sample size for this pilot investigation (N=10) was established after considering both the statistical implications and the amount of project effort and resources required to recruit and study this unique patient population.

**Data Analysis Plan:** Data related to subject recruitment will be summarized, including the frequency of calls and the reasons for failing screening criteria. In all cases, data will be summarized using mean ± SD for continuous variables and frequency percentages for nominal variables. Treatment adherence will be quantified for each individual by calculating the percentage of sessions attended. The percentage of subjects who discontinue study participation and the reasons for discontinuing study participation will be summarized.

Patient demographics will be summarized using descriptive statistics. Changes in resilience, stress and sleep will be calculated using a paired t test. In all cases, two-tailed p-values ≤ 0.05 will be considered statistically significant.

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