



# Stress Resilience Program for Health Care Professionals During a Pandemic

## A Pilot Program

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**Abstract:** *Background:* The COVID-19 pandemic has led to increased burnout and staff turnover for health care providers (HCPs). The purpose of this pilot study was to evaluate the safety and acceptability of a Stress Resilience Program (SRP) for reducing perceived stress and improving resilience among HCPs during a pandemic. *Methods:* Of the 12 HCPs expressing interest in the study, 10 were enrolled. Participants attended three in-person visits (consent/screen, baseline, and end-of-study). The SRP consisted of education related to resilience enhancement and a breathing device (*BreatherFit*®) for combined respiratory muscle training (cRMT). Participants completed 4 weeks of cRMT and applied situational breathing strategies as needed. Outcomes measured were changes in stress (PSS-10), resilience (BRS), depression (PRIME-MD), and sleep (PSQI and *Öura Ring*®). *Findings:* The majority of participants were male (60%) and White (60%) with an average age of 39.7 years. Changes from baseline to end-of-treatment indicated a positive trend with significant stress reduction ( $-3.2 \pm 3.9$ ,  $p = .028$ ) and nonsignificant depression reduction ( $-0.5 \pm 0.7$ ,  $p = .05$ ). Resilience was high at baseline and continued to stay high during the study with a nonsignificant increase at end-of-study ( $+0.07 \pm 0.7$ ,  $p = .77$ ). No changes in overall sleep scores were noted. All participants agreed the study was worthwhile, 80% indicated they would repeat the experience, while 90% indicated they would recommend the study to others. *Conclusion/Application to Practice:* Because of its size and portability, SRP is an easily applicable and promising option for reducing stress among HCPs during a high-stress period, such as a pandemic. Larger studies are needed.

**Keywords:** anxiety, COVID-19, health care provider, respiratory muscle training, stress

## Background

Although health care professionals (HCPs) dedicate significant time and effort toward providing care to others, they often experience negative outcomes in their own physical and mental health leading to burnout (Tan et al., 2020) and staff turnover (Rangachari, 2020). The COVID-19 pandemic has led to increased burnout and staff turnover for HCP (Ratner et al., 2004). As exposure to occupational factors can be difficult to avoid for HCP, it is important to identify and intervene early on increases in stress and anxiety and reductions in resilience with proactive, sustainable, and validated physical and mental health solutions.

Anxiety and stress have been associated with cardiopulmonary symptoms such as hyperventilation, chest tightness, dyspnea, tachycardia, and palpitations (Hamasaki, 2020; Kavan et al., 2009). Breathing interventions including yoga breathing (pranayama; Brown & Gerbarg, 2009), Diaphragmatic (Deep) Breathing (Hamasaki, 2020; Hooper et al., 2018), and respiratory muscle training (RMT) may aid with stress and anxiety and decrease cardiovascular disease risk (Arnold et al., 2020; Bausek et al., 2020; Shaikh et al., 2019). Complete RMT (cRMT) focuses on strengthening both the expiratory and the inspiratory respiratory muscles (Arnold & Bausek, 2020; Arnold et al., 2020). These breathing interventions have been found to impact cardiovascular, respiratory, gastrointestinal, and brain systems through modulation of the autonomic nervous system (Hamasaki, 2020). Devices have been developed to assist the patient in using cRMT as a self-aid approach in a cost-effective and easily accessible manner. One such device is the *BreatherFit*®. This device has been used to improve dysphagia and speech in stroke patients (Arnold & Bausek, 2020; Arnold et al., 2020) and pulmonary function (Bausek et al., 2019; Nina et al., 2019).

Sleep disorders, including insomnia (Mellman, 2006), sleep apnea (Garbarino et al., 2020), narcolepsy (Chen et al., 2020),

## Applying Research to Occupational Health Practice

Burnout is a critical factor affecting the engagement and productivity of health care workers and has been implicated in medical errors and career shifts. Burnout is especially prevalent in those on the frontlines of the COVID-19 pandemic. Support of these colleagues is imperative but needs to be done in a manner that is both highly effective and not time-consuming. The interventions presented in this manuscript are simple, short, effective, and easily implemented in any clinical setting. Participants perceived that the interventions made a difference and had a high level of follow-through with the protocol. The effect size was moderate in a small sample size of already highly resilient individuals, which makes this intervention an attractive option for occupational health professionals to deploy when caring for health care workers who are under stress.

restless leg syndrome, and REM sleep behavior disorders (Baglioni et al., 2016), have also been associated with mental health issues such as stress and anxiety (Pires et al., 2016). Monitoring sleep patterns before, during, and after a behavioral intervention will identify sleep disorders as well as the efficacy of the intervention in realigning sleep pattern (Adami et al., 2003). Recently wearable devices, such as the *Öura Ring*®, have been introduced which can monitor activity levels and sleep quality and quantity (Berryhill et al., 2020; Penzel et al., 2018; Roberts et al., 2020).

The purpose of this pilot was to evaluate the feasibility of an integrated Stress Resilience Program (SRP) utilizing the *BreatherFit*® for cRMT and the *Öura Ring*® for sleep tracking in providing an effective and sustainable solution for frontline HCPs.

## Methods

This open-label pilot study aimed to evaluate the feasibility of an SRP addressing physical and mental health. Each participant received an *Öura Ring*® and *BreatherFit*® device, education, and weekly emailed recommendations during the 4-week study period.

Potential participants were recruited via fliers and email from a large health care facility in the Midwestern United States. Enrollment took place between January and February 2021. This report is based on all participants who participated in the study and adheres to CONSORT guidelines on reporting clinical trials (*Consort: Transparent Reporting of Trials*).

Of 12 HCP who expressed interest in this study, 10 were enrolled. The two HCPs who failed to enroll either had scheduling difficulties or were unable to be contacted. Eligibility criteria for this study included employment as a frontline HCP

and having access to a smart device (phone or tablet). Currently, practicing regular mindfulness training, participating in other clinical or research to improve quality of life or sleep, or had an unstable medical or mental health condition are exclusionary. All interested individuals were prescreened via the telephone. Once they passed this prescreen, they were invited to attend an in-person visit where they were screened for study eligibility, consented, and enrolled.

*Stress Resilience Program (SRP)*: Upon study entry and receiving study supplies, participants had a kick-off session which included an overview of specific resilience tools and respiratory muscle training as well as situational stress and respiratory muscle interventions. Prerecorded video material was available throughout the study on a reference webpage. The participant was specifically asked not to make any lifestyle changes such as a new exercise regimen during the 4-week trial period. Study data were monitored by the SRP coaches to create insights and adjustments that were communicated to individual participants via emailed weekend scorecards. Recommendations could include changes to sleep, instrument use, use of situational breathing strategies, and changes to the cRMT program.

## Data Collection

Participants were taught how to utilize the *BreatherFit*® device and asked to use it daily to activate and build-up their pulmonary health through cRMT. The use of the *BreatherFit*® device was to be recorded in their *BreatherFit*® diary. Participants were asked to wear the *Öura Ring*® throughout study participation during their daily sleep and rest times. The *Öura Ring*® would wirelessly sync data with the *Öura Ring*® APP.

*The BreatherFit*® Device is a respiratory device made of medical-grade plastic and is for oral use. It 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 (<https://www.pnmedical.com/products/>; see Supplemental Figure 1). The *Öura Ring*® 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 *Öura Ring*® captures distinct parameters during the day and night, respectively. The *Öura Ring*® app reports trend analyses of comprehensive sleep data, heart rate, heart rate variability, respiratory rate, and overnight body temperature which is used to calculate the *Öura Ring*® sleep score (<https://ouraring.com/>; Supplemental Figure 2).

Stress was evaluated through the Perceived Stress Scale (PSS), a 10-item Likert-type scoring system that measures global life stress by assessing the degree to which experiences are appraised as uncontrollable or unpredictable. Scores range from 0 to 40, with higher scores indicating greater perceived stress (0–13 is considered low stress, 14–26 is moderate stress, and

27–40 is high stress). Resilience was evaluated through the Brief Resilience Scale (BRS), a validated 6-item Likert-type scoring system (Smith et al, 2008). The higher the BRS score the higher the resilience. The Sleep Quality Index (PSQI) is a validated 9-item Likert-type scoring system that is effective in measuring quality and sleep patterns in adults. The PRIME-MD Questionnaire (Spitzer et al., 1999; Whooley et al., 1997) comprises two questions. This was self-reported by participants and a score of  $<3$  suggests a major depressive disorder. A modified Was-It-Worth-It Questionnaire (WIWI) (Chauhan 2012), a satisfaction survey, was administered at the end-of-study visit to assess the feasibility and acceptability of the entire research experience. Basic demographic information was collected at the study entry. Adherence to the *Öura Ring*® was collected through the smart device application; adherence to the *BreatherFit*® device was collected through the self-reported diary.

Participants attended three in-person study visits along with participation in the SRP. At the consent visit, participants completed a demographic survey, PSQI, PSS, BRS, and PRIME-MD questionnaires. They viewed an introductory video introduction to the *Öura Ring*® device and were sized for their rings. An in-person baseline visit was scheduled upon arrival of the participant's *Öura Ring*®, during which they installed the *Öura Ring*® application to their personal smart device and received the study tools (*Öura Ring*®, *BreatherFit*® device and Diary, and a Pedometer). The cardiorespiratory fitness test comprised completing a 6-minute walk test with the pedometer.

Participants were instructed on the three phases of the SRP: Run-In, Education, and Active. During the Run-in Phase, participants wore the *Öura Ring*® during sleep and rest times and did not modify their lifestyle habits to gain baseline biometric trends. The Education Session was scheduled 5 to 7 days from the baseline visit. This 3-hour education phase was presented by the SRP coach, and involved a real-time introduction to the active intervention, viewing of prerecorded training videos, and ended with a live Question & Answer session. The Active Phase, Weeks 2 to 4 of the study. Throughout this phase participants continued to wear the *Öura Ring*®, and to incorporate the use of the *BreatherFit*® device and self-report use in the *BreatherFit*® diary. The SRP was modified based on weekly emailed individualized recommendations. At the end of the study (end of week 4, visit 2), participants were asked to complete the PSQI, BRS, PSS, PRIME-MD, and WIWI study questionnaires as well as return their *BreatherFit*® diary and complete a final 6-minute walk-test.

In accordance with the Declaration of Helsinki, this study was reviewed and approved (ID 20-005017) by our Institutional Review Board (IRB), and all study participants provided written informed consent prior to participation.

### Data Analysis

The sample size for this pilot investigation ( $N = 10$ ) was based on the primary aim of feasibility. In all cases, data are

summarized using mean  $\pm$  standard deviation (*SD*) for continuous variables and frequency percentages for nominal variables. Treatment adherence was quantified for each individual by calculating the percentage of sessions attended.

All four surveys (BRS, PSS-10, PRIME-MD, PSQI) were analyzed to estimate the difference between pretest scores and post-test scores using paired *t* tests. The 6-minute walk test measured in miles and steps was analyzed between pre- and post-data using a paired *t*-test. Sleep data collected by the *Öura Ring*® included scores for sleep, REM, deep sleep, total sleep, and heart rate average per night. The baseline measures for these outcomes were computed as the average scores during a participants' run-in phase. Changes over time for these scores were analyzed using linear mixed models, with a random intercept and slope for participants and using an autoregressive 1-covariance matrix. The *p*-values for the fixed effect of time are reported in the table for each score. In all cases, two-tailed *p*-values  $\leq .05$  were considered statistically significant.

### Results

In this study, the majority were male (60%), White (60%), and with an average age of  $39.7 \pm 5.55$  years (*SD*; Table 1). Their activity level at baseline was 3.0 (range 2.0, 4.0) with moderate stress ( $5.9 \pm 1.9$ ).

The changes from baseline to end of treatment (1-month post-baseline) included a significant reduction in stress ( $-3.2 \pm 3.9$ ,  $p = .028$ ) and a nonsignificant reduction in depression ( $-0.5 \pm 0.7$ ,  $p = .05$ ). Resilience was high at baseline and continued to stay high during the study with a nonsignificant increase at the end of study ( $+0.07 \pm 0.7$ ,  $p = .77$ ; Table 2).

When asked about their experience during the trial, 100% of the participants agreed it was worthwhile and 80% indicated they would repeat the experience, while 90% indicated they would recommend the study to others. Overall, 60% reported their study experience was better than they expected (vs. 40% indicating the experience was about what they expected) and 60% indicated the study exercises were useful.

No significant change was noted for sleep score, as measured by the PSQI ( $0.0 \pm 2.1$ ,  $p = 1.00$ ) or the *Öura Ring*® (Table 3). There was a significant change from baseline in sleep scores for one individual in the outcomes of overall sleep score, total sleep score, and two individuals for REM sleep score when adjusting for random slopes.

The average number of days of compliance with the *BreatherFit*® exercises was  $18.2 \pm 3.97$  (range = 9.0–21.0 days). During the study days ( $N = 21$ ), the average use was  $50.7 \pm 45.5$  (range = 17.0–170.0). The correlation coefficient between days compliant and the difference between pre- and post-surveys was  $-.3$  for PSS,  $.1$  for BRS, and  $.2$  for PHQ-2. None of the correlations were statistically significant.

### Discussion

This study provides preliminary data suggesting the benefit of an integrated SRP in reducing stress and anxiety in frontline

**Table 1. Demographic and Self-Reported Health Measures Among Health Care Professionals During a Pandemic (N = 10)**

Variables	Total (N = 10)
<b>Age<sup>a</sup></b>	
<i>M (SD)</i>	39.7 (5.55)
Median	39.0
Range	34.0, 52.0
<b>Gender, n (%)</b>	
Male	6 (60.0%)
Female	4 (40.0%)
<b>Race, n (%)</b>	
Asian	3 (30.0%)
White	6 (60.0%)
More than one race	1 (10.0%)
<b>How would you describe your current level of activity</b>	
<i>M (SD)</i>	3.0 (0.82)
Median	3.0
Range	2.0, 4.0
<b>Stress (PSS-10), 0–10 scale</b>	
<i>M (SD)</i>	5.9 (1.91)
Median	6.0
Range	3.0, 8.0
<b>Concern about their resilience during this pandemic (0–10 scale)</b>	
<i>M (SD)</i>	4.7 (2.26)
Median	5.0
Range	0.0, 8.0
<b>Motivation to make lifestyle changes to improve resilience during pandemic (0–10 scale)</b>	
<i>M (SD)</i>	6.8 (1.87)
Median	6.0
Range	4.0, 10.0
<b>Importance to make lifestyle changes to improve resilience during pandemic (0–10 scale)</b>	
<i>M (SD)</i>	6.7 (2.21)

(continued)

**Table 1. (continued)**

Variables	Total (N = 10)
Median	6.5
Range	4.0, 10.0
<b>Confidence in ability to make lifestyle changes to improve resilience during pandemic (0–10 scale)</b>	
<i>M (SD)</i>	6.2 (2.25)
Median	6.0
Range	3.0, 10.0
<b>Number of the 21 study days compliant</b>	
<i>M (SD)</i>	18.2 (3.97)
Median	20.0
Range	9.0, 21.0

*Note.* PSS = Perceived Stress Scale.

<sup>a</sup>One person had the current date and not their date of birth listed.

HCP. Furthermore, this feasibility study suggested that the integration of a resilience program into physicians' schedules was acceptable to the HCP. The adherence rate was high with 9 of 10 HCP completing all aspects of the training and 80% indicating it was valuable. Despite the small samples size, there was a statistically significant drop in perceived stress for participants who completed the educational component of the SRP and used the *BreatherFit*® device for cRMT.

This correlates with findings from other resilience programs involving breathing techniques to reduce stress and bolster resilience (Gilbert et al., 2013; Hopper et al., 2018; Ma et al., 2017; Perciavalle et al., 2017; P. Sharma et al., 2015). Most of these studies involve interventions with breathing exercises up to 90-minute duration and in a variety of formats, with and without behavioral programs or monitoring. While breathing techniques have positive effects on perceived stress, they have not been associated with a decrease in oxidative stress (Briskey et al., 2020). Longer term studies are required to objectively assess the sustainability of such stress reductions over time.

While improvement in depression did not reach significance, the trend was in a favorable direction. Low baseline depression scores among a small number of participants may have limited our ability to detect a measurable effect. In fact, a recent randomized study that included a 2-month intervention of breathing exercises, walking, and meditation reduced depression, dyspnea, and anxiety while improving quality-of-life in patients with chronic obstructive pulmonary disease (Lin et al., 2019). Another randomized trial found that a breathing-based yoga intervention improved depression among patients

Table 2. Assessment of Workplace Stress and Burnout Among Health Care Professionals Before and After the Breatherfit Intervention ( $N = 10$ )

	Pre-score, $M \pm SD$	Post-score, $M \pm SD$	Difference, $M \pm SD$	$p$ value*
Perceived Stress Scale (PSS)	17.9 $\pm$ 5.5	14.7 $\pm$ 4.0	-3.2 $\pm$ 3.9	.028
Brief Resilience Scale (BRS)	4.0 $\pm$ 0.7	4.1 $\pm$ 0.8	0.07 $\pm$ 0.7	.770
PRIME-MD	0.9 $\pm$ 1.0	0.4 $\pm$ 0.7	-0.5 $\pm$ 0.7	.052
Pittsburgh Sleep Quality Index (PSQI)	4.3 $\pm$ 1.8	4.3 $\pm$ 2.1	0.0 $\pm$ 2.1	1.00
Miles in 6 Minutes**	0.3 $\pm$ 0.1	0.4 $\pm$ 0.1	0.05 $\pm$ 0.06	.045
Steps in 6 Minutes**	788.1 $\pm$ 204.6	750.2 $\pm$ 46.8	-46.6 $\pm$ 212.7	.530

Note. PSS = Perceived Stress Scale; BRS = Brief Resilience Scale; PSQI = Sleep Quality Index.

\*Paired  $t$  test results between pre and post surveys

\*\*one person did not do post-walk.

with treatment-resistant major depressive disorder (A. Sharma et al., 2017).

Contrary to other studies that report an improvement in resilience for participants who perform daily breathing training (Lai et al., 2020; Melnyk et al., 2020), we did not observe a significant change in resilience as measured by the BRS. This may be due to a number of factors. First, the study was relatively short in duration, and it is possible that measurable changes in resilience would require longer practice. Second, our population had a very high baseline resilience score, which may not have allowed much room for improvement. Third, the sample size may have been too small to detect these differences with power. A longer study with additional resilience-outcome measures is required to evaluate the full impact of the intervention. Further studies should also target individuals with lower resilience scores and non-Caucasian race to enhance generalizability.

While our study demonstrated comparability between the *Óura Ring*® and PSQI, no significant changes were noted in sleep patterns. These findings differ from those obtained in a study of 140 Chinese nurses who were instructed to follow the Deep-Breathing-Exercises at least once a day (30-minute duration) for 2 weeks during the COVID-19 outbreak. At the end of those two weeks, self-reported sleep as measured by the PSQI, had improved, and anxiety had reduced (Liu et al., 2021). This may be due to multiple factors including that *BreatherFit*® use was self-reported which may have contributed to some reporting errors.

While all participants report that study participation was worthwhile, 80% of participants planned to keep using the *Óura Ring*®, and 50% reported they would continue using the *BreatherFit*®. Satisfaction comments concerning suggestions for

improving this intervention included comments such as “I needed more time”; “Recommendations to account for severe cold weather/COVID closures/etc.”; and “On-site breather training.”

This pilot study provided details for improvement of the intervention for a larger more generalized population. Lessons learned include ways to optimize the HCP time while completing training and delivery of the intervention. While refresher training was available to the participants at any time during the study, the HCP had to find the place (computer availability) and time to complete initial/refresher training during a busy COVID-19 work schedule and remember to document daily adherence. As HCPs were experienced in using smart devices, the option of delivering the training and logging the use on a smart device application would have solved accessibility issues.

Intrinsic characteristics of a more generalized population may be inherently different from HCP in that their baseline resilience may be lower and baseline depression may be higher, leading to a higher impact. In addition, this current pilot was of short duration (1 month) and small sample size. A larger study of longer duration may yield different results. The longer duration of use would give participants an opportunity to familiarize themselves with the SRP routine and device. Finally, despite the fact that there are two types of devices available for RMT (*Breather*® and *BreatherFit*®) due to the small sample size of this pilot, and to avoid confounding, only the *BreatherFit*® was used. The *BreatherFit*® was designed to be used by individuals with normal and above normal lung capacity (i.e., athletes), and the *Breather*® for individuals with below normal lung capacity. The study did not screen for lung capacity; therefore, whether the device used was a good fit for the participant is unknown. Addressing these issues will greatly improve the ability to assess the impact of the intervention itself on HCP.

Table 3. Sleep Results From *Ōura Ring*® Output Among Health Care Professions (*N* = 10)

	Baseline ( <i>N</i> = 10)	Change from timepoint to baseline ( <i>N</i> = 195)*	Mixed model <i>p</i> value for time**
Sleep score			.886
<i>M</i> ( <i>SD</i> )	78.0 (7.7)	−0.7 (7.4)	
Median	79.7	−1.0	
Range	64.0, 87.3	−25.6, 23.3	
Rapid Eye Movement (REM) score			.808
<i>M</i> ( <i>SD</i> )	78.6 (23.0)	0.0 (18.8)	
Median	90.9	1.5	
Range	40.2, 97.5	−66.2, 54.8	
Deep sleep score			.678
<i>M</i> ( <i>SD</i> )	70.3 (23.5)	−0.5 (17.8)	
Median	75.3	1.0	
Range	35.2, 99.0	−51.6, 44.8	
Total sleep score			.895
<i>M</i> ( <i>SD</i> )	75.1 (13.4)	−2.2 (13.8)	
Median	76.5	−0.6	
Range	54.6, 92.0	−43.4, 42.8	
Heart Rate (HR) average per night			.653
<i>M</i> ( <i>SD</i> )	66.6 (11.2)	−0.9 (4.1)	
Median	69.1	−0.9	
Range	48.3, 82.0	−11.7, 14.3	

\*Each time point per individual was counted as an observation for a total of 195. The difference in score was calculated using the score at each timepoint—baseline score (positive scores meant that they did better than baseline).

\*\*Mixed model with the autoregressive covariance matrix. Intercept and slope were adjusted for as random effects.

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### Author Contributions

Ivana T. Croghan provided a significant contribution to the study concept and design, obtained all the regulatory approval and designed the data collection process, oversaw data collection She contributed to the interpretation of the data analysis and study conclusions. She wrote the initial draft of this manuscript and was a contributor to the revisions. She has approved the final submitted manuscript. Ryan T. Hurt provided a significant contribution to the study design, participated in data analysis discussions and interpretations, and contributed to manuscript revisions. He has approved the final submitted manuscript. Shawn C. Fokken provided a significant contribution to the study design, coordinated the filing for regulatory requirements, and assisted in the collection of data and manuscript writing. She participated in data analysis discussions and interpretations and contributed to manuscript revisions. She has approved the final submitted manuscript. Karen M. Fischer participated in refining the study design and data collection process as well as conducting the data analysis, contributing to the interpretation of the data, and assisting in writing and editing the manuscript. She has approved the final submitted manuscript. Stephanie A. Lindeen supported this study by assisting in the regulatory process, coordinating and conducting study visits with the subjects, data collection, and contributed to the writing and revising of the manuscript. She has approved the final submitted manuscript. Darrell R. Schroeder participated in drafting the statistical section of the study design and refining the data collection process as well as conducting the data analysis, contributing to the interpretation of the data, and assisting in writing and editing the manuscript. He has approved the final submitted manuscript. Ravindra Ganesh contributed to the interpretation of the data, writing, and editing of the final manuscript and critical revisions. He has approved the final submitted manuscript. Karthik Ghosh has contributed to the study data interpretation, writing, and editing the final manuscript. She has approved the final submitted manuscript. Nina Bausek has contributed to study design, data acquisition, and analysis, critical reviewing of the manuscript, and has approved the final version of the manuscript and has approved the final submitted manuscript. Brent A. Bauer provided substantial contributions to the conception of the work and revised the work critically for important intellectual content. He has approved the final submitted manuscript.

## Conflict of Interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Bausek serves as Independent Chief Scientist for PN Medical. All other authors declare no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; and no other relationships or activities that could appear to have influenced the submitted work.

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## Ethical Approval and Informed Consent


In accordance with the Declaration of Helsinki, this study was reviewed and approved (ID 20-005017) by the Mayo Clinic Institutional Review Board (IRB) on July 21, 2020. Mayo Clinic IRB-approved written informed consent was obtained for all study participants prior to study participation.

## Trial Registry Information

Trial registration: NCT04536376. Registered September 26, 2020.

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## Supplemental Material

Supplemental material for this article is available online.

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