Breathing Techniques and Meditation for Health Care Workers During COVID-19

PI: Santhosshi Narayanan MD

Collaborators: Jegy Tennison, Yisheng Li, Balachundhar Subramaniam MD Dave Balachandran MD Smitha Mallaiah MS

Senior Authors: Lorenzo Cohen PhD Eduardo Bruera MD

Introduction:
Pranayama is a term used to describe breathing techniques that are an integral part of yoga practice. Numerous studies have shown the benefit of yoga in healthy volunteers and cancer patients. (1,2, 3,4, 5, 6, 7) The benefits range from decreasing inflammation as evidenced by reduction of inflammatory cytokines to improvement in immune system as evidence by increasing non-killer/NK cells. (8) In our own studies, we have shown evidence of yoga improving chemotherapy-related cognitive dysfunction and reducing anxiety in cancer patients and caregivers in addition to improving both their quality of life. (1,9) The pandemic COVID-19 has created chaos and distress for the entire world, especially for healthcare workers. Here we suggest a series of 3-minutes breathing or pranayama practices followed by 2 minutes of meditation – overall 5 minutes to complete. The purpose of this study is to determine the effects of web-based breathing techniques and meditation on lung health and building resilience among health care workers dealing with the COVID-19 pandemic.

AIMS:

Primary Outcome:

To demonstrate the feasibility of a short pranayama or breathing techniques and meditation during Covid-19 pandemic. Feasibility will be defined as recruitment of 50 participants to the study within 2 months and acceptance of the study defined as more than 50% of participants perceive the intervention as useful.

Secondary Outcomes:

1. To determine the adherence to the practice assessed as at least 50% of participants implement the intervention for 3 or more times in a week by the end of week 1/day 7 (+ 3 days)
2. To determine the change in resilience, perceived stress and psychological impact from day 0 to day 28 as measured by the Brief Resilient Coping Scale (BRCS), Perceived Stress Scale (PSS4), and COVID-19 Stress among health care workers questionnaire
3. To determine the changes in breath holding time measured weekly for 4 weeks
4. To determine the differences in breath holding time between those who are adherent and those who are not adherent to the practice

Background/Rationale:

Current COVID-19 climate and stress on health care:
COVID-19 is a war-like situation where health care workers (HCW) are faced with unprecedented challenges with the novel coronavirus global pandemic. Studies have been done examining previous experience with disease outbreaks and pandemics such as MERS-CoV and Ebola management and its effect on HCWs. (10,11) These studies suggested that although HCW's ethical obligations propelled them to continue with their jobs, their perceived levels of stress were higher than normal. As a consequence, these HCW's were also more likely to suffer from long term psychological effects.

While the health care community has been exemplary under this enormous pressure, many health care workersare showing early signs of burnout in terms of anxiety, fear, ethical dilemma due to risks associated with coronavirus spread, in the setting of limited resources such as medical and personal protective equipment. (12) To minimize the long-term negative effects of the intense stress, fear, and anxiety HCWs are experiencing at the moment, it is important to support them with wellness tools. One such non-pharmacological and easily adaptable tool is a time-tested behavioral program that can help to build resilience, and that is yoga and meditation. Numerous studies have been conducted indicating the effectiveness of yoga and meditation as effective strategies to manage stress. In addition, there is a growing body of literature suggesting that even short-term meditation improves measures of attention and well-being.

Breathing techniques:
COVID-19 results in multiple respiratory symptoms and those with prior respiratory conditions are more vulnerable to infection with SARS-CoV-2 (the virus that causes COVID-19 disease). As such, learning techniques that help to improve lung capacity, volume and function may play a role in decreasing risk and simultaneously lowering stress levels. A short powerful stroke of exhalation and inhalation in quick succession with contraction of abdominal and diaphragmatic muscles helps to make full use of diaphragm and abdominal muscles in breathing. It also aids in removal of secretions from the bronchial tree, clearing up respiratory passages and the alveoli.

Studies have shown improved ventilatory functions in the form of lowered respiratory rate (RR), and increases in the forced vital capacity (FVC), forced expiratory volume at the end of 1st second (FEV1%), maximum voluntary ventilation (MVV), peak expiratory flow rate (PEFR-lit/sec), and prolongation of breath holding time. (6,7) These practices have also led to increases in parasympathetic tone and decreases in sympathetic activation. Importantly, participants engaging in yogic breathing practices report reduced stress, better quality of life, and improvement in multiple physiological and biological outcomes. "Dog breathing" is one such yogic breathing technique that has been shown to improve lung volume and capacity, helps to reduce stress, and is relatively easy to learn and perform compared to other complex breathing/pranayama techniques requiring more extensive training and practice. The "Dog breathing" practice and meditation that will be tested in this pilot study were designed by Sadhguru, a Yogi and founder of Isha Institute of Inner Sciences. (13) The reason for choosing these practices are that it is short (less than 5 minutes), readily available free of cost, with clear instructions.

Methods:

Enrollment:

MD Anderson Email will be used for advertisements at the hospital. Recruitment will also involve word of mouth, announcements, and flyers on social media and official websites of MD Anderson.

Interested participants will receive a link where they can confirm their interest in the study and get detailed information of the study procedures. If they are interested in participating after receiving the email, they will be directed to REDCap where they will be asked a few screening questions to ensure study eligibility. Participants who are eligible will be directed to an electronic consent form. They will be enrolled into the study following submission of the evaluation of the consent process. Participants will be informed that their decision to participate or not to participate is entirely voluntary. Participants will have the ability to discontinue their participation at any time.

Study Population:
All employees at the University of Texas MD Anderson Cancer Center are eligible to participate.

Inclusion Criteria:
Participants must be able to read and understand English.
Must be employed at MD Anderson Cancer Center.

Exclusion criteria
Epilepsy
Brain tumor
Brain aneurysm
Pregnant or trying to get pregnant
Brain bleeding in the past 1 year
>70 years of age
Recent abdominal surgery and not cleared to exercise

Study Procedures:
Subjects will be sent a link to the video with instructions. They will also be requested to maintain weekly activity logs to document their daily practice. A survey will be completed at study recruitment, before receiving the video link, and then again 1, 2, 3, and 4 weeks after starting the breathing practices.

Intervention:
The practice will consist of a 3-minute breathing practice followed by a 2-minute meditation. The participants will be encouraged to practice at least once a day and ideally more often, especially first thing in the morning, anytime they are feeling stressed or have time to take a 5 minutes break from work during the day, and at the end of the day.

Participants will be instructed to start the practice when somewhat hungry or have empty stomach. It is not ideal to do these practices after meals. To begin, sit in a comfortable position where your spine is straight and your abdomen is not compressed. Some options include:

- An upright seated cross leg position
- A seated position on a chair with your feet flat on the floor, resting your hands on knees, palms facing down.

Step 1: Shawna kriya (Dog breathing)

To perform Dog breathing, lengthen your spine, inhale lifting your diaphragm by pushing your chest/ribcage out, keep your hands on your knees with palms facing downwards elongating your hands, open your mouth wide and stick your tongue out as far as it can go.

Start panting the way a dog pants. All of the breathing will take place from the mouth while doing Dog breathing. Do not force any muscles to contract while abdomen will automatically contract during exhalation when you will pant like a dog. The inhales and exhales during Dog breathing or Panting Dog Breath should be even in depth, time and force. Participants will be instructed to do this practice for 21 breaths.

Step 2: Dog breathing with tongue rolled upwards

Fold your tongue backwards as much as you can. Now inhale and exhale in the same way you did for Dog breathing. The mouth is opened wide; the tongue is rolled backwards to its maximum. Inhale and exhale through constriction in the throat and make the sound 'HHHHHAAAA' while exhaling as demonstrated in video. You will feel the touch of air in your throat. Participants will be instructed to perform this practice for 21 breaths.

- While performing this practice, participants will be instructed to take a 15- 20 seconds break if feeling dizzy.
- Participants will be instructed to not stress the body or overdo the exercise beyond capacity.

Step 3: Participants will be instructed to close mouth, inhale fully and simply sit for 30-60 seconds in full inspiration. After 30-60 seconds, exhale with a constriction in pit of throat and relax.

Upon completion of breathing techniques, participants will be instructed to sit in meditation for 2 minutes or longer with eyes closed. Participants will be instructed to not judge their thoughts, to be an observer, and just let their thoughts pass by without focusing on anything.

If you feel short of breath, or unable to perform the practices please do not continue with the practice. Please contact your doctor for further medical attention and notify the study team.

Video link *of the practice is as follows-*
https://www.youtube.com/watch?v=lP1Y1bk1YgU

Measures: The following measures will be completed during the course of 4 weeks through a REDCap data base

Adherence: Participants will keep a record of when they practiced each day to report in the survey how many times a day and how many days a week participant practiced for each of the 4 weeks.

Breath holding time: At baseline and the end of each week, participants will count how many seconds they can hold their breath at one time. Participants will be asked to use the stopwatch on their smartphones to time breath holding. They will first empty their lungs as much as possible with an extended exhale pulling in their diaphragm using abdominal breathing. They will then inhale fully extending their diaphragm out and start timing how many seconds they can hold their breath. After a 2-

minute rest period they will repeat and record the second number. They will record both numbers at end of each week and report the results in the survey.

Meditation perception questionnaire (including perception of usefulness): At the end of each week, participants will be asked 7 questions regarding their perception of practice such as feeling more peaceful, hopeful, relaxed, in more control of life, if they noticed improvement in their breathing, if they found the practice useful, and if they will continue to engage in the practice. We used this questionnaire in our previously published meditation study (14) and added 2 questions.

Global Symptom Evaluation (GSE): The GSE has 2 parts and participants will only complete part 2. (15) Part 2 consists of 5 questions that evaluate whether participating in the study was worthwhile, whether they would participate in the study if they had to do over again, whether they would refer the study to others, and whether it had a positive or negative impact on quality of life. The answers consist of yes, no, and uncertain. We will only use the second part of GSE (Modified GSE Questionnaire) and it will only be asked at the end of the study. These questions will help determine if participating in the study was burdensome or beneficial to the participants. Participants will complete the questionnaire at the end of the study at week 4, or at the time of removal from the study.

Perceived Stress Scale 4 (PSS-4): The PSS will be asked at baseline and the end of the study. (16) The questions in this scale ask about participants feelings and thoughts during THE LAST MONTH. In each case, please indicate your response by placing an "X" over the square representing HOW OFTEN you felt or thought a certain way.
1. In the last month, how often have you felt that you were unable to control the important things in your life?
2. In the last month, how often have you felt confident about your ability to handle your personal problems?
3. In the last month, how often have you felt that things were going your way?
4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?
The responses include: Never, Almost Never, Sometimes, Fairly Often, Very Often.
(0 1 2 3 4)
Lowest score: 0, Highest score: 16. Higher scores are correlated to more stress

Stress among healthcare workers: This measure will be asked at baseline and the end of the study. Drawing from published measures that have assessed the impact of pandemics (H1N1) (17) and other major national stressors such as 9/11, a 29-item measure was developed to assess COVID-19 specific psychological distress (e.g., fear, anxiety and depressive symptoms), and financial and social disruptions. Items also assess resiliency factors such as social support, perceived benefits under times of stress, and ability to manage stress. Responses are provided in a Likert like scale (from 1 to 4) where participants are asked to rank statements from "strongly disagree" to "strongly agree." The measure provides a total score summary that indicates the degree to which the COVID-19 pandemic has negatively impacted the participant. Items that tap into resiliency are reverse scored. In addition to the summary score, based on psychometric analyses upon collection of the data, the scale is expected to yield 5 subscale scores: COVID-19 Specific Distress; Disruption to Daily Activities and Social Interactions; Financial Hardship; Perceived Benefits; and Perceived Stress Management Skills. These answers may not change over time, and may even worsen with time depending on the pandemic effect such as number of cases and burden on health care organization.

Brief Resilient Coping Scale-BRCS: The BRCS will be asked at baseline and the end of the study. The BRCS has four items. (18) The participants are asked to select one option for each statement to indicate their level of disagreement or agreement with each item on a 5-point Likert-type scale, ranging from 1 = *strongly disagree* to 5 = *strongly agree*

1. I look for creative ways to alter difficult situations
2. Regardless of what happens to me, I believe I can control my reaction to it
3. I believe that I can grow in positive ways by dealing with difficult situations
4. I actively look for ways to replace the losses I encounter in life

Demographic information includes age, gender, race, ethnicity, occupation, marital status, COVID status, directly managing patients with COVID (Yes/No), work location, and h/o respiratory disorder (type, medications on daily basis or as needed). At the end of study, we will also ask the participants if they tested positive for COVID during the study time.

Statistical Considerations:

Sample Size Justification:
This study is being conducted with HCWs who are currently at the forefront of pandemic management. Due to overwhelming response and willingness to participate in the study, we decide to increase our accrual from 50 to 100. The increased sample size will allow for increased precision or power in assessing both the primary and secondary objectives, When the sample size is 100, a two-sided 95% confidence interval (CI) for the proportion of perception of the intervention as usual using the large sample normal approximation will extend 0.098 from the observed proportion for an expected proportion of 0.500. In addition, a sample size of 100 will have 80% power to detect a difference in mean of 0.283 standard deviation (SD) unit between baseline and a time point after baseline, using a paired t-test with a 0.050 two-sided significance level. Attrition is unlikely in our study setting given that the participants are HCWs during the pandemic of COVID-19. However, in the unlikely case of a 10% attrition, a resulting sample size of 90 (=100*0.9) will have 80% power to detect a difference in mean of 0.299 SD unit between baseline and a time point after baseline, using a paired t-test with a 0.050 two-sided significance level. In both scenarios, the detectable effect size is considered medium.

Data Analysis:
Baseline characteristics of participants will be recorded. Continuous data will be presented as means ± standard deviation or median (interquartile range) depending on the distribution of the data and assessed with a parametric paired t-test or non-parametric Wilcoxon signed rank test for the changes between time points, as appropriate. Normality will be assessed with the Shapiro-Wilk test. Categorical data will be presented as frequencies and percentages and assessed with a chi-square or Fisher's exact test, as appropriate. SPSS will be used for all analyses with two-sided p-values < 0.05 considered statistically significant.

Feasibility will be defined as recruitment of 50 participants to the study within 2 months and acceptance of the study defined as more than 50% of participants perceive the intervention as useful. Adherence will be assessed using data from how often participants complete their breathing techniques. This will be reported as the percentages of completed activities out of the total required per protocol.

Exploratory regression analysis for adherence to protocol for various outcomes is also planned. Protocol adherence for the study has been defined as participation in the intervention for more than 3 days in a week. Participant perception will be measured using a survey. Continuous and dichotomous data will be reported and assessed in a similar fashion as above.

Given the continuous nature of the scale, differences between scores will be assessed with a paired parametric or non-parametric t-test. In the absence of randomization, unadjusted and adjusted linear regression will be utilized in order to account for differences that persist. Our primary analyses will be assessed using intention-to-treat principles. In order to assess whether there are differences between baseline and at various intervals, we will employ the use of paired t-tests as appropriate.

For the analyses of the changes of variables over time (starting from baseline), we will also use linear mixed-effects models.

Risks:

The risk to the subject is minimal as intervention involves breathing techniques based on yoga and meditation.

Potential physical risks of the study interventions:

The interventions offered in this study are simple and only involves meditation and breathing practices. Participants may feel light headed for a short period of time. As such, there are no physical risks expected with these interventions. Similarly, by assessing stress or well-being measures, we do not anticipate any risk of physical harm to any of the research subjects. Hand held spirometer is easy to use. The twenty participants selected for this extra measure will be nurses, physicians or respiratory therapists who report knowing how to use the spirometer.

Potential psychological risks:

It is possible that there could be psychological or emotional risk to subjects in this study if they were to become aware of their performance in assessments and more so than they would be if they were not participating in the study. Subjects will not be given the scores of their assessments, but if they were to become aware of a decline in their performance this could be stressful or disconcerting to the subject. For additional counseling regarding any psychological or emotional distress stemming from this, participants will be referred to Employee Assistance Program (EAP) at the request of the subject.

Data security and privacy:

Risk of breach of confidentiality:

As with any research study, there is a small risk associated with a breach of confidentiality. All research staff for this trial has been extensively trained in how to handle confidential data and how to minimize the possibility of this risk. To mitigate this risk, electronic data and that on paper will be kept in confidential, locked file cabinets and secure offices and/or on password-protected computers. Subjects will also be assigned a unique study ID to minimize this risk.

Privacy:

All efforts will be taken to ensure participant privacy. All study interactions such as follow up assessments will be completed electronically or via the phone. Throughout the study, only the minimum required information will be collected, assuring participant privacy during the study protocol.

Data collection will occur only on password-protected computers secured or in REDCap directly. Data collected will be limited to only the minimum necessary to accomplish the stated research purposes.

No individual identifier will be obtained from the company other than the email for sending surveys. Each subject will be assigned a study-specific ID number. A crosswalk between the participants and their study IDs will be maintained on password-protected computers by members of the research team. At no time will this crosswalk be shared outside the study team.

All data would be directly entered into REDCap database and at the completion of the study all identifiable will be deleted and data analysis will occur using only the participant's study ID, to further ensure confidentiality of their responses.

References:

1. Chandwani KD, Thornton B, Perkins GH, et al. Yoga improves quality of life and benefit finding in women undergoing radiotherapy for breast cancer. *J Soc Integr Oncol*. 2010;8(2):43–55.
2. Mustian KM, Sprod LK, Janelsins M, et al. Multicenter, randomized controlled trial of yoga for sleep quality among cancer survivors. *J Clin Oncol*. 2013 Sep 10;31(26):3233–3241. doi:10.1200/JCO.2012.43.7707. Epub 2013 Aug 12.
3. Narayanan S, Francisco, R., Lopez, G., Chaoul, M. A., Meegada, S., Liu, W., Mallaiah, S., Milbury, K. & Cohen, L. Role of yoga across the cancer care continuum: From diagnosis through survivorship. Journal of Clinical Outcomes Management. 2019;26(5):p. 219-28
4. Infante JR, Peran F, Rayo JI, et al. Levels of immune cells in transcendental meditation practitioners. Int J Yoga. 2014;7(2):147-51
5. Kochupillai V, Kumar P, Singh D, Aggarwal D, Bhardwaj N, Bhutani M, et al. Effect of rhythmic breathing (Sudarshan Kriya and Pranayam) on immune functions and tobacco addiction. Annals of the New York Academy of Sciences. 2005;1056:242-52
6. Chandla SS, Sood S, Dogra R, Das S, Shukla SK, and Gupta S. Effect of short-term practice of pranayamic breathing exercises on cognition, anxiety, general well being and heart rate variability. Journal of the Indian Medical Association. 2013;111(10):662-5.
7. Joshi LN, Joshi VD, and Gokhale LV. Effect of short term 'Pranayam' practice on breathing rate and ventilatory functions of lung. Indian journal of physiology and pharmacology. 1992;36(2):105-8
8. Rao RM, Telles S, Nagendra HR, , et al. Effects of yoga on natural killer cell counts in early breast cancer patients undergoing conventional treatment. Comment to: recreational music-making modulates natural killer cell activity, cytokines, and mood states in corporate employees Masatada Wachi, Masahiro Koyama, Masanori Utsuyama, Barry B. Bittman, Masanobu Kitagawa, Katsuiku Hirokawa Med Sci Monit, 2007; 13(2): CR57-70. Med Sci Monit. 2008;14(2):LE3-4. Brooks M. COVID- 19: 'Striking' rates of anxiety, depression in Healthcare workers. Medscape. March 26,2020. Retrieved from: https://www.medscape.com/viewarticle/927581

9. Biegler KA, Chaoul MA, Cohen L. Cancer, cognitive impairment, and meditation. Acta Oncol. 2009;48(1):18-26
10. Khalid I, Khalid TJ, Qabajah MR, Barnard AG, Qushmaq IA. Healthcare Workers Emotions, Perceived Stressors and Coping Strategies During a MERS-CoV Outbreak. Clin Med Res. 2016;14(1):7–14. doi:10.3121/cmr.2016.1303 Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4851451/
11. Paladino L, Sharpe RP, Galwankar SC, et al. Reflections on the Ebola Public Health Emergency of International Concern, Part 2: The Unseen Epidemic of Posttraumatic Stress among Health-care Personnel and Survivors of the 2014-2016 Ebola Outbreak. J Glob Infect Dis. 2017;9(2):45–50. doi:10.4103/jgid.jgid_24_17 Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5452550/
12. Lai J, Ma S, Wang Y, et al. Factors Associated With Mental Health Outcomes Among Health Care Workers Exposed to Coronavirus Disease 2020. JAMA Netw Open. 2020;3(3):e203976. doi:10.1001/jamanetworkopen.2020.3976 Retrieved from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2763229?utm_campaign=articlePDF%26utm_medium%3darticlePDFlink%26utm_source%3darticlePDF%26utm_content%3djamanetworkopen.2020.3976
13. Isha foundation: https://www.innerengineering.com/sadhguru
14. Narayanan S, Reddy A, Lopez G, Liu W, Wu J, Liu D, et al. Randomized Feasibility Study of Meditative Practices in Hospitalized Cancer Patients. Integrative cancer therapies. 2020;19:1534735420909903.
15. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. Ann Intern Med. 1993;118:622-629.
16. Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. Journal of Health and Social Behavior, 24, 385-396
17. Matsuishi K, Kawazoe A, Imai H, Ito A, Mouri K, Kitamura N, et al. Psychological impact of the pandemic (H1N1) 2009 on general hospital workers in Kobe. Psychiatry and clinical neurosciences. 2012;66(4):353-60.
18. Kocalevent RD, Zenger M, Hinz A, Klapp B, and Brahler E. Resilient coping in the general population: standardization of the brief resilient coping scale (BRCS). Health and quality of life outcomes. 2017;15(1):251