

Brief Mindfulness based Intervention  
Compared to Psychoeducation for Front-  
Line Medical Staff in the COVID19  
Pandemic to Improve Psychological  
Wellbeing, a Randomized Controlled  
Multicenter Trial.

## Introduction

Coronavirus Disease 2019 is declared as the undetectable adversary, the messenger of death, a determined and heartless assailant that has infected millions of people worldwide with a possibly deadly illness. COVID-19 is a quickly spreading novel infection that spread between people through coughing, sneezing, and contaminated surfaces. An occurrence of the infection was pronounced by WHO on the 30th of January and as of 23th of June, more than 9 million infected cases were announced with 474.000 losses of life around the world (["European Centre for Disease Prevention and Control," 2020](#)). Coronavirus pandemic is a challenge to the health care system and a disaster to both individuals and institutions. Anxiety and fear have been created by this pandemic among health care providers from physicians to nurses. Unluckily, it has been seen that there is a high risk of the negative effects of stress in health care respondents ([Brooks et al., 2011](#)).

Health care worker mental wellbeing protection is of prime importance who look after patients with COVID-19 for the long-lasting ability of health workers ([Organization, 2020](#)).

Specifically, giving psychological care to frontline health care workers is an important challenge in the upcoming days and months ([Kluge, 2020](#)).

In pandemics depression, anxiety, and stress seen as emotional reactions. Frontline health care staff in china looking after patients of COVID-19 are seen with insomnia, stress, and anxiety and had more severe mental health problems than those in lesser roles ([Lai et al., 2020](#); [Lu et al., 2020](#); [Zhang et al., 2020](#)).

On the contrary, a higher prevalence of psychological sufferings has been reported by some studies in non-front line health care workers, might be these health care workers have less approach to physiological support and important information ([Tan et al., 2020](#)). This is the

reason support mechanisms are required for all health care staff regardless of their job description and level of exposure to the virus.

Awareness of the existing moment and recognition of thoughts and emotions devoid of judgment is known as mindfulness ([Kabat-Zinn, 1990](#)). Mindfulness-based interventions (MBIs) are generally short-term interventions (normally eight sessions) carried in a group setting, which include mindfulness meditation training and ethics. Mindfulness-Based Stress Reduction (MBSR) ([Kabat-Zinn, 1990](#)) and Mindfulness-Based Cognitive Therapy (MBCT) ([Segal et al., 2002](#)) are the most commonly calculated and available methods. Previous researches propose that mindfulness is linked with an acceptance attitude ([Bishop et al., 2004](#)). Therefore, people with great levels of mindfulness are less likely to be overcome by the painful emotions such as depression ([Carmody & Baer, 2008](#); [Barnes & Lynn, 2010](#); [Alzahrani et al., 2020](#)) and anxiety ([Belen, 2020](#); [Singh et al., 2020](#)). A vast number of studies in support acknowledged that person levels of depression ([Zemestani & Nikoo, 2019](#)) and anxiety symptoms ([La Torre et al., 2020](#)) are reduced by mindfulness training and sessions.

Mindfulness training has been connected with a curiosity attitude, association to self and patient, listening attentively, recognition of error, and clinical understanding ([Epstein, 1999](#)). Specific mindful exercise has thus been provided as a technique to strengthen medical decision-making, be it suitability of antibiotic treatment ([Vaughn & Flanders, 2016](#)), indwelling urinary catheters, ([Kiyoshi-Teo et al., 2013](#)) or worker results, such as work commitment ([Leroy et al., 2013](#)) and performance of the job ([Dane & Brummel, 2014](#)). It is not astonishing then, that combined mindfulness is a trademark of organizations with high reliability ([Sutcliffe et al., 2016](#)) and also lower turnover rates, improved safety, and quality are related to it ([Vogus et al., 2014](#)).

A significant obstacle to extensive execution of mindfulness in health care sites is the time needed for exercise and training. Mindfulness ranges from eating mindfully (i.e., eating slowly, savoring each morsel) to multi-hour meditation training, where the attention is on emotional state and breathing ([Khoury et al., 2013](#)). As for backing to psychological well-being, mindfulness is an important concept in the course of the period of an emergency, such as the COVID-19 pandemic. Mindfulness is measured as focused attention on solid experience in the current moment ([Svendsen et al., 2017](#)). On the contrary, fear of COVID-19 is placed soon of getting the virus or losing their beloved ones from this horrific disease. In his aspect, mindfulness may counter the negative effect of anxiety and fear linked with COVID-19 and improve the person's mental health. Furthermore, immediate research priorities newly are to probe the constructs that will update interventions to manage with COVID-19 anxiety and fear that will shrink mental health problems rates like depression and anxiety ([Holmes et al., 2020](#))

To our knowledge this is the first psychological intervention study done in the age of COVID19 pandemic to front-line medical staff in the COVID19 Pandemic, our aim is to evaluate the effectiveness of brief mindfulness based interventions in frontline HCP to cope for (COVID19). Our specific objectives are: To measure frontline HCP's level of anxiety, resilience, and how mindfulness based interventions affect anxiety and psychological resilience of HCP.

## **Materials and Methodology**

### Design

Parallel randomized controlled clinical trial. 1:1 intervention to control group.

### Settings and Participants

This randomized clinical trial is a multicenter trial on COVID19 frontline health care professionals, namely physicians, nurses and respiratory therapist.

The trial will be conducted virtually using mp3 audios and pre/ post trial electronic questionnaires that will be delivered and tracked through a customized website for this purpose.

The 2 largest Eastern province hospitals are involved in the trial;

King Fahad Hospital of Imam Abdulrahman bin Faisal University and Qatif Central Hospital

Recruitment of study participants will be through their hospitals' human resources department.

From the date of IRB approval to mid of June, 2020.

Outcome will be assessed once for a 4 week period, comprising a 2-week intervention interval and a 2-week follow-up period.

### **Information technology and Cybersecurity**

For the sake of this study a new system was developed to be used for data collection. The system was designed as an electronic questioner with audio clips that is sent automatically to the participants' email and phones, where each participant receives their own special link. The system was also designed to send daily reminders if the participant for the duration of the study. Once a participant clicks on the link they will be taken to their own site where they can listen to the audio file dedicated for them and fill the survey created for them. The system was designed to have a different site for admins (authors of this paper) with a dashboard that allowed them to create, edit, and control participants, groups, and hospitals. It also allowed them to track the participants' adherence to the study by frequency and duration. The admin site also allowed them to easily download the collected data as an excel file, to be imported to SPSS later.

This system was built as a cloud service that can be accessed from anywhere with the right credentials. The authors choose the domain 'CPWR2020.com' to be the address for this cloud system. To be sure that the collected data is protected and safe, a proper penetration testing and

vulnerability assessment was done on the system and the website. A cybersecurity expert performed the testing using advanced tools such as GreenBone. All tests are done after getting the proper consent.

The website was first assessed using the GreenBone Vulnerability Assessment System. The IP address of the server was configured in GreenBone and it was customized to check certain scenarios on the tested server depending on the requirement and specification for the assessment. Keeping in mind that the server needs to be kept alive during the assessment and not to hinder the server availability to other users. The server was tested for all known TCP and UDP ports. Port scanning is one of the important factors to make sure the server is posing a good security posture as ports act as opening gates to adversaries. After testing the website, the results were checked for false positives using common tools such as clicking on a crawled link from the assessment report. The firewall has to be configured to allow the ongoing traffic from the vulnerability assessment server to reach the server which resides outside the testing server network. The traffic generated by the vulnerability scanner mimics those of real attacks. The final report of the testing showed that there is no threats and that the system is safe to be used, and the collected data will be safe.

## **Interventions**

Brief Mindfulness-Based Interventions have become popular after time commitment challenges for the traditional mindfulness meditation. Brief mindfulness interventions may be effective in improving health care providers' well-being and can impact numerous health related outcomes. ([Gilmartin et al., 2017](#); [Howarth et al., 2019](#))

### **Intervention group: brief mindfulness-based audio recording**

Participants in the intervention group will be given an mp3 audio recording of a 20-minute mindfulness will be download directly to a personal device of their choice, such as a smart phone.

The 20 minute daily mindfulness sessions for 2 weeks consist of the following guided meditation practices: 1. Bring your attention to a primary object of focus, e.g. your breath. 2. Maintain a moment-to-moment awareness, e.g., the feeling of your breath entering and exiting the body. 3. When your mind naturally drifts into thinking (mind wandering); just notice you are thinking, and then bring your attention back to your object of focus, e.g. your breath. 4. When a strong sensation or emotion arises, again, notice the sensation or emotion and return to your breath. 5. As you gain confidence, you may practice maintaining this focus while observing thoughts flowing through your mind or sensations in your body while showing no concern for the content; you may practice this anytime throughout your day. 6. You may even label your thoughts, i.e., thinking, planning, worrying, or your feelings, i.e., anger, fear, love, anxiety, etc., or your body sensations, i.e., hot, cold, sharp, tight, tingly. At any point you may shift your attention back to your breath or object of focus while still being aware of your thoughts and feelings. 7. Thank yourself for your efforts and for taking this time. ([Howarth et al., 2016](#))

### **Control group:**

Control group will be given an mp3 audio recording of a 20-minutes of progressive muscle relaxation will be download directly to a personal device of their choice, such as a smart phone. The 20-minute daily sessions of the progressive muscle relaxation for 2 weeks involves tensing up a group of muscles so that they are as tightly contracted as possible , holding them in a state of tension for few seconds , and then relaxing the muscle .

Both the intervention and control group will receive the same follow-up and frequency of sessions, time matched. Sessions will be provided virtually for home practice through Emails and SMS messages with Smart-phones coaching support for settings of intervention guide.

### Outcomes

Primary outcomes are reduction of anxiety symptom severity assessed using the (state trait anxiety–7 Item Scale) and change in the level of psychological resilience assessed using the (Connor-Davidson Resilience Scale (CD-RISC)).

Secondary outcomes are factors associated with mental wellbeing, correlation between anxiety and psychological resilience, and functional status (12-Item Short Form Survey).

### Sampling technique and sample size:

All COVID19 frontline physicians, nurses and respiratory therapists working at the hospitals under investigation - during the study period will be approached about the study aim through their human resources departments, the ones who accept to participate will be enrolled.

Exclusion criteria:

- 1- History of psychotic disorder,
- 2- Substance abuse or dependence within the last 6 months



3- Current severe neurotic disorder, severe depression or severe anxiety.

4-Concurrent psychotherapy.

5- Significant personality disorder.

Assuming a response rate of 80%, we expect to have 50 HCP in each hospital, who will be divided into 50 for each arm.

#### Randomization/ Allocation Concealment

Using central randomization.

Sequence Generation

Computerized random number generator

#### Blinding

Triple blinded conduction of the study

The participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.

#### Statistical analysis:

Statistical analyses were performed using 'IBM SPSS Statistics for Windows, version 21', the level of statistical significance was set at 0.05 (two-tailed).

For describing the sample characteristics, Categorical data were demonstrated as number and percent. Numerical data, including the results of the 3 scales, were presented as minimum, maximum and average.

Scores were tested for normality using skewness and kurtosis coefficients (less than one were considered normal), besides box plots and normal Q-Q plot.

Effect of the intervention and factors associated with the magnitude of change in the three studied scales were tested using General linear models (repeated measures ANOVA).

Further investigation was done to present the percent of improvement in each scale. Change of the scores were computed as post-pre scores, improvement was considered if WHO-5 and resilience change was >zero and if change in anxiety scores was <zero.

Logistic regression was used to test for potential factors associated with improvement of each scale.

Secondary Bivariate analyses were done using correlation coefficient, independent samples t-test and Mann Whitney u test, one-way ANOVA (for relations with numerical variables) and chi square test (for testing association between categorical variables).

- Alzahrani, A. M., Hakami, A., AlHadi, A., Batais, M. A., Alrasheed, A. A., & Almigbal, T. H. (2020). The interplay between mindfulness, depression, stress and academic performance in medical students: A Saudi perspective. *Plos one*, *15*(4), e0231088 .
- Barnes, S. M., & Lynn, S. J. (2010). Mindfulness skills and depressive symptoms: A longitudinal study. *Imagination, Cognition and Personality*, *30*(1), 77-91 .
- Belen, H. (2020). Fear of COVID-19 and Mental Health: The Role of Mindfulness in During Time of Crisis .
- Bishop, S. R., Lau, M., Shapiro, S., Carlson, L., Anderson, N. D., Carmody, J., . . . Velting, D. (2004). Mindfulness: A proposed operational definition. *Clinical psychology: Science and practice*, *11*(3), 230-241 .
- Brooks, S. K., Chalder, T., & Gerada ,C. (2011). Doctors vulnerable to psychological distress and addictions: treatment from the Practitioner Health Programme. *Journal of Mental Health*, *20*(2), 157-164 .
- Carmody, J., & Baer, R. A. (2008). Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of behavioral medicine*, *31*(1), 23-33 .
- Dane, E., & Brummel, B. J. (2014). Examining workplace mindfulness and its relations to job performance and turnover intention. *Human relations*, *67*(1), 105-128 .
- Epstein, R. M. (1999). Mindful practice. *Jama*, *282*(9), 833-839 .
- European Centre for Disease Prevention and Control. (2020). 2020, from <https://www.ecdc.europa.eu/en/covid-19-pandemic>
- Holmes, E. A., O'Connor, R. C., Perry, V. H., Tracey, I., Wessely, S., Arseneault, L., . . . Everall, I. (2020). Multidisciplinary research priorities for the COVID-19 pandemic: a call for action for mental health science. *The Lancet Psychiatry* .
- Kabat-Zinn ,J. (1990). Using the wisdom of your body and mind to face stress, pain, and illness. *New York, NY: Bantam Doubleday Dell* .
- Khoury, B., Lecomte, T., Fortin, G., Masse, M., Therien, P., Bouchard, V., . . . Hofmann, S. G. (2013). Mindfulness-based therapy :a comprehensive meta-analysis. *Clinical psychology review*, *33*(6), 763-771 .

- Kiyoshi-Teo, H., Krein, S. L., & Saint, S. (2013). Applying mindful evidence-based practice at the bedside using catheter-associated urinary tract infection as a model. *Infection Control & Hospital Epidemiology*, 34(10), 1099-1101 .
- Kluge, H. (2020). WHO Regional Director for Europe—Statement to the Press: Physical and Mental Health Key to Resilience during COVID-19 Pandemic. *WHO: Copenhagen, Denmark* .
- La Torre, G., Raffone, A., Peruzzo, M., Calabrese, L., Cocchiara, R. A., D'Egidio, V., . . . Mannocci, A. (2020). Yoga and Mindfulness as a Tool for Influencing Affectivity, Anxiety, Mental Health, and Stress among Healthcare Workers: Results of a Single-Arm Clinical Trial. *Journal of Clinical Medicine*, 9(4), 1037 .
- Lai, J., Ma, S., Wang, Y., Cai, Z., Hu, J., Wei, N., . . . Li, R. (2020). Factors associated with mental health outcomes among health care workers exposed to coronavirus disease 2019. *JAMA network open*, 3(3), e203976-e203 .976
- Leroy, H., Anseel, F., Dimitrova, N. G., & Sels, L. (2013). Mindfulness, authentic functioning, and work engagement: A growth modeling approach. *Journal of Vocational Behavior*, 82(3), 238-247 .
- Lu, W., Wang, H., Lin, Y., & Li, L. (2020). Psychological status of medical workforce during the COVID-19 pandemic: A cross-sectional study. *Psychiatry research*, 112936 .
- Organization, W. H. (2020). Mental health and psychosocial considerations during the COVID-19 outbreak, 18 March 2020: World Health Organization.
- Segal, Z. V., Teasdale, J. D., Williams, J. M., & Gemar, M. C. (2002). The mindfulness-based cognitive therapy adherence scale: Inter-rater reliability, adherence to protocol and treatment distinctiveness. *Clinical Psychology & Psychotherapy*, 9 .138-131 ,(2)
- Singh, R., Singh, B., Mahato, S., & Hambour, V. K. (2020). Social support, emotion regulation and mindfulness: A linkage towards social anxiety among adolescents attending secondary schools in Birgunj, Nepal. *Plos one*, 15(4), e0230991 .
- Sutcliffe, K. M., Vogus, T. J., & Dane, E. (2016). Mindfulness in organizations: A cross-level review. *Annual Review of Organizational Psychology and Organizational Behavior*, 3, 55-81 .
- Svendsen, J. L., Kvernenes, K. V., Wiker, A. S., & Dundas, I. (2017). Mechanisms of mindfulness: Rumination and self-compassion. *Nordic Psychology*, 69(2), 71-82 .
- Tan, B. Y., Chew, N. W., Lee, G. K., Jing, M., Goh, Y., Yeo, L. L., . . . Khan, F. A. (2020). Psychological impact of the COVID-19 pandemic on health care workers in Singapore. *Annals of internal medicine* .
- Vaughn, V. M., & Flanders, S. A. (2016). Annals for Hospitalists Inpatient Notes-Mindfulness and Antibiotic Appropriateness—How Point-of-Care Stewardship Begins With Hospitalists. *Annals of internal medicine*, 165 ,(10)HO2-HO3 .
- Vogus, T. J., Cooil, B., Sitterding, M., & Everett, L. Q. (2014). Safety organizing, emotional exhaustion, and turnover in hospital nursing units. *Medical care*, 870-876 .
- Zemestani, M., & Nikoo, Z. F. (2019). Effectiveness of mindfulness-based cognitive therapy for comorbid depression and anxiety in pregnancy: a randomized controlled trial. *Archives of Women's Mental Health*, 1-8 .
- Zhang, W.-r., Wang, K., Yin, L., Zhao, W.-f., Xue, Q., Peng, M., . . . Du, J.-l. (2020). Mental health and psychosocial problems of medical health workers during the COVID-19 epidemic in China. *Psychotherapy and psychosomatics*, 89(4), 242-250 .

- Gilmartin, H., Goyal, A., Hamati, M. C., Mann, J., Saint, S., & Chopra, V. (2017). Brief mindfulness practices for healthcare providers—a systematic literature review. *The American journal of medicine*, 130(10), 1219-e1.
- Howarth, A., Perkins-Porras, L., Smith, J. G., Subramaniam, J., Copland, C., Hurley, M., ... & Ussher, M. (2016). Pilot study evaluating a brief mindfulness intervention for those with chronic pain: study protocol for a randomized controlled trial. *Trials*, 17(1), 273.
- Howarth, A., Smith, J. G., Perkins-Porras, L., & Ussher, M. (2019). Effects of brief mindfulness-based interventions on health-related outcomes: A systematic review. *Mindfulness*, 1-12.