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Efficacy of pranayama in preventing COVID-19 in exposed healthcare professionals: A quasi-randomized clinical trial

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1. Introduction

COVID-19 pandemic is a global challenge to public health. Among other measures, most countries have enforced lock-downs or stay-at-home orders as a mitigation measure. Health Care Professionals (HCPs) being exposed to cases as a part of their professional duties have been in particular susceptible to COVID-19 infection.

HCPs being on the front lines of COVID-19 crisis, have reported psychological stress, tiredness, sleep problems because of fear, and interruption of normal life due to heavy patient loads. HCPs are under extreme stress due to their long working hours, wearing of Personal Protective Equipment (PPE), lack of specific drugs and being away from their families.

At present, there is no definite treatment for COVID-19. However, researchers and clinicians are working on various antibiotics and antiviral agents, like monoclonal antibodies, oseltamivir, ganciclovir,
Yoga, which originated in ancient India, is also recognized as a form of a Complementary Medicine, as well as an alternative therapy that can positively influence the mind-body continuum [17]. Yoga has been practiced since times immemorial for the prevention of disease and promotion of health. Substantial research has already been done on the effectiveness of Yoga in the management of lifestyle disorders, preventing infection and accelerating healing and recovery. Yoga has two key practices—one of rhythmic, controlled breathing called Pranayama and another is effortless concentration of mind called Dhyana. The former helps to improve lung capacity, cardio-respiratory functions, neuro-endocrine activity and also mental activity [17,18]. Several other studies suggest the effects of various components of Yoga in infectious diseases. A study conducted in a Bangalore sanatorium showed efficacy of Integrated Yoga (IY) protocol as an add-on to Anti Tuberculosis Treatment in reducing symptoms of Tuberculosis [17]. One month of practice of integrated yoga in patients suffering from HIV-1 infection led to a significant reduction in viral load, increase in the number of CD4 immune cells and improvement in psychological state [18]. Several clinical trials have suggested an overall positive effect of Yoga in improving pulmonary and immune functions in patients with tuberculosis [17]. HIV-1 infection [18] and anxiety [19].

Therefore, the present study was conducted to assess the efficacy of Pranayama, which is a part of yoga, in preventing COVID 19 infection in the HCPs exposed to COVID-19 infection [20].

2. Methodology

2.1. Ethical considerations

After obtaining approval of the Institutional Ethics Committee, the study was registered on Clinical Trials Registry of India (CTRI No. CTRI/2020/07/026667). Five hospitals dedicated for handling COVID-19 cases were included for the study. HCPs meeting inclusion criteria of exposure to COVID-19 suspects or cases, were in quarantine and ready to practice Pranayama, but did not have comorbidities that avert practice of Pranayama or Severe cardiac disease were enrolled for the study and their informed consent obtained. One Yoga instructor was assigned to each of the five identified hospitals to train and guide the study participants in twice daily practice of Pranayama, supervise its practice and collect data on the intervention. The HCPs in the control group were advised to continue their normal daily routine, but no pranayama sessions.

2.2. Sample size

Sample size was estimated on the assumption of a prevalence of COVID-19 infection of 10% in the population of HCPs, and expectation that our treatment group will have a 90% lower prevalence i.e. 1%. For a power of 80%, alpha of 0.05, 95% confidence interval, the sample size estimate was 121 in each arm (Table 3).

2.3. Study sample

Inclusion criterion was HCPs (age range: 19–65 years, any gender), being on COVID-19 duty (duty cards were taken as proof), not previously infected with COVID-19 (negative antibody test) but with a recent history of exposure to COVID-19 suspects or cases and who were in quarantine. 288 HCPs were registered for the study. Out of these, 8 were found positive on rapid Antibody tests at baseline. Positive rapid antibody test of HCPs indicates previous infection of COVID-19; therefore, such HCPs were excluded from the study. HCPs like doctors, nursing staff, housekeeping staff/ caretaker and Yoga instructors who were directly in contact with COVID-19 positive patients were classed as “directly exposed”. Others like Medical Superintendent, Chief Medical Officers, Pharmacists, Lab technician, Hospital administration staff like Managers, Supervisors, DEO, MTS who were not in close contact with COVID-19 cases were classed as “indirectly (remotely) exposed”.

2.4. Randomization

Medical in-charge of the hospitals/COVID-19 care units were authorized to enroll study participants but had no other role in the trial. Eligible HCPs were quasi-randomized on admission through alternate allocation (ratio 1:1) into two groups. Subsequently, the two groups were designated as ‘intervention group’ and the ‘Control group’ by the coordinator of the study, who was blinded to the initial allocation.

2.5. Masking

It is difficult to assess yoga/pranayama practices in double blind trials because the intervention requires active participation of the participants and hence their identities become known after allocation. Soon after enrollment, antibody test was administered by a lab staff who did not otherwise participate in the trial and was blinded to the study groups. In addition, the outcome assessor was blinded to the group of study.

2.6. Study groups

Of the 280 enrolled participants, 17 (Intervention — 15, Control — 2) did not adhere to the 80% attendance requirement, and 13 (Intervention — 2, Control — 11) did not give their post-intervention data, and thus 30 study participants (Intervention — 17, Control — 13) were excluded. Thus, 250 participants completed the study which included 123 in the intervention group (administered Pranayama protocols) and 127 in the control group. Profession wise break up of 250 participants was: Resident Doctors-29, Nursing staff-63, Caretakers/House-keeping staff-82, Lab technicians-22, CMos/Medical Superintendent — 20, Pharmacist-15, Yoga Instructors-4, Hospital Administration staff like Accountants, Multi-Tasking Staff, Data Entry Operator, Receptionists-15.

2.7. Study parameters and tools

Basic demographic information, medical history and dietary habits were collected at baseline. Antibody test for COVID-19 was done on all the study participants at baseline and on completion of the study at end-line.

2.8. Antibody test

An antibody serology test (Accucare COVID-19 kit) approved by ICMR; was used to detect prior COVID-19 infection in all study participants. This test detects two types of antibodies — IgM and IgG. During the study, the participants who developed COVID-19 symptoms were also administered the Rapid Antigen Test/RT-PCR for confirmation of a diagnosis of COVID-19.
2.11. Statistical analysis

Data collected was entered in Microsoft Excel and cleaned. In bivariate analysis, categorical variables were presented as frequencies (%), continuous data as mean (with Standard Deviation) or median. Mean difference in pre-post intervention was examined for statistical significance using Fisher’s exact test. A P-value of 0.01 was considered significant. Data was analyzed using IBM Statistical Package for the Social Sciences (SPSS) Version 20.0 (Armonk, NY: IBM Corp).

3. Results

Flowchart diagram of recruitment process of participants and design of the study has been provided in Fig. 1.

Two groups of HCPs had comparable age, socio demographic characteristics, exposure status and comparable co-morbidities (Table 4).

During the period of the study, three participants from the control group developed symptoms suggestive of COVID-19 such as fever, cough, etc. They tested positive on Rapid Antigen test/RT-PCR. At the end of the study, one participant from the intervention group and 9 from the control group (including three symptomatic participants who had tested positive on Rapid Antigen Test/RT-PCR) tested positive on COVID-19 Antibody Test. This difference was statistically significant (P-value: 0.01), indicating a protective effect of the intervention of Pranayama in preventing COVID-19 infection (odds ratio: 0.107, 95% CI: 0.86; risk ratio: 0.11, 95% CI: 0.89) (Table 5). The 10 HCPs who tested positive with COVID-19 at the end line showed no particular socio-demographic pattern (Table 6). They belonged to both genders, diverse age and professional groups with 80% of them being middle-aged. Of the 10 HCPs (4 females, 6

2.10. Modules

Specially designed Pranayama modules included preparatory Yoga practices for 9 min, Pranayama practice for 16 min and meditation for 5 min each in the morning session, and 15 min of breathing exercises in the evening session. Detailed procedure to perform the protocol has been provided as supplementary data (Annexure-1)

These modules were also publicly hosted (https://www.youtube.com/watch?v=RD1huW5S7w8&feature=youtu.be). The intervention group was provided this link from the beginning for their better understanding and aid in practice.

2.9. The intervention: administration of pranayama protocols

Two Pranayama modules lasting 30 min for the morning (Table 1) and 15 min for the evening (Table 2), were developed by the principal investigator. Participants in the intervention group were trained and guided through Video-Conference by Yoga Instructors to practice Pranayama twice a day for 28 days. A daily attendance record was maintained. All the participants were closely monitored by the Yoga Instructors for confirmation to the protocol.

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males) who contracted COVID-19 infection, nine were from the highly exposed group and 8 were healthy with no comorbidities (Table 6). The lone participant from the experimental group who tested positive on antibody testing at the end of intervention probably had asymptomatic COVID 19 infections.

4. Discussion

The present study was conducted in 5 different hospitals dedicated for COVID-19 patients with a reasonable (250) sample size. To the best of our knowledge, this is the first study to assess the effect of Pranayama in preventing COVID-19. The results of our study suggesting a role of Pranayama in infection is in agreement with earlier studies [11,17,18]. The only participant in the Intervention group who developed COVID-19 was a caretaker (male) in the 35–50 years age group, with no comorbidity, who was in contact with COVID-19 patients. He had no regular exercise routine, but was practicing the Pranayama intervention.

The biological processes underlying the protective effects of Pranayama remain to be fully investigated. Each component of the Pranayama module would have played a role in preventing COVID-19 infection. Vaata-neti helps to clean the nasal passages and maintain the sinuses and helps to get rid of pathogens. Kapalabhati kriya is a process of forceful exhalation and normal inhalation which help to improve pulmonary function and clean the frontal sinuses, removing congestion in nasal and respiratory tract [22] and easing movement of the diaphragm [21]. These two are very useful preparatory practices for Pranayama. Deep breathing helps to improve lung’s vital capacity. Nadi-shodhana pranayama helps to reduce sympathetic activity and stimulate the vagal (parasympathetic activity) [23]. It helps to reduce stress and anxiety, thus balancing autonomic function. Ujjayi pranayama increase oxygen (O₂) saturation in the body, removal of congestion from the throat and strengthens the larynx and pharynx [23]. Bhramari pranayama is similar to humming that increases nasal Nitric Oxide (NO) by improving blood flow to the ciliary epithelium [24,25]. Meditation helps to reduce stress & anxiety by reducing cortisol.
levels in the blood and enhances alpha (α) waves in the brain. The above pranayama and Dhyanas practices make the body comfortable, keep the mind calm and help to balance the neuro-endocrine system, and thereby the immune system. The preparatory practices for pranayama (eg. Vaataneti & kapalabhati) performed at the rate of one breathing per sec and pranayama practices in the morning session involved a ratio of 6 (inhalation):3 (retention): 6 (exhalation):3 (retention), while those in the evening session followed a breathing ratio of 6:6. At rest, one breath normally lasts 3 s, which gets extended to 18 s during pranayama. In our protocol, emphasis was on deep, slow, rhythmic breath with awareness. The breathing practices for the evening followed by shavasana (with the palm upwards) would have given relaxation to body and mind and improved the quality of sleep. In thoracic breathing, the chest expands and contracts with each breath while the abdominal area does not. The subjects were encouraged to breathe in more oxygen by slow and deep thoracic breathing with total awareness [26]. Practice of thoracic breathing immediately after performing abdominal breathing helps the practitioner to adapt to more chest expansion, before doing the clavicular breathing. Thus, in the next step, i.e., the practice of deep breathing, the subject naturally and effectively expands thorax for effective ventilation. The selected combination of Pranayama modules makes it a comprehensive intervention for the purpose of reducing the possibility of contracting COVID-19 infection.

There is strong evidence on the positive effects of Yoga practice on stress management among HCPs [27]. Stress is known to suppress immune function and increase susceptibility to infections [28]. Chronic stress is associated with global immuno-suppression, as well as decreases in almost all immune measures. Increased duration of stress can result in a shift from potentially adaptive changes to potentially detrimental changes, initially in cellular immunity and then in broad immune function [29]. Pranayama practices have been found to have a direct impact on reduction in vaata aggravation and Vagus Nerve stimulation [31,32]. Vagus Nerve Stimulation has been found to have a direct effect in managing stress and diseases born out of it [30]. A strong host immune response to the novel coronavirus is a key factor for protection against infection. The efficacy of our especially designed Pranayama protocol could be because of the above-mentioned mechanisms, whose modalities of action need further exploration. This study has also revealed that COVID-19 infection in the intervention group tends to be mild and asymptomatic, thus strengthening the conclusion of a positive, preventive effect of Pranayama.

4.1. Strength, limitations and future recommendations

This study has some limitations. Due to pandemic conditions, the Pranayama protocols could be administered through online mode only. Yoga Practices like Pranayama need Guru-Shishya (Yoga teacher – Yoga student) interaction. HCPs could have had a lowered interest in Pranayama classes due to prolonged working hours. As the control group was not administered with any comparable practice, they might not have had any expectation of a lower chance of contracting the infection. Future studies are required with a set of comparable practices for the control group also. Since the Antibody test alone was used for pre-test assessment of COVID-19 infection, there could be a theoretical probability in both the groups of a prior infection with COVID-19, but without any detectable antibodies. Of the 10 HCPs (9 Control + 1 Experimental group) who contacted COVID-19 at the end-line, 6 were from the lower Socio-economic groups. Only 2 of the 10 participants turning covid-19 positive were from the doctors/nurse category, while the rest were from allied and support staff, whose household and social conditions like food intake, home environment, stress of life might not be comparable. The study has not investigated the effect of confounding variables like environmental factors (such as food intake, home environment, stress of life). This is an area of further research. Our intervention lasted 28 days, which is a relatively short length for the study and longer periods of practice of the intervention are critical to knowing the lasting benefits and efficacy of the intervention. Hence, a multi-centric study with a larger sample and longer duration/period is recommended for further testing of our Pranayama Protocol. The pranayama protocol can also be compared to and supplemented with other yoga/pranayama programs. Considering the implications of the study for Health care professionals and the general public living in fear of COVID-19, larger studies across different geographical, ethnic and cultural backgrounds are needed to verify its generalizability.

Despite limitations, the data presented in this study draws attention to the benefits of our Pranayama modules to prevent COVID-19 in HCPs routinely exposed to the virus.

### Table 4
Baseline socio demographic profile of 250 HCPs.

| Variables             | Experimental Grp N (%) | Control Grp N (%) |
|-----------------------|------------------------|-------------------|
| Total                 | 123 (100.00%)          | 127 (100.00%)     |
| Age (in years)        |                        |                   |
| 18–35                 | 74 (60.16%)            | 70 (55.12%)       |
| 36–50                 | 40 (32.52%)            | 49 (38.58%)       |
| 51–65                 | 9 (7.32%)              | 8 (6.30%)         |
| Gender                |                        |                   |
| Male                  | 67 (54.47%)            | 65 (51.18%)       |
| Female                | 56 (45.53%)            | 62 (48.82%)       |
| Diet                  |                        |                   |
| Veg.                  | 69 (56.10%)            | 52 (40.94%)       |
| Mixed diet            | 54 (43.90%)            | 75 (59.06%)       |
| Exposure              |                        |                   |
| In-directly exposed   | 86 (69.92%)            | 87 (68.50%)       |
| Admin staff           | 4 (3.3%)               | 11 (8.7%)         |
| Lab technician        | 14 (11.4%)             | 8 (6.3%)          |
| Pharmacist            | 5 (4.1%)               | 10 (7.9%)         |
| Senior officers/CMO   | 11 (8.9%)              | 9 (7.1%)          |
| Directly exposed      | 37 (30.08%)            | 40 (31.50%)       |
| Doctor                | 17 (13.8%)             | 12 (9.4%)         |
| Nursing staff         | 30 (24.4%)             | 33 (26.0%)        |
| Caretaker/housekeeping| 39 (31.7%)             | 43 (33.9%)        |
| Yoga instructor       | 3 (2.4%)               | 1 (0.8%)          |
| Health status         |                        |                   |
| HCPs (healthy)        | 102 (83%)              | 106 (84%)         |
| HCPs (with co-morbidities) | 21 (17%) | 21 (16%) |

Grp: group; N: number; Veg.: vegetarian.

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### Table 5
Post-intervention COVID-19 assessment results in intervention vs. control groups.

| Total no. of HCPs          | COVID-19 positive cases | COVID-19 negative cases | Fisher’s exact test score | P-value | Effect size |
|---------------------------|-------------------------|-------------------------|---------------------------|---------|-------------|
| Experimental grp N (%)    | 123 (100%)              | 1 (0.8%)                | 122 (99.2%)               | 0.0192  | 0.01*       |
| Control Grp N (%)         | 127 (100%)              | 9 (7.1%)                | 118 (92.9%)               |         |             |

* Indicate level of significance.
The intervention of twice daily practice of Pranayama administered by trained Yoga instructors in HCPs exposed to active cases might have helped and made a noteworthy contribution in significantly preventing COVID-19 infection. The present study suggests that the Pranayama modules can be promoted among all sections of the population to prevent COVID-19.

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Declaration of competing interest

No conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajim.2022.100586.

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