Efficacy of Pranayama in Preventing COVID-19 in Exposed Healthcare Professionals: A Randomized Controlled Trial

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ABSTRACT

Background: The global outbreak of COVID-19 has created a challenging situation, especially among the frontline Health Care Professionals (HCPs), who are routinely exposed and thus at a relatively higher risk of infection. A few studies have shown the practice of Pranayama, a component of Yoga, to be effective in improving immune function and reducing infection. However, no clinical trial on the efficacy of Pranayama in preventing COVID-19 has been conducted.

Aim & Objective: This randomized clinical trial assessed the effect of Pranayama in preventing COVID-19 infection in Health Care Professionals (HCPs) routinely exposed to COVID-19 cases.

Methodology: The study was conducted at 5 different COVID-19 hospitals in New Delhi, India during September-November, 2020. 280 HCPs assigned duties with COVID-19 patients who were found negative in COVID-19 antibody test in pre-intervention assessment were recruited and randomly assigned to intervention and control groups. The intervention group practiced especially designed Pranayama modules twice a day (morning and evening) for 28 days under the supervision of Yoga instructors through online mode, while those in the control group were advised general fitness practices (like walking, jogging, running). Participants who became symptomatic underwent RTPCR / Point of Care Rapid Antigen test for confirmation of COVID 19 diagnosis. All the patients also underwent antibody testing for COVID-19 on 28th day of the intervention to detect asymptomatic infection.

Results: 250 participants, comprising 123 in the intervention group and 127 in the control group, completed the study. The intervention and control groups had comparable demographics and baseline characteristics. Three participants (all controls) developed COVID 19 symptoms during the study. On the completion of the study, only one participant in the Intervention group

tested positive, while 9 participants in the control group (Including three symptomatic participants) tested positive for COVID-19 antibodies. This difference was statistically significant (P-value: 0.01).

Conclusion: Practice of our especially designed Pranayama module, every day for 28 days was highly effective in preventing COVID-19 infection in exposed healthcare professionals (HCPs).

CTRI Number: **CTRI/2020/07/026667**

Keywords: COVID-19, Pranayama, Health Care Professionals, Yoga, Pandemic, Prevention

INTRODUCTION

COVID-19 pandemic is a global challenge to public health¹. To limit its spread, almost all countries have adopted lock-down measures or implemented stay-at-home orders¹. Health care professionals have been in particular highly susceptible to COVID-19 infection.

Health Care Professionals, as true corona warriors, have been reported to be experiencing psychological stress², tiredness, sleep problems² from fear of being infected and spreading the virus among relatives, and having had to interrupt their normal life due to heavy patient loads³. Health Care Professionals are under extreme pressure due to their long working hours, wearing of Personal Protective Equipment (PPE), lack of specific drugs or protocols and being away from family^{4 5}. Therefore, an intervention to prevent COVID-19 infection, particularly among Health Care Professionals, is necessary.

At present, there is no definite treatment for COVID-19. However, researchers and clinicians are working on various antibiotics and anti-viral agents like oseltamivir, ganciclovir, ribavirin, favipiravir, nelfinavir, arbidol, remdesivir and galidesivir^{6 7 8 9}. Since body's immunity plays an important role in COVID-19 infection, non pharmacological interventions which have an immune-modulatory effect, could serve as a preventive as well as a therapeutic measure for patients with COVID-19 infection^{10 11 12 13 14}. During this outbreak, numerous herbal products have also been explored as alternative therapies^{15 16}.

Yoga, which originated in ancient India, is also recognized as a form of complementary and alternative therapy that positively influences mind- body continuum¹⁷. Yoga is practiced for the prevention of disease and promotion of health. There are several studies 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 second is effortless concentration of mind called Dhyana. The former helps to improve lung capacity and cardio-respiratory functions. Several other studies suggest the effects of various component of Yoga in infectious diseases. One of the studies conducted in a Bangalore sanatorium suggests that an Integrated Yoga (IY) protocol used as an add-on to Anti Tuberculosis Treatment is efficacious in achieving sputum negativity¹⁷. One month of Integrated Yoga in patients suffering from HIV-1 infection has been found to lead to a significant reduction in their viral load, increase in the number of CD4 immune cells and improvement in their psychological state¹⁸. Several clinical trials suggest an overall positive effect of Yoga practice in improving pulmonary and immune functions in patients with pulmonary tuberculosis¹⁷, HIV-1 infection¹⁸ and anxiety¹⁹. Hence, practice of Pranayama offers a worthy candidate for prevention and treatment of COVID-19 infection²⁰.

The present randomized clinical trial was therefore conducted to assesses the efficacy of Pranayama to prevent COVID-19 infection in HCPs, routinely exposed to cases.

METHODOLOGY

Ethical Considerations

Approval of the Institutional Ethics Committee at Morarji Desai National Institute of Yoga (MDNIY), New Delhi, to the study was obtained, and it was registered on ICMR's Clinical Trials Registry (CTRI No. **CTRI/2020/07/026667**). Permission was obtained from the government of Delhi for conducting the study in five COVID-19 hospitals. One Yoga instructor each was assigned to the five identified hospitals in Delhi to train, guide and supervise HCPs to practise Pranayama and to collect data. Before commencement of the study, its objectives were briefed to the participants, and their informed consent obtained. The HCPs in the control group were advised general fitness practices (like walking, jogging, running).

Study Sample: This was a Randomized Controlled Trial (RCT) with a pre and post test. The inclusion criterion was HCPs working on COVID-19 duty (duty cards were taken as proof) and not previously infected with COVID-19 (negative antibody test). 288 HCPs who were assigned duties in five COVID-19 hospitals in Delhi were registered for the study. Out of these, 8 were found positive on Anti-body test at baseline, and were thus excluded. The remaining 280 participants were enrolled for the study. HCPs were classed as “severely exposed” if they were directly in contact with COVID-19 positive patients (doctors, nursing staff, housekeeping staff/care taker and Yoga instructors); “low exposed” if they were not in close contact with COVID-19 cases (Medical Superintendent, Chief Medical Officers, Pharmacists, Lab technician, Hospital administration staff like Managers, Supervisors, DEO, MTS).

Study groups

280 participants were randomly distributed, into the intervention and control groups in the ratio of 1:1. Out of those, 17 (Intervention - 15, Control - 2) did not adhere to the 80% attendance mark, and 13 (Intervention - 2, Control - 11) did not give their post-intervention data, and thus 30 study participants (Intervention - 17, Control - 13) were excluded in the final data analysis. Thus, final analysis was done on 250 participants which included 123 in the intervention group (administered Pranayama protocols) and 127 in the control group who were advised general fitness practices (like walking, jogging, running). The profession wise break up of 250 participants was: Resident Doctors-29, Nursing staff-63, Caretakers / House-keeping staff-82, Lab technicians-22, CMOs/Medical Superintendant-20, Pharmacist-15, Yoga Instructors-4,

Hospital Administration staff like Accountants, Multi Tasking Staff, Data Entry Operator, Receptionists -15.

Study Parameters and Tools

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

Antibody Test: The antibody serology test (Accucare COVID-19 kit) approved by ICMR, Delhi was used to detect prior COVID-19 infection. This test detects two kinds of antibodies – IgM and IgG. During the study, the participants who developed COVID-19 symptoms were also subjected to Rapid Antigen Test / RT-CPR for confirmation of COVID-19 diagnosis.

Administration of Pranayama Protocols

Two Pranayama modules, 30 minutes for the morning (Table-1) and 15 minute for the evening (Table-2), were developed by the Principal Investigator who is also the corresponding author. Study participants in the intervention group were trained and guided in the practice of morning and evening modules of Pranayama on a daily basis through real-time, video conferencing by Yoga Instructors. A daily attendance record was maintained. All the practices were closely monitored by Yoga Instructors for confirmation to the protocol. The control group was advised general fitness practices (like walking, jogging, running).

Modules: Specially designed Pranayama modules included preparatory Yoga practices for 9 minutes, Pranayama practice for 16 minutes and meditation for 5 minutes each in the morning session, and 15 minutes of breathing exercises in the evening session.

In Yoga tradition, Pranayama is not only breathing but rhythmic, controlled respiration with awareness, which has four phases: inhalation, retention inside, exhalation and retention outside. The ratios of four phases of Pranayama in the intervention modules was developed based on traditional Yogic texts to regulate the respiratory function²¹. These modules have been publicly hosted (https://www.youtube.com/watch?v=RD1huWS_7w8&feature=youtu.be). The intervention group was provided this link from the beginning for better understanding and practice.

Statistical Analysis

Data was entered on Microsoft Excel and validated. Categorical variables were presented as frequencies (%), continuous data was presented as mean (SD) or median. Mean difference in pre-post intervention was examined for statistical significance using paired t- test. A P-value of less than 0.05 was considered significant. To adjust for possible confounding, multiple regression analysis was done. Data was analyzed using SPSS Version 20.0. (Armonk, NY: IBM Corp).

RESULTS

Socio demographic characteristics

Health Care Professionals were randomly categorized into an intervention group of 123 participants and a control group of 127. Both groups had comparable demographic characteristics and exposure status, with age ranging from 19 years to 65 years (Table 3). The proportion of participants with co-morbid conditions was comparable in both the groups (Table-4).

COVID-19 Infection

During the study period, three participants (from control group) developed symptoms of COVID-19 and were tested positive on Rapid Antigen test / RTPCR (Table 5). After 28 days of intervention, all the participants were subjected to COVID-19 Antibody Testing in which one participant from the intervention group and 9 participants from the control group (including three symptomatic participants who had tested positive on Rapid Antigen Test / RTCPR) tested positive. This difference was statistically significant (P-value: 0.01), showing a protective effect of Pranayama in preventing COVID-19 infection (Table 6). The socio-demographic details of the 10 HCPs who got infected with COVID-19 at post-intervention show no particular pattern (Table 7). The infected cases were from both gender, different age and professional groups. Of the 10 HCPs (4 females, 6 males) who contacted COVID-19 infection, nine were from the highly exposed group and 8 were healthy with no co-morbidities (Table 7). Among those turning COVID-19 positive, 80% were in the lower and middle aged categories, 80% were free from any chronic illness or medication. One participant from the experimental group who was

found to be positive on antibody testing at the end of intervention probably had asymptomatic COVID 19 infection.

DISCUSSION

Our study reveals that twice daily practice of especially designed Pranayama Modules administered by trained Yoga instructors in HCPs exposed to active cases lead to a significant protective effect in preventing COVID-19 infection.

To the best of our knowledge, this is the first study to assess the effect of especially designed Pranayama protocol in preventing COVID-19 infection. The results of our study suggesting the 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 results indicate that the especially designed Pranayama modules were highly effective in preventing COVID-19 infection.

The psycho-biological processes underlying the effects of Pranayama protocol remain yet to be investigated. A possible modality of protective effect of Pranayama could be by keeping the upper respiratory tract healthy, and thus preventing entry of SARS-CoV-2 virus in the body. Each and every component of the intervention module is likely to play an important role in reduction of infection. The morning protocol comprised Vaata-neti, Kapalabhati, Deep Breathing, Nadi-shodhana, Ujjayi, Bhramari and Dhyana (Tables 1,2). Vata-neti helps to clean the nasal passages and maintain the sinuses and helps to get rid of pathogens. Kapalabhati is a process of forceful exhalation and normal inhalation which helps to improve pulmonary functions and secretions, also cleanse the frontal sinuses and ease movement of diaphragm²¹. These two are very useful preparatory practices for Pranayama. Deep breathing helps to

improve lung vital capacity. Nadi shodhana pranayama helps to reduce sympathetic activity & stimulates vagal (parasympathetic activity). It helps to reduce stress & anxiety, thus helps to balance autonomic function, also removes congestion in nasal and respiratory tract²². Ujjayi pranayama increases oxygen (O₂) saturation in the body and remove congestion from the throat and strengthens the larynx and pharynx²³. 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 level and enhances alpha (α) waves. The above pranayama and Dhyana practices make the body comfortable, keep the mind calm and help to balance the neuroendocrine system, thereby the immune system. The preparatory practices for pranayama (eg. Vaataneti & kapalabhati) performed as 1 breathing/sec and pranayama practices proposed in the morning session involve a ratio of 6 (inhalation):3 (retention): 6 (exhalation):3 (retention), while those in the evening session follow a ratio of 6:6. At rest, one breath normally takes is 3 seconds, which is being extended to 18 seconds per breath during pranayama. Emphasis has been laid on deep, slow, rhythmic breath with awareness. The breathing practices in the evening followed by Shavasana gives complete relaxation to body & mind and improves the quality of sleep. The selected combination of Pranayama modules makes it a comprehensive intervention to reduce COVID-19 infection.

There is a strong evidence on the positive effects of Yoga practice on stress management among HCPs^{26 27}. Stress is known to suppress immune function and increase susceptibility to infections²⁸. Chronic stress is associated with global immuno-suppression, as well as decreases in almost all immune measures. Increasing duration of stress is expected to result in a shift from potentially adaptive changes to potentially detrimental changes, initially in cellular immunity and then in immune function more broadly²⁹. Vagus Nerve Stimulation has been found to have a direct effect in managing stress and diseases born out of it³⁰. Pranayama practices have been

found to have a direct impact on Vagus Nerve stimulation^{31 32}. 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 molecular 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 effect of Pranayama in preventing COVID 19 infection.

This study has a few limitations. Due to pandemic conditions, the Pranayama protocols were administered through online mode. Yoga Practices like Pranayama need Guru-Shishya (Yoga teacher - Yoga student) interaction. Prolonged working hours did lead to lowered interest in HCPs for Pranayama classes. Since the pre-test assessment for COVID-19 infection was through Antibody test only, there could be a theoretical probability in both the groups of a prior infection with COVID-19, but without any detectable antibodies.

Despite these limitations, our study has several strengths: it was conducted in 5 different hospitals of Delhi (dedicated for COVID-19 patients) with a reasonable (250) sample size. This is a pilot study, and restricted to Delhi only. A multi-centric study with a large sample size is recommended for further validation of our Pranayama Protocol.

Despite limitations, the data presented in this study draws attention to (i) Benefits of our Pranayama modules as a preventive measure against COVID-19 for those routinely exposed to the virus (ii) Pranayama modules may be promoted and adopted to improve immunity in all

sections of the population. Considering the implications of the study for health care professionals and general public living in fear of COVID-19, larger studies across different geographical, ethnic and cultural backgrounds are needed to extend and verify the generalization of the present results.

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Supporting information

The study was conducted in the following hospitals:

- Dr. Hedgewar Arogya Sansthan, New Delhi
- Guru Tegh Bahadur Hospital, Dilshad Garden, Delhi
- Deep Chand Bandhu Hospital, Delhi
- Govt. of NCT Delhi Dispensary, Batla House, Jamia Nagar, New Delhi
- Sultanpuri Quarantine Centre, Sultanpuri, New Delhi.

File no. MDNIY/IEC/2018
To,

Date: 29-07-2020

Dr. I.V. Basavaraddi
Principal Investigator (Research Project) &
Director
Morarji Desai National Institute of Yoga
68, Ashoka Road, Near Gole Dak Khana
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Dear Dr. Basavaraddi ji,

The Institutional Ethics Committee reviewed and discussed your application for the amendment (As per the amendment, now the subjects will be assessed at both pre-intervention and post-intervention level with antibody test or rapid antibody test, in the previous protocol it was mentioned that assessment with antibody test will be done only at post-intervention level) in already IEC approved research work entitled "Efficacy of Pranayama on Positivity rate in People exposed to Covid-19 Patients and mental status" on 28th July 2020.

The following members of the ethics committee reviewed the amendment and detailed project and giving the approval:

S.N.	Name and Designation	Designation	Signature
1	Dr. Balakrishnan Menon, Professor, VPCI	Chairperson
2	Dr Vishal Bansal, Assistant Professor, VPCI	Member
3	Dr Rakesh Kumar, SMO, MDNIY	Member
4	Dr Sanjay Gupta, Medical Superintendent, AIIA	Member
5	Dr. Abha Chaudhury, Chairman, NGO (Anugraha, Delhi)	Member
6	Dr Lakshmi Kandhan, Assistant Professor (Y.T), MDNIY	Member
7	Dr Neha Kathuria Bhatnagar, ARO (Yoga), MDNIY	Member
8	Dr Khushbu Jain, Assistant Professor (Biochemistry), MDNIY	Member Secretary

We approve the research work to be conducted with the above mentioned amendment. The Institutional Ethics Committee expects to be informed about the progress of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Chairperson,
IEC, MDNIY &
Professor, VPCL,
Delhi
Dr. Balakrishnan Menon
MD
Reader
V.P. Chest Institute
University of Delhi

Approval of the Institutional Ethics Committee at MDNIY

TABLE 1: PRANYAMA PROTOCOL FOR THE MORNING SESSION (30 Minutes)

S. No	Practices	Name of Practice	Rounds	Duration (in Minutes)
1	Preparatory Practices for Pranayama	Prayer	3-5 deep breathing/ prayer of individual	1
2		Vaata Neti	3 rounds (30 secs/round) (1 Breathing/sec)	2.5
3		Kapalabhati	3 rounds (30 secs/round) (1 Breathing/sec)	2.5
4		Deep Breathing	10 rounds	3
5	Pranayama Practices	Nadishodhana	10 rounds	8
6		Ujjayee	10 rounds	4
7		Bhramari	10 rounds	4
9	Meditation	Dhyana	Awareness of breathing, thoughts and emotions	5
	Total Duration			30

TABLE 2: PRANYAMA (BREATHING)PROTOCOL FOR THE EVENING SESSION (15 Minutes)

S. No	Name of Practice	Rounds	Duration (in Minutes)
1	Savasana (Corpse Pose)- Pristhabhumi Tadasana		1
2	Abdominal Breathing	15 Rounds	3
3	Thoracic Breathing	15 Rounds	3
4	Clavicular Breathing	15 Rounds	3
5	Deep Breathing (lying down position)	15 Rounds	3
6	Relaxation in Shavasana with awareness on Abdominal breathing		2
Total Duration			15
Note: Each breathing is comprising 6 seconds inhalation and 6 seconds exhalation.			

TABLE 3: SOCIO DEMOGRAPHIC DATA OF 250 HCPS

Variables	Experimental Grp N (%)	Control Grp N (%)
TOTAL	123 (100.00%)	127 (100.00%)
Age (in Years)		
19-35	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		
Mildly Exposed	37 (30.08%)	40 (31.50%)
Severely Exposed	86 (69.92%)	87 (68.50%)
Grp: Group; N: Number; Veg. : Vegetarian		

TABLE 4: HEALTH STATUS OF PARTICIPATING HCPs

	Intervention Group N (%)	Control Group N (%)
HCPs (Healthy)	102 (83%)	107 (84%)
HCPs (with Co-morbidities)	21 (17%)	20 (16 %)
Total no. of HCPs	123 (100%)	127 (100%)

TABLE 5: POST-INTERVENTION COVID-19 ASSESSMENT RESULTS IN INTERVENTION/EXPERIMENTAL GROUP AS COMPARED TO CONTROL

	Total no. of HCPs	COVID-19 Positive Cases	COVID-19 Negative Cases	Chi- Score	P-Value
Experimental Grp N (%)	123 (100%)	1 (0.8%)	122 (99.2%)	6.4	0.01**
Control Grp N (%)	127 (100%)	9 (7.1%)	118 (92.9%)	510.4	

** indicate level of significance

TABLE 6- TEST DETAILS OF THE PARTICIPANTS WHO WERE INFECTED WITH COVID -19 AT POST-INTERVENTION

HCP	Group	Gender	Symptomatic /Asymptomatic	Type of Test
SUB 012	Control	F	Symptomatic	Rapid Antigen Test
SUB 034	Control	M	Asymptomatic	Antibody Test
SUB 084	Control	F	Symptomatic	Rapid Antigen test
SUB 114	Control	F	Symptomatic	RT-PCR
SUB 164	Control	M	Asymptomatic	Antibody Test
SUB 171	Control	M	Asymptomatic	Antibody Test
SUB 173	Control	M	Asymptomatic	Antibody Test
SUB 186	Control	F	Asymptomatic	Antibody Test
SUB 196	Control	M	Asymptomatic	Antibody Test
SUB 227	Experimental	M	Asymptomatic	Antibody Test

TABLE 7- SOCIO-DEMOGRAPHIC DETAILS OF STUDY PARTICIPANTS WHO WERE INFECTED WITH COVID -19 POST-INTERVENTION

HCPs	Group	Gender	Dietary habits	Age grp	Exposure (COVID - 19)	Duty in COVID-19 Wards
SUB 012	Control	F	Veg	18-35	High	Asha Worker/ Care Taker/ Housekeeping
SUB 034	Control	M	Veg	51-65	High	Care Taker/ Housekeeping
SUB 084	Control	F	Non Veg	36-50	High	Care Taker/ Housekeeping
SUB 114	Control	F	Non Veg	36-50	High	Nursing Off
SUB 164	Control	M	Veg	36-50	Low	Courier Boy/ Admin staff
SUB 171	Control	M	Veg	18-35	Low	Lab Tech
SUB 173	Control	M	Non Veg	51-65	High	Doctor
SUB 186	Control	F	Veg	18-35	High	Care Taker/ Housekeeping
SUB 196	Control	M	Non Veg	18-35	High	Care Taker/ Housekeeping
SUB 227	Experiment	M	Veg	36-50	High	Care Taker/ Housekeeping

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