# Effect of Structured Yoga Program on Stress and Professional Quality of Life Among Nursing Staff in a Tertiary Care Hospital of Delhi—A Small Scale Phase-II Trial

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#### **Abstract**

Background. Nursing staff suffer from various level of stress and burnout. We aimed to assess the effect of 12 weeks of structured yoga on stress and the professional quality of life among nursing staff. Design and method. An open-label, phase-II randomized clinical trial was undertaken considering a sample size of convenience was done. In service nursing staff were randomized (1:1) to intervention group and wait-list control group. Primary outcome was perceived stress which was measured by Perceived Stress Scale (PSS). Secondary measures were professional quality measured by Professional Quality of Life (ProQOL) scale, blood pressure, serum cortisol, and high-sensitive C-reactive protein. Both the per-protocol and intention to treat analysis was done. Results. Total 113 participants were allocated to intervention group (n = 58, mean = 35 years, SD = 7.9 years) and wait-list control group (n = 55, mean = 32.5 years, SD = 6.8 years). After 12 weeks, 19 participants of intervention group and 32 participants of wait-list control group were included in the per-protocol analysis. Follow-up mean PSS score was 15.4 (95% CI 12.6-18.2, SD 5.8) in intervention group, 20.7 (95% CI 19.7-21.7, SD 2.8) in wait-list control group (p-value < 0.0001). The other parameters didn't differ between the groups and from baseline to end line too. Conclusions and relevance. The finding showed supervised structured yoga may be efficacious to reduce stress. Studies with larger sample size are needed to confirm the findings. Trial registration. It was approved by the Institute Ethics Committee (Reference no: IECPG-543/20.12.2017, RT-57/31.01.2018) and was registered prospectively in the Clinical Trial Registry of India prospectively (No. CTRI/2018/02/012206).

# Keywords

yoga, nursing staff, stress, perceived stress, professional quality, burnout, phase-II trial

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#### Introduction

Stress in the work field is an important occupational health hazard. A growing number of research studies have shown moderate to severe levels of stress and burnout at a very alarming level. It also showed the deleterious effects of perceived stress on personal, professional and social life.<sup>2</sup>

The health care field also faces a high burden of work-related stress and burnout both outside as well as in India.<sup>2-5</sup> Nursing staff are reported to have occupational stress levels as high as 87% and burnout rate of 30%.<sup>2,6</sup> The prevalence of perceived stress as per the study by Kshetrimayum et al is 55.4%.<sup>7</sup> Apart from stress and burnout, lower levels of compassion satisfaction and higher levels of secondary traumatic

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stress are being reported by staff nurses which lower the overall professional quality of life. <sup>8,9</sup> Inherent nature of the job involving shift work, strained work relation, low organizational sufficiency, complex nature of care, and other factors are some of the reported factors. <sup>10</sup> Moreover unpredictable, uncontrollable or high performance demanding situations like the death of patients, intense morbidity, violence against health workers are also responsible for this. <sup>11,12</sup>

Increased stress has physical as well as a psychological effect on one's health. Higher risk of having depressive, anxiety disorder, endocrinal, cardiovascular, autonomic abnormalities are caused by stress. Dysfunction of immune system has been reported on exposure to chronic professional stress among nursing staff. Work related and personal stress during pregnancy affect fetal health. Is Increased hospital-acquired infection, wrong medication, miscommunication with the patient and patient's relatives have been seen. Stress increases the economic burden directly due to absenteeism, health care cost of employees and indirectly by decreasing the quality of patient care, which increases the health care cost of patient.

Nurses having the coping skill by self-reflection, self-care, resilience are more likely to tackle the stressful situation and providing a higher quality of patient care. 17,18 Changing the perceptions and behavior toward stressful situations helps to gain effective coping strategies. 18 It has also been seen that nurses facing stress adopt some ineffective coping strategies like smoking, overeating, using some other addictive substances etc. 19,20 Apart from the risk of lifestyle-related diseases these persons are more prone to get affected by stress and burnout when exposed to a chronic or significant stressor. 21

Mind-body practices are a diverse group of strategies to boost coping strategy, increasing emotional resilience preventing burnout, and stressful situations along with higher patient satisfaction.<sup>22,23</sup> It involves bodily exercise and mind based practice trained in a specific pattern and it includes acupuncture, therapeutic massage, meditation, mind-body relaxation techniques, spinal manipulation, body stretching, yoga etc.<sup>24,25</sup>

Yoga, a recognized form of mind-body practice integrates an individual's physical, mental, and spiritual components to ameliorate several aspects of health, particularly stress-related illnesses. <sup>26</sup> It improves physical, psychological wellbeing and increases metabolic and autonomic integrity. <sup>27</sup> It decreases body oxidative stress and increases hypophyseal-pituitary-adrenal axis stability. <sup>28</sup> Yoga activates the parasympathetic nervous system triggering relaxation which improves the self-compassion and decreases stress, anxiety. <sup>29</sup> It has an effect on professional quality also like increasing coping ability, lesser emotional exhaustion, and lesser depersonalization. <sup>30,31</sup> Improved health care delivery after regular yoga practice also reported among nursing staff. <sup>22</sup>

Yoga is easy, low cost and safe preventive as well as curative approach in nature. 32-34 Basic research on adults practicing yoga showed the safety and potential to reduce stress. 35

There was no conclusive evidence on the effect of structured yoga on stress and professional quality of life among nursing staff in India. Moreover, the level and severity of perceived stress greatly vary from person to person and situation to situation. <sup>12,36,37</sup> There is enough evidence regarding the safety <sup>33,34,38</sup> but adequate data whether yoga can reduce stress among nursing staff is inconclusive. This necessitates the exploration of the possible strategy of intervention by undergoing a preliminary phase-II trial.

We aimed to study the efficacy of structured yoga and also to assess the sustainability of this yoga program among this nursing staff of a tertiary care hospital in Delhi.

# **Methods**

# Study Design and Participants

We did this open-label, parallel, small-scale phase II randomized controlled clinical trial considering a sample size of convenience, carried out at the institutional yoga facility of a tertiary care hospital of Delhi, India. We included all the in-service nursing staff working at the hospital for at least 1 year. We excluded those who were already under pharmacological treatment for any psychiatric disorder at the time of enrolment; having service left for less than a year (from the date of enrolment); any clinical condition that would affect the ability to practice yoga.

Participants were recruited from the main campus of the institution. The rural campus could not be included as they were not within the main campus.

The study protocol was approved by the Institute Ethics Committee (Reference no: IECPG-543/20.12.2017, RT-57/31.01.2018) on 31/01/2018. The trial was registered in the Clinical Trial Registry of India prospectively (No. CTRI/2018/02/012206, Registered on 28/02/2018). Informed written consent was taken from the participants.

### Randomization and Masking

The investigation team collected unpredictable allocation sequence [using computer software and permuted block randomization] generated by a third party not involved in the study. The block size was multiple of 2 and variable in size. After the baseline assessment was over, the sealed opaque envelop at her/his respective enrolment number was opened in front of the participants to maintain the allocation concealment. The participants were allocated in either of the 2 groups; intervention i.e. yoga group or the wait-listed group. Masking of the allocated group was not feasible in the study.

#### Interventions Procedure

The yoga module which consisted of asana, pranayama, and deep relaxation technique was developed by a committee of yoga physicians and yoga therapists at the institutional yoga facility (Figure 1). We adopted the 5 minutes deep relaxation technique practiced in supine position, Shavasana (Corpse Pose) which is an evidence based scientific way to relax the whole body completely within a short amount of time. It is usually, which literally translates to dead body posture. The yoga therapists were trained professionals who completed their post-graduation in the subject from reputed yoga institute. Two sessions in a week each with a duration of 50 minutes for 12 consecutive weeks were conducted. A minimum 20 sessions in the 12 weeks period was considered completed intervention. Each session was recorded in their logbook as well as the register maintained at the yoga facility. All the yoga sessions were provided before or after their

Preparatory practices		Duration		
		(minutes)		
Sukshma Vyayama (SKSHVY)	1.Jogging 2.Twisting 3.Forward and Backward Bending	05		
Preparatory movements with breathing	1.Hands stretch breathing 2.Ankle Stretch Breathing 3.Straight leg raise breathing 4.Pavanmuktasana breathing	05		
Suryanamaskar	6 Rounds	10		
Asanas				
Standing	1.Ardha-kati chakrasana 2.Trikonashana 3.Veerabhadrasana 4.Vrikshasana	05		
Sitting	Vakrasana/Ardhamatchyandrasana     Ustrasana     Paschimauttanasana	05		
Prone	<ol> <li>bhujangansana</li> <li>Shalabhasana- ardha or full</li> <li>Dhanurasana</li> </ol>	05		
Supine	upine 1. Setubandhasana 2. Ardha-halasana 3. Naukasana			
Pranayama	anayama 1. Nadisudhi 2. Kapalbhati 3. Bhramari			
Relaxation Technique	Deep relaxation technique	05		
Total duration in minute				

Figure 1. Yoga module consisting of the asanas and preparatory practices.

duty hours. The participants were reminded by text message/email a day before the scheduled yoga session.

# **Outcomes Variables**

The primary outcome was change of perceived stress and improvement of professional quality of life. Perceived stress was measured by a Likert scale and serum cortisol level. The serum cortisol level is a non-specific biomarker, a higher level of which indirectly indicates the presence of perceived stress. Another primary outcome was the professional quality of life. It included compassion satisfaction and compassion fatigue component. Compassion fatigue had 2 subcomponent; burnout and secondary traumatic stress.<sup>39</sup> The

professional quality of life was also assessed by a Likert scale measuring the compassion satisfaction and compassion fatigue. Higher score in each component of the scale denoted higher compassion satisfaction, higher burnout, and higher secondary traumatic stress respectively. Other non-specific outcome of stress was serum high sensitive C-reactive protein (HSCRP), systolic, and diastolic blood pressure. The higher the mean value of HS-CRP, blood pressure also indirectly indicates a higher level of stress.

**Study tools.** Perceived stress was assessed by the Perceived Stress Scale (PSS), a 10 item psychometric Likert scale, and morning serum cortisol level. The English version of PSS scale was a validated scale and had been used in Indian settings with an internal consistency  $\alpha =$ 

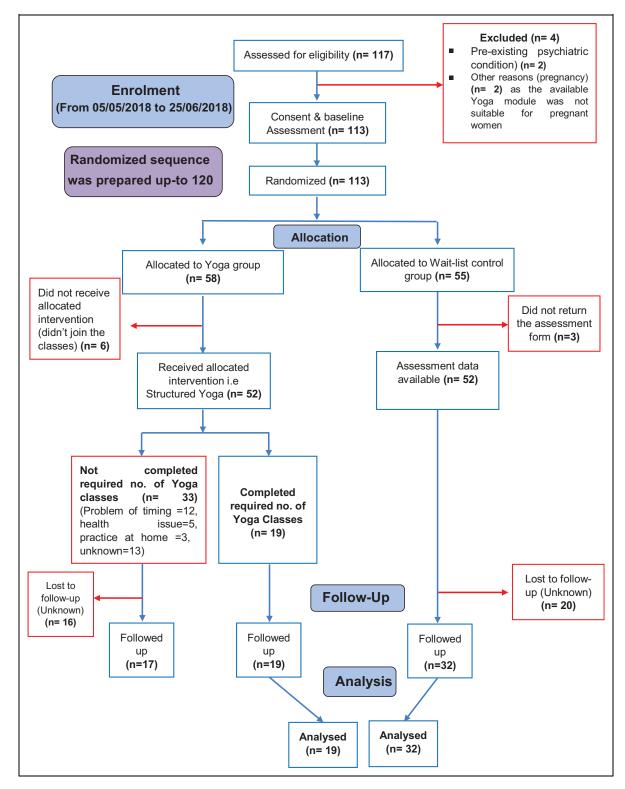


Figure 2. Flow diagram of the study participants.

0.79. 40-42 It had a total score of 0-40 where higher score denoted higher perceived stress. Serum cortisol was measured from fasting venous blood by Chemiluminescence assay (Cantaur XP). The professional quality of life was measured by the English Professional Quality of Life (ProQOL) scale, a 30 item Likert scale validated with

an internal consistency  $\alpha$  for compassion satisfaction (CS) = 0.87, burnout (BO) = 0.72, and secondary traumatic stress (STS) = 0.80 and used in many Indian study. Significantly Compassion satisfaction, burnout and secondary traumatic stress each had 10 items in the scale with a total score ranging from 10 to 50. Serum high sensitive C-reactive

Table 1. Distribution of Study Participants by Baseline Characteristics.

Parameters			Intervention group (n $=$ 58)	Wait-list control group (n $=$ 52)	
Sex (%)		Male	8 (13.8)	22 (42.3)	
. ,		Female	50 (86.2)	30 (57.7)	
Age (Mean $\pm$ SD)			35 ± 7.9	32.5 ± 6.8	
(95% CI)			(32.9-37.1)	(30.6-34.5)	
Marital status* (%)		Single	Ì I (18.9)	13 (25.5)	
( )		Married	44 (75.8)	36 (70.6)	
		Widowed	2 (3.5)	0 ` ′	
		Divorcee	I (1.7)	2 (3.9)	
Educational Qualifica	ation# (%)	Graduate	42 (87.5)	43 (93.4)	
	(1.5)	Post-graduate	6 (12.5)	3 (6.5)	
Physical/Emotional P	Problem <sup>\$</sup> (%)	Yes	10 (17.8)	8 (16.3)	
i nysican Emotionar i	100iciii (70)	No	46 (82.1)	41 (83.8)	
Relation in personal	life <sup>€</sup> (%)	Excellent	12 (21.1)	15 (30.0)	
relation in personal	1110 (70)	Good	40 (70.2)	28 (56.0)	
		Moderate	5 (8.8)	7 (14.0)	
		Poor	0	0	
Sleep <sup>¥</sup> (%)				<del>-</del>	
Sieep (%)		Enough	31 (56.4)	27 (52.9)	
D . I DI % (0/)		Not-enough	24 (43.6)	24 (47.1)	
Posted Place $^{\alpha}$ (%)		Outdoor	5 (9.1)	3 (6.4)	
		Indoor	30 (54.5)	23 (48.9)	
		ICU	6 (10.9)	2 (4.3)	
		Operation room	1 (1.8)	1 (2.1)	
ρ		Others	13 (23.6)	18 (38.4)	
Job Duration <sup>β</sup> (Days	5)	Total	$12.1 \pm 7.7$	$10.3 \pm 7.7$	
(Mean $\pm$ SD)			(10.0-14.1)	(8.2-12.3)	
(95% CI)		At AIIMS	9.7 ± 7.3	7.6 ± 6.4	
			(7.7-11.7)	(5.8-9.4)	
Duty Hours/Week <sup>£</sup>			43.2 ± 5.4	41.5 $\pm$ 4.0	
(Mean $\pm$ SD) (95%	CI)		(41.6-44.8)	(40.3-42.7)	
Night Shift/Month <sup>µ</sup>			$4.8 \pm 2.2$	5.3 ± 2.1	
(Mean $\pm$ SD) (95%	CI)		(4.1-5.4)	(4.7-5.9)	
Job Satisfaction $^{\Omega}$ (%)	)	Excellent	3 (5.6)	7 (13.7)	
		Good	31 (57.4)	32 (62.7)	
		Moderate	19 (35.2)	12 923.5)	
		Poor	1 91.8)	0	
Interpersonal Relation	$on^\infty$	Excellent	5 (8.7)	9 (17.6)	
at work (%)		Good	43 (70.6)	36 (70.6)	
` '		Moderate	9 (Ì5.8)	6 (11.7)	
		Poor	0 ` ′	0 ` ′	
Pressure $^{\sum}$ (%)	Higher Authority	Yes	30 (55.6)	24 (52.2)	
()		No	24 (44.4)	22 (47.8)	
	Patient	Yes	28 (51.2)	25 (54.3)	
		No	26 (48.1)	21 (45.6)	
Skip Meal at Work□ (%)		Yes	28 (51.8)	30 (60.0)	
o.ap i ioui uc i ioik	(~)	No	26 (48.2)	20 (40.0)	
Paid Leave Granted <sup>6</sup> (%)		Adequate	31 (55.4)	32 (64.0)	
		Inadequate	25 (44.6)	18 (36.0)	
Support from colleague <sup>E</sup> (%)		Yes	53 (94.6)	50 (98.0)	
Support ironi colleas	gue - (/0)	No	* *	I (2)	
		INU	3 (5.4)	I (Z)	

<sup>\*</sup>One participant of wait-list control didn't respond.

<sup>&</sup>quot;Ten participants of intervention group and 6 of wait-list control group didn't respond.

<sup>\$</sup>One participant of intervention group and 2 of wait-list control group didn't respond.

 $<sup>^{\</sup>varepsilon}$ One participant of intervention group and 2 of wait-list control group didn't respond.

<sup>\*</sup>Three participants of intervention group and I of wait-list control group didn't respond.

 $<sup>^{\</sup>alpha}\text{Three participants of intervention group and 5 of wait-list control group didn't respond.$ 

<sup>&</sup>lt;sup>β</sup>One participants of intervention group and 2 of wait-list control didn't respond.

<sup>&</sup>lt;sup>£</sup>Twelve participants of intervention group and 5 of wait-list control didn't respond.

<sup>&</sup>lt;sup>µ</sup>Seven participants of intervention group and 7 of wait-list control didn't respond.

 $<sup>^{\</sup>Omega}\textsc{Four}$  participants of intervention group and I of wait-list control didn't respond.

One participant of intervention group and 5 of wait-list control didn't respond.  $^{\textstyle \Sigma} \mbox{Four participants of intervention group and 6 of wait-list control didn't respond.$ 

Four participants of intervention group and 2 of wait-list control didn't respond.

<sup>&</sup>lt;sup>8</sup>Two participants of intervention group and 5 of wait-list control didn't respond.

<sup>&</sup>lt;sup>E</sup>Two participants of intervention group and 1 of wait-list control didn't respond.

Table 2. Distribution of Study Participants by Baseline Characteristics of Anthropometric, Clinical, and Biochemical Parameters.

Parameters		Intervention group (n $=$ 58) Mean $\pm$ SD (95% CI)	Wait-list control group (n $=$ 52) Mean $\pm$ SD (95% CI)
BMI* (kg/mt²)		25.9 ± 4.2	24.4 ± 4.4
		(24.8-27.1)	(23.1-25.7)
Blood Pressure# (mm Hg)	SBP	116.9 <u>+</u> 12.4	119.2 ± 12.8
		(113.5-120.4)	(115.3-123.1)
	DBP	76.6 <u>+</u> 9.3	77.4 ± 9.0
		(74.1-79.2)	(74.7-80.2)
Perceived Stress Scale Score		19.9 ± 5.4	19.8 v 4.8)
		(18.6-21.4)	(18.5-21.2)
Professional Quality of Life	Compassion Satisfaction	48.7 ± 6.4	49.5 ± 6.8
	·	(47.0-50.5)	(47.9-51.8)
	Secondary traumatic stress	70.5 ± 5.4	70.1 ± 6.3
	,	(69.0-71.9)	(68.3-71.9)
	Burnout	$\hat{57.7} \pm 6.2$	$\hat{5}6.2 \pm 5.4$
		(56.0-59.3)	(54.7-57.7)
Cortisol (mcg/dl) <sup>\$</sup>		$9.8 \pm 4.7$	$9.4 \pm 3.7$
, ,		(8.5-11.0)	(8.3-10.5)
HS-CRP(mg/dl) <sup>¥</sup>		$3.7 \pm 6.0$	2.7 ± 4.8
· • /		(2.I-5.4)	(I.3-4.I)

<sup>\*</sup>Three participants of intervention group and 7 of wait-list control didn't respond.

protein (HS-CRP) was measured from venous blood (Immuno-turbid metric method by Beckman Coulter AU 680 USA). Systolic and diastolic blood pressure was measured by a digital blood pressure machine (model no. Health sense BP100).

Sample size. Efficacy means "ability to produce an effect" whereas effectiveness is "the ability to produce the desired effect." We did expect only "any amount of effect" rather than "a desired level of effect." Since it was a phase-II clinical trial, the thumb rule of sample size under the phase-II trial had to be considered. However, keeping the feasibility in mind, it was proposed to take a total of 100 participants with 50 participants in each arm. <sup>44</sup> Being an institution based study, the participants often came for the recruitment in a group, which was expected to increase planned number of registered participants. As a precaution, we started with a randomization sequence for 120 participants.

### Statistical Methods

Data collection was done at baseline and 3rd month. Data was entered in Microsoft Excel and was analyzed in STATA version 12. Per protocol analysis was done. The categorical variables were summarized using absolute frequency and proportions and the quantitative variables were summarized by mean, standard deviation. The significance between the 2 groups was assessed by Fisher Exact/Chi-square test for categorical variables and unpaired t-test/Wilcoxon rank-sum test for the continuous variables. The effect size for the primary outcome variable was calculated by standardized mean difference. The level of statistical significance was considered as 5%.

#### Results

Out of total 117 participants, 113 were found eligible. They were randomized into intervention group (n = 58) and wait-list control group (n = 55). Six participants of intervention group didn't join the class whereas 3 participants of wait-list control group didn't complete assessment. Of the 52 participants joining the class, 25 participants discontinued in the first month, 5 participants in the second month and 3 participants in the third month. Therefore, the remaining 19 participants completed the minimum required 20 yoga sessions. At the end of the 12 weeks of follow up, 19 participants of intervention group and 32 participants of wait-list control group was included in the analysis. (Figure 2).

The baseline characteristics were comparable in both the groups except sex, where a higher proportion of males were present in the wait-list group (Table 1). The main outcome parameters were similar in both groups (Table 2). As per the per-protocol analysis the baseline parameters also showed the similar findings.

After the 12 weeks of follow up, the PSS score differed in the intervention group from the wait-list control group significantly (p < 0.05). From the baseline, the mean score declined by 6.3 (SD 8.6) which was significantly different (p < 0.05) from the mean change in the wait-list control group (Table 3). The calculated standardized mean difference of PSS score was -1.3 (95% CI -1.9 to -0.7).In the intervention group, mean systolic blood pressure was significantly lower than the wait-list control group (Table 3). The components of the ProQOL

<sup>\*</sup>Two participants of intervention group and 5 of wait-list control didn't respond.

 $<sup>{}^{\$}\</sup>text{Two participants of intervention group and 5 of wait-list control didn't respond.}$ 

<sup>\*</sup>Two participants of intervention group and 5 of wait-list control didn't respond.

Table 3. Post-Intervention Comparison of Mean Values of Outcome Variables.

Parameters		Intervention group $(n=19)$ Mean $\pm$ SD $(95\%$ CI)	Wait-list control group (n $=$ 32) Mean $\pm$ SD (95% CI)	p-value
Blood Pressure	SBP	116.9 ± 12.5	123.9 ± 8.9	0.023
(mm Hg) <sup>¥</sup>		(110.9-122.9)	(120.7-127.1)	
(n = 19 & 32)	DBP	77 ± 8.6	80.4 ± 6.6	0.121
		(72.8-81.2)	(77.9-82.7)	
Perceived Stress Scale Score		15.4 <u>+</u> 5.8	$20.7 \pm 2.8$	<0.0001
		(12.6-18.2)	(19.7-21.7)	
Professional Quality of Life#	CS	50.4 ± 8.6	48.8 ± 6.0	0.467
•		(46.2-54.7)	(46.6-51.1)	
	STS	66.9 ± 6.8	69.6 ± 6.9	0.322
		(63.5-70.3)	(67.1-72.1)	
	ВО	$\dot{5}4.7 \pm 5.4$	56.5 + 4.ĺ	0.169
Cortisol (mcg/dl) <sup>€</sup>		8.6 ± 3.5	9.9 + 3.8	0.757
( '6' )		(6.8-10.3)	(8.4-11.4)	
HS-CRP $(mg/dl)^{\epsilon}$		3.5 ± 3.1	4.7 ± 1.5	0.089
(8,)		(1.9-5.0)	(1.6-7.9)	0.007

 $<sup>{}^{\</sup>mathrm{F}}\mathrm{Two}$  participants of wait-list control didn't respond.

Table 4. Post-Intervention Mean Change From Baseline of the Outcome Variables.

	Baseline		Post-intervention		Change			
Group	n	Mean (SD)	n	Mean (SD)	n	Baseline to end line difference, mean (SD)	Standardized mean difference, (95% CI)	p value
PSS								
Intervention Group	58	$20.7 \pm 5.9$	19	15.5 ± 5.4	19	$6.3  \pm  8.6$	-1.3	0.0003
Wait-list Control Group CS-PrOQOL	52	19.8 ± 4.7	32	20.7 ± 2.8	32	$-0.9  \frac{-}{\pm}  4.5$	(-1.9  to  -0.7)	
Intervention Group	58	$48.3 \pm 7.3$	18	50.4 ± 8.6	18	1.7 ± 11.5	0.2	0.578
Wait-list Control Group BO-PrOQOL	52	47.1 ± 10.0	30	48.8 ± 6.0	30	3.3 ± 9.5	(-0.4 to 0.6)	
Intervention Group	58	58.7 ± 6.5	18	54.6 ± 5.3	18	5.3 ± 6.6	-1.9	0.142
Wait-list Control Group STS-PrOQOL	52	56.9 ± 4.9	30	56.5 ± 4.1	30	1.3 ± 6.1	(-0.8 to 0.4)	
Intervention Group	58	71.2 ± 5.6	18	66.8 $\pm$ 6.7	18	$3.9 \pm 7.0$	-0.4	0.089
Wait-list Control Group Cortisol	52	68.7 ± 6.9	30	69.6 ± 6.9	30	$0.9  \frac{-}{\pm}  6.4$	(-1.0 to 0.2)	
Intervention Group	55	$10.2 \pm 5.2$	18	8.3 ± 3.5	18	$2.2 \pm 7.4$	-0.4	0.112
Wait-list Control Group HS-CRP	45	9.2 ± 4.1	29	9.8 ± 3.8	29	$-0.9  \stackrel{-}{\pm}  5.0$	(-0.9 to 0.2)	
Intervention Group	55	$4.2 \pm 6.5$	18	$3.5 \pm 3.1$	18	$0.2  \pm  3.4$	-0.3	0.784
Wait-list Control Group	45	$2.9~\pm~5.3$	29	$2.7 \pm 3.2$	29	$0.5 \pm 5.5$	(-0.3 to 0.8)	

didn't differ significantly between the group and the mean change from the baseline were not also significant (Tables 3 and 4). The biochemical parameters also didn't differ significantly between the 2 groups (Table 3). The post-intervention period, the mean change of serum cortisol in the intervention group didn't differ than the mean change of the waitlist control group (Table 4). No participant reported any injury or morbidities requiring medical attention due to the yoga sessions.

#### **Discussion**

This small-scale exploratory phase II trial assessed whether structured yoga program was able to reduce the perceived stress or not. Since perceived stress is subjective, we used the objective parameters and biomarkers along with the subjective scale. Out of the total enrolled, 45% of participants completed the study. The reasons of drop out of 55% participants were issue

<sup>\*</sup>One participant of intervention group and 2 of wait-list control group didn't respond.

 $<sup>^{\</sup>epsilon}$ One participant of intervention group and 3 of wait-list control group didn't respond.

of time, health issues of family members etc. Though we used a permuted block randomization method to allocate group equally, still there was a difference over male-female participants between the groups at baseline. All other baseline characteristics were comparable between the 2 groups. The yoga sessions were held both before and after the duty hours. The impact of the schedule of yoga is not clear. A tiring hectic duty day, as well as delay in coming to the duty place, could have decreased the compliance. Extra time required for a yoga session, over and above their duty hours could have negatively affected the participation in yoga sessions.

Despite this limitation, the finding showed early level evidence of the potency of weekly twice sessions of structured yoga in stress reduction. Compared with the wait-list control the intervention group showed a lower score on PSS after 12 weeks of the yoga program. This finding is supported by a previous study by Monali Devaraj Mathad et al. among 100 nursing students where a significant decrease of PSS score was seen after 8 weeks of the daily 1-hour yoga program. Another study by Alexander et al. in 2015 among 40 staff nurse found significantly lesser emotional exhaustion and depersonalization after 8 weeks of yoga. A study was done by Kozasa EH et al. in 2016 among 13 nursing staff that showed 28% reduction of mean PSS score, which is similar to this study where we observed 29% reduction in mean PSS score.

The mean systolic blood pressure reduced in the intervention group from baseline, which was statistically significant. There was no significant change in diastolic blood pressure. A community based randomized trial done by Saptharishi et al. in South India among 113 young adults showed mean change of SBP/DBP: 2/2.6 mm Hg after 8 weeks of 5 days/week of yoga practice.<sup>47</sup> Though the magnitude of change of blood pressure was statistically significant, the clinical significance is debatable since all participants were normotensive to start with.

We didn't find any statistically significant difference in the components of the ProQOL scale after the intervention. It was not also significant when the mean change from baseline to follow up assessed in the intervention group. This finding is similar to this study done among social worker by Gregory Amber showed yoga practice didn't change the compassion satisfaction and the compassion fatigue as well. 48 The cortisol didn't significantly differ between the groups at follow up in the intervention group compared to the wait-list control group. Though serum cortisol is a non-specific biomarker of stress, the positive mean reduction in the intervention group might be due to the reduction of stress levels in contrast to negative change in the wait-list control group. The pre and post intervention level of cortisol being within normal range, the direction of the changes was in accordance with the change of stress as per the PSS score. Perceived stress and professional quality of life vary over the subject, situation and it may change instantaneously. So even after the practice of yoga, there might be repeated exposure of stressor and incidence of stress. Yoga is thought to increase the coping ability also. This might be another mode of getting a decreased perceived stress level in the intervention group.

Other parameter like HS-CRP though reduced but were statistically not significant. The reason may be the small sample size or the insufficient number of yoga sessions. A study was done by Shete et al. among 48 industrial workers reported that the CRP level was significantly different between the group after a daily 1 hour yoga session of 6 days /week for 12 weeks. Whereas, another study was done by Azami et al. among 24 women found no significant change in CRP even after 26 weeks, 3-session/week. So

Our study had several strengths, which gives it uniqueness. This was the first phase-II exploratory trial assessing the efficacy of yoga in stress reduction. We used both the psychometric questionnaire as well as serum biomarkers, which gave the unique opportunity to assess the change of overall perceived stress. Participants were recruited from different sections of the hospital, which ensured the generalizability as different sections or wards had different types of work pattern load and work culture, and stressors. Well-established yoga facility and trained professionals were involved in this study, which maintained the quality and uniformity of the intervention.

This study also had a few limitations. The sample size was small; moreover, the completion rate was low. Only 45% of the participants completed the study, which resulted in a further decline in the eventual number of participants. In spite of all our efforts to keep drop out at the minimum, our study had 67% dropout in the intervention and 58% in the wait-list control group. The usual dropout rate is variable in the available literature. According one systematic review done by Cramer et al. the expected dropout rate in RCT of voga was 15\% to 20\% though beyond 40% is possible. This systematic review included the studies done among participants with some diagnosed medical conditions.<sup>33</sup> Another systematic review and meta-analysis done by Vollbehr et al. showed variable dropout rate from 0% to 47% with a follow up dropout 14% to 67%.<sup>51</sup> In our study all the participants were apparently well which might have decreased the perceived benefit contributing for the dropout. In this study masking was not feasible as the lead author was the only person who collected all the data, including allocation group.

Supervised yoga practice showed some suggestive findings of its efficacy to reduce the perceived stress and improving the professional quality of life. The changes in both the psychometric scale and the serum cortisol level might be due to the reduction of overall perceived stress. Supervised yoga might be an effective and feasible way to deal with the stress level among nursing professionals. On the other hand, after the end of the supervised yoga session, all the participants discontinued practicing independently within 2 months. This indicated that unsupervised yoga has low sustainability. Overall, the result was encouraging. However further study with larger sample size is needed to confirm the finding, and to find the barriers leading to the low sustainability of unsupervised yoga.

#### **Authors' Note**

Puneet Misra: Study concepts, study design, protocol development, literature search, finalizing study tools, study supervision, supervision

of data collection, data analysis, data interpretation, manuscript writing, manuscript editing. Suprakash Mandal: Protocol development, literature search, study conduct, data collection, data analysis, manuscript writing, manuscript editing. Gautam Sharma: Protocol development, preparation of yoga module, study supervision, manuscript writing, manuscript editing. Rajesh Sagar: Protocol development, finalizing study tools, data interpretation, manuscript writing, manuscript editing. Shashi Kant: Protocol development, study design, finalizing study tools, data interpretation, manuscript writing, manuscript editing. Sadanand Dwivedi: Protocol development, study design, data analysis, data interpretation, manuscript writing, manuscript editing. R Lakshmi: Protocol development, conducting biochemical analysis, data interpretation, manuscript writing, manuscript editing. Kiran Goswamy: Protocol development, study design, finalizing study tools, data interpretation, manuscript writing, manuscript editing. Ethical Approval: The study protocol was approved by the Institute Ethics Committee (Reference no: IECPG-543/20.12.2017, RT-57/ 31.01.2018) on 31/01/2018. The trial was registered in the Clinical Trial Registry of India prospectively (No. CTRI/2018/02/012206, Registered on 28/02/2018). Informed written consent were taken from the participants. The protocol is available on http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=21130&EncHid=&userName=stress

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