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Efficacy of a 4-week yoga module on the sympatho-vagal balance among healthcare workers in a tertiary care hospital: a randomised controlled trial

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ABSTRACT

Healthcare workers (HCWs) actively involved in patient care at tertiary care hospitals face significant stress and workload, which may adversely impact their sympatho-vagal balance (SVB). Research has extensively investigated SVB using various techniques, such as heart rate variability (HRV). With its multifaceted approach, yoga has been suggested to influence autonomic nervous system function and, consequently, SVB. Thus, this study aims to investigate the efficacy of a 4-week yoga module on SVB among HCWs. This randomised controlled trial will involve 108 HCWs aged 19–60 years. Participants will be randomised to either (1) a yoga intervention group or (2) a medium-paced walking control group. The primary outcome is a change in HRV after 4 weeks of intervention. Secondary outcomes comprise immediate change in state anxiety, selective attention and HRV compared pre- and post-intervention on days 1, 14 and 28. Intention-to-treat and per-protocol analysis will be performed to gain a comprehensive understanding of the effects of intervention. Multivariate linear model will adjust covariates in baseline HRV data in both groups. Independent t-test will compare pre- and postdata on all outcomes between groups. Paired t-test will be used to compare pre- and postdata on all outcomes within the group. The study protocol is registered on the Clinical Trials Registry – India (CTRI) (CTRI/2024/09/074132).

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Sympatho-vagal balance (SVB) is crucial for maintaining homeostasis, and healthcare workers (HCWs) face stress that adversely affects SVB. Yoga has been suggested to positively influence SVB through autonomic modulation.

WHAT THIS STUDY ADDS

⇒ This study evaluates the efficacy of the Defence Institute of Physiology & Allied Sciences (DIPAS) yoga module, validated with high content validity and reliability, in improving SVB among HCWs in a tertiary care hospital.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings could inform stress management programmes for healthcare professionals, contributing to their well-being and encouraging the integration of evidence-based yoga practices in healthcare settings.

INTRODUCTION

The concept of sympatho-vagal balance (SVB) shows how our body's autonomic system is affected by both the sympathetic (fight or flight) and parasympathetic (rest and digest) influences, essentially indicating the balance between these two systems.[1] The balance between these two systems is crucial for maintaining homeostasis in the body, and an imbalance can lead to various health issues, including cardiovascular diseases, gastrointestinal disorders and mental health problems.[2] Research has extensively investigated SVB using techniques such as heart rate variability (HRV).[3–6]

The fluctuation in the time intervals between adjacent heartbeats is called HRV.[7] It measures the dynamic interactions between the heart and brain, influenced by the autonomic nervous system.[8] In simpler terms, HRV provides insights into the coordination between the heart and brain, influencing various aspects of the body's functioning. HRV analysis techniques can distinguish between the activation of the parasympathetic nervous system, indicating a relaxed state that reflects good health, and the sympathetic nervous system, indicating an agitated state that, when persistently activated, leads to ill health.[9]

Healthcare workers (HCWs) actively involved in patient care at tertiary care hospitals face significant stress and workload, which may adversely impact their overall well-being, including cardiovascular health. According to Joseph and Joseph, 'a healthcare worker is one who delivers care and services to the sick

Table 1 Classification of HCWs according to WHO

Classification	Occupational group
Health professionals	Generalist medical practitioners, nursing professionals, paramedical practitioners, pharmacists
Health associate professionals	Medical technicians, nursing associate professionals, ambulance workers, counsellors
Personal care workers in health services	Healthcare assistants, first-aid attendants, hospital orderlies, medical imaging assistants, phlebotomists, sterilisation aides
Health management and support personnel	Health service managers, clerical workers, plant and machine operators and assemblers
Health service providers not elsewhere classified	Medical student interns, hospital volunteers

HCWs, healthcare worker.

and ailing either directly as doctors and nurses or indirectly as aides, helpers, laboratory technicians or even medical waste handlers'.[10] The WHO classifies HCWs into five broad categories: (a) health professionals; (b) health associate professionals; (c) personal care workers in health services; (d) health management and support personnel; and (e) other health service providers not elsewhere classified.[11] Table 1 presents a concise form of this classification.

HCWs often face substantial stressors in their professional environments, significantly impacting their SVB.[12 13] The demanding nature of healthcare duties, including long working hours, emotional strain and exposure to high-pressure situations, can lead to chronic sympathetic activation and reduced parasympathetic tone among HCWs.[14 15] Prolonged imbalance in sympathovagal activity has been associated with increased risk of cardiovascular disease, impaired immune function and psychological distress, highlighting the importance of implementing strategies to support the well-being of healthcare professionals.[16 17]

The dynamic interaction of SVB has frequently been associated with various mind-body interventions, including yoga practices. With its multifaceted approach encompassing physical postures, breath control and meditation, yoga has been suggested to influence autonomic nervous system function and, consequently, SVB.[18] The mechanisms through which yoga influences SVB are multifaceted. Respiratory modulation, a key component of many yogic practices, is believed to play a pivotal role.[19]

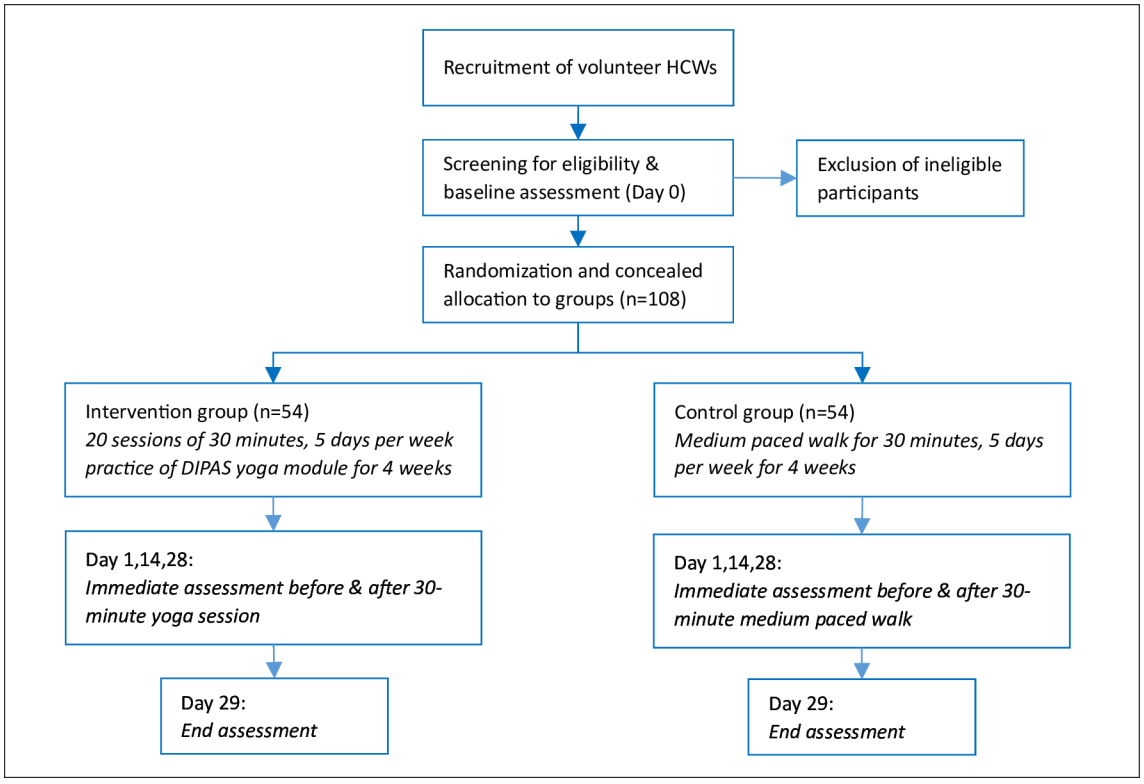

Figure 1 Trial design. DIPAS, Defence Institute of Physiology & Allied Sciences; HCWs, healthcare workers.

Table 2 DIPAS yoga module

Sukshma vyayama (4 min)	
1. Griva shakti vikasaka	6. Janu shakti vikasaka
2. Anguli shakti vikasaka	7. Pindali shakti vikasaka
3. Manibandha shakti vikasaka	8. Gulpha-pada-prastha-pada-tala-shakti vikasaka
4. Karaprastha shakti vikasaka	9. Instant relaxation technique
5. Kati shakti vikasaka	
Yogasana and others (15 min)	
1. Surya namaskara: three rounds	9. Pashchimottanasana
2 Quick relaxation technique	10. Vakrasana
3. Ardhkati chakrasana	11. Ardha matsyendrasana
4. Trikonasana	12. Bhunamanasana
5. Parivritta trikonasana	13. Chakki chaalan
6. Parsvakonasana	14. Bhujangasana
7. Vajrasana	15. Setubandhasana
8. Ushtrasana	
Pranayama (10 min)	
1. Vibhagiya shavasana	3. Nadi shuddhi pranayama (three rounds)
2. Kapalabhati kriya (30 strokes)	4. Bhramari pranayama (three rounds)
Meditation (1 min)	
Aum chanting	

DIPAS, Defence Institute of Physiology & Allied Sciences.

Additionally, the mind-body connection fostered by yoga practices may impact the central nervous system, further influencing SVB.[20]

Hence, the purpose of the present study is to assess the efficacy of a yoga module (*consisting of asana, pranayama, and relaxation and meditative practices*) developed by the Defence Institute of Physiology & Allied Sciences (DIPAS) *(Defence Research and Development Organisation (DRDO), Ministry of Defence, Government of India)* on SVB among HCWs in a tertiary care hospital. This module is henceforth referred to as the DIPAS yoga module. It incorporates a comprehensive approach that combines physical postures, controlled breathing techniques and mindfulness practices, aligning with stress reduction. This module has been validated with a content validity ratio of 0.89 and an intraclass correlation of 0.78.[21]

To date, no empirical studies have systematically investigated the potential impact of the DIPAS yoga module on SVB within the healthcare professional population. Thus, this study aims to investigate the efficacy of the 4-week DIPAS yoga module on SVB among HCWs, thereby contributing valuable insights into the well-being of healthcare professionals and informing the development of targeted stress management programmes within healthcare settings.

METHODS

Study design

This study is a two-arm, parallel-group randomised controlled trial with a 1:1 allocation of participants in each group. The trial design is shown in figure 1. This trial has been designed following the Consolidated Standards of Reporting Trials guidelines[22] and its reporting adheres to the Standard Protocol Items: Recommendations for Interventional Trials recommendations.[23]

Sample size

A sample size of 108 with 54 participants in each arm is calculated, with G*Power software (V.3.1.9.4),[24] for a two-tailed hypothesis based on an effect size of 0.6 for the high-frequency (HF) power component of the primary outcome HRV as reported in a study by Mitra *et al*,[25] with type I error (α) at 0.05, power (1-β) at 0.80 and an attrition rate of 20%.

Recruitment

The participant recruitment process has been initiated from 01 October 2024 onwards and is ongoing. Participants are recruited from among the male and female HCWs aged 19–60 years who are currently employed at the All India Institute of Medical Sciences (AIIMS) in Rishikesh, Uttarakhand, India. Participants in any of the following conditions are being excluded: pregnant females; surgery during the past 3 months; physical inability to practice yoga module; cardiac conditions or abnormalities that could affect HRV measurements, such as arrhythmias, atrial fibrillation, heart failure, or structural heart disease; or already practising medium paced walking or yoga.

Individuals are invited to participate in the study via telephone and electronic mail. Flyers have been circulated to various institute departments in hard copies and on official WhatsApp groups. Subsequently, the study details are explained to interested individuals, and any queries are answered. Furthermore, all interested individuals are provided with written information about the study, and signed informed consent will be obtained from them before enrollment in the study.

Randomisation

After obtaining consent and completing all baseline measurements, participants will be randomised in a ratio of 1:1 to either the intervention or control group using a computer-generated random number sequence in Microsoft Excel. The participant allocation sequence will be concealed in opaque and sealed envelopes.

Intervention group DIPAS yoga module

It will consist of the practice of the validated 30-min yoga module developed by DIPAS,[21] comprising loosening exercises, asanas, breathing techniques and meditative practices for a minimum of 5 days per week for 4 weeks. A concise form of the DIPAS yoga module is provided in table 2. Furthermore, the elaborate details of the steps and contraindications of these yogic postures and breathing techniques[26 27] are provided in supplementary material.

Control group medium-paced walk

The control group participants will practice a 30-min medium-paced walk for a minimum of 5 days/week over 4 weeks. This includes 'purposeful walking at a pace of 3–6 km/hr (ie, 1500–3000 metres in 30 min) on level firm ground which elicits a moderate, noticeable increase in depth and rate of breathing while still allowing comfortable talking and is relative to a given individual'.[28] Data for distance and duration of walking will be monitored through the Google Fit app installed on the participants' mobile phones. The Metabolic Equivalent of Task (MET) level associated with this activity is estimated to range between 3.5 and 5 METs, corresponding to moderate-intensity exercise, as determined by previous research.[29]

The interventions provided to the intervention and control groups are further described using the template for intervention description and replication (TIDieR) checklist[30] in table 3.

Outcomes

Primary outcome

The primary outcome will be assessing the change in HRV on day 0 and day 29 among participants practising DIPAS yoga intervention compared with participants practising medium-paced walking for 4 weeks. Two domains of HRV analysis are time domain analysis and frequency domain analysis.[7]

Time domain analysis

It will comprise the measurement of R-R intervals and root mean square of successive differences (RMSSD). The R-R interval represents the time between successive heartbeats, measured in unit milliseconds (ms). RMSSD is the root mean square of successive differences between normal heartbeats, and it will also be measured in unit ms. Additionally, a 30:15 ratio (R-R interval at beat 30)/(R-R interval at beat 15) will be calculated, which has been recommended as an index of cardiovagal function.[31]

Frequency domain analysis

The frequency domain analysis will involve the calculation of low-frequency (LF) power and HF power components. LF is the absolute power of the

Table 3 Description of interventions using the TIDieR checklist

1. Brief name	DIPAS yoga module for improving SVB among HCWs in a tertiary care hospital compared with medium-paced walking.
2. Why	With the relentless demands of the healthcare environment taking a toll on the physical and mental health of professionals, it becomes imperative to identify interventions that not only alleviate stress but also bolster the cardiovascular resilience of HCWs. Hence, with the growing interest in mind-body interventions for stress management, it is relevant to investigate how a structured yoga programme influences SVB, which will provide valuable insights into potential interventions for stress reduction and improved physiological health among this crucial workforce.
3. What materials and procedures	► Participants in the intervention group will be provided offline yoga sessions of 30 min for 5 days/week for 4 weeks at the Department of Community and Family Medicine, AIIMS Rishikesh or online yoga sessions using Google Meet as per suitability of the participant. Information relevant to yoga sessions will be shared through WhatsApp group messaging. ► Participants in the control group will practice medium-paced walking for 5 days/week for 4 weeks. They will be required to walk at least 1500 metres in 30 min with their mobile phones during their walk. Participants will be required to instal the Google Fit app on their mobile phones to record the number of steps, total distance and duration of walk. Daily screenshots of this data will be collected from the participants.
4. Who provided	Certified yoga instructors well informed about the study protocol and DIPAS yoga module intervention will deliver the yoga sessions. Participants in the control group will be encouraged to practice medium-paced walking.
5. How	Yoga sessions for the intervention group participants will be provided online or offline. The participants of the control group will practice medium-paced walking at their discretion.
6. Where	Offline yoga sessions will be conducted at the Department of Community and Family Medicine, AIIMS Rishikesh, and online yoga sessions will be conducted via Google Meet. Medium-paced walking will be performed at home or the workplace at the participant's convenience.
7. When and how much	Yoga sessions will be conducted for 30 min 5 days/week over 4 weeks. Medium-paced walking will also be performed for the same duration.
8. Tailoring	The DIPAS yoga module's practices will be tailored per the participant's capability. Similarly, the control group participants can practice medium-paced walking for a distance of 1500–3000 metres according to their capability.

DIPAS, Defence Institute of Physiology & Allied Sciences; HCWs, healthcare workers; SVB, sympatho-vagal balance; TIDieR, template for intervention description and replication.

Box 1 Heart rate variability (HRV) protocol

Participant preparation
- ⇒ Participant will be instructed to have a light breakfast and consume no caffeine on the day of the HRV recording.
- ⇒ The participant will be positioned comfortably, seated or lying down, and asked to remove any metal objects or jewellery.
- ⇒ HRV recording will be taken at the same time of the day for all participants.

Data recording
- ⇒ The computer on which the recording is to be made will be turned ON, and the MP46 device will be connected via USB.
- ⇒ The electrode lead set (SS2L)-CH 1one will be plugged in.
- ⇒ The participant's skin will be cleaned before clipping the electrode lead set according to the colour code, that is, white lead on the right forearm, black lead on the right leg and red lead on the left leg.
- ⇒ After this, the participant will be instructed to relax for 10 min after the electrodes have been attached.
- ⇒ After 10 min, BIOPAC software will be opened, and the 'L05 – Electrocardiography (ECG) I' lesson will be selected to record the ECG signal for 6 min.
- ⇒ Participants will be instructed to remain still and relaxed but not sleep during the recording.
- ⇒ Once the recording is complete, the data acquisition in the BIOPAC software will be stopped and saved with a unique filename.

Data analysis
- ⇒ Clean and artefact-free ECG signals for 5 min will be used for analysis.
- ⇒ Kubios software (V.4.1.0) will calculate HRV parameters such as time-domain and frequency-domain measures.
- ⇒ Appropriate filters and processing techniques will be applied to clean the data and remove artefacts or noise.

low-frequency band measured in normalised units (nu), and HF is the absolute power of the high-frequency band, which is also measured in nu. Also, the ratio of LF-to-HF power (LF/HF) will be measured.

HRV measurements of the participants will be performed through the portable BIOPAC MP46 HRV instrument according to the protocol[32] outlined in box 1.

Secondary outcomes

State anxiety

Immediate change in state anxiety among participants undergoing DIPAS yoga intervention versus medium-paced walking will be compared immediately before and after intervention on days 1, 14 and 28. State anxiety is a temporary emotional state marked by consciously felt tension, apprehension and increased autonomic nervous system activity.[33] It will be measured through the Spielberger State-Trait Anxiety Inventory.[34] This psychological assessment, developed by psychologist Charles Spielberger, is based on a 4-point Likert scale and comprises 40 self-reported questions.

Selective attention

Immediate change in selective attention among participants undergoing DIPAS yoga intervention versus medium-paced walking will also be compared immediately before and after intervention on days 1, 14, and 28. Selective attention refers to an individual's ability to focus on a task over a specific duration. It involves sustained attention, particularly in complex or challenging tasks.[35] It will be measured through the Six Letter Cancellation Task (SLCT) test.[36] It involves a worksheet containing 22 rows and 14 columns of randomly arranged alphabet letters. At the top of each sheet, six specific target letters are listed. Participants must identify and mark as many of these target letters as possible within a 90-sec time limit. Each worksheet will feature a unique random arrangement of letters to minimise the influence of memory effects.

Statistical analysis of outcomes

Statistical calculations will be performed by SPSS (V.26.0). Intention-to-treat and per-protocol analysis will be performed to provide a comprehensive understanding of the effects of intervention. Proportions and mean will be calculated for descriptive analysis. The normality of the data will be checked using the Shapiro-Wilk test. Continuous data will be reported as mean±SD and compared using the independent t-test. Categorical data will be reported as frequencies and will be compared using the χ^2 test. Multivariate linear model will adjust covariates in baseline HRV data in both groups. Independent t-test will compare pre- and post-data on all outcomes between groups. Paired t-test will be used to compare pre- and post-data on all outcomes within the group. Subgroup analysis will also be done.

Patient and public involvement

Patients and/or the public were not involved in this research's design, conduct, reporting, or dissemination plans.

DISCUSSION

The existing body of literature lacks comprehensive exploration regarding the efficacy of a 4-week DIPAS yoga module on SVB among HCWs in a tertiary care hospital. The absence of research in this specific domain represents a notable lacuna in the current scientific literature. Addressing this research gap will not only contribute to the body of knowledge concerning yoga interventions but also hold implications for developing targeted well-being programmes for healthcare professionals, potentially enhancing their overall job satisfaction, performance and long-term health outcomes.

Hence, with the growing interest in mind-body interventions for stress management, it is relevant to investigate how a structured yoga programme influences SVB, which will provide valuable insights into potential interventions for stress reduction and improved physiological health among this crucial workforce.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Institute Ethics Committee of AIIMS Rishikesh, Uttarakhand, India, with reference number (AIIMS/IEC/24/443). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; internally peer-reviewed.

Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study. No data are available.

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