Original Article

Effect of *Bhramari Pranayama* on Heart Rate Variability (HRV) in Hypertension - A Study Protocol for a Randomized Controlled Trial.

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ABSTRACT

Background: Hypertension is a major risk factor for cardiovascular diseases and is often managed through medication and lifestyle modifications. Non-pharmacological interventions like yoga and pranayama, particularly *bhramari pranayama*, have been shown to improve cardiovascular health by enhancing autonomic regulation and reducing stress. **Objectives**: This study aims to evaluate the effect of *bhramari pranayama* on heart rate variability (HRV) and blood pressure in individuals with primary hypertension. **Methods**: A randomized controlled trial will be conducted at the International Institute of Yoga and Naturopathy Medical Sciences, Chengalpattu. Eighty participants with moderate hypertension will be randomly assigned to an intervention group or a control group. The intervention group will practice *bhramari pranayama* for 10 minutes daily for 14 days. Heart Rate Variability (HRV) and blood pressure will be measured before and after the intervention. The control group will rest for 10 minutes without intervention. **Results**: Statistical analysis will be performed using Prism GraphPad Software Version 10.2.2. Unpaired Student's *t* test will be used to determine the significance of the difference between the two independent groups among continuous variables. Significance will be set at a 5% level, and *p* value less than or equal to 0.05 will be taken as significant. Statistical significance between and within the group will be analyzed. We anticipate that, after practice of *bhramari pranayama*, parasympathetic dominance of HRV and reduced blood pressure. **Conclusion**: *Bhramari pranayama* effectively improves HRV and reduces blood pressure in individuals with primary hypertension. It may offer a non-pharmacological approach to managing hypertension.

Key words: Bhramari Pranayama; Hypertension; Heart Rate Variability; Blood Pressure; Non-communicable disease.

Hypertension is defined as persistent elevation of blood pressure with a systolic of 140 mmHg or higher and/or a diastolic of 90 mmHg or higher. This higher blood pressure value is a critical risk factor for cardiovascular diseases (CVD) and contributes significant global mortality rates. According to the World Health Organization (WHO), hypertension accounts for approximately 41 million deaths annually, representing 74% of all deaths worldwide [1, 2]. In recent years, the prevalence of hypertension has shown alarming trends. In India, studies have reported varying prevalence rates of hypertension. Oommen et al. (2016) found a prevalence of 17.2% in rural Tamil Nadu, while national surveys indicated rates as high as 47.1% in suburban Tamil Nadu [3]. These statistics underscore the urgent need for effective management strategies.

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Hypertension is categorized into two types: primary hypertension, which comprises about 90% of cases and has no identifiable cause, and secondary hypertension, accounting for around 10% of cases and resulting from underlying conditions. This condition may lead to severe complications such as stroke, coronary heart disease, kidney failure, and blindness due to damage to vital organs [4, 5]. Conventional treatments include lifestyle modifications and pharmacological interventions. However, complementary therapies such as yoga have gained attention for their potential benefits. Yoga emphasizes holistic health through physical postures (asanas), breathing techniques (Pranayama), and meditation. Research indicates that regular yoga practice can reduce both systolic and diastolic blood pressure by approximately 4-6 mmHg [6]. This minor decrease in blood pressure can lead to improved cardiovascular health.

Bhramari pranayama is a simple yogic breathing technique, its procedure is production of humming bee sound. Traditional

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yogic text describes that *bhramari pranayama* may help to reduce blood pressure [7]. Compared to other breathing techniques, *bhramari pranayama* has larger scientific literature which shows it enhances heart rate variability (HRV) and reduces blood pressure [8, 9]. HRV is a well-established non-invasive method for assessing autonomic nervous system regulation of cardiac functions. Studies suggest that consistent yoga practice not only aids in blood pressure management but also enhances overall well-being by reducing stress and improving mental health.

Integrating yoga with traditional medical treatments offers a comprehensive approach to managing hypertension. This synergy addresses both the physical and psychological dimensions, potentially improving patient adherence to treatment protocols. Future research focusing on *bhramari pranayama* may provide valuable insights into non-pharmacological interventions for hypertension management. This study aims to evaluate the effect of *bhramari pranayama* on HRV in hypertension patients.

MATERIALS AND METHODS

Study design & setting

The present study is a randomized controlled trial. Subjects will be recruited from the Out-patient department of the International Institute of Yoga and Naturopathy Medical Sciences and Hospital, Chengalpattu, Tamilnadu. Institutional Ethical Committee (IEC) approval was obtained, vide letter number IEC-IIYNMS/Approval/019/2023. The study is registered with the Clinical Trial Registry (CTRI/2023/11/059417).

Sample size

Sample size calculation will be based on a similar study, which has a sample size of 70 subjects. 80% power, two-tailed significance, an expected drop-out rate of 20%, and a 1:1 allocation, a total sample of 80 participants was estimated in this study [9]. Participants will be randomly allocated to either the intervention or control group (1:1 ratio) using computerized randomization. Random concealment will be implemented using the SNOSE technique. Participants will not be blinded to group allocation.

Selection of Participants

Adults aged 30 to 70 years, both male and female participants, Patients on single or two-drug combinations (ACE Inhibitors or Beta Blockers), Willingness to participate in the study, diagnosed with moderate hypertension (systolic 140–179 mmHg, diastolic 90–109 mmHg) as per 2017 AHA guidelines will be included. Secondary hypertension, Comorbidities such as diabetes mellitus, coronary artery disease, heart failure, arrhythmias, rheumatic heart disease, congenital heart disease, and other significant systemic diseases, Regular yoga practitioners for more than one month, Pregnant or menstruating women, Hypertensive patients with blood pressure exceeding moderate hypertension will be excluded.

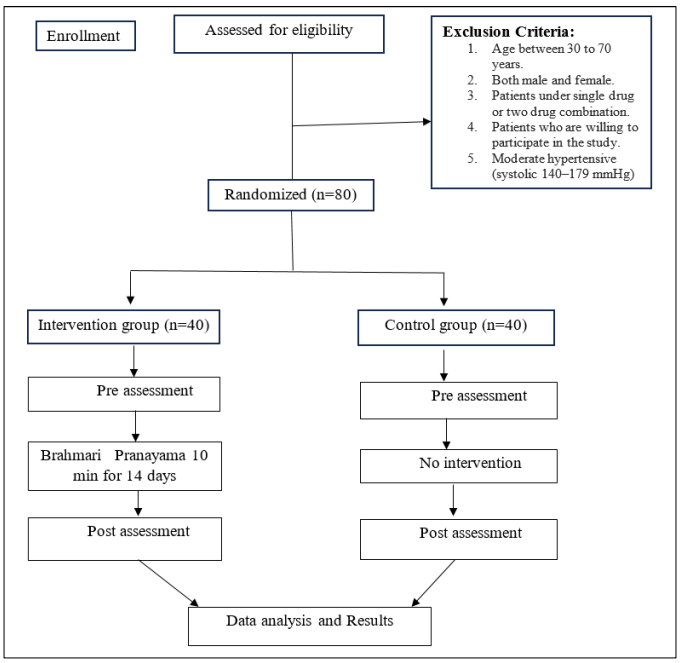

Figure 1: Trial profile of the study

Intervention procedure

The study participants will receive one day of orientation before the trial. The study participants will be asked to sit with crossed legs and keep their eyes closed throughout the practice. Raise the arms sideways and bend the elbows, bringing the hands to the ears. Use the index or middle finger to plug the ears. Inhale slowly and deeply through the nose. Exhale slowly and in a controlled manner while making a deep, steady humming sound like that of the black bee. The humming sound should be smooth, even, and continuous for the duration of the exhalation. This is one round. At the end of exhalation, breathe in deeply and repeat the process [7]. Continue to practice in the same way, performing for 10 minutes. When finished, keep your eyes closed and listen for any subtle sounds. Study participants will receive ten minutes of intervention per day for fourteen days. Participants in the control group will be in a resting position for 10 minutes daily for14 days without any intervention.

Outcome Measures

Primary Outcome: Heart Rate Variability will be assessed before and after the intervention using a 16-channel polygraph (BIOPAC MP160), Electrodes will be placed in standard limb lead II configuration for ECG recording, Data will be collected at a sampling rate of 2000Hz, and analysis will be performed using Kubios-HRV software, focusing on time-domain and frequency-domain parameters [10].

Secondary Outcome: Systolic and diastolic blood pressure will be measured before and after the intervention sessions using a non-invasive automatic blood pressure monitor (HEM-8712 Omron Health Care Co. Ltd, Kyoto), two measurements will be

taken, with a one-minute rest between them, and the average will be calculated.

Data Extraction

Time domain and frequency domain analysis of baseline and post-intervention HRV data will be performed using HRV analysis software (Kubios-HRV version 2.0) developed by the Biomedical Signal Analysis Group (University of Kuopio, Finland). The time domain HRV variables such as the mean of the intervals between adjacent QRS complexes, standard deviation of RR intervals (SDNN), HR, the square root of the mean of the sum of the squares of differences between adjacent NN intervals (RMSSD), the number of interval differences of successive NN intervals greater than 50 ms (NN50) and the proportion derived by dividing NN50 by the total number of NN intervals (pNN50) will be analyzed. Similarly, the frequency domain of HRV such as low frequency (LF) band (0.04–0.15 Hz) and high-frequency (HF) band (0.15–0.4 Hz) in normalized units and the LF/HF ratio will be analyzed [10].

Statistical analysis

Statistical analysis will be performed using Prism GraphPad Software Version 10.2.2. Unpaired Student's *t* test will be used to determine the significance of the difference between the two independent groups among continuous variables. Significance will be set at a 5% level, and *p* value less than or equal to 0.05 will be taken as significant.

Expected result

Based on previous literature [8], we anticipate that, after practice of *bhramari pranayama*, high frequency component of HRV may increase, which is parasympathetic dominance and reduce blood pressure

DISCUSSION

The current study is to explore the effect of *bhramari pranayama* on heart rate variability and blood pressure in hypertensive patients. Previous literature suggests that yoga decreases blood pressure by relieving stress, tension, and fatigue and relaxing the body and mind [11]. Time domain variables of HRV and the frequency domain's high frequency (HF) band power are primarily indicative of parasympathetic activities. Earlier studies show that during practice, if *bhramari pranayama* HF increases and also produces gamma waves that indicates the dominance of parasympathetic activity [12].

The possible mechanism of parasympathetic stimulation is lung stretch receptors, inhibitory impulses and baroreceptors. During inhalation tidal volume increases, it stimulates lung stretch receptors by increasing tidal volume [13], this slow-adapting receptors in the lungs produce inhibitory impulses [14], these inhibitory impulses, elevates the baroreceptors that suppresses the vasoconstrictor nerves and stimulates the cardiac vagus innervations, which results in vasodilation, thereby it reduces blood pressure and bradycardia [15].

Bhramari practice has short inhalation and prolonged exhalation phase. This extensive exhalation leads to stretching the lung tissue and decreases the dead space ventilation [16]. This leads not only to the improvement in the lung function but also produces inhibitory signals by the action of slow adapting stretch receptors and hyperpolarization current by the action of fibroblast, which results in parasympathetic system activation. It has also been suggested that stretch-induced inhibitory signals from the abdominal muscles especially diaphragm, and the nostril may also induce the similar effect [17].

Humming sound produced during *bhramari* practice plays a vital role in regulating the autonomic function. The vibratory humming sound acts as an auditory stimulus and leads to changes in the scaling exponents of the electroencephalogram in the temporal and frontal regions of the brain. The slow breathing has been seen to increase the amplitude of the theta and delta waves of EEG, indicating parasympathetic activity. Moreover, humming sound may stimulate the auricular branch of the vagus nerve which is contributing to the parasympathetic nervous system activation [18]. Another factor is frequency of the breathing, *bhramari* keeps the frequency of the respiration close to 10 seconds each cycle (6/minutes) without concentrating on the breathing rate. This results in efficient synchronization of the cardiovascular and respiratory rhythmic fluctuation causing significant improvement in the sympathovagal balance [19].

CONCLUSION

The study proposes that *bhramari pranayama* will significantly improve heart rate variability and reduce blood pressure in individuals with primary hypertension. These anticipated findings suggest that integrating Bhramari pranayama as a complementary therapy could enhance cardiovascular health and autonomic balance, providing a promising non-pharmacological approach to managing hypertension.

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