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Effect of yam chanting with Hridaya mudra on blood pressure and Heart Rate Variability (HRV) in hypertension - A randomized control trial protocol

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Abstract

Background: Primary Hypertension is a prevalent chronic condition, defined by systolic blood pressure (SBP) ≥ 130 mmHg and/or diastolic blood pressure (DBP) > 80 mmHg. Its prevalence is approximately 4.6% in the general adult population, with a higher prevalence in Indian villages (10%). Yam chanting with Hridaya mudra is a yogic practice with potential therapeutic effects, but its impact on Primary Hypertension has not been scientifically validated.

Objective: To evaluate the effect of Yam chanting with Hridaya mudra on blood pressure in individuals with Primary Hypertension.

Materials and Methods: A Randomized Controlled Trial (RCT) design will be employed. Eligible participants will be randomly assigned to either the study group or the control group. The study group will practice Yam chanting with Hridaya mudra for 10 minutes daily, while the control group will rest in a lying position for the same duration, over 21 days. Pre- and post-intervention blood pressure measurements will be recorded. Data will be analyzed using SPSS version 16, with a significance level set at $p < 0.05$.

Results: The study will analyze changes in blood pressure in both groups, with results presented in bar diagrams illustrating the mean values of the dependent variables.

Conclusion: This study seeks to provide clinical evidence on the safety and efficacy of Yam chanting with Hridaya mudra in managing Primary Hypertension. If effective, this practice could be recommended as an adjunct therapy to conventional treatments for patients with Primary Hypertension.

Keywords: Blood pressure, hypertension, meditation technique, yoga, adjuvant therapy, quality of life

Introduction

HTN ranks among the most common chronic medical conditions characterized by a persistent elevation in arterial pressure. The current definition of hypertension is systolic blood pressure (SBP) values of 130mmhg or more and diastolic blood pressure (DBP) of more than 80 mmHg^[1, 2]. Essential hypertension accounts for 95% of all cases of hypertension and remains a major modifiable risk factor for cardiovascular disease^[3]. Genetic predisposition along with environmental factors such as high sodium intake, poor sleep quality, excess alcohol intake, and high mental stress contribute to the development of essential hypertension^[4]. Sympathetic overactivity is consistently observed in patients with essential hypertension^[5]. HTN is an important non-communicable disease risk factor in India with an estimated burden of two hundred million persons^[6]. A nationwide survey done in 2015 in India reported that one in every three participants above the age of eighteen has hypertension^[7] In India 16% of coronary artery disease (CAD) and 29% of strokes are attributable to HTN^[8]. Heart rate variability (HRV) is widely used to assess cardiac autonomic regulation by measuring the changes in the cardiac rhythm through time^[9]. Cardiac autonomic disturbances precede the incidence of clinical hypertension and are potentially involved in its pathophysiological basis and progression^[10]. Abnormal HRV reflects sympathovagal imbalance which is associated with cardiovascular morbidity and progression of atherosclerosis^[11, 12]. Prevention and management of HTN is a global public health challenge. According to the World Health Organisation more than half of the people with HTN, a total of 720 million people were untreated^[13].

The Eighth Joint National Committee guidelines mention lifestyle modifications as the first step in the management of hypertension which is combined with pharmacotherapy in most cases [14]. Based on the results of clinical and observational studies, it has been recommended that more emphasis be placed on lifestyle and behavior modification to control Blood Pressure and also to improve the efficacy of pharmacologic treatment of Hypertension [15]. The World Health Organization has advised repeatedly Hypertension and other chronic disease to be treated with Alternative and traditional medicine [16]. Yoga is a viable antihypertensive lifestyle therapy that produces the greatest benefits [17]. Yogic interventions reduce blood pressure by reducing stress, increasing para-sympathetic activation, and altering baro receptor sensitivity [18]. Higher resting HRV is associated with better performance of cognitive skills and lower resting HRV is associated with a lack of prefrontal control of subcortical activity which results in poor functioning of self-regulatory systems [19].

Yoga is an ancient science of living that is now 10,000 years old. The word yoga was derived from the Sanskrit word “Yuj” and its meaning is to connect. Yoga links the individual consciousness with the universal Consciousness [20]. It was Re-explained profoundly by Patanjali nearly 7000 years ago in his collection called Patanjali Yoga Sutras. In the first chapter, he explained yoga as Yoga Chitt Vritti Nirodhal which means Yoga is control of thought based on the mind and Calming of the mind through meditative Yoga [21]. As per the scriptural descriptions, often the vision of the syllables for subtle sounds (Nada) in the etheric ocean had been revealed to the rishis (Indian sages of the Vedic times) through an afflatus or intuition in their inner selves or the mantras were just heard ‘by them in a state of trance. The phonemes of the Vedic hymns and the seven fundamental nodes - Sa, Re, Ga, Ma, Pa, Dha, Ni of the Indian classical music have originated (distinctly recognized by the Rishis) from the vibrations of the sublime sound of Om in the Nature. The Vedic quote - *Ekoham Bahusyami* ‘implies that all the sounds, all the energies, all the motions, and everything existing in the universe have originated from the vibrations of this single Anahata nada. This is the source of the manifestation of the habda-Brahm and the Nada Brahm. Arvachint N Amuts Ijya arvachesht vivarjita N damev nusanddhy nn de Chitta Vil yate - Naadbindupnishad: 41 Meaning: practitioner should drop his thoughts and only concentrate on Nada only because through this practice the mind merges into Nada [22]. Hand Gestures or Yoga hand Mudras are a part of yoga and they Generate positive feelings and health improvement by working on fingers touching specific hand palm locations [23].

Aims and Objectives

AIM

To evaluate the effect of yam chanting with Hridaya Mudra on HRV and blood pressure in Hypertension.

Primary objective

To study the effect of yam chanting with Hridaya mudra on HRV in hypertension.

Secondary objective

To study the effects of yam chanting with Hridaya mudra on Blood pressure in hypertension

Research question & hypothesis

Research question: Does yam chanting with Hridaya mudra

have an effect on hypertensive patients?

Null hypothesis: Yam chanting with Hridaya mudra may not produce any change on HRV in patients with hypertension.

Alternative hypothesis: Yam chanting with Hridaya mudra may produce any change in HRV in patients with hypertension.

Methods and Materials

Study design

The study will employ a randomized control study design, as it is a widely recognized method for testing the effectiveness of interventions. This design involves randomly assigning participants to either a treatment group or a control group, to compare the outcomes of the two groups. By utilizing this rigorous approach, we can ensure that the results of the study are accurate and reliable and can be used to inform future research and practice in the field.

Study setting

The present study is a randomized controlled trial. Subjects will be recruited from the Outpatient department of the International Institute of Yoga and Naturopathy Medical Sciences and Hospital, Chengalpattu, Tamilnadu. The study is planned to start in December 2023 and be completed by September 2024. Institutional Ethical Committee (IEC) approval was obtained, vide letter number IEC-IYNMS/Approval/012/2023, and also registered this study protocol Clinical Trial registration vide No. CTRI/2023/11/0595557.

Sample size

Sample size calculation will be based on a similar study that was conducted on 80 samples. With 80% power, two-tailed significance, an expected drop-out rate of 20%, and a 1:1 allocation, a total sample of 80 participants is estimated [12].

Randomization and blinding: All the subjects will be randomly allocated to either a subject or a control group (1:1 ratio) using computerized randomization. Random concealment will be done using the SNOSE (Sequentially numbered, opaque, sealed envelope) technique. The participants will not be blinded to the study and control group.

Selection of participants: Participants will undergo an initial screening to ensure they meet the inclusion and exclusion criteria.

Inclusion criteria [24]

- 1) Age between 30 to 70 years
- 2) Both male and female
- 3) Patients under single-drug or two-drug combination
- 4) Patients who are willing to participate in the study
- 5) Moderate hypertensive (systolic 140-179 mmHg) and (diastolic 90-109 mmHg) (2017 AHA guidelines)

Exclusion criteria

1. Patients with secondary hypertension
2. Neurological conditions (Epilepsy, Stroke, Parkinson’s disease)
3. Psychiatric comorbidities (Psychosis, Pyro phobia)
4. Hypertensive patients with Blood Pressure beyond Moderate hypertension (2017 AHA guidelines)
5. Women during pregnancy and menstruation

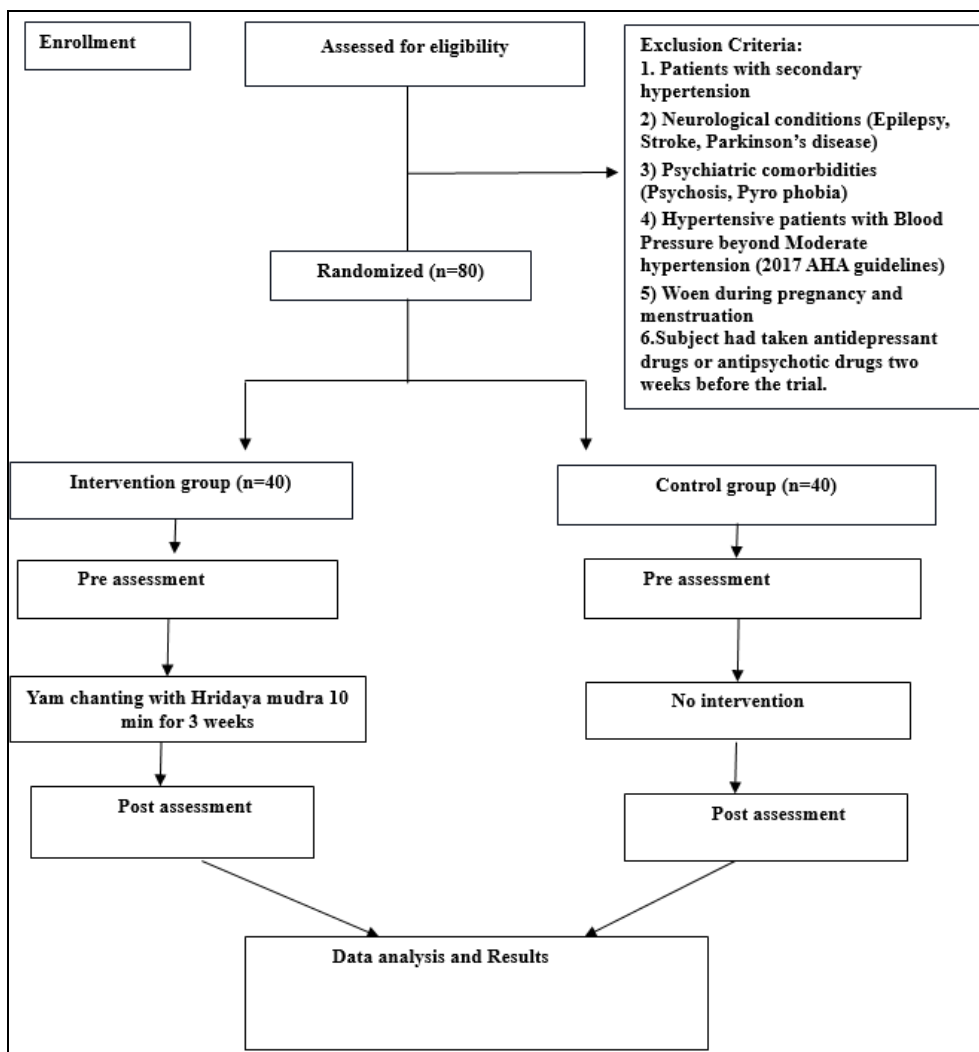


Fig 1: Trail profile

Intervention group: The intervention group will undergo the practice of Yam chanting with Hridaya mudra for 10 min for 21 days. Yam chanting with Hridaya mudra will be performed with closed eyes for 10 minutes (Table 1).

Intervention procedure: The study participants will receive one day of orientation program before the trial. The study participants will be asked to sit in Sukhasana with the head and spine erect. Ask the participants to adopt Hridaya mudra by placing the tips of the index finger at the root of the thumbs and joining the tip of the middle and ring fingers to the tip of the thumbs so that the little finger remains straight. Place the hands on the knees with the palms facing upwards.

Keep the eyes closed throughout the practice and relax the whole body. Slowly inhale and exhale by chanting ‘Yam’. Continue to practice in the same way, for 10 minutes. When finished, keep the eyes closed and feel for vibrations that run through the chest & throat. Study participants will receive ten minutes of intervention per day for Twenty-one days along with their regular intake of medication.

Table 1: Intervention study session

Yam* chanting	Normal breathing	Yam chanting
4 Minutes	2 Minutes	4 Minutes

*Yam - Beeja mantra of Anahata Chakra

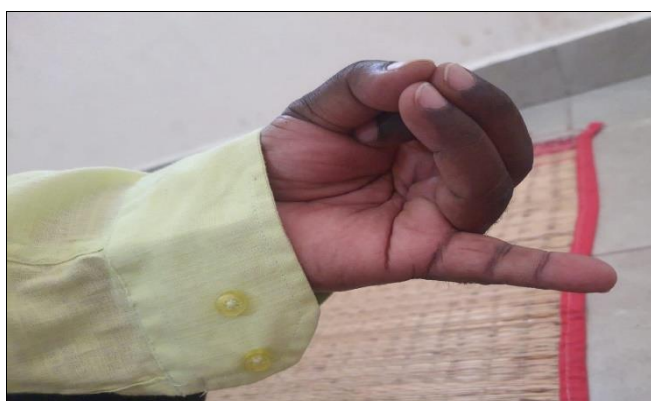


Fig 3: Hridaya mudra

Control group

Subjects in the control group will be receiving no intervention and they will be sitting quietly for 10 minutes a day for 21 days.

Withdrawal criteria

Subjects can withdraw from the study at any point in time, for any reason, with or without prior intimation to investigators or with or without prior permission from investigators.

Outcome**Primary outcome**

Measure the difference in HRV parameters, such as SDNN, RMSSD (time-domain), and LF/HF ratio (frequency domain), before and after the 21-day intervention of Yam chanting with Hridaya Mudra in hypertensive patients. This will assess the impact of the intervention on cardiac autonomic regulation.

Secondary outcome

Change in systolic and diastolic blood pressure from baseline to post-intervention (Day 21).

Results

Assessment: Heart rate and HRV will be evaluated before and after each intervention using a 16-channel polygraph (BIOPAC MP160). Ag/AgCl pre-gelled electrodes will be positioned following the standard limb lead II configuration to record the electrocardiogram. Data will be acquired at a sampling rate of 2000 Hz.

Data extraction

Time domain and frequency domain analysis of baseline and post-intervention Heart Rate Variability (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) [25]. The time domain HRV variables such as the mean of the intervals between adjacent QRS complexes or the instantaneous HR (RRI), 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. [26]. 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 [27].

Blood pressure

Assessment of systolic blood pressure and diastolic blood pressure will be measured before and after the intervention sessions using a non-invasive arm-type automatic blood pressure monitor (HEM-8712 Omron Health Care Co. Ltd, Kyoto). A minimum of two measurements with a rest period of 1 minute between the measurements will be taken and averaged to get a final value. In case of a difference between the two measurements by >10-mmHg, a third measurement will be taken after a 1-min rest period followed by the second measurement, and the average of the two measurements which did not differ >10-mmHg will be averaged to get a final value.

Data analysis

Data analysis will be done using the appropriate statistical test in the statistical package for the social science version, 16.

Discussion

The study evaluates the effects of Yam chanting combined with Hridaya Mudra on heart rate variability (HRV) and blood pressure in hypertensive individuals. As hypertension is a key modifiable risk factor for cardiovascular disease, incorporating traditional practices like Yoga into its management is gaining attention. The study focuses on HRV, a marker of autonomic function, hypothesizing that these interventions will enhance parasympathetic activity, improve HRV, and reduce blood pressure [28].

While positive outcomes are expected, the study's limitations, including its short duration and adherence variability, suggest that further research with longer follow-ups and larger sample sizes is needed to fully understand the long-term benefits of these practices.

Conclusion

This study proposes that Yam chanting combined with Hridaya Mudra may offer a promising complementary approach to managing hypertension by improving heart rate variability and reducing blood pressure. If the findings support the hypothesis, these traditional practices could be integrated into holistic treatment plans for hypertensive patients, potentially enhancing the effectiveness of conventional therapies and contributing to better cardiovascular health outcomes. Further research is warranted to explore the long-term effects and mechanisms underlying these interventions.

Ethical consideration

Institutional ethics committee (IEC) clearance will be obtained from the International Institute of Yoga and Naturopathy Medical Sciences (vide letter number IEC-IYNSM/Approval/012/2023 and also registered this study protocol Clinical Trial registration vide no CTRI/2023/11/0595557, before the recruitment of the first subject. Study protocol will be explained to the subjects and a signed consent will be obtained from each subject.

Consent for publication

All participants provided consent for the publication of anonymized data and study findings.

Conflict of interests: The authors declare that they have no conflict of interest.

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