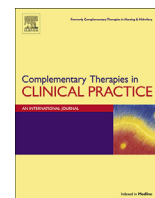




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Combination of music with lifestyle modification versus lifestyle modification alone on blood pressure reduction – A randomized controlled trial



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ABSTRACT

Objective: To evaluate the change in blood pressure (BP) after 3 months of music intervention combined with lifestyle modifications, in comparison with conventional lifestyle modifications.

Methods: A Prospective randomized control trial was conducted on hundred prehypertensives or stage I hypertensives who were randomly divided into two groups (n = 50 each). Both the groups were given lifestyle modifications while one had added music intervention (*raga bhimpalas*) for 3 months. Main outcome measures were 24 h ambulatory BP monitoring, stress levels, and biomarkers of hypertension. **Results:** Mean (SD) of diastolic BP (DBP) pre and post intervention were overall = 85.1(6.8) and 83(8.7) {P = 0.004}, awake = 87.7(7.6) and 85.9(9.2){P = 0.021}. Regression analysis showed association between diastolic BP change and post-intervention stress score in the music intervention group. Significant change in BP was seen among those who were prehypertensives prior to intervention.

Conclusion: Music decreased DBP and when used as an adjunct benefitted subjects with initial BP in prehypertension range.

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1. Introduction

Hypertension prevalence is increasing and globally, the number of hypertensives has been predicted to be 1.56 billion by 2025 [1]. The Seventh report of the Joint National Committee (JNC VII) has indicated lifestyle modifications (weight reduction, dietary modifications, salt restriction and physical activity) and pharmacological therapy for the management of hypertension [2].

Non-pharmacological modes aimed at reducing stress and promoting relaxation have been evaluated for the treatment of hypertension [3]. Listening to music, offers advantages of low cost, ease of administration, better compliance and safety. Music can be used for stress reduction through active music making, as well as

passive listening.

Music as a non-pharmacological therapy for hypertension has been tried by a few investigators (listening to music, for durations ranging between 10 and 25 min for 1–3 months). Most of the studies have used clinical sphygmomanometric recordings and shown significant reduction in blood pressure (BP) [4–8]. Effect of music on 24 h ambulatory BP (ABP) measurements, with a prehypertension group and simultaneous measurements of biomarkers of hypertension has not been studied [9–13].

Raga, a word used to denote musical scale, is a set of musical notes presented in an orderly manner in order to generate a melody out of the same, in Indian music. Different ragas have the property of evoking different emotions among humans (example: *raga Mishra Mand* – refreshing light touch, *Neelambari* – sleep). According to *Sama veda and raga chikitsa* (Ancient Indian music literature), ragas that normalize BP are *Ahir bhairav*, *Bhupali*, *Puriya*, *Todi*, *Kausi Kanada*, *Hindol* and *Bhimpalas* [14,15]

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The objective of the present study was to evaluate the change in stress levels, 24 h ABP and biomarkers of hypertension after 3 months of music intervention (using *raga Bhimpalas*) combined with lifestyle modifications, in subjects with prehypertension or stage I hypertension, in comparison with conventional lifestyle modifications. The hypothesis was that there would be a decrease in 24 h ABP in subjects exposed to music and a concomitant change in the level of stress and biomarkers.

2. Methods

2.1. Inclusion and exclusion criteria

Subjects were recruited by the first author from the out-patient department patients and staff of a tertiary care centre. Inclusion criteria were as follows: Age group between 30 and 60 years; prehypertensives and stage I hypertensives as per JNC VII classification [2]. Pregnant women, subjects with body mass index (BMI) ≥ 35 kg/m², stage 2 hypertension, renal impairment, uncontrolled diabetes, stroke, epilepsy, hearing problems, psychiatric disorder, other cardiovascular and respiratory disorders were excluded.

The study period ranged from May 2012 to August 2013. The study protocol was approved by the institutional scientific committee on human research and ethical review board.

2.2. Sample size

The sample size was calculated (using nMaster 2.0 sample size software, Department of Biostatistics, CMC, Vellore) based on literature survey [7] which indicated that before lifestyle modifications the mean SBP was 133.03 ± 4.4 mm Hg. To calculate sample size, a SBP of 133.03 ± 4.4 mm Hg was predicted to reduce after lifestyle modification to 130 ± 8 mm Hg; and the group undergoing both lifestyle modifications and music intervention the SBP was predicted to reduce to 126 ± 8 mm Hg; expecting a decrease of 4 mm Hg due to music intervention. Using, independent t-test and considering a mean difference of SBP as 4 mm Hg (SD = 8) with 90% power and 5% level of significance the estimated sample size was 50 per group. A total of 100 prehypertensives and hypertensives were studied.

2.3. Randomization

This was a prospective, open labelled, parallel group, randomized controlled study. The study protocol was explained and informed consent was obtained. The subjects were informed about their rights to withdraw their participation from the study. The study's biostatistician randomly placed subjects in the control or treatment group in 1:1 ratio, by permuting the total sample size into 2 arms; the first 50 numbers were allotted to the music intervention combined with lifestyle modifications (group 1) by tossing the coin and the next 50 into the other group (for only lifestyle modifications – group 2). No stratification for age, sex, or BP range was performed. The random number indicating intervention or control was kept in an opaque and sealed envelope and the serial number of the patients were written on the top of the envelope. The envelope was opened by the research assistant after the baseline assessment of each participant had been completed and assigned the participants to both the arms. All the other investigators who did the outcome assessments were blinded to the interventions.

2.4. Baseline characteristics

Detailed baseline characteristics recorded on a pretested, semi-structured proforma, included general health questionnaire

(GHQ12) [16], involvement in physical activity, diet history, family history, smoking, alcohol intake history and drug history and a short questionnaire that included questions related to music preference such as type of instrument, genre, and frequency of listening and formal training, if any. Standard questionnaires were used in this study. The research assistant was trained for 6 months prior to collection of data. Biostatistician analyzed this data collected after 6 months and assured uniformity in sample collection.

2.5. Experimental outcome measures (at the beginning and at the end of 3 months)

The primary end point of this study was change in 24 h ABP at the end of intervention. Secondary end points were change in stress levels (State Trait Anxiety Inventory (STAI)), biomarkers and correlation of this with change in BP.

Stress levels were assessed using STAI. It is a standardized tool with forty questions, with four possible responses to each [17,18]. On reliability generalization testing the measures of STAI demonstrated excellent internal consistency (average α s > 0.89), and excellent test–retest reliability (average $r = 0.88$) at multiple time intervals [19]. The reliability of STAI in patients with anxiety disorder is found to be between 0.87 and 0.93 [20]. The BP (clinical sphygmomanometry), anthropometric measurements, BMI and waist hip ratio (WHR) were recorded according to standard protocol [21].

Those subjects satisfying our inclusion criteria (prehypertensive or stage I hypertensives) were now subjected to 24 h ABP recording using Schiller BR 102 Plus 24/48 h ABP monitor (ABPM), Schiller India. The device was programmed to measure half hourly BP between 07:00 to 22:00 h and hourly BP between 22:00 to 07:00 h. Subjects who had ≥ 18 readings (out of 39) were included for final analysis. The values of 24 h overall (average 24 h BP), awake and asleep SBP and DBP were recorded. This device has been standardized and validated by British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) [22,23].

Five mL of whole venous blood was collected under aseptic conditions between 09:00 to 10:00 h to avoid diurnal variations. Plasma was separated and stored at -70 °C until further analysis. Plasma catecholamines were measured using CAT Enzyme linked immunosorbant assay (DLD Diagnostica GMBH, Germany) within one week of its collection. The intra-assay precision as measured by coefficient of variance (CV) was 8.35%, 9.7% and 9.6% for adrenaline, noradrenaline and dopamine respectively. Plasma Renin Activity (PRA) was determined via radioimmunoassay (Immunotech, Czech Republic). The inter-assay CV was <10.5%.

2.6. Intervention

2.6.1. Lifestyle modification (as per JNC VII) [2].

Counselling for lifestyle modifications and various non-pharmacological measures was given to all the subjects as per JNC VII guidelines. Handouts were given to enhance compliance and to help them recall the instructions.

2.6.2. Music intervention

Music was provided to the subjects based on their personal preference (compact discs, mobiles, i-pods). A 22 min instrumental (*Bansuri*) music, playing *raga Bhimpalas* without any accompaniments was used. According to study protocol, the subjects had to listen to this music for about 15 min daily (during the same time every day, preferably without interruptions) at least 5 days a week for 3 months, irrespective of the music which they listen to

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