

# Effect of music in high blood pressure

<b>Submission date</b> 06/11/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/08/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cardiovascular disease is one of the leading causes of mortality and morbidity in India and worldwide. The global prevalence of hypertension was estimated to be 1.3 billion in 2015. It is related to nearly 17 million deaths per year worldwide. Hypertension is amenable to a minimum of 45% of deaths due to heart disease and 51% of deaths due to stroke. WHO called hypertension a silent killer. There is increasing evidence suggests that psychological factors may play an important role in the development of hypertension. Stress, depression and emotional personality traits like trait anxiety and trait anger are also connected with other cardiovascular disorders, especially with coronary heart disease. Music has a wide application with each stage of the development of human life. Music therapy is a novel approach for the management and control of anxiety and hypertension. The study aims to evaluate the effect of music therapy on blood pressure, physiological and biochemical parameters in hypertensive patients

### Who can participate?

Patients with high blood pressure aged 25 - 65 years

### What does the study involve?

Music therapy was given as a physiological intervention. The instrumental music of Ananda Bhairavi Raga was used for 30 minutes per day for three months. The modifications in blood pressure, anxiety level, and oxidative stress markers were evaluated before and after music therapy.

### What are the possible benefits and risks of participating?

Music therapy may reduce blood pressure, anxiety, and oxidative stress. Since music therapy is a noninvasive intervention, there is no risk of participation in the study.

### Where is the study run from?

Little Flower Hospital and Research Centre, India

### When is the study starting and how long is it expected to run for?

June 2018 to June 2019

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?  
Elsa Mathew  
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## Contact information

### Type(s)

Public

### Contact name

Ms Elsa Mathew

### ORCID ID

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

The therapeutic effect of music on selected physiological and biochemical parameters in hypertension

### Acronym

TEMSPBPH

### Study objectives

There will be a significant difference in the selected physiological and biochemical parameters in hypertension after music therapy

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 08/06/2018, Institutional ethics committee of Little Flower Hospital and Research Centre, (Angamaly, Kerala, India; +91 484 2452546; admin@lfhospital.org), ref: IEC/LFMRC/18/1

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Hypertension

**Interventions**

Current intervention as of 24/08/2020:

Subjects were randomly divided into the experimental and control groups by block randomization with equal numbers of subjects in each group. Instrumental music of Ananda Bhairavi raga was provided to the experimental group 15 min per day for 3 months. The physiological and biochemical parameters were measured for all the participants before the beginning of the study and after 3 months

Previous intervention:

Subjects were randomly divided into the experimental and control groups by block randomization with equal numbers of subjects in each group. Instrumental music of Ananda Bhairavi raga was provided to the experimental group 30 minutes per day for 3 months. The physiological and biochemical parameters were measured for all the participants before the beginning of the study and after 3 months

**Intervention Type**

Other

**Primary outcome measure**

Blood pressure measured at baseline and 3 months

## Secondary outcome measures

At baseline and three months:

### 1. Anthropometry:

- 1.1. Waist to Hip Ratio (cm)
- 1.2. Body Mass Index (BMI) (kg/m<sup>2</sup>)

### 2. Physiological variables:

- 2.1. Heart rate (bpm)
- 2.2. SPO<sub>2</sub>
- 3. Anxiety level measured using the stress assessment questionnaire - STAI (State Trait Anxiety Inventory)
- 4. Lipid profile (blood test):
  - 4.1. Total Cholesterol (TC)
  - 4.2. High Density Lipoprotein (HDL)
  - 4.3. Low Density Lipoprotein (LDL)
  - 4.4. Very Low Density Lipoprotein (VLDL)
  - 4.5. Triglycerides (TG)
- 5. Oxidative stress markers (blood test):
  - 5.1. Malondialdehyde level (MDA) (spectrophotometric method)
  - 5.2. Superoxide dismutase (SOD) (spectrophotometric method)

## Overall study start date

01/01/2018

## Completion date

30/11/2019

## Eligibility

### Key inclusion criteria

Current participant inclusion criteria as of 24/08/2020:

- 1. Express a willingness to participate in the study
- 2. Aged 30-60 years
- 3. Diastolic blood pressure >80 mmHg and systolic blood pressure >130 mmHg

Previous participant inclusion criteria:

- 1. Express a willingness to participate in the study
- 2. Age between 25 - 65 years
- 3. DBP >80mm Hg and SBP >130mm Hg

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

240

**Key exclusion criteria**

1. Deafness, ear surgeries, and ear infections
2. Ear implants and hearing aids
3. Terminally ill patients
4. Planned surgery during the course of the study

**Date of first enrolment**

01/11/2018

**Date of final enrolment**

30/09/2019

**Locations****Countries of recruitment**

India

**Study participating centre**

Little Flower Hospital and Research Centre

Kerala

Angamaly

India

683572

**Sponsor information****Organisation**

Little Flower Hospital and Research Centre

**Sponsor details**

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Angamaly

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+91 (0)484 2458327

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.lfhospital.org>

**ROR**

<https://ror.org/0375jhj23>

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded

## **Results and Publications**

### **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

### **Intention to publish date**

30/11/2020

### **Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

### **IPD sharing plan summary**

Other