

Effect of music in high blood pressure

Submission date 06/11/2019	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/11/2019	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/08/2020	Condition category Circulatory System	☐ Individual participant data ☐ 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
elsamathewchetttoor@gmail.com

Contact information

Type(s)

Public

Contact name

Ms Elsa Mathew

ORCID ID

<https://orcid.org/0000-0001-9954-0637>

Contact details

Little Flower Medical Research Centre
Angamaly
Ernakulam
India
683572
+91 484 2675000
elsamathewchetttoor@gmail.com

Additional identifiers

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

Primary study design

Interventional

Study design

Randomized controlled trial

Study type(s)

Treatment

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(s)

Blood pressure measured at baseline and 3 months

Key secondary outcome(s)

At baseline and three months:

1. Anthropometry:

1.1. Waist to Hip Ratio (cm)

1.2. Body Mass Index (BMI) (kg/m²)

2. Physiological variables:

2.1. Heart rate (bpm)

2.2. SPO₂

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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