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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?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

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 3months

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes