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Exploring an individualised homoeopathic treatment (similimum) to modify anger and reduce blood pressure in patients with mild to moderate essential hypertension

Submission date
10/10/2022

Recruitment status
No longer recruiting

Registration date
18/10/2022

Overall study status
Completed

Last Edited
20/01/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Blood pressure is the force of blood against the arterial walls as the heart pumps blood through the body. Hypertension occurs when the force of the blood is higher than normal. Essential hypertension is high blood pressure that does not have a known cause. According to current research, anger, hostility, and aggression play a prominent role in the cause of high blood pressure. This research is about how anger affects blood pressure and how an individualised prescription of homoeopathic medicine affects the state of mind, especially anger and hostility. The blood pressure readings may be temporarily higher or lower throughout the day. They change after exercise, after rest when one is in pain, and when happy or sad. Occasional high blood pressure readings do not necessarily mean the person has hypertension. A diagnosis of hypertension is not usually made unless the blood pressure readings are consistently high. The higher the blood pressure is, the harder the heart must work. A stronger force of blood can damage the arteries, blood vessels, and heart muscles. This can eventually cause reduced blood flow through the body, leading to atherosclerosis (hardening of the arteries from cholesterol build-up, which can lead to a heart attack), stroke, heart attack, heart failure, eye damage, and kidney damage. Most people do not have symptoms of essential hypertension and only discover that their blood pressure is high during a regular medical check-up. Hence hypertension is known as a silent killer. Essential hypertension can begin at any age. It most often occurs first during the middle-age years.
This study aims to understand how people respond physiologically to stress and the feelings of anger and irritation that arise with daily life and whether lifestyle changes, along with homoeopathic treatment, can reduce the occurrence of essential hypertension.

Who can participate?
Adults suffering from essential hypertension

What does the study involve?
Participants were asked to report their degree of anger in a questionnaire to better understand

how people respond physiologically to stress and the feelings of anger and irritation they must deal with daily. Their answers were kept in the strictest confidence. We also ruled out heart and kidney problems by performing a blood test to check blood sugar and cholesterol levels, an electrocardiogram test (that records the electrical activity of the heart), a blood test and a urine test to check kidney function and an x-ray of the chest to check the heart and lungs. First, participants began with lifestyle changes to lower their blood pressure, by eating a low-sodium, low-fat diet that is rich in potassium and fibre, exercising at least 30 minutes a day, losing weight if they were overweight, quitting smoking, limiting daily alcohol intake to no more than one drink for a woman and two drinks for a man, and reducing their stress levels. When lifestyle changes did not lower the blood pressure levels enough, participants received antihypertensive treatment if it was stage II hypertension under the medical specialist's advice, along with homoeopathic treatment. Blood pressure and emotional state were monitored for six months.

What are the possible benefits and risks of participating?
Participants will benefit by being made aware of their unhealthy lifestyle and diet and developing insights about their anger. Their blood pressure will be better controlled, and they should foster better interpersonal relationships. Individualised homoeopathic medicine will also help with any associated illnesses (comorbidities) from which these participants may be suffering. There are no foreseeable risks as far as this study goes.

Where did the study run from?
Dr M L Dhawale Memorial Homoeopathic Institute (India)

When is the study starting and how long is it expected to run for?
March 2014 to July 2018

Who is funding the study?
Investigator initiated and funded (India)

Who is the main contact?
Dr Leena S Bagadia, leenabagadia@gmail.com (India)

Contact information

Type(s)
Principal investigator

Contact name
Dr Leena Bagadia

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Additional identifiers

Study information

Scientific Title
Exploring the role of the homoeopathic similimum in modifying anger: state, trait and expression in patients of mild to moderate essential hypertension.

Acronym
MAHT

Study objectives
1. Anger is an emotion that can be measured, and STAXI-2 can be successfully used for this purpose in our study population
2. There is a positive relationship between the components of anger and hypertension
3. Patients with a family history of hypertension are more prone to hyper-react to stressors and thereby more susceptible to hypertension
4. Essential hypertension can be improved by better anger coping mechanisms
5. There is a difference in the values of the different anger variables in rural and urban participants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2015, Ethics Committee of the Dr M L Dhawale Memorial Homoeopathic Institute (Palghar, Rural Homoeopathic Hospital, Palghar-Boisar Road, Opp. S.T. workshop, Palghar - 401404, India; +91 02525 256932/33; mldmhipg@gmail.com), ref: MLDMHI/M12- /2015

Primary study design
Interventional

Study design
Randomized parallel-group placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reduction of anger state, trait and expression in patients with essential hypertension

Interventions
This trial was a randomized, placebo-controlled, comparative, open-label study conducted at an urban and a rural charitable homoeopathic hospital and a plastics factory. The study protocol was conducted as per the latest revision of the Helsinki declaration. Statistical software was used to generate a random allocation sequence by an independent statistician before subject recruitment. After collecting an initial case history, participants were allocated to different

groups at a 1:1 ratio. Intervention arm patients were given individualised homoeopathic treatment (the similimum) using homoeopathic medicines procured from Good Manufacturing Practices-certified pharmacies, along with their standard antihypertensive treatment.

Individualised homoeopathic remedies will be prescribed depending on the totality of symptoms. It will be administered as medicine liquid, added as a drop onto sugar of milk powder and/or pills, and administered orally. Pills (which may or may not contain medicinal substance) will be given as 4 pills 3 times a day and powder 2-3 times a week or as per requirement. Therapy is continued for a 6-month study period and, if required, can be continued later. The comparator agent, the placebo is sugar of milk globules without adding homoeopathic medicine.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Individualised homeopathic medicines

Primary outcome(s)
1. Anger variables measured using the State-Trait Anger Expression Inventory-2 (STAXI-2) scale at the onset of the study and the end of six months study period:
1.1. State Anger (S-Ang) - the intensity of angry feelings at the time of completion
1.2. Trait anger (T-Ang) - a disposition to experience anger
1.3. Anger Expression-Out (Ax-O) - the expression of angry feelings out
1.4. Anger Expression-In (AX-I) - the suppression of angry feelings
1.5. Anger Control-Out (AC-O) - the prevention of anger expression toward other people or objects
1.6. Anger Control-In (AC-I) - the control of suppressed anger
1.7. Anger Expression Index (AX-index) - overall index of the frequency of anger expression, regardless of direction

2. Systolic and diastolic blood pressure measured using an Omron machine at every follow-up visit at 2-week intervals

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Suffering from essential hypertension (pre-hypertensives: SBP 120-139 mm Hg, DBP 80-89 mm Hg, stage I hypertensives: SBP 140-159 mm Hg, DBP 90-99 mm Hg; stage II hypertensives: SBP more than or equal to 160 mm Hg, DBP more than or equal to 100 mm Hg
2. Patients on antihypertensive treatment

3. Aged 18-65 years
4. Patients whose history, examination and routine investigations revealed no evidence of apparent secondary cause

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
172

Key exclusion criteria
1. Physical examination or routine investigations produced suspicion of a secondary cause for HT
2. Provisional or confirmatory diagnosis of secondary HT
3. Patients with uncontrolled Diabetes Mellitus or any uncontrolled endocrine disorders
4. Patients diagnosed with psychiatric disorders like schizophrenia or endogenous depression
5. Pregnant or breastfeeding mothers having HT

Date of first enrolment
01/01/2016

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
India

Study participating centre
Dr M L Dhawale Homoeopathic Institute and Hospital Institute
Palghar
Mumbai
India
401404

Study participating centre
Shree Mumbadevi Homoeopathic Hospital
Natakkar Gadkari Marg
Vile Parle west Mumbai (Suburban) Maharashtra
Mumbai
India
400056

Study participating centre
Polyset Plastic Factory
Daman
Daman
India
396210

Study participating centre
Om Shiv Clinic
15, Radhikaniwas society
M. V. Road, Andheri East
Mumbai
India
400069

Sponsor information

Organisation
Dr M L Dhawale Memorial Homoeopathic Institute

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from the principal investigator Dr Leena S Bagadia, leenabagadia@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/06/2022	20/01/2023	No	No
Participant information sheet			18/10/2022	No	Yes
Participant information sheet			18/10/2022	No	Yes
Protocol file			18/10/2022	No	No
Statistical Analysis Plan			18/10/2022	No	No