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Effect of meditation combined with breathing technique on mental and exercise-induced hypertension

Submission date 21/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/01/2006	**Overall study status** Completed	
Last Edited 09/11/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Meditation Study

Study objectives
Meditation in the Christian tradition combined with breathing techniques reduces ambulatory and stress-induced blood pressure in essential hypertension

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Essential untreated hypertension

Interventions
Randomisation 1:1 into meditation versus no meditation. The intervention consists of a four-week introductory course and a four-week intensive training phase. During these eight weeks, meditation in the Christian tradition and breathing techniques are taught by a certified meditation facilitator. Meditation sessions (40 minutes) are held daily as group meetings in the early evening. In addition, meditation is practiced daily individually at home in the morning. At baseline and after eight weeks, all participants undergo the following tests:
1. Standardised computerised mental stress test
2. Bicycle ergometry
3. 24 hour ambulatory blood pressure (BP) measurement
4. 24 hour Holter electrocardiogram (ECG)
5. Echocardiography

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Median change in systolic BP during mental stress in the intervention group compared with controls.

Secondary outcome measures
1. Median change in systolic and diastolic resting BP, during 24 hour ambulatory BP monitoring, exercise test (intervention group versus controls, respectively)
2. Difference in heart rate variability (Holter)
3. Diastolic function in echocardiography

Overall study start date
01/03/2004

Completion date
30/06/2004

Eligibility

Key inclusion criteria
1. Age between 30 and 65 years
2. Written informed consent
3. Elevated resting blood pressure (more than 140/85 mmHg) on three occasions within four weeks
4. Primary hypertension confirmed by laboratory testing, clinical history and examination, abdominal ultrasound

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
52

Key exclusion criteria
1. Previous training in contemplative meditation
2. Secondary hypertension
3. Blood pressure more than 180/110 mmHg
4. Antihypertensive therapy within the last 12 months
5. Pregnancy

6. Alcohol abuse
7. Immunosuppressive medication
8. Diabetes

Date of first enrolment
01/03/2004

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
Germany

Study participating centre
Joseph-Schneider-Strasse 2
Wuerzburg
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Sponsor information

Organisation
University of Wuerzburg (Germany)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00fbnyb24

Funder(s)

Funder type

Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2008		Yes	No