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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Prof Wolfram Voelker

#### Contact details

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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 Germany 97070

# 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

## 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