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Evaluation of the sustained effect of Viniyoga in the rehabilitation of hypertensive patients

Submission date	Recruitment status	[ ] Prospectively registered
06/06/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/11/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/11/2007	Circulatory System	[ ] Record updated in last year

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
1

Study information

Scientific Title

Study objectives
We hypothesise that patients who receive training in Viniyoga will continue practising the method 15% more often than those who receive training in Progressive Relaxation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of Arztekammer Nordrhein in May 2007 (ref: 2007113).

Study design
Randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Arterial hypertension

Interventions
Viniyoga or Progressive Relaxation group training (maximum 10 people per group), 45 minutes per session, five days a week for three weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To assess whether more participants in the intervention group will maintain the method taught compared to those in the control group, assessed at three weeks (i.e. at the moment of discharge from our hospital) and six months after the discharge from the hospital.

Secondary outcome measures

The following will be measured at six months:
1. Hospital Anxiety and Depression Scale [HADS]
2. 36-item Short Form health survey (SF-36)
3. Heart rate variability
4. Blood pressure
5. Use of antihypertensive medication

Overall study start date
07/05/2007

Completion date
06/05/2009

Eligibility

Key inclusion criteria
Arterial Hypertension.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Congestive heart failure (New York Heart Association [NYHA] II or more)
2. Relevant rhythm disorders
3. Relevant pulmonary disease
4. Dialyses
5. Surgery within the last four weeks
6. ST-elevation myocardial infarction within the last four weeks

Date of first enrolment
07/05/2007

Date of final enrolment
06/05/2009

Locations

Countries of recruitment
Germany

Study participating centre
Klinik Roderbirken
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Sponsor information

Organisation
Refonet (Germany)

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Sponsor type
Research organisation

Website
http://refonet.de

ROR
https://ror.org/04yeh2x21

Funder(s)

Funder type
Industry

Funder Name
Refonet (Germany)

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