

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

Submission date 06/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/11/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/11/2007	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
Leichlingen
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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