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

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s))

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

Completion date

06/05/2009

Eligibility

Key inclusion criteria

Arterial Hypertension.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Germany D-42799

Sponsor information

Organisation

Refonet (Germany)

ROR

https://ror.org/04yeh2x21

Funder(s)

Funder type

Industry

Funder Name

Refonet (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration