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Randomised, controlled, multicenter, pilot study comparing qigong and back school for elderly patients with chronic neck pain

Submission date
09/05/2006

Recruitment status
No longer recruiting

Registration date
23/05/2006

Overall study status
Completed

Last Edited
06/02/2008

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N/A

Study information

Scientific Title

Acronym
QIBANE

Study objectives
Primary hypothesis: there is a significant difference between the qigong and the waiting list groups for the primary outcome (visual analogue scale [VAS]) after 3 months.
Secondary hypothesis: there is a significant difference between the qigong and the back school groups for the primary outcome (VAS) after 3 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, date of approval: 23/02/06; reference number: EA1/265/05

Study design
Multicenter, three-armed, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic neck pain

Interventions
Patients are randomized into the qigong and back school exercise groups (each 24 sessions of 45 min over a period of three months)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain measured on the VAS (visual analogue scale) after three months

Secondary outcome measures
1. Neck pain (Neck Pain and Disability Scale, Wheeler)
2. Depression (Depression Scale, Hautzinger)
3. Quality of life (Short-form Questionnaire-36 [SF-36], Bullinger)
4. Frequency of falls and anxiety to fall
5. Sleep quality and satisfaction
6. Overall treatment effect (OTE) (Wiklund)

Overall study start date
09/03/2006

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Age ≥55 years of age
2. Chronic neck pain (duration >6 months)
3. Average pain during the last 7 days before randomisation ≥20 mm on 100 mm VAS
4. Informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
120 (40 per group)

Key exclusion criteria
1. Serious acute or chronic disease which would not allow the exercises to be performed
2. Planned start of physiotherapy for chronic neck pain during study participation
3. Participation in another study during the last 6 months before study entry

Date of first enrolment
09/03/2006

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Germany

Study participating centre
Institute for Social Medicine
Berlin
Germany
10098

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details
University Medical Center
Institute for Social Medicine
Berlin
Germany
10098

Sponsor type
University/education

Website
http://www.charite.de/epidemiologie

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin), Institute for Social Medicine, University Medical Center (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