

Traditional Chinese Medicine in Routine care of Orthopaedic Rehabilitation - sustainability and acceptance by patients of the German Pension Fund

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| Submission date 16/03/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 20/04/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 20/04/2009 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

07001

Study information

Scientific Title

Traditional Chinese Medicine in Routine care of Orthopaedic Rehabilitation - sustainability and acceptance by patients of the German Pension Fund: a randomised controlled trial

Acronym

TCMROR

Study objectives

By integrated therapy elements of the traditional Chinese medicine within an inpatient orthopaedic rehabilitation procedure over three weeks, there is a greater improvement of health-related quality of life and subjective employment forecast six month after treatment.

More details can be found at: http://www.refonet.de/projekte/laufendeprojekte_7001.php

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Physicians Chamber, Rheinland Pfalz, Mainz, approved on 14/01/2009 (ref: 837.433.08)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Chronic back pain and/or osteoarthritis of one or more joints

Interventions

Participants are randomised to Groups A and B (randomisation ratio: 1:1). Both groups are treated according to usual school medical therapy concept for three weeks.

For Group B, in this treatment programme, the elements of traditional Chinese medicine are integrated. These include acupuncture, tuina-massage, herbal therapy, qi gong or tai chi and consultations to way of life and dietetics.

Total duration of interventions: 3 weeks/per participant. Six month after treatment there is a follow-up questioning (for both groups).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Improvement in health-related quality of life:

1.1. SF-12® Health Survey at T1 and T3

1.2. Interview at T1 and T2

2. Improvement in subjective employment forecast:

2.1. Subjective employment forecast (Subjektive Prognose der Erwerbstätigkeit [SPE]) questionnaire at T1 and T3

2.2. Interview at T1 and T2

T1 = Baseline

T2 = At 3 weeks

T3 = At 6 months

Secondary outcome measures

1. Treatment satisfaction:

1.1. Patient Satisfaction Questionnaire (Fragebogen zu Patientenzufriedenheit [ZUF-8])

1.2. Interview

2. Acceptance of the traditional Chinese therapy:

2.1. Questionnaire: wish of treatment with a renewed rehabilitation

2.2. Patient Satisfaction Questionnaire (Fragebogen zu Patientenzufriedenheit [ZUF-8])

All secondary outcome measures will be assessed at T2.

T1 = Baseline

T2 = At 3 weeks

T3 = At 6 months

Overall study start date

01/01/2009

Completion date

30/06/2011

Eligibility

Key inclusion criteria

1. Chronic back pain and/or arthritis pain
2. Both males and females, aged 30 to 60 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

520

Key exclusion criteria

1. Pension required
2. Spinal or joint surgery in the last three months
3. Psychiatric diseases
4. Epilepsy
5. Coagulopathy
6. Pregnancy

Date of first enrolment

01/01/2009

Date of final enrolment

30/06/2011

Locations**Countries of recruitment**

Germany

Study participating centre

Orthopaedic Rehabilitation Centre

Bad Ems

Germany

D-56130

Sponsor information**Organisation**

Refonet (Germany)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.refonet.de>

ROR

<https://ror.org/04yeh2x21>

Funder(s)

Funder type

Research organisation

Funder Name

Refonet (Germany) (Project no.: 07001)

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