

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

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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pension required
2. Spinal or joint surgery in the last three month

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)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Refonet (Germany) (Project no.: 07001)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration