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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
16/03/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/04/2009	Completed	Results
Last Edited	Condition category	Individual participant data
20/04/2009	Musculoskeletal Diseases	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Werner Kühn

#### Contact details

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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

Nο

#### 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

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes