

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

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<b>Registration date</b> 20/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/04/2009	<b>Condition category</b> 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](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)

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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 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)

**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