

# Effectiveness of tailored pain management in patients with chronic back pain

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/06/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2009	<b>Condition category</b> Musculoskeletal Diseases	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A.

# Study information

## Scientific Title

Effectiveness of tailored pain management in subgroups according to the three-cluster solution of the multidimensional pain inventory (MPI) in patients with chronic back pain in an inpatient rehabilitation setting: a randomised controlled trial

## Acronym

RCT cBPsub

## Study objectives

A combination of graded exercise therapy and cognitive behavioural therapy a priori matched to subgroups of patients based on the MPI with chronic non-specific back pain shows better short-term and long-term outcome than non-matched interventions.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Ethics Committee of the Health Department in Aarau gave approval on the 6th February 2009 (ref: 2008/033)
2. Ethics Committee of the Health Department in Zurich gave approval on the 12th March 2009 (ref: 15/09)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## 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

## Interventions

The purpose of this randomised controlled trial is to examine the effectiveness of combinations of graded activity exercise (GA) with individual cognitive behavioural therapy (CBT) in subgroups of patients with chronic non-specific back pain (CNSBP) who are hypothesised to benefit from

these treatments compared with similar persons who will receive strengthening and stretching exercises and CBT in a group setting. All subjects are participants in a four week inpatient pain management program and attend 20 physiotherapy sessions and 12 sessions with a clinical psychologist.

1. Control group: standard group therapies and individual physiotherapy (strength and stretching exercises)
2. Intervention group: standard group therapies and MPI-subgroup specific individual physiotherapeutic (graded activity exercise) and psychological (cognitive behavioural therapy or systemic therapy) interventions

Duration of treatment: 4 weeks inpatient rehabilitation. Booster sessions by telephone for the intervention group 3 and 7 weeks after discharge. Participants will be followed-up for 12 months after entry.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Self-reported functional disability (Oswestry Disability Index), measured at T0, T2, T3 and T6.

Timepoints:

T0: 4 weeks before entry

T1: entry to pain programme

T2: discharge from pain programme

T3: 3 months follow-up

T6: one year follow-up

### **Secondary outcome measures**

1. Observed functional disability: the physical performance tests Back Performance Scale (BPS) and 5-Minute Walk Distance, measured at T1 and T2
2. Global perceived effect on daily functioning, measured at T2, T3 and T6
3. The Numeric Rating Scale (NRS) for pain, measured at T1, T2, T3 and T6
4. The subscales "Ability to decrease pain", and "Ability to control pain" of the Coping Strategies Questionnaire (CSQ), measured at T1, T2, T3 and T6
5. Mental health (Hospital Anxiety and Depression Scale [HADS]), measured at T1, T2, T3 and T6
6. Pain Catastrophising Scale (PCS), measured at T1, T2, T3 and T6
7. Treatment expectancy and credibility (Credibility/Expectancy Questionnaire [CEQ]), measured at T1

Timepoints:

T0: 4 weeks before entry

T1: entry to pain programme

T2: discharge from pain programme

T3: 3 months follow-up

T6: one year follow-up

### **Overall study start date**

01/01/2009

**Completion date**

31/12/2012

## **Eligibility**

**Key inclusion criteria**

1. Stationary patients of RehaClinic of at least 18 years old, either sex
2. Diagnosis of chronic back pain: at least 3 months of continuous back pain localised in the lumbar, thoracic, and/or cervical region
3. Willingness to learn behavioural patterns and motivation to participate in graded activity exercise programs
4. Ability to formulate realistic functional goals
5. Sufficient cognitive abilities and German language skills to understand the content of the interventions
6. Agreement to participate in the program and the assessment by written, signed informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

A total of 120 patients (across all arms and both study centres) will be recruited

**Key exclusion criteria**

1. Severe somatic illness requiring specific treatment such as cancer, inflammatory rheumatic disease, neurological disease, pain after a recent operation (less than 6 months)
2. Specific back pain, defined as herniated disc, ankylosing spondylitis, spondylolisthesis, spinal fracture, or other relevant neurological diseases
3. Specific medical disorders and cardiovascular diseases, preventing participation at physical exercise
4. Pregnancy
5. Manifest psychiatric disorder such as dementia, psychosis, suicidality
6. Whiplash associated disorders

**Date of first enrolment**

01/01/2009

**Date of final enrolment**

31/12/2012

# Locations

## Countries of recruitment

Switzerland

## Study participating centre

Physiotherapy Institute

Bern

Switzerland

3010

# Sponsor information

## Organisation

Zurzach Rehabilitation Foundation SPA (Switzerland)

## Sponsor details

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## Sponsor type

Research organisation

## Website

<http://www.reha-clinic.ch/cms/>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Zurzach Rehabilitation Foundation SPA (Switzerland)

# 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