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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
05/05/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
17/06/2009	Completed	Results
Last Edited	<b>Condition category</b> Musculoskeletal Diseases	☐ Individual participant data
17/06/2009		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** 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

# Study type(s)

Treatment

# 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(s)

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

# Key secondary outcome(s))

- 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

### 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** 

### Healthy volunteers allowed

No

# Age group

Adult

### Lower age limit

18 years

#### Sex

Αll

### 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)

# Funder(s)

# Funder type

Research organisation

### **Funder Name**

Zurzach Rehabilitation Foundation SPA (Switzerland)

# **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 11/11/2025 No Yes