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Effectiveness of tailored pain management in patients with chronic back pain

Submission date	Recruitment status	[ ] Prospectively registered
05/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/06/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/06/2009	Musculoskeletal Diseases	[ ] 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
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3010

Sponsor information

Organisation
Zurzach Rehabilitation Foundation SPA (Switzerland)

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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