# Early management of psychological factors for subjects with sub-acute low back pain.

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
24/02/2019	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
26/06/2019	Completed	☐ Results
Last Edited	Condition category	Individual participant data
10/06/2020	Musculoskeletal Diseases	Record updated in last year

## Plain English summary of protocol

Background and study aims

It is increasingly recognised that psychological factors such as maladaptive beliefs, fear of movement and catastrophising play an important role in the transition from acute to chronic pain and the development of disability of subjects suffering from back complains Maladaptive coping and behaviour strategies are also found to be risk factors of persistent back complaints. Recently, a Cochrane review found that multidisciplinary bio-psychosocial rehabilitation induces pain reduction, disability improvement, favours return-to-work and fewer sick leave days when compared to usual care. However, current research yielded studies with low to very low-quality evidence, and poor effect sizes in terms of clinical meaningfulness. Therefore, additional high-quality trials were recommended before this approach can be implemented in clinical practice. Therefore, we decided to undertake this trial.

Who can participate?

Adults, both males and females.

What does the study involve?

A multidisciplinary rehabilitative programme incorporating psychological interventions based on patient-reported questionnaires targeted at the detection of main maladaptive thoughts and behaviours in comparison to general physiotherapy alone in the treatment of subacute LBP.

What are the possible benefits and risks of participating?

Clinically significant improvements in disability, pain, and quality of life. No side effects are expected.

Where is the study run from?

Scientific Institute of Lissone, Via Monsignor Bernasconi, 16, Lissone, Italy

When is the study starting and how long is it expected to run for? January 2013 to December 2014

Who is funding the study?

Dept. Medical Science and Public Health - Faculty of Medicine, University of Cagliari, Italy

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Marco Monticone

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

21/2011

# Study information

#### Scientific Title

Early management of psychological factors reduce disability of subjects with sub-acute low back pain. Results of a randomized controlled study with one year follow-up.

# Study objectives

A 10-week program based on early management of psychological factors integrated to taskoriented exercises would induce clinically significant improvements in disability, pain, and quality of life in subjects with subacute LBP vs. usual care, and that these would be maintained at least one year.

# Ethics approval required

#### Old ethics approval format

#### Ethics approval(s)

Approved 18/12/2011, Ethical Committee Salvatore Maugeri Foundation (Via Monsignor Ennio Bernasconi, 16, 20851 Lissone MB, Italy; +39 039 46571; marco.monticone@fsm.it), ref: 21

#### Study design

Randomized parallel-group superiority-controlled trial.

## Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Subacute low back pain

#### **Interventions**

Experimental group. Task-oriented exercises and cognitive-behavioural therapy aimed at modifying wrong beliefs and behaviours concerning subacute pain.

Control group. exercises for passive spinal mobilisation, strengthening, muscle segmentary stretching, and postural control.

Randomization: the biostatistician randomized the subject to one of the two treatment programmes using a permuted-block randomization procedure. The list of treatment codes was previously generated and stored in Matlab and an automatic assignment system, also developed in Matlab, was used to conceal the allocation.

Treatment took place at the outpatient rehabilitative gym at the hospital, delivered by two physiatrists, a psychologist, and two equally-experienced physiotherapists.

During the treatment period, the questionnaires were administered by secretarial staff who checked them and returned any uncompleted part to the subjects for completion. At follow-up, the subjects were contacted personally by the same secretarial staff in order to ensure that the questionnaires were properly completed.

# Intervention Type

Behavioural

# Primary outcome(s)

Disability assessed using the validated Italian version of the self-reported 10-item Oswestry Disability Questionnaire (ODI) before interventions, 10 weeks later (post-training), and 12 months (12M follow-up) after the end of treatment

# Key secondary outcome(s))

Before interventions, 10 weeks later (post-training), and 12 months (12M follow-up) after the end of treatment

- 1. Pain intensity assessed using an 11-point numerical rating scale
- 2. Kinesiophobia assessed using the validated Italian 13-item version of the self-report Tampa Scale for Kinesiophobia (TSK)

- 3. Unhelpful beliefs assessed by the 16-item questionnaire Pain Beliefs and Perceptions Inventory (PBAPI)
- 4. Anxiety and depression investigated by the Hospital Anxiety and Depression Score (HADS)
- 5. Strategies for coping pain were evaluated by the Coping Strategies Questionnaire-revised (CSQ-R)
- 6. Quality of Life assessed using the Italian version of the self-report Short-Form Health Survey (SF-36)
- 7. Return to work
- 8. Sick leave days
- 9. Patient-rated efficacy of treatment using the Global Perceived Effect scale (GPE)

#### Completion date

31/12/2015

# Eligibility

#### Key inclusion criteria

- 1. Sub-acute (i.e., a documented history of pain lasting from 4 weeks to up to 12 weeks) non-specific low back pain attending our rehabilitation hospital
- 2. Good understanding of Italian
- 3. Age < 18 years

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Total final enrolment

150

# Key exclusion criteria

- 1. Acute (lasting up to 4 weeks) and chronic LBP (lasting > twelve weeks)
- 2. Cognitive impairment (MMSE<24)
- 3. All causes of specific LBP, such as previous spinal surgery, deformity, infection, fracture or malignancy, unstable cardiovascular and pulmonary diseases, and systemic or neuromuscular diseases, ruled out by means of case histories and imaging
- 4. Previously received cognitive-behavioural therapy

#### Date of first enrolment

01/01/2013

# Date of final enrolment

31/12/2014

# Locations

#### Countries of recruitment

Italy

# Study participating centre Scientific Institute of Lissone

Via Monsignor Bernasconi, 16 Lissone (Monza Brianza) Italy 20851

# Sponsor information

# Organisation

Dept. Medical Science and Public Health - Faculty of Medicine

#### **ROR**

https://ror.org/003109y17

# Funder(s)

# Funder type

University/education

#### **Funder Name**

Università degli Studi di Cagliari

#### Alternative Name(s)

Università degli Studi di Cagliari, Università di Cagliari, UNICA

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

# IPD sharing plan summary

Available on request

#### **Study outputs**

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Participant information sheetParticipant information sheet11/11/202511/11/2025NoYes