

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

Submission date 24/02/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 complaints. 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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 task-oriented 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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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)

Overall study start date

30/11/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

135

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

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Sponsor information**Organisation**

Dept. Medical Science and Public Health - Faculty of Medicine

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Sponsor type

University/education

Website

https://www.unica.it/unica/it/dip_scienzemedsanpub.page

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

Italy

Results and Publications

Publication and dissemination plan

Peer-reviewed journal with special interest to spinal disorders.

Intention to publish date

31/12/2019

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