ISRCTN55789697 https://doi.org/10.1186/ISRCTN55789697

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

Submission date
24/02/2019

Recruitment status
No longer recruiting

Registration date
26/06/2019

Overall study status
Completed

Last Edited
10/06/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Who is the main contact?
Dr. Marco Monticone, marco.monticone@unica.it

Contact information

Type(s)
Scientific

Contact name
Prof Marco Monticone

ORCID ID
https://orcid.org/0000-0002-6526-888X

Contact details
Dept. Medical Sciences and Public Health - Faculty of Medicine - Cittadella Universitaria
S.S. 554
Bivio Monserrato
Sestu
Cagliari
Italy
09042
+39 0706753109
marco.monticone@unica.it

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 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

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

Italy

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