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Multidisciplinary programme for failed back surgery syndrome.

Submission date
24/02/2019

Recruitment status
No longer recruiting

Registration date
12/03/2019

Overall study status
Completed

Last Edited
17/06/2022

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
Possible surgical criticisms to Failed Back Surgery Syndrome (FBSS) onset have been outlined pre-operatively, intra-operatively, and postoperatively. Successful clinical results are expected by the appropriate treatment of these problems. However, authors suggested a role for multidisciplinary rehabilitation when specific reasons for persisting pain are absent, but disability, mood disorders, or maladaptive thoughts co-exist post-operatively. Despite multidisciplinary programmes based on exercises and cognitive-behavioural therapy being increasingly used in subjects with chronic low back pain, there are doubts about their clinical impact when conducted in FBSS populations as well as their long-term effects. Therefore, evidence is still required in defining the characteristics of exercises and cognitive-behavioural interventions. Hence, we decided to undertake this trial based on the premises above.

Who can participate?
Adults, both males and females.

What does the study involve?
An enriched programme incorporating multimodal exercises and CBT in comparison with general physiotherapy alone in the treatment of FBSS.

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?
Physical Medicine and Rehabilitation Unit, Scientific Institute of Lissone, Istituti Clinici Scientifici Maugeri (Italy)

When is the study starting and how long is it expected to run for?
From the beginning of 2012 to the end of 2016.

Who is funding the study?
Physical Medicine and Rehabilitation Unit, Scientific Institute of Lissone, Istituti Clinici Scientifici Maugeri (Italy)

Who is the main contact?
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
20/2011

Study information

Scientific Title
Multimodal exercises integrated with cognitive-behavioural therapy improve disability of subjects with failed back surgery syndrome: A randomized controlled trial with one-year follow-up.

Study objectives
A 10-week rehabilitation programme of multimodal exercises integrated with cognitive-behavioural therapy would induce clinically significant improvements in disability, pain, and

quality of life in subjects with failed back surgery syndrome vs. general physiotherapy, and that these would be maintained at least one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/11/2011, Ethical Committee Salvatore Maugeri Foundation (Via Monsignor Ennio Bernasconi, 16, 20851 Lissone MB, Italy; +39 039 46571; marco.monticone@fsm.it), ref: 20

Study design
Randomised, parallel-group superiority-controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lumbar pain, with or without leg involvement, following lumbar surgery (failed back surgery syndrome).

Interventions
Experimental group. Multimodal and task-oriented exercises and cognitive-behavioural therapy. Control group. 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

The treatment programme took place at the outpatient rehabilitative gym at the hospital and was led 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-ups, the patients 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 was assessed using the validated Italian version of the self-reported 10-item Oswestry Disability Questionnaire (ODI) at baseline, 10-weeks and 12-months.

Key secondary outcome(s))
1. Kinesiophobia was assessed using the validated Italian 13-item version of the self-report Tampa Scale for Kinesiophobia (TSK) at baseline, 10-weeks and 12-months.

2. Catastrophising was evaluated by means of the 13-item validated Italian version of the self-reported Pain Catastrophising Scale (PCS) at baseline, 10-weeks and 12-months.
3. Pain intensity was assessed using an 11-point numerical rating scale at baseline, 10-weeks and 12-months.
4. Quality of life was assessed using the Italian version of the self-report Short-Form Health Survey (SF-36) at baseline, 10-weeks and 12-months.
5. Patient-rated efficacy of treatment using the Global Perceived Effect scale (GPE) at end of treatment.

Completion date
30/03/2016

Eligibility

Key inclusion criteria
1. Presence of lumbar pain, with or without leg involvement, following lumbar surgery
2. Lumbar surgery occurred once or more, being within the first (if more interventions, in the last) postoperative year
3. Good understanding of Italian
4. Age of >18 years
5. Expert spinal surgeons confirmed the accuracy of their pre-op diagnoses and excluded new surgical indications for pain persistence, such as the presence of residual lumbar foraminal and /or central stenosis, residual painful disc, epidural fibrosis, improper screw placement, non-union or abnormal motion at a fusion level, before sending for conservative treatment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
130

Key exclusion criteria
1. Cognitive impairment (MMSE<24)
2. Specific causes of LBP, such as deformity, infection, fracture or malignancy, unstable cardiovascular and pulmonary diseases, and systemic or neuromuscular diseases, ruled out by means of case histories and imaging.
3. Previously received workers’ compensation
4. Previously received CBT

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Italy

Study participating centre
Scientific Institute of Lissone
Via Monsignor Bernasconi, 16
Lissone (Monza Brianza)
Italy
20851

Sponsor information

Organisation
Istituti Clinici Scientifici Maugeri

ROR
https://ror.org/00mc77d93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Physical Medicine and Rehabilitation Unit, Scientific Institute of Lissone, Istituti Clinici Scientifici Maugeri

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