

# Multidisciplinary programme for failed back surgery syndrome.

<b>Submission date</b> 24/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2022	<b>Condition category</b> 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

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**  
<http://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

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

### **Secondary study design**

Randomised controlled 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**

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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

31/10/2011

## **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

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

135

**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

**Sponsor details**

Physical Medicine and Rehabilitation Unit  
Scientific Institute of Lissone  
Via Monsignor Bernasconi 16  
Lissone (MB)  
Italy  
20851  
+39.0706753109  
marco.monticone@unica.it

**Sponsor type**

Hospital/treatment centre

**Website**

www.fsm.it

**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**

**Publication and dissemination plan**

Peer-reviewed journals 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