

# Effectiveness of a multidisciplinary intervention in subacute low back pain in the working population

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| <b>Submission date</b><br>17/04/2008   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>09/05/2008 | <b>Overall study status</b><br>Completed              | <input checked="" type="checkbox"/> Protocol                 |
| <b>Last Edited</b><br>18/02/2021       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan           |
|  |   | <input checked="" type="checkbox"/> Results                  |
|  |   | <input type="checkbox"/> Individual participant data         |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
071610

## Study information

**Scientific Title**  
Effectiveness of a multidisciplinary intervention in the evolution of non-specific subacute low back pain in the working population

## Acronym

MILUPA

## Study objectives

1. A multidisciplinary intervention (including physical, psychological, educational and pharmacological aspects), reduces intensity of pain, improves functional status and quality of life and diminishes progression towards chronicity in patients with non-specific subacute low back pain, compared to standard clinical practice
2. The multidisciplinary approach manages to reduce both the period of sick leave and duration of pharmacological treatment, compared to standard clinical practice
3. Patient satisfaction is higher with the multidisciplinary approach than that obtained with standard clinical care
4. Differences exist among individual features of those patients that develop non-specific chronic low-back pain and of those who recover

Added 01/02/10:

The study will be a randomised controlled clinical trial with Primary Health Care Centers randomly allocated to a multidisciplinary intervention or to usual clinical care

Please note that as of 01/02/10 this record has been extensively updated. All updates can be found in the relevant field with the above update date. Please also note that the number of participants has increased from 696 to 932 in total between both arms and the anticipated end date has been extended from 31/12/2010 to 31/12/2011.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Research Ethics Committee of the Jordi Gol i Gurina Primary Care Research Institute (IDIAP), Barcelona Date of approval: 04/04/2007 (ref: P07/25)

## Study design

Multicentre cluster randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Subacute low back pain

## Interventions

Current information as of 01/02/10:

Control Group (Standard clinical practice): Individual intervention based on the application of the Clinical Practice Guidelines in the Pathology of the Lumbar Spine in Adults recommendations, published by the Institut Català de la Salut. Multidisciplinary Intervention Group: Individual intervention following the recommendations of clinical practice guidelines in addition to a biopsychosocial multidisciplinary intervention consisting of group educational sessions lasting a total of 10 hours and the Educational digital video disc (DVD).

Initial information at time of registration:

Control group (Standard clinical practice):

Individual intervention based on the application of the "Clinical Practice Guidelines in the Pathology of the Lumbar Spine in Adults" recommendations, published by the Catalan Institute of Health (Institut C atala de la Salut).

Multidisciplinary intervention group:

Individual intervention following the recommendations of the clinical practice guidelines plus educational group intervention plus educational DVD.

Educational group intervention: Intervention will consist of 4 sessions over 1 month, 2 hours per session. The first 50 min of the session will be theoretical and the rest practical. There will be 2 sessions about physical measures to prevent back pain and 2 sessions on psychological aspects to control back pain. They will be given by a nurse trained by an expert psychologist and an expert physiotherapist.

Educational DVD: Educational DVD will cover general aspects of back pain and physical and psychological aspects to prevent it in usual life. It will also give answers to the most frequently asked questions about back pain.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

Current information as of 01/02/10:

1. Disability (Roland Morris Questionnaire)
2. Pain intensity (Questionnaire Spanish version)
3. Mc Gill Pain Questionnaire, Melzac, 1975)
4. Quality of Life Questionnaire (SF 12)
5. Duration of the current episode of LBP (pre-study and study duration)
6. Work sick leave (yes or not)
7. Duration in days of work sickleave
8. Percentage of change in pharmacological treatments.
9. Fear Avoidance Beliefs Questionnaire (FAB)
10. Goldberg Scale (Anxiety and Depression) Questionnaire

Outcomes will be measured at baseline, 3 moths, 6 and 12 months

Initial information at time of registration:

1. Pain intensity, assessed by the Spanish version of the Mc Gill Pain Questionnaire (Melzac, 1975)
2. Disability, assessed by the Roland Morris Questionnaire
3. Quality of Life, assessed by the 36-item Short Form health survey (SF-36)
4. Duration of the current episode of low back pain (pre-study and during the study)
5. Work sick leave (yes or no)
6. Duration in days of work sick leave
7. Percentage of change in pharmacological treatments

Outcomes will be measured at baseline, 3 and 12 months

## **Key secondary outcome(s)**

Current information as of 01/02/10:

1. Satisfaction with care
  2. Patients assesment of global perceived effect
- Outcomes will be measured at baseline, 3, 6 and 12 months

Initial information at time of registration:

Satisfaction with care measured at baseline, 3 and 12 months

**Completion date**

31/12/2011

## Eligibility

**Key inclusion criteria**

Current information as of 01/02/10:

1. Men and women aged between 18 and 65, who present a current episode of non-specific subacute low back pain, occurs suddenly after a period of a minimum of 6months without LBP and lasts between 15 days and 12 weeks (after ruling out the red flag signs for potentially severe illnesses, listed in the exclusion criteria section)
2. Attended during the study recruiting period
3. Who agree to and sign the informed consent
4. Who understand Catalan or Spanish
5. Who can be accessible for at least twelve months.

Initial information at time of registration:

1. Men and women
2. Aged between 18 and 65
3. Those who present a current episode of non-specific subacute low back pain, the duration of which should last from 15 days to less than 12 weeks (after ruling out the red flag signs for potentially severe illnesses, listed in the exclusion criteria section)
4. Attended during the study recruiting period
5. Who agree to and sign the informed consent
6. Who understand Catalan or Spanish
7. Who remain at the same address for at least six months

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

### **Key exclusion criteria**

1. Unwillingness to participate in the multidisciplinary intervention trial
2. Pregnancy or breast-feeding mothers
3. Concomitant drug or other substances abuse
4. Anti-inflammatory intolerance or allergy
5. Patients who had treatment for physical problems in the preceding three months and those referred for intensive functional restoration programmes
6. Coexisting cognitive impairment or any other cause of inability to answer the various questionnaires
7. Severe psychiatric disorders: Psychosis, major depression, etc.
8. Presence of red flag signs for potentially severe illnesses

Added 01/02/10:

9. Patients referred for intensive functional restoration programmes
10. Confirmed diagnosis of fibromialgia

### **Date of first enrolment**

01/01/2009

### **Date of final enrolment**

31/12/2011

## **Locations**

### **Countries of recruitment**

Spain

### **Study participating centre**

**Institut d'Investigació i Recerca en Atenció Primària (IDIAP)**

Barcelona

Spain

08007

## **Sponsor information**

### **Organisation**

La Marató de TV3 Foundation (Fundació La Marató de TV3) (Spain)

### **ROR**

<https://ror.org/00t5xc355>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

La Marató de TV3 Foundation (Fundació La Marató de TV3) (Spain)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results  | 12/12/2019   | 18/02/2021 | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 12/01/2010   |            | Yes            | No              |