

# Effectiveness of the psychological and pharmacological treatment of catastrophisation in patients with fibromyalgia: a controlled randomised trial

<b>Submission date</b> 11/06/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2014	<b>Condition category</b> Musculoskeletal Diseases	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

ETES n° PI07/90959

# Study information

## Scientific Title

## Study objectives

Pharmacological and psychological treatments are more effective for the treatment of pain catastrophising in patients with fibromyalgia than usual treatment at primary care level.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical Review Board of the Regional Health Authority, February 2007, ref: ETES n° PI07/90959

## Study design

Multicentre three-arm random allocation controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Fibromyalgia

## Interventions

Psychological intervention:

Manualised protocol developed by Prof. Escobar et al, of the University of New Jersey, for the treatment of somatoform disorders that has been adapted by our group for the treatment of fibromyalgia. It includes 10 weekly sessions of cognitive-behaviour therapy.

Pharmacological intervention:

In this group of patients, pregabalin (300 - 450 mg/day), recommended for the treatment of fibromyalgia, associated with duloxetine (60 - 120 mg/day) if there is comorbid depression, will be administered.

Treatment as usual at primary care level:

This group will follow the usual treatment given at primary care level.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Pregabalin, duloxetine

### **Primary outcome measure**

The major outcome is pain catastrophising in patients with fibromyalgia. This construct will be assessed with the Spanish version of the Pain Catastrophising Scale. Assessments will take place at baseline, 3 months, 6 months and 1-year post-intervention

### **Secondary outcome measures**

1. The following socio-demographic data will be collected: sex, age, marital status, education, occupation and social class: administered only at baseline
2. The diagnosis of psychiatric disorders will be made with the Structured Polyvalent Psychiatric Interview, a psychiatric interview extensively used for the study of somatoform disorders: administered only at baseline
3. Hamilton test for Anxiety (HAM-A) and for Depression (HAM-D); assessments will take place at baseline, 3 months, 6 months and 1-year post-intervention
4. Fibromyalgia Impact Questionnaire (FIQ): the FIQ is a 10-item self-report questionnaire developed to measure the health status of fibromyalgia patients; assessments will take place at baseline, 3 months, 6 months and 1-year post-intervention

### **Overall study start date**

01/09/2008

### **Completion date**

31/12/2009

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 - 65 years, either sex
2. Able to understand and read Spanish
3. Fulfil criteria for primary fibromyalgia according to the American College of Rheumatology
4. No previous psychological treatment
5. No pharmacological treatment or acceptance to discontinue it two weeks before the onset of the study
6. Signed informed consent

### **Participant type(s)**

Patient

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

180 patients (60 in each of the three groups)

**Key exclusion criteria**

1. Severe Axis I psychiatric disorder (dementia, schizophrenia, paranoid disorder, abuse of alcohol and/or drug disorders)
2. Severe Axis II disorder from the clinician viewpoint that prevents the patient from following the treatment protocol
3. Pregnancy or lactation
4. Refusal to participate

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

31/12/2009

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

Servicio de Psiquiatría

Zaragoza

Spain

50009

## **Sponsor information**

**Organisation**

The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.isciii.es>

**ROR**

<https://ror.org/00ca2c886>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) (ref: ETES nº PI07/90959)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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="#">Protocol article</a>	protocol	23/04/2009		Yes	No
<a href="#">Results article</a>	results	01/10/2014		Yes	No