

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

Submission date 11/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 02/10/2014	Condition category 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
ETES nº 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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?
Results article	results	01/10/2014		Yes	No
Protocol article	protocol	23/04/2009		Yes	No