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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

Registration date
29/09/2008

Overall study status
Completed

Last Edited
02/10/2014

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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 nº 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)

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