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Efficacy of group acceptance & commitment therapy in fibromyalgia

Submission date
11/08/2012

Recruitment status
No longer recruiting

Registration date
16/08/2012

Overall study status
Completed

Last Edited
11/08/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fibromyalgia is a long-term (chronic) condition that causes pain all over the body. The effects of psychological treatments for fibromyalgia are relatively small but comparable to those reported for drug treatments used for this disorder. Acceptance and commitment therapy, a form of talking therapy, is a promising treatment for chronic pain disorders, but so far there are no studies on fibromyalgia. The aim of this study is to assess the effectiveness of group acceptance and commitment therapy for the treatment of fibromyalgia.

Who can participate?
Patients aged 18–65 with fibromyalgia

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group attend an 8-week group acceptance and commitment therapy program. Participants in the second group receive the recommended pharmacological (drug) treatment for fibromyalgia. Participants in the third group are put on a waiting list for treatment. Fibromyalgia symptoms are assessed in all three groups after 6 months.

What are the possible benefits and risks of participating?
Possible benefits include an improvement in fibromyalgia symptoms with either of the two treatments as has been demonstrated in previous studies. The risks in the acceptance and commitment therapy group are minimal. In the drug treatment group the drugs used may have minor side effects.

Where is the study run from?
Spanish Research Network of Preventative Activities in Primary Care, Instituto de Salud Carlos III, from the Spanish Ministry of Health

When is the study starting and how long is it expected to run for?
September 2012 to June 2013

Who is funding the study?
Spanish Research Network of Preventative Activities in Primary Care, Instituto de Salud Carlos III, from the Spanish Ministry of Health

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Protocol 7/2011

Study information

Scientific Title
EFFIcacy of Group Acceptance & Commitment Therapy in fibromyalgia (EFFIGACT): a three-armed randomized controlled trial

Acronym
EFFIGACT

Study objectives
Group acceptance & commitment therapy will be more effective than recommended pharmacological treatment and more effective than wait-list for the treatment of fibromyalgia (FM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Aragón Ethical Review Board, 06/05/2011, ref: 07/2011

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Fibromyalgia (chronic pain conditions)

Interventions
Patients with FM will be randomly assigned to:

Group Acceptance & Commitment Therapy (GACT):
Consists of an 8-week structured program in groups (90 minutes duration, 12-15 participants in each group) based on Acceptance & Commitment Therapya and specifically tailored for fibromyalgia.

Recommended pharmacological treatment:
Pharmacological treatment as recommended by Clinical Guidelines. In summary, main treatment: pregabaline (300-600mg/day), and whether depression is diagnosed duloxetine (60-120 mg/day). Analgesics, hypnotics and other symptomatic treatments are allowed following guides.

Wait-list:
No active treatment will be offered during the period of study.

Intervention Type
Mixed

Primary outcome(s)
Fibromyalgia Impact Questionnaire (FIQ) - a 10-item self-report questionnaire developed to measure the health status of FM patients

Key secondary outcome(s)
1. Sociodemographic variables (gender, age, marital status, ethnic group, living arrangements, educational level, employment status and income)
2. Psychiatric diagnosis (assessed with MINI)
3. Pain catastrophising scale
4. Pain visual analog scale
5. Chronic Pain Acceptance Questionnaire
6. Pain threshold assessed by sphygmomanometer
7. Hospital Anxiety Depression Scale

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Patients will be recruited from the primary care health centres in the region of Aragon, Spain
2. Patients aged 18-65 years, able to understand and read Spanish
3. Patients who fulfil criteria for FM according to the American College of Rheumatology criteria
4. Patients with no previous psychological treatment during previous year
5. Patients with 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. Patients with severe Axis I psychiatric disorders (dementia, schizophrenia, paranoid disorder, alcohol and/or drug use disorders)
2. Patients with severe somatic disorders which, from the clinicians point of view, prevent patients from carrying out a psychological assessment
3. Patients participating in other clinical trials

Date of first enrolment
01/09/2012

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Spain

Study participating centre
Miguel Servet University Hospital
Zaragoza
Spain
50009

Sponsor information

Organisation
Miguel Servet University Hospital (Spain)

ROR
https://ror.org/01r13mt55

Funder(s)

Funder type
Research organisation

Funder Name
The Aragon Health Sciences Institute [Instituto Aragonés de Ciencias de la Salud (I+CS)] (Spain)

Funder Name
The Research Network on Preventative Activities and Health Promotion [Red de Actividades Preventivas y de Promoción de la Salud (REDIAPP)] (Spain) ref: B76 & RD06/0018/0020

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	01/04/2014		Yes	No