

## Effectiveness of group acceptance and commitment therapy for fibromyalgia: A 6-month randomized controlled trial (EFFIGACT study)



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### ABSTRACT

In the last decade, there has been burgeoning interest in the effectiveness of third-generation psychological therapies for managing fibromyalgia (FM) symptoms. The present study examined the effectiveness of acceptance and commitment therapy (ACT) on functional status as well as the role of pain acceptance as a mediator of treatment outcomes in FM patients. A total of 156 patients with FM were enrolled at primary health care centers in Zaragoza, Spain. The patients were randomly assigned to a group-based form of ACT (GACT), recommended pharmacological treatment (RPT; pregabalin + duloxetine), or wait list (WL). The primary end point was functional status (measured with the Fibromyalgia Impact Questionnaire, FIQ). Secondary end points included pain catastrophizing, pain acceptance, pain, anxiety, depression, and health-related quality of life. The differences between groups were calculated by linear mixed-effects (intention-to-treat approach) and mediational models through path analyses. Overall, GACT was statistically superior to both RPT and WL immediately after treatment, and improvements were maintained at 6 months with medium effect sizes in most cases. Immediately after treatment, the number needed to treat for 20% improvement compared to RPT was 2 (95% confidence interval 1.2–2.0), for 50% improvement 46, and for achieving a status of no worse than mild impaired function (FIQ total score <39) also 46. Unexpectedly, 4 of the 5 tested path analyses did not show a mediation effect. Changes in pain acceptance only mediated the relationship between study condition and health-related quality of life. These findings are discussed in relation to previous psychological research on FM treatment.

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## 1. Introduction

Fibromyalgia (FM) is a chronic and debilitating syndrome of unknown cause characterized by widespread pain and a constellation of symptoms, including fatigue, disturbed sleep, cognitive problems, and distress [54,55]. FM syndrome has a prevalence of 2.9% in the European general population [8], and among chronic pain conditions, FM causes the highest unemployment rate (6%),

the largest claims for incapacity benefit (up to 29.9%), and the greatest number of days of absence from work [30].

Concerning FM treatment, Nüesch et al. [39] found statistically significant advantages of pharmacological interventions (serotonin–norepinephrine reuptake inhibitors and pregabalin) over placebo on pain and the quality of life of FM patients, but these effects were of questionable clinical relevance. Among nonpharmacological interventions, multicomponent therapy, followed by aerobic exercise and cognitive behavioral therapy (CBT), was most promising for reducing pain and improving quality of life.

Regarding the effectiveness of psychological treatments on FM symptoms, a meta-analysis [21] yielded small to medium mean

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effect sizes in pain intensity, depression, and catastrophizing. CBT was found to be significantly better than the other interventions in alleviating FM pain intensity, with higher treatment doses leading to greater effect sizes. A meta-analysis [6] focused on CBT showed a reduction of depressed mood and an improvement in self-efficacy compared with control arms after treatment. However, the absence of positive effects on the key symptoms of the syndrome prevented a definitive recommendation of CBT-based treatments.

Acceptance and commitment therapy (ACT) has demonstrated effectiveness in treating a wide range of physical and mental conditions. Powers et al. [41] performed a meta-analysis of the results of 18 studies and found that ACT outperformed control conditions on primary and secondary end points (Hedges's  $g = 0.42$  and  $0.59$ , respectively) with all disorders and time variables pooled. In the last decade, there has been growing interest in the effectiveness of ACT and other third-generation psychological therapies [13,28] for clinical improvement of patients with chronic pain. Veehof et al. [47] conducted a meta-analysis of 19 studies to examine the effects of acceptance-based interventions on patients with chronic pain. The results showed small but significant effects on pain intensity, depression, anxiety, physical well-being, and quality of life. Nevertheless, the effectiveness of ACT in managing FM symptoms has not been addressed until recently. Wicksell et al. [52] showed that ACT improves the functioning, mental quality of life, distress, self-efficacy, and psychological inflexibility of FM patients and that psychological inflexibility is also a significant mediator of improvement in study outcomes. However, the absence of an active control group, the relatively small sample sizes ( $n < 25$ ), and a short follow-up period (3 months) impede a high-grade recommendation of ACT in clinical guidelines for the syndrome.

The 2-fold objective of the present study was, first, to extend the findings of Wicksell et al. [52] through an examination of the effectiveness of ACT for FM using a larger sample size in each study arm, a longer follow-up period, and a pharmacological control condition; and second, to analyze the role of pain acceptance as a mediator of clinical improvement.

## 2. Methods

### 2.1. Design

A 6-month controlled trial was performed with a random allocation of the participants into 3 conditions (using a computer-generated randomization list), group ACT (GACT), recommended pharmacological treatment (RPT), or wait list (WL). The randomized controlled trial (RCT) was performed according to the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) [16], which recommends the inclusion of a set of core outcome domains in clinical trials of pain treatments, and the latest updates to the Consolidated Standards of Reporting Trials (CONSORT) [11,38] guidelines. Randomization was stratified by the presence or absence of comorbid major depression to ensure a balance of depressed patients in the 3 conditions. The patients were randomized in blocks; the size of the blocks was randomly selected as comprising either 3 or 6 patients.

A research assistant who was not involved in the study generated the allocation sequence. The sequence was concealed until interventions were assigned. The patients agreed to participate before random allocation and without knowing which treatment they would receive. The patients in the intervention arms (GACT and RPT) were informed that 2 treatments would be compared, one treatment based on psychotherapy and the other on pharmacotherapy. Patients participating in the WL arm were offered their preferred treatment after completion of the RCT.

Informed consent was obtained from all participants before initiating the study. The patients were provided with a general overview of the study and informed that they could withdraw at any time, with the guarantee that they would continue to receive the treatment considered most appropriate by their general practitioner. The study followed Helsinki Convention norms and subsequent updates, and the study protocol was approved through the ethical review board of the regional health authority, Aragon, Spain (Act 07/2011).

### 2.2. Sample size

Sample size was established on the basis of a previous meta-analysis of psychological interventions in FM patients [21] in which a mean effect size of 0.42 was found for functional status. Adopting an alpha risk of 5%, a power equal to 80% in a bilateral contrast, and 20% maximal attrition, approximately 50 patients per group were considered necessary.

### 2.3. Participants

FM patients were recruited from primary health care centers in Zaragoza, Spain. The patients considered for inclusion were aged 18 to 65 years who could speak and read Spanish fluently and who fulfilled the ACR 1990 criteria for FM at screening, with no pharmacological treatment (or agreed to discontinue use to participate in the study) and no previous psychological treatment during the previous year. All participants provided signed informed consent. The patients considered for exclusion were individuals with severe axis I psychiatric disorders (dementia, schizophrenia, paranoid disorder, alcohol and/or drug use disorders) and with severe somatic disorders that, from the clinician's point of view, prevented patients from carrying out a psychological assessment or participating in other clinical trials. All the patients included in the study had been diagnosed with FM by a rheumatologist working for the Spanish National Health Service. General practitioners (GPs) selected FM patients fulfilling the inclusion criteria until the required sample number was achieved, without a quota of patients assigned for each center. The GPs assessed the depression of the patients for the subsequent stratification of the sample. After referral, a research assistant evaluated the patients for all eligibility criteria. Diagnosis confirmation of major depression was carried out by research assistants (highly trained clinical psychologists) using the Mini-International Neuropsychiatric Interview (MINI). Informational brochures, briefly describing the 2 interventions as alternative treatments potentially capable of enhancing the well-being of FM patients, were provided. The study was conducted from September 2011 to June 2012.

The participants were interviewed at baseline, after treatment, and during the 3- and 6-month follow-up. The study personnel who conducted the interviews and assessed the outcomes were blinded to treatment allocation. As a result of the characteristics of the RCT, the patients were not blinded to the treatment allocation.

### 2.4. Interventions

#### 2.4.1. GACT

This intervention was based on the original program [53] adapted to FM patients. One therapist (JAG) delivered the structured intervention, comprising eight 2.5 h sessions with groups ranging from 10 to 15 patients. The sessions covered specific exercises and topics within the context of ACT practice and training, including various types of formal mindfulness practice (Table 1).

At enrollment, the participants were asked to commit to daily homework assignments of 15 to 30 min. The therapist was an

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