Identifying mindfulness and acceptance as mediators between negative affect, functional disability and emotional distress in patients with fibromyalgia

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Abstract

Objective

Fibromyalgia (FM) is a prevalent disabling condition characterised by chronic widespread pain. It is considered a complex illness in which the prognosis is conditioned by affective and cognitive mediators still largely unknown in FM. To investigate the correlation between psychological variables (acceptance, negative affect, and mindfulness) and functional disability or physical impact, anxiety/depression symptoms and emotional distress, and also to evaluate the mediating role of acceptance and mindfulness between negative affect, physical impact, anxiety/depression and emotional distress in individuals with FM.

Methods

Two hundred and fifty-one patients with FM who met the 2010 ACR criteria were included and filled out validated self-reported screening measures. The study explored Pearson's correlation coefficients and multiple mediation using a Preacher and Hayes's computational software tool, including the indirect effect associated with the two mediators (mindfulness and acceptance).

Results

Functional disability or physical impact, anxiety/depression symptoms and emotional distress correlated positively with negative affect (r= 0.580) and negatively with acceptance and mindfulness (r= -0.579 and r= -0.471; all p-values <0.001), respectively. The mediation analyses showed that acceptance and mindfulness mediated the relationship between negative affect and dependent variables such as physical impact, anxiety/depression symptoms and distress.

Conclusion

The findings highlight that mindfulness and acceptance have a significant indirect effect on physical impact, anxiety/depression and emotional distress when controlling for negative affect as an independent variable in the FM patients. Future investigation should replicate and extend these outcomes in other study populations to determine the mediating role of mindfulness and acceptance in FM.

Key-words

acceptance, disability, emotional distress, fibromyalgia, mindfulness, negative affect

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Introduction

The American College of Rheumatology (ACR) defines fibromyalgia (FM) as a common chronic illness of unknown aetiology characterised by widespread musculoskeletal pain of more than three months, with the presence of generalised sensitivity, pain and tenderness in specific regions. FM may be associated with other comorbid health complaints, such as non-restorative sleep, fatigue, irritable bowel syndrome (IBS), mood disorders, anxiety/depression, cognitive impairment and other disturbing symptoms (1-5). Fibromyalgia represents a major health problem in Western countries today, due to its high prevalence and its debilitating clinical impact in terms of disability and quality of life. The high healthcare expenditure that its treatment generates is another cause for concern (6). The worldwide prevalence of FM is as high as 6% (7) and a recent study recorded a significant increase (8). Patients with FM often suffer notable emotional distress and impairment in their health-related quality of life, resulting in a considerable burden of illness (9-11). The diathesis-stress model is a theoretical perspective that explains the causal relationship between chronic pain and psychopathology (12). Malfliet *et al*. study (13) found associations between maladaptive cognitive and emotional factors and several brain regions involved in chronic pain, and proposed that targeting these factors in individuals with FM might normalise specific brain alterations. That study explored neurophysiological alterations and the sensitisation of the central nervous system in chronic pain conditions, along with alterations in mood and high comorbidity with psychopathological phenomena such as anxiety/depression, and psychosomatic syndromes (14, 15). A large number of pharmacological and non-pharmacological interventions for FM have been studied over the last 10 years. Research into FM during the 2020s has focused on the diagnostic criteria, pathomechanisms and therapeutic approaches (16). The evidence shows that the combination of pharmacological and psychological treatment and physical exercise may improve the health status of FM patients (17). Multidisciplinary treatments of a cognitive behavioural orientation have achieved significant changes in the perception of pain control, quality of life and reduction of pain intensity, as well as emotional improvements (18-19).

Certain studies have reported that psychological factors may have a marked impact on the evolution of FM patients, and propose that pain acceptance requires patients to maintain contact with unpleasant or painful experiences without allowing these experiences to influence their behaviour or prevent them from achieving their most important goals (20). Pain acceptance does not entail surrender or resignation, or relinquishing control, but involves facing the uncomfortable experience instead and mediating a prognosis of well-being in patients with chronic pain (21, 22). Acceptance of pain implies maintaining contact with unpleasant or painful experiences, without influencing patients' behaviour or depriving them of the chance to achieve their most important goals (22). Evidence from previous studies indicates that cognitive behavioural therapy plays a significant role in the non-medical therapy of FM and is especially helpful in high-catastrophising patients who present changes in brain connectivity on functional magnetic resonance imaging (23, 24).

Mindfulness is a construct that reflects the capacity to be conscious, centred on the *here and now*, without judging the situations experienced. It has been defined variously as full awareness, conscious attention, awareness of the moment, and so on (25). Brown & Ryan (26) demonstrated the operational character of the term "mindfulness" in its key components of awareness and attention: *awareness* oversees the internal and external environment, and *attention* is a process of consciously focusing perception. They also proposed that it is both a trait and a state construct, and is fundamental for the self-regulation of emotional experience. Mindfulness correlates with a broad battery of symptoms related to psychological wellbeing (27), and some studies reported that mindfulness meditation can be helpful in improving pain symptoms and pain perception (24, 28).

Negative affect is a construct that reflects the emotional states that influence the perception of pain and create feelings of discomfort, which in turn increase anxiety and depression (29). The greater the anxiety, the more difficult it is to cope with the pain, and so the sensation of pain increases. Negative emotions and pain can cause the chronic problem to worsen. Some studies have shown that FM patients present higher levels of negative emotions than the healthy population and also make more use of emotional avoidance strategies (30). Patients with FM have very low scores on positive emotions and have great difficulty in identifying feelings (31).

Based on these premises, we conducted the current study to test the following hypotheses: 1. acceptance and mindfulness correlate with physical impact, anxiety/depression, negative affect, and emotional distress in people with FM; and 2. acceptance and mindfulness mediate the relationship of negative affect with physical impact, anxiety/depression, and emotional distress in FM.

Material and methods

Study design

In this multicentre, prospective, cross-sectional cohort study, attendees were referred from primary healthcare facilities in the Aragon region (Spain) and were assessed by an expert rheumatologist at the outpatient rheumatology clinical unit from the Miguel Servet University Hospital in Zaragoza, Spain, from January 1999 through March 2010.

Participants and procedures

The study was conducted in a sample of 251 eligible participants who met the 2010 ACR criteria for FM (5). All participants were of Caucasian descent and from the same geographical area at the time of study inclusion, and gave written informed consent prior to their participation. The inclusion criteria were: 1. FM diagnosis according to the case criteria aforementioned; 2. aged 18 years or over; 3. ability to speak and understand Spanish; 4. provision of signed informed consent; and 5. absence of any severe mental and psychological disorder and significant medical condition. Exclusion criteria were as follows: 1. previous or current diagnosis of serious medical conditions (*e.g.* major depression disorder, schizophrenia, borderline personality disorder, learning disability, dementia, alcoholism and/or drug addiction) or Axis I/Axis II diagnoses of psychiatry disorder; 2. declined to participate or to sign the informed consent document; and 3. failure to complete the symptom-based screening questionnaires.

All participants were initially contacted by telephone and invited to participate. During the phone call, the nature of the study was explained to them. FM patients who agreed to take part were then recalled for an appointment with a trained postgraduate psychologist, who carried out the clinical interview and completed the face-to-face protocols. In the personal interview, the symptom-based questionnaires, and the study aims were explained to the participants. The diagnosis of FM was made by the hospital's rheumatology clinical unit. The participants were assured that their data would be processed in full confidentiality. After obtaining signed informed consent for those participants who met the eligibility criteria, the interviews, survey instruments and scales were administered over a period of approximately one and a half hours with each patient. The final study protocol was approved by the Institutional Clinical Research Ethics Committee (IRB) at the Zaragoza University Hospital, Aragon, Spain.

Demographic characteristics

Sociodemographic data (age, gender, place of residence, educational level, marital status, work situation and living arrangements) were compiled using a screening questionnaire set, as well as clinical characteristics such as the length of time from symptom onset until the time of inclusion were also recorded for each participant.

Measures

Validated Spanish self-report screening questionnaires were filled out by participants as a symptom assessment tool under the supervision of a trained investigator in clinical psychological assessment (S.M.) who oversaw participant compliance.

Fibromyalgia Impact Questionnaire (FIQ)

The validated Spanish version of the FIQ was used in the study participants. This symptom-based screening questionnaire quantifies the level of health status, dysfunction, frequency and intensity of pain, functional disability and the physical impact for daily living. It comprises 10 scales: physical functioning, feeling well, morning tiredness, days worked, intensity of work, pain, fatigue, stiffness, anxiety and depression. The first scale focuses on the ability of patients to perform certain physical tasks or activities, and can be used in isolation to assess the degree of disability. Each scale has a maximum score of 10, and each item is classified on a 4-point Likert scale (0-3). The next two items require patients to indicate the number of days in the previous week that they felt well, and the number of days they were unable to work because of the illness. The remaining seven (from 4 to 10) refer to the ability to work, pain, general fatigue, rigidity, morning fatigue, anxiety and depression, measured from 0 to 10 using visual analogue scales**.** The overall impact of fatigue is obtained by summing the total scores in the ten scales described. Higher scores indicate a higher degree of impact of the disease, and a score equal to or greater than 70 is considered severe. The Spanish version of the FIQ has shown good psychometric properties and internal consistency of the total score, with a Cronbach's alpha of 0.91 (32).

Hospital Anxiety and Depression Scale (HADS)

The HADS is a self-reported scale used to screen for the presence of anxiety and depression in people with medical illnesses. It consists of a 14-item inventory scored on a four-point Likert scale (from 0 to 3), divided into two subscales, anxiety (7 items) and depression (7 items) which are scored independently. Each subscale score ranges from 0 to 21; the higher the score, the greater the level of anxiety and/or depression.

The Spanish version of the HADS has shown good internal consistency (0.83 for anxiety and 0.82 for depression) and an adequate sensitivity and specificity (33).

Chronic Pain Acceptance Questionnaire (CPAQ)

Acceptance was measured with the validated Spanish version of the CPAQ. The CPAQ measures patients' acceptance of chronic pain as a prognosis of well-being. It consists of a 20-item self-report inventory rated on a scale of 0 (*never true*) to 6 (*always true*). It is composed of two subscales: a) activities engagement (11 items), and b) pain willingness (9 items). The results of the two subscales are summed directly and the total score ranges from 0 and 120, with higher scores indicating greater acceptance and willingness and/or engagement in daily life activities. The CPAQ has good internal consistency (Cronbach's alpha=0.78) and adequate test-retest reliability (34).

Mindful Attention Awareness Scale (MAAS)

Mindfulness was assessed through the MAAS questionnaire validated in Spanish. This 15 item self-report assesses awareness, centered on the present, and without judging the situations experienced. There is only one factor, and the items are scored on a scale from 1 (almost always) to 6 (almost never) and are added together. The score ranges from 15 (minimum) to score 90 (maximum). The scale evaluates cognition, emotions, interpersonal, physical and general domains. In an attempt to control socially desirable responses, patients are asked to respond honestly on the basis of their experience and not according to any preconceptions about how they think they should answer. The Spanish MAAS has high internal consistency (35).

Positive and Negative Affect Scale (PANAS)

The PANAS is a brief measure of positive and negative affect (*e.g.* enthusiastic or distressed). In this study, a validated Spanish version of the Negative Affect Scale (PANAS-NA) was used. The original questionnaire consists of two mood scales with 10 items each, for the evaluation of positive and negative affect respectively. Each item is scored on a 5-point Likert scale ranging from 1 (*very slightly or not at all*) to 5 (*very much or extremely*). The positive affect score is obtained by adding the odd items, and the negative affect by adding the even items. The scores of both affects are obtained by adding the numbers assigned to the 10 items on each of the two scales. Higher scores indicate greater levels of positive/negative affect. This validated Spanish PANAS version has shown adequate test-retest reliability and good psychometric properties, with Cronbach's alphas for construct validity and internal consistency of 0.86 to 0.90 for positive affect and 0.84 to 0.87 for negative affect (36).

Statistical analysis

The statistical analysis was performed with SPSS 21.0 software (IBM Corp., Armonk, NY, USA) and PROCESS SPSS macro for multiple mediation (37). A descriptive analysis was carried out to establish the demographic and clinical characteristics of the sample and the variables under study to test the psychological variables for statistical normality. Mean and standard deviation (SD) of each variable was previously calculated. Preliminary normality analyses were established with the Kolmogorov-Smirnoff test and the skewness (Sk) and kurtosis (K) values were computed from the sample (38). Pearson's correlation coefficients were performed to examine the relationships between variables in the study participants. An alpha level of p-values < 0.05 was considered statistically significant (two-tailed tests). Lastly, a mediation analysis was conducted to test the direct, indirect and total effects of the constructs "acceptance and mindfulness" as mediators of the negative affect on physical impact, anxiety/depression and emotional distress in the study population. The analysis represented the independent variable (*X*), the dependent variable (*Y*) and quantified this effect as the total effect of *X* on *Y* (called *path c)*. The components of the total effect were: *path a*, the effect of the independent variable on the proposed mediator (*M*); *path b*, the effect of the mediator on the dependent variable controlling for the independent variable; and *path c´*, the effect of the independent variable on the dependent variable controlling for the mediator. The authors recommend the bootstrapping of specific indirect effects to reduce omitted parameter bias. The bootstrap estimates were based on 5000 bootstrap samples, and a 95% CI was used. Figures 1-4 illustrate this analysis method; *c'* is the direct effect of *X* on *Y*, and is distinguishable from the total effect (*c*).

Results

Participants' characteristics

Table I shows the descriptive analysis and demographic and clinical characteristics of the study participants (n=251). In relation to sex, 96.1% were women and 3.9% men. Participants had a mean age of 52.4±8.0 years (95% CI: 51.3–53.4, range: 3–70 years) and a mean length of time from onset of symptoms until inclusion of 18.3±11.1 years. In all, 82.9% of the FM patients lived in Zaragoza city and 11.2% in Teruel (capital or province). Most (84%) had finished primary and secondary education. As for their living arrangements, most were married or living with a partner (73.7%) and almost half lived in their own home with their partner and children (47.4%). As regards employment, 25.1% were working, 21.1% were permanently disabled and 12.3% were on sick leave. Table II shows the descriptive statistics of the instruments used to measure the psychological variables evaluated in our study. The entire sample was analysed and the descriptive data were reported for the overall scores on each questionnaire. Anxiety and depression assessed using the HADS subscales were considered as dependent variables.

Correlational analyses

As shown in Table III, correlation analysis was performed of the psychological variables acceptance, negative affect and mindfulness and the dependent clinical variables, physical impact, anxiety, depression and emotional dis-

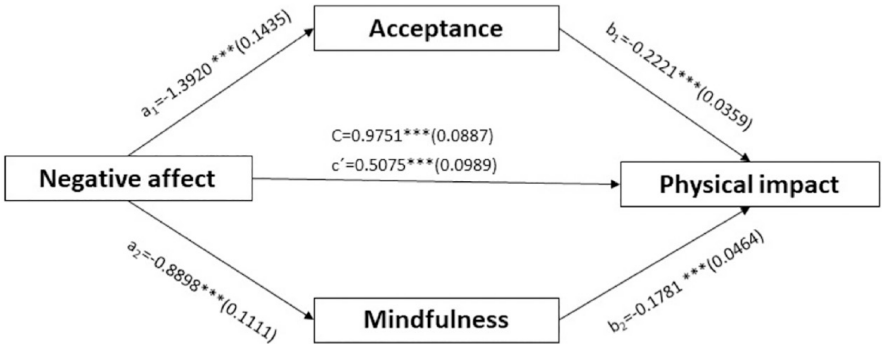

Fig. 1. Mediating role of acceptance and mindfulness between negative affect and physical impact. Significance level was set at ***p<0.001.

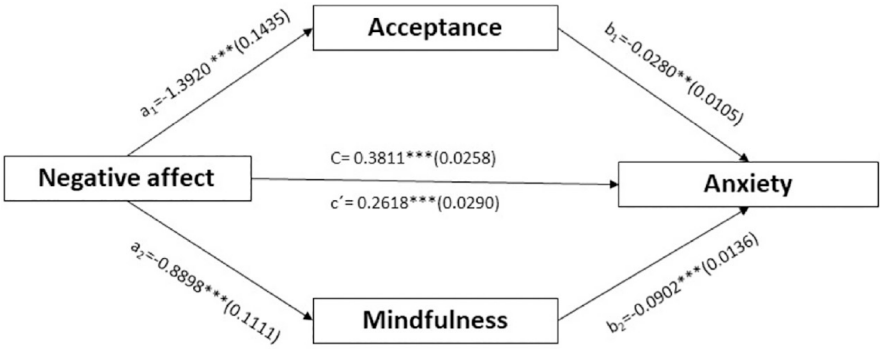

Fig. 2. Mediating role of acceptance and mindfulness between negative affect and anxiety. Significance level was set at **p<0.01, ***p<0.001.

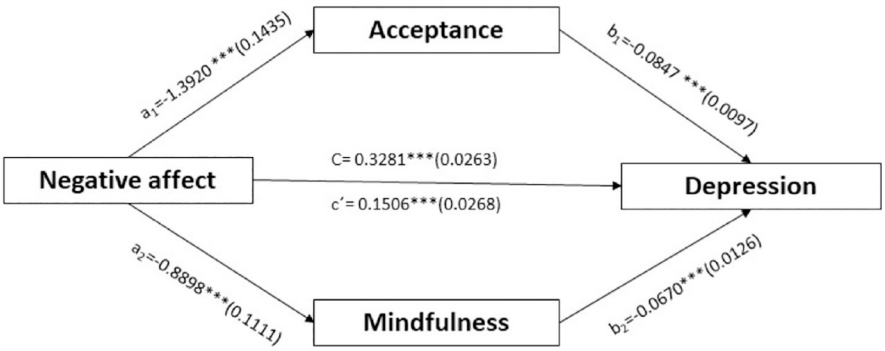

Fig. 3. Mediating role of acceptance and mindfulness between negative affect and depression. Significance level was set at ***p<0.001.

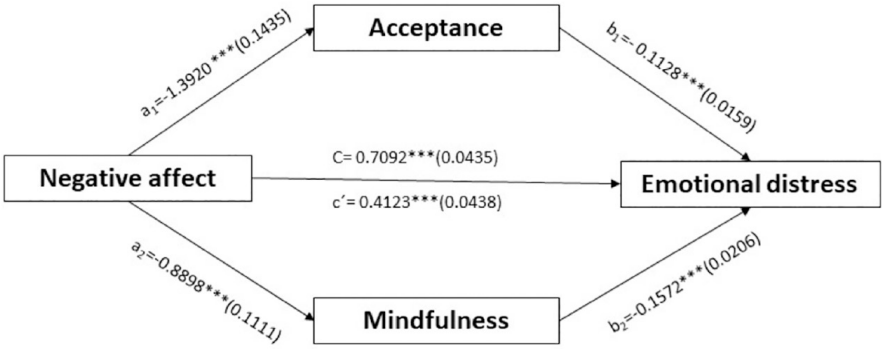

Fig. 4. Mediating role of acceptance and mindfulness between negative affect and emotional distress. Significance level was set at ***p<0.001.

Table I. Demographic and clinical characteristics of the study population (n=251).

Variable	n (%)
Age at enrolment (years)	52.4±8.0
Gender	
Female	241 (96.1)
Male	10 (3.9)
Illness duration at diagnosis (years)	10.2±9.3
Illness duration at time of inclusion (years)	18.3±11.1
Marital status	
Married/living with partner	185 (73.7)
Separated/divorced	32 (12.8)
Single	23 (9.2)
Widower	11 (4.3)
Place of residence	
Zaragoza	221 (88.1)
Huesca	20 (7.9)
Teruel	10 (3.9)
Living arrangements	
Living with partner/spouse and children	119 (47.4)
Living with partner/spouse	80 (31.8)
Living alone	28 (11.2)
Living with other family	10 (3.9)
Others	14 (5.6)
Education	
Finished primary school	116 (46.2)
Finished secondary school	95 (37.8)
University graduate	32 (12.8)
No qualifications	8 (3.2)
Employment	
Employed	63 (25.1)
Disabled	53 (21.1)
Unemployed	38 (15.1)
Retired	34 (13.5)
Homemaker	32 (12.7)
Sick leave	31 (12.3)

All values, except for age and illness duration at diagnosis and at time of inclusion shown as mean ± standard deviation (SD), are displayed as numbers (percentages) of individuals.

tress. Significant correlations were observed for all the variables evaluated. The physical impact score (FIQ) was positively correlated with negative affect (r= 0.580) but negatively with acceptance (r= -0.579) and mindfulness (r= -0.471). Likewise, distress presented a significant positive correlation with negative affect (r= 0.723), but significant negative correlations with acceptance (r= -0.640), and mindfulness (r= -0.620). Negative affect showed a significant positive correlation with anxiety (r= 0.691) and depression (r= 0.621) but a negative correlation with acceptance (r= -0.527); while mindful-

Table II. Descriptive statistics of the instruments and their subscales used to measure the psychological variables in the study participants.

Measures	median, min.-max.	mean ± SD	95% CI
CPAQ	45, 0-110	47.6 ± 23.4	[44.7-50.5]
Activity engagement	24, 0-66	26.3 ± 15.0	[24.4-28.2]
Pain willingness	19, 0-54	21.2 ± 11.4	[19.8-22.6]
MAAS	57, 18-90	56.6 ± 17.5	[54.4-58.8}
Total HADS	19, 0-40	18.4 ± 8.7	[17.3-19.5]
Anxiety	11, 0-21	10.7 ± 4.9	[10.1-11.3]
Depression	7, 0-20	7.7 ± 4.6	[7.1-8.2]
FIQ	60, 17-87	58.0 ± 15.0	[56.1-59.9]
PANAS -	24, 10-47	24.0 ± 8.9	[22.9-25.1]

CPAQ: Chronic Pain Acceptance Questionnaire; MAAS: Mindful Attention Awareness Scale; HADS: Hospital Anxiety and Depression Scale; FIQ: Fibromyalgia Impact Questionnaire; PANAS: Positive and Negative Affect Scale.
The number of valid cases completing the questionnaires are 248 out of a total of 251.

Table III. Pearson's correlation analysis between psychological variables (acceptance, mindfulness and negative affect) and physical impact (FIQ), anxiety, depression, and emotional distress (Total HADS) in the participants.

Measures	FIQ	Anxiety	Depression	Total HADS
CPAQ	-0.57***	-0.50***	-0.66***	-0.64***
MAAS	-0.47***	-0.59***	-0.53***	-0.62***
PANAS -	0.58***	0.69***	0.62***	0.72***

CPAQ: Chronic Pain Acceptance Questionnaire; MAAS: Mindful Attention Awareness Scale; HADS: Hospital Anxiety and Depression Scale; FIQ: Fibromyalgia Impact Questionnaire; PANAS: Positive and Negative Affect Scale.
All values are shown as Pearson correlation coefficient (Pearson's r). Significance level was set at *** *p*-values <0.001 in all the analysed variables.

Table IV. Multiple mediation analysis through mediator's acceptance (M1) and mindfulness (M2) between negative affect (Affect-X) and the dependent variables physical impact (FIQ-Y1), anxiety (Y2), depression (Y3), and emotional distress (Y4) in the study population.

	Point estimated	SE	95% CI (BCB)
Indirect effect affect - and FIQ			
Acceptance	0.309***	0.066	0.189-0.450
Mindfulness	0.158***	0.045	0.075-0.251
Total indirect effect	0.467***	0.079	0.323-0.637
Indirect effect affect - and anxiety			
Acceptance	0.039***	0.016	0.009-0.073
Mindfulness	0.080***	0.016	0.050-0.113
Total indirect effect	0.119***	0.020	0.080-0.160
Indirect effect affect - and depression			
Acceptance	0.118***	0.018	0.085-0.155
Mindfulness	0.059***	0.014	0.032-0.091
Total indirect effect	0.177***	0.021	0.137-0.222
Indirect effect affect - and distress			
Acceptance	0.157***	0.028	0.106-0.216
Mindfulness	0.139***	0.026	0.091-0.195
Total indirect effect	0.296***	0.035	0.230-0.370

CI: confidence interval; BCB: bias-corrected bootstrap; unless otherwise noted, bootstrap results are based on 5000 samples; SE: standard error.
Statistically significant level was set at ***p<0.001. The point estimate is defined as the indirect effect calculated from the original sample.

ness presented significant negative associations with anxiety, depression and negative affect (r= -0.591; r= -0.534; r= -0.463, respectively). The results showed that all the variables had significant positive and negative correlations (all p-values <0.01).

Mediation analysis

Using a Preacher and Hayes's computational software tool (SPSS MACRO), mediation analysis with more than a single mediator (in this study, a multiple mediation analysis) two hypotheses were proposed: 1) the effect of negative affect (X) on physical impact (Y1) is mediated by acceptance (M1) and mindfulness (M2); and 2) the effect of negative affect (X) on anxiety (Y2), depression (Y3), and distress (Y4) is mediated by acceptance (M1) and mindfulness (M2). Acceptance and mindfulness were proposed as potential mediators between negative affect and physical impact. These variables were scored positively, so the total effect of negative on physical impact was positive and different from zero (c= 0.9751, SE=0.0887, t=10.9935, p<0.001). Thus, negative affect was associated more positively with physical impact (Y1) (Table IV and Fig. 1). Negative affect predicted the putative mediator's acceptance ($a_{1=}$ -0.5276, SE=0.1435, t= -9.7009, p<0.001) and mindfulness ($a_{2=}$ -0.8898, SE=0.1111, t=-8.0091, p<0.001) (Fig. 1). Third, acceptance and mindfulness were significantly related to physical impact when controlling for negative affect (b_1= -0.2221, SE=0.0359, t= -6.1797, p<0.001; $b_{2=}$ -0.1781, SE= 0.0464, t= -3.8366, p<0.001; respectively).

This suggests that the relationship between the mediator's acceptance and mindfulness and the outcome physical impact was not spurious (since both were caused by negative affect) or epiphenomenal (*i.e.* when a predictor is correlated with an outcome only because it is correlated with another variable that is causally related to the outcome). Finally, the direct effect of negative affect on physical impact was smaller than the total effect (c'= 0.5075, SE= 0.0989, t= 5.1298, p<0.001) (Fig. 1). The indirect effects of acceptance and mindfulness on physical impact were significant (a_1b_1= 0.3091, SE= 0.0668 p<0.001; a_2b_2= 0.1584, SE= 0.0454; p<0.001). We found that the total indirect effect was 0.4676 (Table IV). The total effect of negative affect (X) on physical impact (Y1), path c, changed as a function of the nature and number of mediators (M1, M2), and so it remained at 0.5075 and statistically

different from zero. The total effect of negative affect on physical impact was significant (c=0.9751, SE=0.0887, $p<0.001$). Further, the direct effect of negative affect on physical impact became less significant (c'= 0.5075, SE= 0.0989, $p<0.001$). The acceptance and mindfulness explained 46.9% of variance in physical impact ($F=71.3452$, $p<0.001$).

Table IV and Figure 1 show that the total indirect effect and the specific indirect effects of acceptance and mindfulness were all significant. The confidence intervals indicate that acceptance had a greater indirect effect on physical impact than mindfulness. We determined whether acceptance (M1) and mindfulness (M2) mediated the effect of negative affect (X) on anxiety (Y2), depression (Y3) and emotional distress (Y4). The results for the mediation process, direct effect, indirect effect and total effect of the constructs analysed are shown (Table IV and Fig. 1-4).

The total effect of negative affect on anxiety (c=0.3811, SE=0.0258, t=14.7627, $p<0.001$), depression (c= 0.3281, SE=0.0263, t=12.4814, $p<0.001$), and distress (c=0.7092, SE=0.0435, t=16.3118, $p<0.001$) was positive and different from zero (Table IV). Thus, negative affect was positively associated with anxiety, depression and distress (Fig. 2-4). Finally, the direct effect of negative affect on anxiety was c'=0.2618, SE=0.0290, t=9.0312, $p<0.001$; on depression it was c'= 0.1506, SE=0.0268, t=5.6266, $p<0.001$, and on distress it was c'=0.4123, SE=0.0438, t=9.4051, $p<0.001$ (Fig. 2-4) and all smaller than the total effect. The indirect effects of acceptance and mindfulness on anxiety, depression and distress were significant ($p<0.001$). The total indirect effect on anxiety was 0.1193 (SE=0.0204); on depression it was 0.1776 (SE= 0.0216), and on distress it was 0.2969 (SE=0.0355) (Table IV). It explained 47.1% of the variance in anxiety ($F=217.9362$, $p<0.001$), 38.9% of variance in depression ($F=155.7861$, $p<0.001$) and 68.9% of variance in emotional distress ($F=179.4249$, $p<0.001$).

Figures 2-4 show parameter estimates for the total and specific indirect effects on the associations between negative affect and anxiety, depression and emotional distress as mediated by acceptance and mindfulness. Table IV indicates that acceptance had a more significant indirect effect on depression and distress than mindfulness (though the latter was also significant); however, mindfulness had a more significant indirect effect on anxiety than acceptance. Therefore, the hypotheses were accepted and acceptance and mindfulness mediated the relationship between negative affect and physical impact, anxiety/depression and distress.

Discussion

In this study, the relationships between clinical and psychological variables were examined in individuals with FM. Significant correlations were found between acceptance, mindfulness, anxiety/depression, distress and physical impact. In addition, negative affect was correlated with higher levels of emotional distress, anxiety/depression and functioning disability, a finding that is consistent with previous studies (39). This research presents new findings on the mediating effect of the psychological variable acceptance, mindfulness and negative affect on physical impact and emotional distress, since they contributed directly to the explanation of FM patients' health status.

Acceptance and mindfulness explained 46.9% of the variance between negative affect and physical impact among study participants. A possible explanation might be the joint contribution of a way of controlling and processing the experience of pain (acceptance) and the influence of the thoughts and emotional reactions (negative affect). In addition, given the negative relationship between acceptance and negative affect, it may be that people who accept and face painful sensations process and regulate emotions better, thus achieving a beneficial effect over the functional disability caused by the illness itself (40, 41).

Some studies have also shown that FM patients have serious difficulties with emotional attention, emotional clarity and emotional repair, and that these factors are associated with increases in anxiety/depression symptoms, anguish, and disability (42). This study underlines the significant differences regarding emotional regulation strategies between FM patients, patients with other chronic conditions and healthy population. Our results coincide with those of other studies that showed a relationship between an optimistic disposition towards activities (acceptance) and a greater resistance to the psychological or biological effects of emotional distress (43, 44). Pressman and Cohen's study (45) found that FM present negative relationships between pain and positive affect, and highlighted the role of emotions and positive affect in achieving physical and psychological wellbeing. In patients with chronic pain, high emotional attention, low emotional clarity and low tendency to regulate were associated with worse health status and greater perception of pain (46).

More specifically, some studies have also observed a relationship between chronic pain and positive and negative affect in patients with rheumatoid arthritis, reporting that the presence of positive affect reduced the size of the relationship between the pain reported daily by the patient and negative affect (47, 48). However, Vallejo *et al*. (49) proposed that accepting pain, discomfort, and one's limitations is not an end in itself but a starting point. All these studies represent important contributions and the interventions aimed at the expression of both positive and negative emotions and acceptance can help to improve the locus of control over pain and increase self-efficacy and coping in FM, with a positive effect on health-related quality of life and well-being (50).

The findings of our study are in line with approaches to manifestations of chronic pain and disability that do not seek to ignore, eliminate or control them. Interventions such as Acceptance and Commitment Therapies (ACT) have achieved very positive results in pathologies which present with chronic pain and in chronic disorders such as epilepsy, diabetes mellitus and major depression. Also, ACT programmes postulate that negative thoughts, emotions and feelings arise from the reaction or response of an organism to a specific context. This conceptualisation should not be understood as the

cause, but as a circular explanation of the health problem (21). The present study also explores whether the problem is the reaction of people with FM rather than the events themselves, and whether avoiding negative experiences only helps to maintain levels of anxiety/depression. According to Forman *et al*. (51), fighting tirelessly against unpleasant thoughts and emotions and thinking about them insistently actually contributes to their maintenance and involuntary reinforcement. Therefore, accepting negative emotional and affective states helps patients to cope more effectively with their functional status and disability (31, 52).

Acceptance and mindfulness explained 68.9% of the variance between negative affect and emotional distress, 47.1% of the variance between negative affect and anxiety, and 38.9% of the variance between negative affect and depression. These results confirmed the modulating role of the mediators in the relationship between negative affect and the distress and physical impact caused by the disease; they also showed the direct contribution of mindfulness to the explanation of these results through its mediation and its impact on the way the painful experience is processed.

This result coincides with the original theory of self-efficacy (53) with regard to its influence through thoughts and emotional reactions. The negative relationship between mindfulness and negative affect suggests that people with higher levels of mindfulness, who accept and do not judge their experience of pain, have less difficulty in managing and regulating their emotions and thus enjoy better health status.

Mindfulness interventions perform between than usual care in all medical diagnoses of chronic pain, but they are not necessarily superior to cognitive-behavioural therapy (CBT). Comparisons between mindfulness interventions are scarce; at present, stress reduction-based mindfulness is the therapy that has been studied the most in chronic pain management. More investigation is needed to differentiate between diagnoses and interventions and also to assess the differential efficacy between mindfulness-based interventions and CBT (54, 55).

These results may support the application of personalised interventions that focusing on increasing acceptance and mindfulness and encourage positive mental attitudes in order to experience the positive emotions of gratitude, love, or interest after a painful or traumatic event. Previous studies have suggested that ACT is a viable and accessible treatment, with an effectiveness apparently equivalent to that of traditional cognitive therapy (TCT). The mechanisms of the two approaches appear to differ. In the study by Forman *et al*. (51), in the TCT group, changes in "observing" and "describing" one's experiences seemed to mediate outcomes, whereas in the ACT group, "experiential avoidance", "acting with awareness", and "acceptance" had this mediating role in outcomes (51, 56). Mindfulness and ACT increases the experience of positive subjective experiences, enhances active coping and promotes physiological deactivation in the short term, and in the long term, it minimises the risk of depression and reinforces coping resources (27, 47, 55, 57).

The Tirado-Zafra *et al*. study (58) established predictive models for exploring the modulating effect of self-efficacy in the relationship between catastrophising and fear of pain on the one hand and physical and emotional impact on the other. It should be borne in mind that at the neurophysiological level processing is bottom up, with input of information from the sensory organs unfiltered by any previous experience; in contrast, the processing of the thalamus-cortical networks is top-down, creating predictions from incoming sensory stimuli and presenting a strong neuronal connection (59).

In this study, acceptance and mindfulness emerged as significant mediators of the ability of FM patients to maintain important goal-directed activity, and as useful predictors of the disease impact on this activity. Assessing negative affect and promoting more functional cognitions associated with disability and distress also proved important for mitigating negative emotional experiences. These results are in line with recent studies proposing the clinical use of strategies and interventions involving these psychological variables.

Strengths and limitations

This study may have theoretical implications, and also implications for clinical practice. It contributes to the literature on affect by proposing therapies and clinical assessment programmes as a way of controlling and processing the experience of chronic pain (pain acceptance) and the influence of thoughts and emotional reactions (negative affect). The improvements in the functional status of the FM patients point to the great potential and therapeutic value of operationalising the cognitive variables of mindfulness and acceptance. Increasing acceptance and full attention will not only produce benefits in different areas of the health status of FM, but will also favour a less emotive-affective processing of painful information. This is likely to have positive effects both on emotional distress and on the functional impact in FM.

In spite of the efforts made to ensure the study's validity and reliability, it still has certain limitations. First, it is limited by the cross-sectional and naturalistic design of a correlational nature. A longitudinal design would have been better suited to testing the mediating relationships and to check the mediating role of certain variables over others, and in turn to assess the effects on health outcomes in individuals with FM. The role new psychological variables which can explain the differences in physical impact, anxiety, and depression between FM patients and healthy controls might also be explored. More outcomes of health, affectivity and emotionality should be taken into consideration for a better understanding of the conceptualisation of FM and the functional disability it causes. The participants might have received other psychological or behavioural interventions and the selection of FM patients and the type of the assessments used might also have been improved: in this study, the variables were evaluated with self-report questionnaires.

Conclusions and future directions

This study has highlighted the usefulness of the relationship between nega-

tive affect and physical impact, anxiety/depression and emotional distress, and the assessment of the mediating role of these variables in the context of FM and chronic pain. Acceptance and mindfulness, both directly and in conjunction with negative affect, have explanatory validity in the area of functional disability in rheumatological disorders. They also have a mediating role in emotional distress in FM patients. More broadly, this study contributes to the discussion of the mediating role played by acceptance and mindfulness in physical and mental health from individuals with FM.

Our working group uses integrated multidisciplinary and multimodal strategies based not only on the biomedical aspects of chronic rheumatological disorders, but also, at the behavioural and affective level, on evaluation and treatment as part of a biopsychosocial model in fibromyalgia. Our recommendations consist of identifying treatments using these third-generation therapies based on acceptance and mindfulness and of transferring scientific evidence to daily clinical practice. To improve all aspects of FM a comprehensive multidisciplinary approach to pain management is necessary; however, in some cases, prioritising non-pharmacological treatments such as acceptance and commitment therapies and mindfulness has proven clinically effective and entails less risk than non-multidisciplinary treatment or usual care. In summary, these results call for a more holistic approach to chronic pain management among clinicians (rheumatologists) when treating FM patients.

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