

The efficacy of a brief acceptance-based group intervention in a sample of female patients with fibromyalgia and comorbid obesity: a randomised controlled trial

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Abstract Objective

A two-arm parallel randomised controlled trial was conducted to evaluate the efficacy of a group acceptance-based treatment (ABT) in improving pain acceptance, pain catastrophising, kinesiophobia, pain intensity and physical functioning compared to treatment as usual in patients with fibromyalgia (FM) and comorbid obesity.

Methods

Female individuals diagnosed with FM and obesity ($n = 180$) were randomly assigned to either a three-weekly group acceptance-based treatment plus treatment as usual (ABT+TAU) or only TAU. The variables of interest were assessed at baseline (T0) and after the interventions (T1). The treatment protocol for the ABT+TAU condition, designed for an inpatient rehabilitation context, is based on acceptance and commitment therapy but focuses specifically on pain acceptance, a crucial factor in fostering a more functional adaptation to chronic pain.

Results

Participants in the ABT+TAU group showed significant improvements in pain acceptance (i.e. the primary outcome), but also in pain catastrophising, kinesiophobia, and performance-based physical functioning (i.e. the secondary outcomes) compared to those in the TAU group. However, there were no significant differences in pain intensity between the two groups.

Conclusion

These findings indicate that a brief group-based ABT intervention is effective in enhancing pain acceptance, reducing pain catastrophising and kinesiophobia, and improving performance-based physical functioning. Furthermore, the observed improvements in kinesiophobia and physical functioning may have particular relevance for individuals with comorbid obesity, as they can facilitate greater adherence to physical activity and promote weight loss.

Key words

fibromyalgia, chronic pain, obesity, rehabilitation, acceptance and commitment therapy, pain acceptance, pain catastrophising, kinesiophobia, performance-based physical functioning, pain intensity

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Received on April 26, 2023; accepted in revised form on June 15, 2023.

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Introduction

Fibromyalgia (FM) is a chronic pain condition marked by chronic widespread pain, sleep disturbance, fatigue and psychological distress (1). Despite recent advancements in understanding physiological features (*e.g.* altered central pain processing (2) such as central sensitisation) and psychosocial components (3-5) the aetiology of FM is not completely understood. The global prevalence ranges from 0.2 to 6.6%, with a female predominance (6). FM severely impacts overall functioning and quality of life, affecting multiple facets of the individual's life: occupational, interpersonal and social (7-9).

Other chronic health conditions, such as obesity, frequently co-occur, thereby exacerbating the overall disease burden for both the individuals affected and their families (10-13). The prevalence of FM in individuals with obesity is alarmingly high, ranging from 37% to 51% (14). Patients with FM and obesity experienced greater pain severity and decreased physical functioning than their normal-weight counterparts (15, 16). Notably, these two conditions exacerbate each other, as the pain and fatigue associated with FM can lead to sedentary behaviour, physical inactivity, and weight gain. These factors further contribute to increased pain and disability, thus establishing and perpetuating a detrimental cycle (14, 17). Traditionally, pharmacological treatments of chronic pain have set the reduction of pain intensity as a primary goal (18). Several pharmacological options for pain relief are available, even if none of them are curative (19, 20). Current treatment guidelines for FM recommend multidisciplinary interventions that combine pharmacological treatment with complementary therapies. For example, the European League Against Rheumatism (EULAR) recommends non-pharmacological therapies as a first-line treatment (21) with the goal of enhancing quality of life and functional abilities, rather than solely focusing on pain reduction. Cognitive behavioural therapy (CBT) and mindfulness-based stress reduction have emerged as evidence-supported treatment options for FM (22-25).

This shift from pain reduction to improved functioning and quality of life is of utmost significance. Indeed, the idea of pain control or reduction harbours potential pitfalls, as it may encourage chronic pain sufferers to prioritise pain avoidance goals and behaviours. However, avoidance behaviours are a pivotal disabling factor and contributor to the self-perpetuating pain cycle (26, 27) as proposed by the Fear Avoidance Model (28). According to this model, several psychological factors such as pain catastrophising and kinesiophobia contribute to symptomatology and disability (29-34). These two constructs are central components of the Fear Avoidance Model (28, 35), which posits that pain catastrophising leads to the development of pain-related fear and kinesiophobia, resulting in the adoption of pain-avoidance behaviours that ultimately contribute to disuse and reduced physical functioning.

Specifically, pain catastrophising is defined as an excessive and negative cognitive-affective response to real or expected pain events (36, 37), characterised by magnification of pain threat, pain-related rumination, and helplessness. Kinesiophobia, on the other hand, is defined as an excessive, irrational, and debilitating fear of movement or physical activity (38, 39). Importantly, higher levels of catastrophising and kinesiophobia are associated with higher levels of pain intensity and greater disability in chronic pain and FM (30, 31, 40-42). For this reason, pain catastrophising and kinesiophobia are targets of CBT interventions that have been the psychological treatment of choice for chronic pain in recent decades (43-45). Recent developments in CBT, in particular acceptance and commitment therapy (ACT), emphasise the importance of acceptance-related processes in contrast to treatments that aim to reduce or control symptom severity (46, 47) and have proven effective in improving several health conditions (48-50), including chronic pain (51-53). ACT aims to improve functioning and quality of life by enhancing psychological flexibility defined as the ability to observe and accept aversive and interfering thoughts, emotions, and bodily

Funding: this research was funded by the Italian Ministry of Health.

Competing interests: none declared.

sensations without acting on them, and to facilitate behaviour in accordance with personal values and long-term goals in the presence of such negative experiences (54). Acceptance plays a crucial role in the psychological flexibility model (52, 55), which serves as the theoretical foundation of ACT. Pain acceptance is a subset of this broader psychological acceptance, and it is defined as the willingness to continue experiencing pain without attempting to reduce, avoid, or otherwise alter it (56). Pain is a warning signal, alerting us to potential damage in the body, and avoidance represents a necessary and functional response that promotes healing in cases of acute pain. Therefore, accepting pain may seem counterintuitive. However, when pain becomes chronic, a paradox arises, as pain is typically no longer an indicator of actual danger and avoidance loses its adaptive role, fuelling a path towards increased disability, pain severity, and depression (26, 57). On the contrary, pain acceptance is associated with decreased pain intensity, depression, and higher levels of physical functioning (29, 34) and psychological wellbeing (58, 59). This process has been extensively studied in chronic pain (55, 60-63) and (though to a lesser extent) FM (30, 33, 34), garnering interest and leading to the development of acceptance-based treatments that primarily target this aspect (51). However, a recent systematic review highlighted the paucity of studies evaluating the efficacy of this type of intervention in the specific population of patients with FM (24).

Also, although ACT has been extensively studied in the treatment of chronic pain, few studies have examined its effect on critical factors, such as pain catastrophising (41, 63-66) and kinesiophobia (40, 67), which are typically treated with CBT interventions and are not specific and distinct target of ACT or acceptance-based interventions. Thus, the purpose of this study was to compare the efficacy of a brief acceptance-based group treatment plus treatment as usual (ABT+TAU) to TAU alone in *i*) improving pain acceptance (*i.e.* primary outcome); *ii*) improving physical functioning; *iii*) reducing pain catastrophising,

iv) reducing kinesiophobia and *v*) reducing pain intensity (*i.e.* secondary outcomes) in patients diagnosed with FM and comorbid obesity.

Materials and methods

A two-arm parallel randomised controlled trial was conducted. Patients were recruited from the Osteoarticular Recovery and Rehabilitation Department of the IRCCS Istituto Auxologico Italiano in Piancavallo (Italy), a tertiary care institution specialised in the treatment of obesity and its associated comorbidities. The Osteoarticular Recovery and Rehabilitation Department admits patients with obesity, chronic pain, and post-surgical pain conditions. Patients undergo a 4-week residential multidisciplinary rehabilitation programme that is administered independently from this study and includes a nutritional intervention for weight loss, physiotherapy, and adapted physical activity for weight loss and pain management. The recruitment started in January 2019 and ended in January 2020.

Inclusion and exclusion criteria

Patients were eligible if they (*i*) were aged between 18 and 65 years; (*ii*) had FM diagnosed by a rheumatologist according to the criteria of the American College of Rheumatology; (*iii*) had FM diagnosed for more than one year; (*iv*) met the FM research criteria measured with the Fibromyalgia Survey Questionnaire (68, 69). Participants were excluded if they had: (*i*) severe psychiatric conditions, (*ii*) surgical intervention (*e.g.* arthroplasty) in the previous 12 months, (*iii*) modification of the usual pharmacological treatment in the previous 6 months, (*iv*) previous or current psychotherapy interventions. All eligible patients received a one-hour patient education session with information about the study. Then, recruited patients provided written informed consent.

The recruited patients completed the measures during the first days of hospitalisation devoted to assessment prior to the beginning of rehabilitative intervention (pre-treatment, T0). Participants completed all self-report measures under the supervision of a

registered psychologist and researcher who clarified any questions regarding the questionnaires and ensured that all responses were present. In addition, participants completed a physical test (*i.e.* six-minute walking test) during in-person sessions with a licensed physiotherapist at the same two timepoints as the self-report questionnaires.

Patients were randomly allocated to either the acceptance-based treatment condition plus TAU (ABT+TAU) or TAU condition. Randomisation with a 1:1 allocation ratio was performed using the Web site Randomization.com [<http://www.randomization.com>]. Concealed allocation was arranged by independent collaborators not involved in patient enrolment, with a numbered sequence of opaque, sealed envelopes containing the allocation code. The list remained inaccessible and the envelopes were opened sequentially after enrolling the patient and obtaining consent. Participants and the psychologists administering interventions could not be blinded. However, both the research collaborators who conducted the assessment of outcomes (*i.e.* a licensed psychologist and physiotherapist) and the statistician who analysed the data were blinded to group assignment.

Patients in the ABT+TAU group attended three weekly group sessions (*i.e.* 60 min of duration) of an acceptance-based treatment plus TAU, whereas patients in the TAU group received one psychological support session per week (*i.e.* 60 min of duration, total of 3 sessions). The primary and secondary outcomes were assessed at two time points: before the intervention (T0) and four weeks later (T1) at discharge. The study procedure is summarised in Table I, presenting the time schedule.

The study was conducted according to the guidelines of the Declaration of Helsinki of 1975, as revised in 1983, and approved by the Ethics Committee of Istituto Auxologico Italiano (V.0.4 30-05-2017).

Description of the intervention

Multidisciplinary Rehabilitation programme (TAU). Throughout the 3-week hospitalisation, the multidisciplinary rehabilitation programme in-

Table I. Time schedule of enrolment, interventions, and assessments for participants.

	Pre-intervention 1 st week	Intervention 2 nd , 3 rd , 4 th week	Post-Intervention 4 th week
Screen for eligibility	X		
Acquisition of informed consent	X		
Allocation	X		
Data collection (T0)	X		
Intervention: ABT+TAU vs. TAU		X	
Data collection (T1)			X

ABT: acceptance-based treatment; TAU: treatment as usual.

cluded individual nutritional intervention, individual psychological counseling, supervised physical activity and physiotherapy. A balanced hypocaloric diet was provided to all patients, consisting of 18-20% protein, 27-30% fats (8% saturated fat), 50-55% carbohydrates (15% simple sugars), and 30 grams of vegetable fibre. The nutritional plan comprised three meals (breakfast, lunch, and dinner) with energy distribution of 20%, 40%, and 40% respectively. Under the supervision of a physiotherapist, patients engaged in two 60-minute physiotherapy sessions per day. These sessions were tailored to each individual and involved progressive aerobic training, postural control, and strengthening exercises. Acceptance-based treatment + treatment as usual (ABT+TAU). Patients in this condition received individual nutritional intervention, supervised physical activity and physiotherapy as participants allocated to TAU. However, instead of an individual psychological support session, participants received acceptance-based treatment. This intervention consisted of three 60-minute weekly group sessions with ten participants per group conducted in a multimedia-equipped classroom. Two psychologists (G.V. and R.C.) with training in ACT administered the acceptance-based treatment. The intervention adhered to a protocol developed by the authors (G.V. and R.C.) based on previous evidence (70, 71). To ensure adherence to the treatment protocol, the two psychologists (G.V. and R.C.) received one hour of weekly group supervision led by a senior author (G.C.). The intervention centred on the limitations of efforts to control or eliminate pain. It aimed to redirect expectations

and treatment goals from pain elimination to living a more fulfilling life with chronic pain. Acceptance was emphasised as a more flexible response in relation to pain and patients were encouraged to be open to experiencing pain and associated emotional distress in a centred, mindful manner, while choosing to act in accordance with their personal values. Examples, experiential exercises and metaphors were frequently used to clarify fundamental components such as experiential avoidance and acceptance. Participants practiced acceptance enhancing exercises in-session and completed homework assignments between sessions. Materials and resources used during sessions and for homework included Power Point presentations, videos, booklets and worksheets. The complete protocol is available from the first author.

Measures

Participants completed a self-report form with sociodemographic information including age, weight (in kilograms), height (in centimetres) that were used to calculate the Body Mass Index (BMI; kg/m²), and pain duration (in years). Outcomes were assessed before the intervention (T0) and four weeks later (T1) at the end of the study protocol.

Primary outcome measures

Pain acceptance. Levels of pain acceptance were evaluated using the Chronic Pain Acceptance Questionnaire (CPAQ) (56). The CPAQ is a self-report measure comprised of 20 items rated on a 7-point Likert scale (0 = “never true” to 6 = “always true”). The total score ranges from 0 to 120, with higher scores indicating higher levels

of pain acceptance. The Italian version of the CPAQ has good psychometric properties in line with the original version (72). The internal consistency of the CPAQ was good in the current study (Cronbach’s $\alpha = 0.85$).

Secondary outcomes measures

Pain catastrophising. Pain catastrophising was measured through the Pain Catastrophising Scale (PCS) which includes 13 items scored on a five-point Likert scale (0 = “not at all” to 4 = “all the time”) (36). The total score ranges from 0 to 52, with higher scores reflecting higher levels of pain catastrophising. The Italian version used in this study has psychometric properties comparable to the seminal version (73). In the present study internal consistency was excellent (Cronbach’s $\alpha = 0.87$).

Kinesiophobia. Kinesiophobia was assessed using the Tampa Scale of Kinesiophobia (TSK) which consists of 13 items rated on a 4-point Likert scale (0 = “strongly disagree” to 4 = “strongly agree”) (38). Higher total scores (which can range from 13 to 52) indicate higher levels of kinesiophobia. The Italian version of the TSK shows a good factorial structure and acceptable psychometric properties (74). In the current study, the internal consistency of this measure was excellent (Cronbach’s $\alpha = 0.84$).

Pain intensity. Levels of perceived pain intensity were measured using the Numeric Pain Rating Scale (NPRS) (75). This is a widely accepted and validated method of measuring the severity of chronic pain. The scale has 11 points, with 0 denoting “no pain” and 10 denoting the “worst possible pain.”

Performance-based physical functioning. The 6-minute walking test (6MWT) is a performance-based measure of physical functioning widely used in chronic pain research (76). The participant must walk for six minutes as fast as possible over a rectangular course of 45.7 metres. The distance walked is measured in meters and better physical functioning is reflected by higher scores.

Statistical analysis

The sample size calculation was per-

formed a priori in order to determine the number of participants required to detect small effect size (0.10) differences between the two treatment arms, with an alpha significance level of 0.05 and a power of 0.80. The recruitment goal was set at 200 participants. The distribution of the data was assessed using the Shapiro-Wilk test and visual inspection. Descriptive statistics, including ranges, means, and standard deviations were performed. Independent t-test were performed to evaluate the differences between groups at baseline. A two-way mixed ANOVA was performed to examine the effects of the two conditions (ABT+TAU vs. TAU) on the outcomes at two time points (two groups x two times). Effect size measures as partial eta squared (η_p^2) was interpreted based on the following thresholds: $\eta_p^2 = 0.01$ indicates a small effect. $\eta_p^2 = 0.06$ indicates a medium effect. $\eta_p^2 = 0.14$ indicates a large effect. Significance levels were set at $p > 0.05$. All statistical analyses were performed using SPSS version 26. Figure 1 summarises the study flow-chart.

Results

Descriptive analysis and t-test results

Even though the calculated sample size was 200, data collection was halted at the end of January 2020 due to the COVID-19 pandemic. Thus, a total of 180 patients were recruited; 90 were assigned to the ABT+TAU group and 90 to the TAU group. A series of independent t-tests were conducted to determine whether there were differences between the groups in the variables. There were no differences in age, BMI, or the other variables of interest. T-tests results, and descriptive statistics are summarised in Table III.

Two-way mixed ANOVA results

A series of two-way mixed ANOVAs were performed to analyse the effect of the interaction between group (ABT+TAU vs. TAU) and time (T0 vs. T1) on pain acceptance, pain catastrophising, kinesiophobia, pain intensity and performance-based physical functioning. A two-way mixed ANOVA revealed that there was a statistically sig-

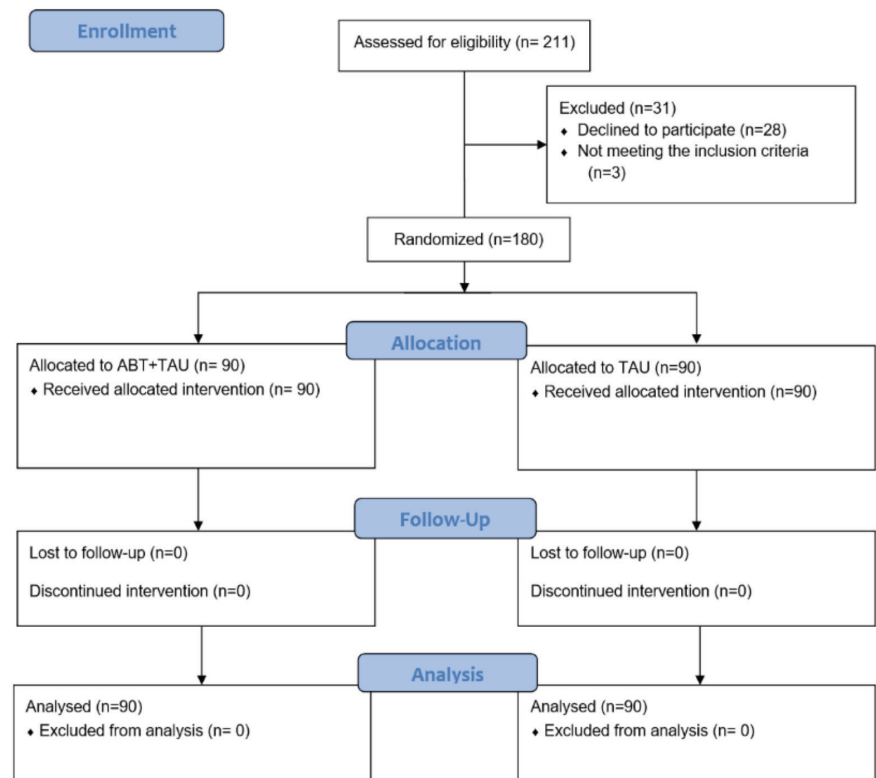


Fig. 1. Study flow-chart.

Table II. Results of the t-test, relative means, and standard deviation for variables measured in the TAU and ABT+TAU groups.

Variable	TAU Mean ± SD	ABT+TAU Mean ± SD	t(178)	p
Age	44.68 ± 6.83	45.16 ± 6.36	-0.49	0.628
BMI	39.82 ± 5.47	40.31 ± 5.57	-0.59	0.553
Pain acceptance	46.97 ± 16.30	50.79 ± 13.96	-1.69	0.093
Pain catastrophising	26.18 ± 14.07	28.43 ± 8.15	-1.17	0.244
Kinesiophobia	27.99 ± 13.81	30.93 ± 8.15	-1.74	0.083
Pain intensity	4.41 ± 1.18	4.91 ± 1.87	-1.83	0.070
Physical functioning	277.54 ± 34.19	276.86 ± 30.56	0.14	0.887

TAU: treatment as usual; ABT: acceptance-based treatment; BMI: body mass index.

nificant interaction between the group and time on pain acceptance $F(1, 178) = 184.25, p < 0.001, \eta_p^2 = 0.52$; pain catastrophising $F(1, 178) = 12.29, p < 0.005, \eta_p^2 = 0.07$; kinesiophobia, $F(1, 178) = 18.12, p < 0.001, \eta_p^2 = 0.09$; and performance-based physical functioning $F(1, 178) = 44.93, p < 0.001, \eta_p^2 = 0.20$. The main effects and interaction effects are shown in Table III with the means and standard deviations of each group at T0 and T1. On the other hand, the interaction between the effects of group and time on pain intensity was not statistically significant ($F(1, 178) = 3.05, p = 0.082$).

Discussion

Although several studies have confirmed the efficacy of ACT in heterogeneous samples of chronic pain patients (52, 70, 77, 78), far fewer studies have been conducted specifically on FM, and none on patients with FM and comorbid obesity. This is the first evaluation of a brief acceptance-based group intervention (ABT+TAU) for patients with FM and comorbid obesity compared to treatment as usual (TAU). As expected, the ABT significantly improved pain acceptance compared to TAU. Also, improvements were highlighted in pain catastrophising, kinesiophobia, and

Table III. Results of the two-way mixed ANOVA.

Variable	Group	T0 Mean \pm SD	T1 Mean \pm SD	Main effect Time			Main effect Group			Interaction Time x Group		
				F(1,178)	p	η_p^2	F(1,178)	p	η_p^2	F(1,178)	p	η_p^2
Pain acceptance	ABT+TAU	50.79 \pm 13.96	75.11 \pm 14.02	112.84	<0.001	0.39	64.54	<0.001	0.27	184.25	<0.001	0.52
	TAU	46.97 \pm 16.30	44.00 \pm 19.38									
Pain catastrophising	ABT+TAU	28.43 \pm 8.15	19.79 \pm 12.54	9.21	0.003	0.05	2.61	0.108	0.01	12.29	<0.001	0.07
	TAU	26.18 \pm 14.07	26.80 \pm 14.56									
Kinesiophobia	ABT+TAU	30.93 \pm 8.15	17.17 \pm 3.86	41.77	<0.001	0.19	4.28	0.040	0.02	18.12	<0.001	0.09
	TAU	27.99 \pm 13.81	25.16 \pm 10.13									
Pain intensity	ABT+TAU	4.91 \pm 1.87	3.60 \pm 2.48	44.48	<0.001	0.20	0.68	0.412	<0.01	3.05	0.820	0.02
	TAU	4.41 \pm 1.18	3.64 \pm 2.30									
Physical functioning	ABT+TAU	276.86 \pm 30.56	350.78 \pm 31.56	127.61	<0.001	0.42	39.71	<0.001	0.18	44.93	<0.001	0.20
	TAU	277.54 \pm 34.19	296.41 \pm 56.59									

TAU: treatment as usual; ABT: acceptance-based treatment.

performance-based physical functioning. Intriguingly, the ABT+TAU group did not improve significantly in pain intensity compared to the TAU group, indicating that changes in the psychological factors examined (*i.e.* pain acceptance, pain catastrophising, and kinesiophobia) and performance-based physical functioning were achieved without significant changes in the primary symptom of FM, *i.e.* pain.

These results are consistent with previous evidence of ACT in chronic pain and FM. Specifically, Simister *et al.* found that participants diagnosed with FM who received an online ACT intervention had significantly higher levels of pain acceptance and significantly lower levels of kinesiophobia than those who received TAU, in line with our results (79). However, the intervention proposed in this study had different characteristics. It was delivered online and in an individual format. Also, participants were required to complete seven intervention modules over the course of approximately two months. Our findings confirm the efficacy of a shorter protocol delivered in groups and based on a single process (*i.e.* acceptance) in patients with FM and obesity, extending these previous results. Furthermore, in the study conducted by Simister *et al.*, the TAU condition was not an active control condition, as patients were required to continue their treatment regimen under the supervision of their general practitioners or specialists. Instead, in our work, the control condition was an active intervention that included

adapted physical activity and physical therapy which are known effective non-pharmacological therapy for chronic pain and FM (21, 80).

According to our results, the ABT also promoted a reduction in the level of pain catastrophising, consistent with previous studies on chronic pain patients (77, 78, 81). Notwithstanding, our results are not in line with those of Simister *et al.* on patients with FM, who did not find an improvement in pain catastrophising levels (79). This different result may be due to the combined effect of acceptance-based treatment and TAU intervention. Acceptance-based treatment in conjunction with physiotherapy and adapted physical activity, may have facilitated the correction of erroneous pain expectations, thereby reducing levels of catastrophising. This hypothesis is supported by a recent study that found that a low-intensity physical exercise programme, that included endurance training and coordination, reduced pain catastrophising levels in patients with FM (82).

Several studies have highlighted improvements in physical functioning after ACT interventions in chronic pain patients (49, 71, 83, 84). However, the majority have measured physical functioning using disability self-report questionnaires. In Simister's study, the authors assess the effect of ACT intervention on physical functioning as measured by the 6MWT, as in our study. However, according to their findings, there was no significant improvement. This difference may be

attributable to the fact that in our intervention, in addition to ABT, patients also participated in physiotherapy and adapted physical activity and that the combined effects of the two interventions may have been mutually reinforcing. For instance, by enhancing pain acceptance, adherence and compliance to physiotherapy and physical activity may have increased, resulting in improved performance-based physical functioning.

Notably, these improvements occurred in the absence of a significant improvement in perceived pain intensity in the ABT+TAU group compared to TAU group. This is not surprising since reducing symptoms (*i.e.* pain in this context) is not among the goals of our intervention. Indeed, ACT and acceptance-based interventions aim to promote greater acceptance of pain rather than a reduction in the pain *per se*. Specifically, acceptance-based treatments and ACT interventions aim to change the context in which pain occurs from non-accepting to accepting, thereby altering the stimulus functions of pain. Thus, our results might suggest that even without significant alterations in pain intensity level, the patient could learn to experience pain more flexibly, resulting in more functional cognitive, emotional, and behavioural responses. In the context of comorbid obesity, an improvement in pain catastrophising, kinesiophobia and physical functioning could encourage a more active lifestyle and greater adherence to physical activity recommendations, which would

positively impact weight loss. Interestingly, there is some evidence that short-term ACT interventions have a positive effect on body weight reduction. In a study conducted by Lillis *et al.* (85), for instance, patients who had completed at least 6 months of a weight loss programme participated in a one-day ACT workshop with the aim of increasing psychological flexibility. At three months, participants in the ACT group lost an additional 1.6% of their body weight compared to those in the control group. Future studies with long term follow-up should evaluate the effect of ACT-based interventions for chronic pain on weight reduction in individuals with comorbid obesity. Interestingly, despite the fact that intervention focused on a specific process (*i.e.* acceptance) of the psychological flexibility model, which is distinct though related to the others, positive results were obtained not only on acceptance, but also on factors such as pain catastrophising and kinesiophobia. These factors were not specifically addressed and are usually targets of standard CBT interventions. The choice to focus on a single process may seem controversial, but it appears consistent with different perspectives. First, at the clinical level, pain acceptance is considered one of the main processes/variables relevant to individuals with chronic pain and FM (29, 30, 33, 34, 86, 87). At the methodological level, existing measures of processes of psychological flexibility (*e.g.* defusion, mindfulness) when the study started showed high correlation, increasing the difficulty in discriminating and identifying distinct processes. Nevertheless, the Multidimensional Psychological Flexibility Inventory is a new promising measure assessing all processes of psychological flexibility and inflexibility and has shown great psychometric properties in people with chronic pain (13, 88). Future studies might examine the impact of the intervention using this measure in order to obtain a better understanding of the unique influence on outcomes and psychological variables. Also, an approach focused on a specific process is consistent with the recent Process-Based literature. In this

sense, it is possible to verify potential overlaps with other variables and processes traditionally connected with the clinical outcomes of FM.

Finally, especially in stigmatised conditions, such as FM and obesity (89, 90), the group format provide additional benefits, including diminished stigma and higher acceptance of feedback from peers as opposed to professionals. Several limitations must be discussed. First, the results only apply to female patients with FM and obesity, so they cannot be extended to populations with different characteristics. In addition, the patients were recruited from a tertiary treatment centre, which limits the generalisability of the findings. The lack of mid- and long-term follow-up prevents us from assessing the intervention's long-term effects.

Conclusions

This is the first study that evaluates the efficacy of brief acceptance-based group intervention for patients with FM and comorbid obesity compared to treatment as usual (TAU). Patients assigned to the acceptance-based treatment (ABT+TAU) reported statistically significant improvements in pain acceptance, kinesiophobia, pain catastrophising, and performance-based physical functioning compared to those assigned to the TAU condition. Notably, these improvements occurred despite the absence of a significant reduction in pain intensity in the ABT+TAU group compared to TAU. The intervention focused specifically on acceptance as a component of the psychological flexibility model. However, not only acceptance but also pain catastrophising and kinesiophobia improved, despite the fact that these psychological factors were not specifically targeted and are typically the focus of standard CBT intervention.

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