EFFICACY OF ACCEPTANCE AND COMMITMENT THERAPY FOCUSED ON REPETITIVE NEGATIVE THINKING IN FIBROMYALGIA: A RANDOMIZED MULTIPLE-BASELINE DESIGN

EFICACIA DE LA TERAPIA DE ACEPTACIÓN Y COMPROMISO CENTRADA EN PENSAMIENTO NEGATIVO REPETITIVO EN FIBROMIALGIA: UN DISEÑO DE LÍNEA BASE MÚLTIPLE ALEATORIZADO

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Abstract

Repetitive negative thinking (RNT), in the form of worry and rumination, is a factor that can have a negative impact on the quality of life and symptomatology of patients with fibromyalgia (FM). The present study analyzes the efficacy of a brief Acceptance and Commitment Therapy (ACT) protocol focused on reducing RNT in four women diagnosed with FM. A randomized, multiple-baseline design across participants was conducted. Participants completed 4-6 weeks of baseline and subsequently received a 4-session individual intervention. The effect of the intervention was assessed by conducting follow-ups for up to 3 months. All four participants showed clinically significant changes in emotional symptoms as measured by the Depression Anxiety and Stress Scale – 21 (DASS-21¸ S. H. Lovibond y P. F. Lovibond, 1995) and the General Health Questionnaire – 12 (Ruiz et al., 2017a). Likewise, participants showed significant improvements in parameters related to sleep quality and improvements in health-related quality of life. As for process measures, all participants showed clinically significant changes in pathological worry, and three of them also in cognitive fusion. Changes in valued actions were more modest. Effect sizes comparable across designs were very large and statistically significant for DASS-Total (d = 1.51), DASS-Depression (d = 1.83), pathological worry (d = 1.79), and cognitive fusion (d = 1.99). These results suggest that brief RNT-focused ACT interventions hold promise for intervention in patients with FM.

Keywords*: fibromyalgia, acceptance and commitment therapy, repetitive negative thinking, worry, emotional symptomatology*

Resumen

El pensamiento negativo repetitivo (PNR), en la forma de rumia y preocupación, es un factor que puede generar un impacto negativo sobre la calidad de vida y sintomatología de los pacientes con fibromialgia (FM). El presente estudio analiza la eficacia de un protocolo breve de la Terapia de Aceptación y Compromiso (ACT) centrado en reducir PNR en cuatro mujeres con diagnóstico de FM. Se llevó a cabo un diseño de línea de base múltiple entre participantes aleatorizado. Las participantes completaron entre 4 y 6 semanas de línea base y, posteriormente, recibieron una intervención individual de 4 sesiones. El efecto de la intervención se evaluó realizando seguimientos hasta los 3 meses. Las cuatro participantes mostraron cambios clínicamente significativos en síntomas emocionales medidos a través del Depression Anxiety and Stress Scale – 21 (DASS-21¸ S. H. Lovibond y P. F. Lovibond, 1995) y el General Health Questionnaire – 12 (Ruiz et al., 2017a). Asimismo, las participantes mostraron mejoras significativas en parámetros relacionados con la calidad del sueño y mejoras en calidad de vida relacionada con la salud. En cuanto a las medidas de proceso, todas las participantes mostraron cambios clínicamente significativos en preocupación patológica y tres de ellas también en fusión cognitiva. Los cambios en acciones valiosas fueron más modestos. Los tamaños del efecto comparables a través de diseños fueron muy grandes y estadísticamente significativos para DASS-Total (d = 1.51), DASS-Depresión (d = 1.83), preocupación patológica (d = 1.79) y fusión cognitiva (d = 1.99). Estos resultados sugieren que intervenciones breves de ACT centradas en PNR son prometedoras para la intervención en pacientes con FM.

Palabras clave*: fibromialgia, terapia de aceptación y compromiso, pensamiento negativo repetitivo, preocupación, sintomatología emocional*

Fibromyalgia (FM) is a medical condition of unknown origin characterized by chronic and generalized musculoskeletal pain, usually accompanied by stiffness, fatigue, and sleep disturbances (Bair & Krebs, 2020). FM has a prevalence of 2.10% of the world population (Cabo-Meseguer et al., 2017) and occurs more frequently in women, with a prevalence 4 to 7 times higher than that presented in males, and with no differences between the different existing ethnic groups. Most FM diagnoses are established for women between 35 and 60 years of age (Cardona-Arias et al., 2012).

Patients with FM experience a higher pain intensity than other rheumatologic diseases. Additionally, FM is considered the rheumatologic disease with the most significant impact on quality of life in terms of social, family, intellectual, and health impact (Bair & Krebs, 2020). Indeed, a frequent comorbid feature in FM patients is psychological symptoms such as anxiety and depression, being the rheumatologic disease with the highest prevalence in both cases (Cabo-Meseguer et al., 2017). Patients with FM also frequently experience sleep disturbances (Bair & Krebs, 2020), which is also a risk factor for FM development (Hamilton et al., 2012; Skarpsno et al., 2019). In economic terms, FM involves a very high cost in developed countries, reaching approximately 1% of the gross domestic product in countries such as Spain (Cabo-Meseguer et al., 2017).

The goal of the treatment of FM should be improving physical function and quality of life because this syndrome is considered a chronic condition. According to recent treatment guidelines, active nonpharmacologic therapies are the mainstay for the treatment of FM (Macfarlane et al., 2017). The treatment should include supervised and graded aerobic exercises programs and cognitive-behavioral therapy (CBT) when emotional symptoms and sleep disturbances are present. Medications are frequently used but only show modest benefits and are associated with adverse effects (Bair & Krebs, 2020).

CBT interventions have been the most widely used psychological treatment for FM. Most CBT interventions evaluated have been relatively long and applied in groups (Bennett & Nelson, 2006). These interventions have shown small-to-medium effect sizes in reducing pain, emotional symptoms, sleep problems, and disability (Glombiewski et al., 2010; Theadom et al., 2015). Although these results are modest, CBT is considered to be safer and more cost-effective than medications (Bair & Krebs, 2020).

Mindfulness- and acceptance-based interventions have been increasingly tested in the last years in the treatment of FM. Haugmark et al. (2019) found that these therapies obtained small to moderate effect sizes in reducing pain, emotional symptoms and improving sleep quality. Among these intervention approaches, acceptance and commitment therapy (ACT; Hayes et al., 1999) showed the most promising results, although the number of studies included in this meta-analysis was small (Luciano et al., 2014; Simister et al., 2018).

In a more recent meta-analysis, Du et al. (2021) found three randomized clinical

trials that evaluated the effect of ACT in FM with moderate quality of evidence. The weighted effect size on the Fibromyalgia Impact Questionnaire (FIQ) was large. According to the systematic review conducted by Gálvez-Sánchez et al. (2021), most of the studies have evaluated group ACT interventions with a range of 8 to 12 sessions and a total duration of 18 to 27 hours. Only two studies evaluated the efficacy of individual ACT interventions. The shorter intervention assessed was an individual, 5-session ACT protocol, which was tested in Gómez-Pérez et al. (2020).

Testing brief psychological interventions for FM is essential because they can increase the patients' adherence, reduce the treatment burden usually observed in this condition, and minimize the treatment cost (Gómez-Pérez et al., 2020). To advance in this direction, it is crucial to consider psychological processes that might exert a particular influence on this syndrome. For example, one characteristic frequently observed in FM patients is repetitive negative thinking (RNT) in the form of worry and rumination (e.g., Catala et al., 2021; Malin & Littlejohn, 2015; Ricci et al., 2016). FM patients usually engage in RNT regarding their pain or other vital aspects. Sustained RNT usually lead to the amplification of negative affect and tension, which usually lead to other forms of experiential avoidance strategies (Ruiz et al., 2016). Accordingly, RNT can be considered a variable of special clinical interest in the treatment of FM.

Following this rationale, brief RNT-focused ACT interventions might be well-suited to be tested in the treatment of FM. Indeed, brief RNT-focused ACT interventions have been recently tested for the treatment of emotional disorders (Ruiz et al., 2016, 2018a, 2019, 2020a, 2020b). These studies have found very large effect sizes in reducing emotional symptoms and RNT. Given these results, the current study preliminarily tested the effect of a brief, individual, 4-session, RNT-focused ACT protocol in FM patients.

Method

Participants

The sample was recruited through advertisements on social networks. The inclusion criteria were the following: (a) medical certificate on the existence of fibromyalgia diagnosis of at least six months provided by a specialist, (b) being between the age range of 35 and 60 years, (c) obtaining scores of 15 or higher on the General Health Questionnaire – 12, (d) scores above 25 on the Depression Anxiety and Stress Scale-21, (e) stable adherence of two or more months to on-going pharmacological treatment (if any) and perception of no improvement on symptoms of FM syndrome, (f) commitment not to initiate psychological treatment during the investigation, and (g) stable adherence of two or more months to any alternative treatment (acupuncture, yoga, hydrotherapy, etc.) and no improvement in symptoms of FM syndrome. Exclusion criteria were as follows: (a) presenting high suicidal risk, psychotic disorder, or abuse of psychoactive substances other

than analgesics, (b) receiving some type of psychological intervention, (c) not presenting significant improvement trends at baseline. The latter occurred with one participant who was excluded from the study since it could not be stated that the improvement was due to the introduction of the intervention. Nevertheless, she was provided with psychological intervention for ethical reasons.

Four participants met the inclusion criteria. All of them had a diagnosis of FM granted by a physician specializing in rheumatology. Their ages ranged from 39 to 55 years. Three of them were single, and one was married. All had technical/professional education and were residents of Bogotá. Table 1 presents the socio-demographic data of the participants, as well as the hierarchical triggers of worry/rumination, experiential avoidance strategies, and medical treatments received.

Table 1

Sociodemographic Data, Hierarchical Triggers for Worry/Rumination, Experiential Avoidance Strategies, and Treatments Received

	Age	Educational level	Profession	Hierarchical trigger for RNT	Experiential avoidance strategies	Medications	Other treatments
P1	53	Graduate	Housewife	Fear of loneliness	Worry, rumination, sleeping, watching TV at late night, housekeeping	Tramadol drops (10 years) Escitalopram (1 year)	NO
P2	55	Technician	Housewife	Fear of loneliness	Worry, rumination, sleeping, watching documentaries at night	Duloxetine (3 years) Acetamino-phen + codeine (4 years)	NO
P3	39	Graduate	Teacher	Fear of failure	Worry, rumination, reviewing the cell phone	NO	Physio-therapy (6 years)
P4	54	Graduate	Cabin crew	Fear of failure	Worry, rumination, writing, tourism, housekeeping, walking, weaving	Devil's claw (7-8 years) Homeopathy (20 years)	Swimming (2 years)

Design

A nonconcurrent, randomized, across participant, multiple-baseline design was used. Participants were randomized to the intervention phase between the third and sixth week of baseline collection. The independent variable was a brief protocol of four 60-min ACT sessions focused on RNT (see Table 2 for a summary of the protocol). Dependent variables were divided into outcome and process measures. Outcome variables were emotional symptomatology, sleep quality, and quality of life measures. Process variables were pathological preoccupation, cognitive fusion, and valued actions.

Table 2
Contents of the RNT-focused Protocol

Session 1	➢ Introduction of the intervention rationale.
	➢ Functional analysis of the psychological inflexibility pattern with central focus on worry/rumination: identification of hierarchical triggers, main contents of the repetitive thought chain, additional experiential avoidance strategies.
	➢ Identification and amplification of the consequences of the inflexible pattern and opening of a flexible alternative. Physical metaphor of pushing worry/ rumination triggers.
	➢ Discrimination training of the process of worry/rumination and its contents, contact with its consequences, and training in distancing from the triggers. Physical metaphor of circling the chair.
	➢ Audio 1. Exercise aimed at developing the skill to differentiate between engaging in RNT or taking distance from triggers while choosing to act in a valued direction.
Session 2	➢ Review of progress and difficulties experienced since Session 1.
	➢ Training in multiple examples in distancing from worry/ rumination triggers: (a) Putting zoom to thoughts exercise, (b) Free association exercise, (c) Conscious fantasizing and worrying exercise, and (e) "I can't possibly..." exercise
	➢ Audio 2. Exercise of observing thoughts in balloons from a hierarchical perspective.
Session 3	➢ Review of progress and difficulties experienced since Session 2.
	➢ Observer exercise (modified to identify triggers of worry/rumination and contact with values).
	➢ Clarification of values and identification of valued actions. Garden metaphor.
	➢ Audio 3. Life movie exercise (contact with values and adversities).
Session 4	➢ Review of progress and difficulties experienced since Session 3.
	➢ General review of the work done in the intervention.
	➢ Exploration of the consequences of monitoring physical sensations as habitual behavior. Experiential exercise of monitoring vs. not monitoring.
	➢ Identification of valued actions.
	➢ Closing of the intervention.

Outcome Measures

Depression, Anxiety and Stress Scale - 21 (DASS-21; Ruiz et al., 2017b). The DASS-21 is a scale that measures the main emotional symptoms: depression, anxiety, and stress. It consists of 21 items describing negative emotional states rated on a four-point Likert-type scale (3 = *it has happened to me a lot, or most of the time*; 0 = *it has not happened to me*).

General Health Questionnaire - 12 (GHQ-12; Ruiz et., 2017a). The GHQ-12 is a self-report that measures mental health status in recent weeks. The scale consists of 12 items answered on a Likert-type scale (0-1-2-3) and has six items in the positive direction and six in the negative direction. Scores equal to or greater than 12 indicate the possibility of experiencing an emotional disorder.

36-Item Short Form Survey (SF-36; García et al., 2014). The SF-36 is a questionnaire that measures the quality of life in relation to health. It is applicable to patients with different medical conditions and to the general population. This scale consists of 36 items that measure both positive and negative health states. The instrument contains eight subscales: Physical Function, Physical Role, Body Pain, General Health, Vitality, Social Function, Emotional Role, and Mental Health.

Sleep quality report. Four questions were used to measure sleep parameters: sleep latency, maintenance, degree of rest the following day, and sleep quality. The question on sleep latency was, "In general, during the last week, how long did it take you to fall asleep?" The response options were (a) It took me no time at all to fall asleep (less than half an hour), (b) It took me a while to fall asleep, but I managed to fall asleep (between half an hour and an hour), and (c) It took me a long time to fall asleep (more than an hour). The question on sleep maintenance was, "On average, how long did you manage to sleep during the night?" The response options were (a) *Less than one hour*, (b) *1 hour*, (c) *2-3 hours*, (d) *4-5 hours*, (e) *6-8 hours*, and (f) *More than 8 hours*.

The question on the degree of rest was, "On average, how tired did you feel in the mornings on a scale of 1-5? (1 = *extremely tired*, 5 = *very rested and energetic*). Finally, sleep quality was measured by the following item, "Overall, on a scale of 1 to 5, how would you rate the quality of your sleep during the past week? (1 = *very bad*, 5 = *very good*).

Process Measures

Penn State Worry Questionnaire - 11 (PSWQ; Ruiz et al., 2018b). The PSWQ assesses the general tendency to worry or trait worry and is widely used to measure the degree of worry characteristic of Generalized Anxiety Disorder. The scale has 11 items answered through a Likert-type scale from 1 to 5 (5 = *very much*; 1 = *not at all*).

Cognitive Fusion Questionnaire (CFQ; Ruiz et al., 2017c). The CFQ is a questionnaire consisting of seven items that responded on a 7-point Likert-type scale (7 = *always true*, 1 = *never true*) that measures cognitive fusion. Cognitive fusion refers to becoming entangled in thoughts, evaluations, judgments, and memories, thus behaving accordingly.

Valuing Questionnaire (VQ; Ruiz et al., 2022). The VQ consists of 10 items that evaluate how much one has acted in accordance with personal values during the last week. The VQ is answered on a Likert-type scale with seven response options (6 = *completely true*; 0 = *not at all*) and consists of two subscales: Progress in valued directions and Obstructing behaviors in those directions.

Procedure

Phase 1. Design of the Intervention Protocol and Researcher Training. The intervention protocol was designed based on previous studies that evaluated

the efficacy of RNT-focused ACT (Ruiz et al., 2018a, 2019). Subsequently, the first author was trained in applying the protocol over ten sessions using role-playing, modeling, shaping, and feedback. Previously, the therapist had received theoretical and practical training in ACT equivalent to 128 hours with the last author throughout her master's studies. Additionally, the therapist received supervision during the implementation of the interventions by the last author.

　　Phase 2. Recruitment of Participants. Recruitment was carried out through social network advertisements and other professionals' referrals. All potential participants were invited to an individual interview in which the objectives and methodology of the study were explained. The Mini-International Neuropsychiatric Interview (MINI) diagnostic interview was applied to identify the presence of high suicidal risk, psychotic disorder, and abuse of psychoactive substances. Participants who met the inclusion criteria signed the informed consent and responded to the previously mentioned outcome and process measures. Those who did not meet the inclusion criteria were referred to clinical psychology services that offered inexpensive psychological consultation.

　　Phase 3. Baseline Data Collection. Participants were randomized as to when they would receive the intervention after 3 to 6 weeks of baseline. Participants were randomized using the software www.randomizer.org. The DASS-21, PSWQ-11, CFQ, and VQ instruments were administered every week during the established baseline period. To avoid participants' burden, the GHQ-12, SF-36, and the sleep quality report were answered only in the pre-treatment, post-treatment, and monthly follow-ups (total of five applications throughout the study).

　　Phase 4. Implementation of the Interventions. The protocol was implemented in 4 weekly individual sessions of approximately 1 hour each. During this time, the weekly measures indicated in the previous phase continued to be administered.

　　Phase 5. Post-Treatment Evaluation and Follow-up. One week after the end of the intervention, participants were summoned for the application of all the questionnaires described in the instruments section. Participants continued to complete the weekly measures during the following month every week. After this, they were summoned to reapply the same measures every month until the three-month follow-up was completed. All participants attended the follow-ups except P2, who declined to continue attending after the first month of follow-up. At the end of the last follow-up, the research was closed.

Data Analysis

　　The data were analyzed both individually and globally for the four participants. The nonparametric Tau-U test (Parker et al., 2011) was computed to perform intrasubject analysis on the weekly measures through the calculator http://single-caseresearch.org/calculators/tau-u. This test provides a nonoverlapping effect size between baseline and intervention data. One of the advantages of Tau-U compared to other nonparametric effect sizes is that it allows correcting for significant trends

during baseline. In addition, Tau-U allows for hypothesis testing to determine if there were statistically significant differences between phases. Tau-U values are between -1 and 1 and are interpreted as the percentage of data that improve through the baseline and intervention phases. This study presents all effect sizes in favor of the intervention phase as positive, regardless of whether its scores should decrease or increase.

The attainment of clinically significant changes was analyzed following a proposal similar to that presented by de Ruiz et al. (2018a). Claiming the presence of clinically significant changes required: (a) the Tau-U value to be statistically significant in favor of the intervention phase, and (b) to show a score at the 3-month follow-up closer to the mean of the nonclinical than the clinical population. To test the latter criterion, we consulted descriptive data obtained from scale validation studies (see Ruiz et al., 2018a).

Intrasubject changes in the GHQ-12 were analyzed by computing the reliable change index and clinically significant change according to the guidelines suggested by Jacobson and Truax (1991). It was established that a change of 10 points represented a significant change in the SF-36. Finally, changes in sleep quality parameters were considered significant when they changed in score in each aspect evaluated.

The between-subjects data analysis was performed by computing the effect size for multiple baseline designs developed by Hedges et al. (2012). This analysis provides a standardized mean difference that shares the same metric as Cohen's *d* effect size frequently used in group designs. This allows the comparison of effect sizes obtained in single-case experimental designs with those reported in group designs.

Results

Outcome Results

The evolution of the DASS-21 scores and each of its subscales throughout the study can be seen in Figure 1. Visual analysis reveals relatively stable baseline trends for most participants and measures. Although some baselines showed improvement or deteriorating trends, none were statistically significant.

P1 showed the lowest DASS-Total scores of the study. However, post-intervention scores tended to decrease after the intervention to minimal levels. Scores on DASS-Depression showed a spike at the 3-month follow-up, which may have been affected by the hospitalization of a family member in serious condition. Table 3 shows that the effect sizes were statistically significant for all variables and all changes were clinically significant. Similarly, P1 showed clinically significant changes on the GHQ-12 during post-treatment and all three follow-ups (see Table 4), with scores below the 12-point cutoff indicating the possible presence of emotional disturbance. Table 5 shows that this participant also showed significant improvements in sleep latency, tiredness, and sleep quality, although the number

of hours of sleep during the night decreased. Finally, P1 experienced significant increases in 5 of the eight subscales of the SF-36

Figure 1
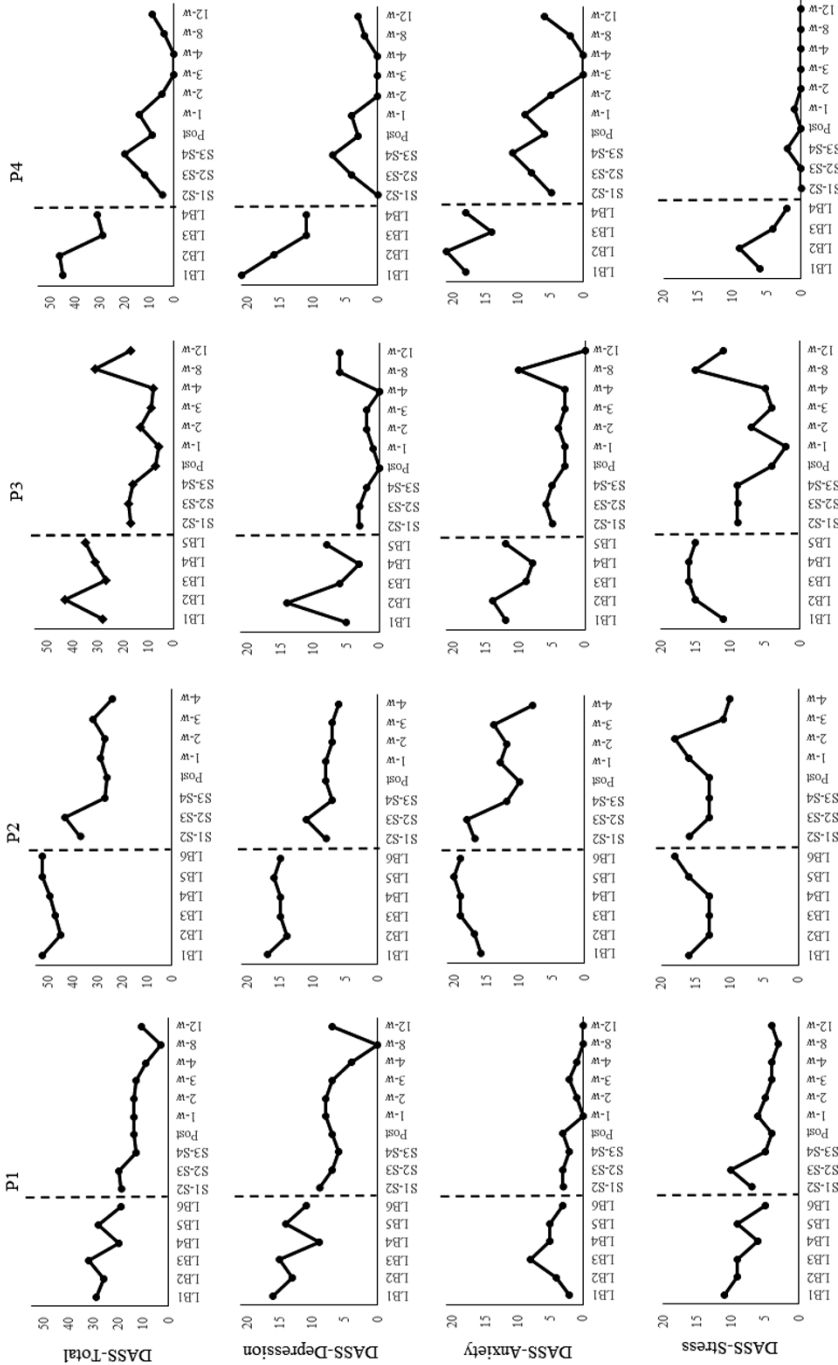*Evolution of the Scores on Emotional Symptoms*

Table 3
Tau-U Results and Clinically Significant Changes

		P1	P2	P3	P4
DASS – Total (emotional symptoms)	*Tau-U*	0.93	1.00	0.90	1.00
	SE	0.31	0.32	0.33	0.35
	p	.002	.002	.006	.005
	CSC	**YES**	NO	**YES**	**YES**
DASS – Depression	*Tau-U*	0.98	1.00	0.76	1.00
	SE	0.31	0.32	0.33	0.35
	p	.001	.002	.020	.005
	CSC	YES	YES	YES	YES
DASS – Anxiety	*Tau-U*	0.82	0.85	0.92	1.00
	SE	0.31	0.32	0.33	0.35
	p	.008	.008	.005	.005
	CSC	**YES**	NO	YES	YES
DASS – Stress	*Tau-U*	0.68	0.25	0.90	0.98
	SE	0.31	0.32	0.33	0.35
	p	.026	.44	.006	.006
	CSC	**YES**	NO	NO	**YES**
PSWQ-11 (pathological worry)	*Tau-U*	0.83	0.81	0.90	1.00
	SE	0.31	0.32	0.33	0.35
	p	.007	.012	.006	.005
	CSC	YES	YES	YES	YES
CFQ (cognitive fusion)	*Tau-U*	1.00	0.85	0.28	0.95
	SE	0.31	0.32	0.33	0.35
	p	.001	.008	.391	.007
	CSC	**YES**	**YES**	NO	**YES**
VQ – Progress (values progress)	*Tau-U*	0.13	0.71	-0.40	0.15
	SE	0.31	0.32	0.33	0.35
	p	.664	.028	.221	.671
	CSC	NO	**YES**	NO	NO
VQ – Obstruction (values obstruction)	Tau-U	0.43	1.00	-0.04	1.00
	SE	0.31	0.32	0.33	0.35
	p	.159	.002	.903	.005
	CSC	NO	**YES**	NO	YES

Note. CSC = Clinically significant change, CFQ = Cognitive Fusion Questionnaire, DASS = Depression, Anxiety and Stress Scale, PSWQ = Penn State Worry Questionnaire, SE = standard error, VQ = Valuing Questionnaire.

P2 showed very intense emotional symptoms during baseline, mainly in depression and anxiety. However, after the introduction of the intervention, she showed noticeable changes in both. Table 3 shows that the effect sizes were statistically significant for all variables except for DASS-Stress. However, P2 only experienced clinically significant changes in DASS-Depression because her total and DASS-Anxiety scores were still closer to the average of the clinical population than the nonclinical one. On the other hand, the participant did show clinically significant changes at post-treatment and one-month follow-up (last follow-up she agreed to answer) on the GHQ-12 (see Table 4). Similarly, Table 5 notes that P2 reported highly significant changes in all sleep parameters assessed. Finally, the participant showed significant improvements in all subscales of the SF-36 except Vitality (Table 6).

Table 4
Scores on the General Health Questionnaire – 12 for each Participant

	Pre	Post	1-month FU	2-month FU	3-month FU	Reliable change	Clinically significant change
P1	20	7	9	2	9	YES	YES
P2	29	2	3	--	--	YES	YES
P3	15	4	4	18	7	YES	YES
P4	31	7	7	4	4	YES	YES

Table 5
Sleep Latency, Maintenance, Tiredness, and Perceived Sleep Quality

	Assessment	Latency	Maintenance	Tiredness	Quality
P1	Pre	30-60 min	6-8 h	Normal	Normal
	Post	<30 min	4-5 h	Rested	Good
	1-month FU	<30 min	4-5 h	Rested	Good
	2-month FU	<30 min	6-8 h	Rested	Good
	3-month FU	**<30 min**	4-5 h	**Rested**	**Good**
P2	Pre	>60 min	2-3 h	Tired	Mala
	Post	<30 min	>8 h	Rested	Good
	1-month FU	<30 min	>8 h	Rested	Good
P3	Pre	>60 min	4-5 h	Extr. tired	Normal
	Post	<30 min	4-5 h	Normal	Good
	1-month FU	<30 min	4-5 h	Normal	Good
	2-month FU	30-60 min	6-8 h	Tired	Normal
	3-month FU	<30 min	6-8 h	Normal	Good
P4	Pre	>60 min	4-5 h	Normal	Normal
	Post	<30 min	4-5 h	Rested	Good
	1-month FU	30-60 min	4-5 h	Normal	Normal
	2-month FU	<30 min	6-8 h	Rested	Good

Assessment	Latency	Maintenance	Tiredness	Quality
3-month FU	30-60 min	6-8 h	Rested	Good

Note. Bold cells indicate an improvement in the indicator at the last follow-up. Underlined cells indicate a worsening in the indicator at the last follow-up.

P3 showed high scores on the DASS-21 throughout the baseline, especially on the anxiety subscale. The participant showed immediate changes upon introduction of the intervention that were maintained at the 1-month follow-up. However, at the 2-month follow-up, she showed a spike in scores associated with being in a divorce period. The scores decreased again at the three-month follow-up. Changes were statistically significant for all DASS-21 indicators, although clinical significance was not reached for the DASS-Stress (see Table 3). Scores on the GHQ-12 followed a similar evolution. The participant experienced clinically significant changes in all measurements except at the two-month follow-up. Likewise, all four sleep parameters showed significant improvements (Table 4). Finally, the participant experienced significant changes in all subscales of the SF-36 at the 3-month follow-up except for Physical Function.

P4 showed high emotional symptoms at baseline, especially depression and anxiety. Scores decreased dramatically at the start of the intervention. All Tau-U values were statistically significant, with clinically significant changes in all cases (Table 3). A similar conclusion can be reached by looking at the GHQ-12 scores in Table 4. Also, Table 5 shows that the participant improved in all sleep parameters assessed. In the SF-36, the participant experienced significant improvement in 5 of the eight subscales, although her score decreased in Emotional Role.

Table 6
Scores on the SF-36

	Assessment	Physical Function	Physical Role	Pain	General Health	Vitality	Social Function	Emotion Role	Mental Health
P1	Pre	45	45	45	45	45	38	67	60
	Post	75	100	42	57	50	75	100	60
	1-month FU	80	100	51	62	70	88	100	68
	2-month FU	75	100	70	16	70	100	100	12
	3-month FU	**80**	**100**	43	**60**	50	**100**	**100**	60
P2	Pre	40	0	0	5	50	38	0	44
	Post	25	25	10	30	50	13	34	52
	1-month FU	55	50	10	**47**	55	**50**	67	**56**
P3	Pre	65	0	22	15	0	50	0	32
	Post	75	0	42	35	10	88	100	80
	1-month FU	85	75	51	50	35	88	100	84
	2-month FU	60	0	10	15	35	13	0	48

	Assessment	Physical Function	Physical Role	Pain	General Health	Vitality	Social Function	Emotion Role	Mental Health
	3-month FU	64	**38**	**51**	**50**	**40**	**75**	**67**	**70**
P4	Pre	65	0	30	12	15	38	34	12
	Post	85	0	51	42	50	63	34	56
	1-month FU	50	25	27	38	34	40	34	24
	2-month FU	44	50	52	38	38	50	50	44
	3-month FU	64	**25**	34	**50**	**50**	**50**	<u>17</u>	**30**

Note. Bolded values indicate an increase in scores at the last follow-up of at least 10 points. Underlined values indicate that the decrease in scores at the last follow-up was at least 10 points.

Process Results

Figure 2 presents the evolution of scores on the process measures. All four participants showed high scores on pathological worry (PSWQ) during baseline, mainly P3 and P4. All participants showed statistically and clinically significant changes after the introduction of the intervention.

Cognitive fusion (CFQ) scores were also high during baseline. P1, P2, and P4 showed statistically and clinically significant changes during the intervention. P3 showed declining scores during the follow-up period and ended with a low score at the last follow-up. However, given the slow evolution of scores, the Tau-U value did not reach a statistically significant level.

The evolution of scores on valued actions (VQ) was less clear. Participants showed average scores similar to the nonclinical population on VQ-Progress. Only P2 showed clinically significant changes in this subscale of the VQ. For the VQ-Obstruction, P1 and P3's scores at baseline were close to the average score for the nonclinical population. These participants showed no change in this variable. P2 and P4, who showed clinical scores at baseline, did show clinically significant changes.

Figure 2
Evolution of Scores on Pathological Worry, Experiential Avoidance, Cognitive Fusion, and Values
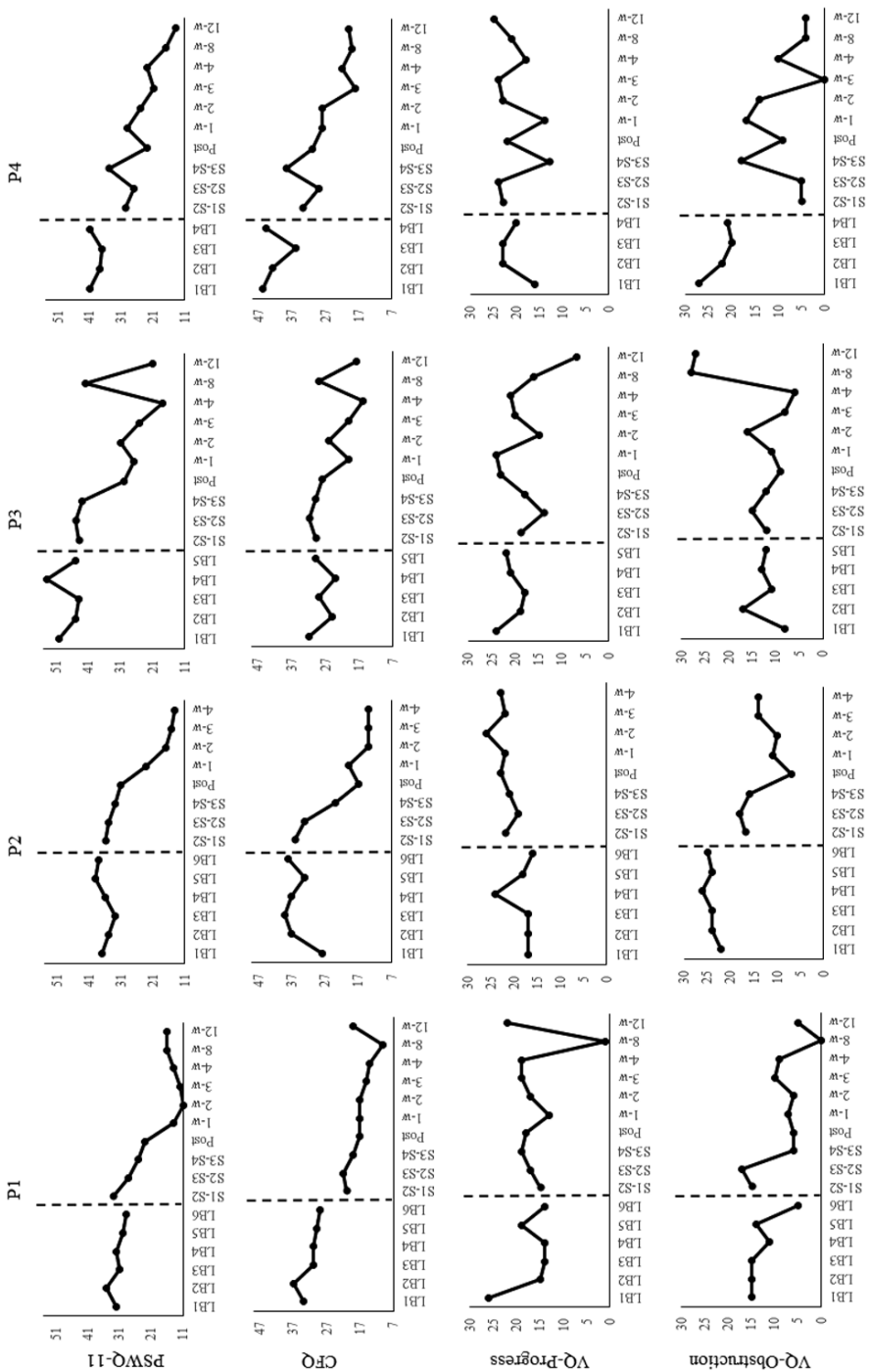
Standardized Mean Differences

Table 7 presents the overall effect sizes obtained by the intervention on the variables that were assessed weekly. The effect sizes for DASS-Total and DASS-Depression were very large and statistically significant (DASS-Total: $d = 1.51$, 95% CI [0.01, 3.02]; DASS-Depression: $d = 1.83$, 95% CI [0.54, 3.11]). However, although the effect sizes were also large for DASS-Anxiety ($d = 0.95$) and DASS-Stress ($d = 0.89$), they were not statistically significant.

For process measures, effect sizes were very large and statistically significant for pathological worry and cognitive fusion (PSWQ-11: $d = 1.79$, 95% CI [0.77, 2.80]; CFQ: $d = 1.99$, 95% CI [0.95, 3.03]). The effect size for the VQ-Progress was null ($d = 0.01$), but the effect size was large and statistically significant for the VQ-Obstruction ($d = 0.93$, 95% CI [0.21, 1.65]).

Table 7
Design-Comparable Standardized Mean Differences

Measure	BC-SMD	SE	95% CI (lower)	95% CI (upper)
DASS-Total	1.51	0.61	0.01	3.02
DASS-Depression	1.83	0.56	0.54	3.11
DASS-Anxiety	0.95	0.48	-0.32	2.21
DASS-Stress	0.89	0.42	-0.16	1.93
PSWQ-11	1.79	0.49	0.77	2.80
CFQ	1.99	0.50	0.95	3.03
VQ-Progress	0.01	0.27	-0.53	0.55
VQ-Obstruction	0.93	0.33	0.21	1.65

Note. CFQ = Cognitive Fusion Questionnaire, DASS = Depression, Anxiety and Stress Scale, PSWQ = Penn State Worry Questionnaire, SE = standard error, VQ = Valuing Questionnaire.

Discussion

This study aimed to analyze the efficacy of a 4-session RNT-focused ACT protocol in patients with FM in relation to emotional symptoms, sleep quality, and health-related quality of life. All four participants showed clinically significant changes in at least one of the subscales of the DASS-21. All participants showed clinically significant changes in DASS-Depression and three in DASS-Anxiety. Scores on DASS-Stress were not as high and relevant in this study, although two participants also showed clinically significant changes. As for the DASS-Total, all participants showed statistically significant changes, and three of them showed clinically significant changes. The data obtained with the GHQ-12 are consistent. All the participants showed clinically significant changes, being clearly below the cutoff point for considering the presence of emotional disturbance. The effect of the intervention was also notable in the sleep parameters evaluated. All participants improved in latency, tiredness, and sleep quality. Finally, notable changes were also observed in the quality of life as measured by the SF-36. In particular,

all participants improved in Physical Role, General Health, and Social Function.

As for process measures, all participants showed clinically significant changes in pathological worry and three of them in cognitive fusion. However, changes in values were clearly more modest: only one participant showed clinically significant changes in VQ-Progress and two in VQ-Obstruction. This difference in intervention effect could be related to the fact that the participants did not show excessive impairment in values according to VQ scores.

The effect sizes comparable across designs were large and statistically significant for DASS-Total, DASS-Depression, pathological worry, cognitive fusion, and obstruction in values. These results are promising and compare very well with the weighted effect sizes found in recent meta-analyses of ACT efficacy in FM (Haugmark et al., 2019). This is important because brief psychological interventions are especially appropriate for patients with FM, given the frequent dropout and difficulty in attending interventions (Gómez-Pérez et al., 2020).

The high effect of the protocol in reducing pathological worry and cognitive fusion is similar to previous studies that analyzed the efficacy of brief, RNT-focused ACT interventions (Dereix-Calonge et al., 2019; Ruiz et al., 2016, 2018a, 2019, 2020a, 2020b). This might indicate that a significant process of change of the intervention could be the reduction of RNT, as found in Dereix-Calonge et al. (2019). However, we could not conduct a mediation analysis of the effect of the intervention because the number of assessment points was not sufficient. Future studies could make use of more intensive assessment through ecological momentary assessments. In addition, the large effect size found in the reduction of RNT is especially important in this context, given its relevance to FM compared to other chronic pain syndromes (Ricci et al., 2017).

Some limitations of the study are worth mentioning. First, the sample used was small, and further replications are needed to confirm the efficacy of brief RNT-focused ACT interventions. Second, the effect of the intervention was only assessed through self-report measures. Future studies could analyze the effect of the intervention in a clinical interview and behavioral tests of pain tolerance. Third, because the recruitment process was spread over several weeks, a nonconcurrent multiple baseline design was conducted. These designs have lower internal validity than concurrent designs, although additional limitations would not be particularly problematic in this type of study (see discussion in Ruiz et al., 2018b). Fourth, we did not measure pain intensity and interference directly as it is typical in studies investigating the efficacy of psychological interventions in chronic pain conditions. Further studies should analyze the effect of RNT-focused ACT interventions on pain intensity and interference and its relationship with RNT using ecological momentary assessment. Finally, all participants were women, which reduces the results' generalizability. However, this bias in the recruitment is understandable given the higher prevalence of FM in women.

In conclusion, this study should be considered a preliminary investigation of

the effect of brief RNT-focused ACT interventions in patients suffering from FM. This type of intervention holds promise, and the conduction of further studies is warranted. Additionally, this study extends the applicability of brief, RNT-focused ACT interventions to health conditions and has found similar results as previous studies that analyzed their effect on emotional disorders.

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