



The Effectiveness of the Unified Protocol on Emotional Dysregulation and Cognitive Emotion Regulation Strategies in Patients with Psychosomatic Disorders

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Quantitative Study

Abstract

Background: The unified treatment approach (UP) is an emotion-focused cognitive-behavioral therapy in which the main object of treatment is emotional processes. The aim of the present research was to examine the effectiveness of The Unified Protocol (UP) on emotional dysregulation and cognitive emotion regulation strategies in patients with psychosomatic disorders.

Methods: Emotion-focused cognitive behavioral therapy (ECBT), a unified treatment, with 12 weekly group sessions of 2 hours, was presented to 14 patients with psychosomatic complaints at the Subspecialty Center of Psychiatry in Isfahan in 2013. Pre- and post-intervention assessments were done by means of the self-report tests of Difficulties in Emotion Regulation Scale (DERS) and Cognitive Emotion Regulation Questionnaire (CERQ).

Results: Significant reductions in post-test scores of total emotional dysregulation ($p < 0.01$) as well as the factors of non-acceptance ($p < 0.05$) and strategy ($p < 0.01$) were seen, while the other factors (goal, impulse, awareness, and clarity) did not change. Moreover, a significant reduction was observed in the catastrophizing strategy score ($p < 0.05$), in comparison with other cognitive strategies.

Conclusion: This pilot study including 14 patients with psychosomatic disorders indicates that the Unified treatment approach is an effective treatment in improvement of emotional dysregulation and in reduction of utilizing maladaptive cognitive strategies.

Keywords: The unified protocol, Emotional dysregulation, Cognitive emotion regulation strategies, Psychosomatic disorders

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Introduction

Emotions are one of the important aspects of

human psychology. They occur due to difference between the perceived actuality and individual desires (Payne, 2013). Emotions are a multifaceted phenomenon that involve alterations in the domains of subjective experience, behavior, and peripheral physiology

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(Mauss, Levenson, McCarter, Wilhelm, & Gross, 2005). Thus, they can affect physiological responses, social interactions, and subjective processes such as attention, memory, and decision making at any time (Hassani, Azadfallah, & Rasoulzade-Tabatabaei, 2009). The flexibility feature of emotions raises the possibility of their regulation (Gross, 2008). Therefore, individuals will be able to influence the intensity, and duration of their emotional experiences (Hassani, 2011).

As such, the term emotion regulation does not refer to the same phenomenon, indeed, it is known as a broad concept that includes the domain of partly related processes (Thompson, 1994). In general, the concept of emotion regulation consists of awareness and understanding of emotions, acceptance of emotions, and the ability to control impulsive behaviors and behave according to the intended targets when experiencing negative emotions, and the ability to use situationally suitable emotion regulation strategies flexibly to adjust emotional responses in encountering personal goals and situation needs. The relative lack of any or all of these capabilities represent difficulties in emotion regulation or emotional dysregulation (Gratz & Roemer, 2004).

Difficulties in emotion regulation may underlie many clinical behaviors and psychological difficulties for individuals who are seeking treatment (Grat & Tull, 2013). In fact, emotion regulation is a psychological process integral to mood stabilization and also psychopathology (Heiy, 2010). Besides, emotional dysregulation may interfere with the important domains of life and personal performance (e.g., work and relationships) (Erismana, Salters-Pedneaultb, & Roemer, 2013).

One of the factors engaged in emotion regulation is the use of coping strategies that regulate emotions in the cognitive and behavioral aspects, and the combination of both (Parkinson & Totterdell, 1999). Emotion regulation strategies are considered further from

two frameworks. The first consists of strategies that are activated before the occurrence of an accident or at the beginning of it. These strategies are important in the controlling of negative emotions caused by accidents. The second consists of strategies that are activated after the occurrence of an accident or the formation of emotion (Gross, 1998). Garnefski, Kraaij, and Spinhoven (2001, 2002) introduced 9 cognitive emotion regulation strategies and divided them into two categories of adaptive (acceptance, positive reappraisal, putting into perspective, planning refocusing, and positive refocusing), and maladaptive (rumination or focus on thought, self-blame, blaming others, catastrophizing). Emotion regulation through cognitions is one of the basic necessities of human life, because they help us respond to our surrounding environmental events with greater flexibility (Garnefski, Rieffe, Jellesma, Terwogt, & Kraaij, 2007; Rezwan, Bahrami, & Abedi, 2006).

Individuals who utilize maladaptive cognitive strategies such as rumination, self-blame, and catastrophizing may be more vulnerable to emotional problems than others. However, others who use adaptive strategies, such as positive reappraisal, may be less vulnerable (Garnefski & Kraaij, 2006a). According to Garnefski et al. (2001) and Salehi, Baghban, Bahrami, and Ahmadi (2011), using the strategies of rumination and catastrophizing in encountering stress leads to further emotional problems. The results of a meta-analysis review showed that internalizing disorders (depression and anxiety) were more consistently associated with dysfunctional regulatory strategies than externalizing disorders (Aldao, Nolen-Hoeksema, & Schweizer, 2010). Actually, it seems that the model of adaptive versus maladaptive strategy is an important predictor of mood as well as symptoms of depression. Especially, the use of an adaptive strategy alone or in conjunction with a maladaptive strategy is accompanied with higher mood than the use of at least one maladaptive strategy alone (Heiy, 2010).

The treatment approach for patients with difficulties in emotion regulation should involve treatment manners that have the ability to increase emotional awareness, and to regulate internal tensions and states of emotional arousal through cognitive processes (Taylor, 1984, 1987). The Unified Protocol (UP) is a transdiagnostic, emotion-focused cognitive behavioral therapy, which accentuates the adaptive and functional nature of emotions, and seeks to identify and correct maladaptive attempts to regulate emotional experiences, thereby facilitating appropriate processing and extinction of extreme emotional answering to both internal and external signs (Wilamowska et al., 2010). Unified treatment approaches, based on emotion regulation skills, are applicable to a wide range of emotional disorders (Allen, Tsao, Seidman, Ehrenreich-May, & Zeltzer, 2012). According to Allen, McHugh, & Barlow (2007), a Unified Protocol for the treatment of emotional disorders has four basic treatment components of (a) increasing emotional awareness; (b) facilitating flexibility in assessments; (c) identification and prevention of emotional and behavioral avoidance; (d) internal and situational encountering of emotional symptoms and changing emotion driven behaviors.

The efficacy of the Unified Protocol in the transdiagnostic treatment of emotional disorders has been studied in adults in (a) a case study on one patient with anxiety disorders (obsessive-compulsive, panic, and generalized anxiety) (Boisseau, Farchione, Fairholme, Ellard, & Barlow, 2010); (b) 3 patients with generalized anxiety disorder with a comorbid emotional disorder (Abdi, 2012); (c) a clinical sample of 15 patients with mood and anxiety disorders (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010); (d) a diagnostically heterogeneous sample of 37 patients with a principal anxiety disorder (Farchione et al., 2012). Moreover, it has been studied in adolescences in (a) a clinical sample of 15, 14-18 year old, girls with epilepsy (Esmaeili, Aghaei, Abedi, Esmaeili, & Aghaei, 2012); (b) 3 adolescents presenting an array of anxiety

and depression symptoms (Ehrenreich, Goldstein, Wright, & Barlow, 2009). In addition, the treatment model was examined in decreasing preclinical anxiety and depression symptoms (depression, anxiety, stress, emotion regulation, positive and negative emotions, and occupational and social adjustment) of 15 students (Mohammadi, Birashk, & Gharaie, 2013). In general, the results of all of the above studies have confirmed the efficacy of this protocol in the form of individual or group therapy for emotional disorders, and have supported transdiagnostic treatment approach in the process of emotion regulation.

Since psychosomatic medicine is the domain that evaluates physical diseases from the standpoint of emotional disorders, it is assumed that psychosomatic disorders likely profit from the interventions based on emotion regulation. On the other hand, it seems that the unified treatment approaches have not been implemented on psychosomatic diseases so far, especially in the form of group therapy. Hence, this study intends to evaluate the effectiveness of the Unified Protocol on emotional dysregulation and cognitive emotion regulation strategies in patients with psychosomatic disorders.

Methods

Subjects

The present research was a clinical-trial among patients with psychosomatic complaints (digestion and skin). Twenty patients referred to the psychosomatic clinics (located in the Subspecialty Center of Psychiatry of Isfahan) were recruited. However, at the end, fourteen patients (13 patients with FGID and 1 patient with dermatitis) fulfilled the whole treatment course. All patients were suffering from emotional problems that were diagnosed by psychiatrists when examined in psychosomatic clinics.

Instruments

The difficulties in Emotion Regulation Scale (DERS)

The scale is a self-report measure developed by Gratz & Roemer (2004) to assess difficulties in

emotion regulation. The DERS can distinguish adaptive emotion regulation from emotional avoidance and expressive control. The scale is composed of 6 factors, including non-acceptance of emotional responses (non-acceptance), difficulties in engaging in goal-directed behavior (goal), impulse control difficulties (impulse), lack of emotional awareness (awareness), limited access to emotion regulation strategies (strategy), and lack of emotional clarity (clarity). The DERS has 36 items that are rated on a five-point Likert scale, ranging from 1 (almost never) to 5 (almost always), and are recoded so that higher scores in every case indicate greater difficulties in emotion regulation (i.e., greater emotion dysregulation). The scale has high internal consistency; Cronbach's $\alpha = 0.93$ for total DERS, Cronbach's $\alpha > 0.80$ for each factor, and test-retest = 0.87 for total DERS and ranging from 0.69 to 0.89 for all factors (Gratz & Roemer, 2004). In an Iranian normal sample, internal consistency of the scale using Cronbach's α ranged from 0.66 to 0.88 for all factors (khanzadeh, Saidiyan, Hosseinchary, & Edrissi, 2012).

Cognitive Emotion Regulation Questionnaire (CERQ)

The multidimensional CERQ was constructed to define what someone thinks after the experience of threatening or stressful events. The CERQ comprises 9 conceptually distinct subscales; acceptance, putting into perspective, positive refocusing, planning refocusing, positive

reappraisal, catastrophizing, rumination, self-blame, and blaming others. The original scale of the CERQ has 36 items that must be measured on a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always) (Garnefski, Kraaij, & Spinhoven, 2001). Score of each subscale can be obtained by summing the scores of items belonging to the particular subscale. The higher the subscale score, the more the specific cognitive strategy is used (Garnefski, Teerds, Kraaij, Legerstee, & van den Kommer, 2004). The short 18-item version of the CERQ with two-item subscales was developed by Garnefski & Kraaij (2006b). In assessing validity and reliability, the Persian version of CERQ-18 had good psychometric features. Cronbach's alpha coefficients were estimated for the subscales; ranging from 0.68 (acceptance) to 0.82 (planning refocusing) (Hassani, 2011).

Procedure

Before intervention, emotional dysregulation and cognitive strategies in the patients were assessed by means of the self-report tests of DERS and CERQ. Thereafter, the patients attended the ECBT in 12 weekly group sessions of 2 hours. Finally, the same assessments were done after the intervention. Two researchers, both of whom were trained in psychotherapy, took part in the study as psychotherapists. Content of the sessions (presented in Table 1) originated from the Unified Protocol based on instructions of Allen et al. (2007).

Table 1. The Topics of Group Sessions of ECBT Originated from the Unified Protocol

The main components	Sessions	The titles of each of the sessions
Psychological concepts training	1	Emotion identification and naming (emotional self-awareness)
	2	Recognition of the consequences of emotions and recognition of traumatic emotions
	3	Overcoming obstacles of positive emotions
Cognitive reappraisal	4	Evaluation and interpretation of external events (cognitive errors)
	5	Interpretations and their modification
	6	Reducing cognitive vulnerability
	7	Recognition of and understanding the problem-solving process
Avoid emotional inhibition	8	Awareness of the consequences of emotional avoidance
	9	Acceptance of emotions
Emotional encountering	10	Encountering emotions
	11	Action tendency against emotions
	12	Summary and wrap-up of the titles of previous sessions

Statistical Analysis

Descriptive analysis was expressed as mean \pm standard deviation. Pearson correlation coefficient was used to evaluate the correlation between emotional dysregulation and cognitive strategies.

To assess the effectiveness of the intervention, differences between means were analyzed with paired t-test. Dependent variables were the CERQ subscales (acceptance, putting into perspective, positive refocusing, planning refocusing, positive reappraisal, catastrophizing, rumination, self-blame, and blaming others), and the DERS and its factors (non-acceptance, goal, impulse, awareness, strategy, and clarity). Moreover, the emotion-focused cognitive behavioral therapy (ECBT), originated from the Unified protocol, was considered as independent variable.

The Statistical Package for the Social Sciences (version 15.0; SPSS Inc., Chicago, IL, USA) was used for statistical analyses. A P-value of < 0.05 was considered statistically significant.

Ethical Considerations

All participants gave their informed consent for participating in the study, and also the study was approved by the Medical Research Ethics Committee of IUMS.

Results

Mean age of the patients was 40.3 ± 11.64 . 11 patients were women with a mean age of 40.3 years (range 26-56 year) and 3 were men with a mean age of 40 years (range 28-60 years). When they were included in the study, 11 were married, 6 graduated, and 10 homemakers, and 3 employed and 1 unemployed.

Mean scores and standard deviations of the difficulties in emotion regulation scale (emotional dysregulation) and its factors, and cognitive emotion regulation questionnaire (cognitive strategies), in pre-test and post-test phases, are presented in table 2. As can be seen, mean scores of emotional dysregulation and its factors, except awareness, were reduced in the post-test phase. In addition, post-test scores of the strategies of putting into perspective, blaming others, and catastrophizing changed more than the others.

Correlations between emotional dysregulation and cognitive strategies were computed. As can be viewed in table 3, only the strategies of blaming others and catastrophizing were positively correlated with emotional dysregulation and some of its factors.

Table 2. Means (M) and Standard Deviations (SD) of Emotional Dysregulation and Cognitive Strategies

DERS	Pre-test		Post-test		DERQ	Pre-test		Post-test	
	M	SD	M	SD		M	SD	M	SD
Total DERS	99	25.36	83.14	18.55	Acceptance	6.28	1.81	6.42	1.42
Non-accept	17.57	7.82	13.85	6.04	Positive refocusing	4.07	1.54	4.57	1.65
Goal	15.64	4.66	12.78	4.00	Planning refocusing	7.07	1.97	7.42	1.55
Impulse	14.85	6.15	12.71	3.56	Positive reappraisal	6.78	3.89	6.85	3.38
Awareness	15.14	3.89	15.71	3.38	Putting into perspective	5.42	1.60	6.57	2.10
Strategy	23.71	7.35	18.57	5.47	Self-blame	4.78	2.00	4.21	1.25
Clarity	12.07	4.58	9.50	3.08	Blaming others	5.35	2.37	4.00	1.66
					Rumination	7.92	1.68	7.14	1.35
					Catastrophizing	6.28	2.05	5.00	1.96

Table 3. Pearson Correlation between Emotional Dysregulation and Cognitive Strategies

DERQ Subscales	DERS						
	T-DERS	Non-accept	Goal	Impulse	Awareness	Strategy	Clarity
Acceptance	0.08	0.02	0.21	0.02	-0.23	0.15	0.15
Positive refocusing	-0.32	-0.38	-0.28	-0.28	-0.42	-0.08	0.07
Planning refocusing	0.04	0.09	0.02	0.03	-0.12	0.13	-0.12
Positive reappraisal	-0.18	-0.34	0.11	-0.06	-0.19	-0.02	-0.24
Putting into perspective	-0.42	-0.44	-0.24	-0.48	-0.47	-0.06	-0.16
Self-blame	0.11	-0.14	0.37	0.23	-0.11	0.03	0.24
Blaming others	0.54*	0.38	0.72**	0.24	-0.13	0.48	0.57*
Rumination	0.05	0.30	-0.05	-0.21	-0.26	0.32	-0.22
Catastrophizing	0.70**	0.67**	0.45	0.54*	-0.11	0.63*	0.68**

** p < 0.01, * p < 0.05

The results of paired t-test on emotional dysregulation, which are illustrated in table 4, showed a significant difference between pre-test and post-test scores of emotional dysregulation and the factors of non-acceptance and strategy. On the other hand, emotional dysregulation was significantly reduced after the intervention. Furthermore, the results showed that although the factors of goal and clarity were significantly reduced, the reductions were not the consequence of intervention because of their

non-significant correlation coefficients.

In paired student's t-test analysis about cognitive strategies, the results showed a significant difference between pre-test and post-test scores of cognitive strategies (presented in Table 5). On the other hand, only the catastrophizing strategy was significantly reduced. Of course, the putting into perspective strategy was also significantly reduced, but it was not the consequence of the intervention because of non-significant correlation coefficient.

Table 4. Paired Student's T-test Analysis of Pre-test and Post-test Scores of Emotional Dysregulation

DERS	Paired correlations		Paired differences				t	df	Sig.
			Mean	SD	95% CI of the difference				
	Correlation	Sig.			Lower	Upper			
Total DERS	0.707	0.005	1.58E1	17.95	26.224	5.489	3.304	14	0.006
Non-acceptance	0.602	0.023	3.41	6.39	0.024	7.403	2.175	14	0.049
Goal	0.518	0.058	2.85	4.29	0.377	5.336	2.490	14	0.027
Impulse	0.493	0.073	2.14	5.37	-0.961	5.246	1.491	14	0.160
Awareness	0.615	0.019	0.57	3.22	-2.435	1.292	-0.662	14	0.519
Strategy	0.771	0.001	5.14	4.68	2.436	7.849	4.105	14	0.001
Clarity	0.417	0.138	2.57	4.32	0.072	5.069	2.223	14	0.045

CI: Confidence Interval; sig: < 0.01, < 0.05

Table 5. Paired Student's T-test Analysis of Pre-test and Post-test Scores of Cognitive Strategies

DERS	Paired correlations		Paired differences				t	df	Sig.
			Mean	SD	95% CI of the difference				
	Correlation	Sig.			Lower	Upper			
Acceptance	0.177	0.544	-0.14	2.28	-1.460	1.174	-0.234	14	0.818
Positive refocusing	0.164	0.575	-0.50	2.06	-1.693	0.693	-0.905	14	0.382
Planning refocusing	0.064	0.827	-0.35	2.43	-1.764	1.050	-0.548	14	0.593
Positive reappraisal	0.615	0.019	-0.57	3.22	-2.435	1.292	-0.662	14	0.519
Putting into perspective	0.470	0.090	-1.14	1.95	-2.271	-0.013	-2.187	14	0.048
Self-blame	0.418	0.137	0.57	1.86	-0.507	1.650	1.144	14	0.273
Blaming others	0.019	0.947	1.35	2.87	-0.300	3.015	1.768	14	0.100
Rumination	0.377	0.185	0.78	1.71	-0.206	1.777	1.712	14	0.111
Catastrophizing	0.689	0.007	1.28	1.58	0.367	2.203	3.026	14	0.010

CI: Confidence Interval; sig: < 0.01, < 0.05

Discussion

The findings of the present study indicated that emotion-focused cognitive behavioral therapy (ECBT) originated from the unified treatment approach (UP) was effective in patients with psychosomatic disorders. It could significantly reduce emotional dysregulation in the patients.

To our knowledge, there are not many studies about emotion regulation interventions, particularly on the Unified treatment approaches. Meanwhile, most of the UP studies have examined the effectiveness of transdiagnostic treatment on emotional disorders (depression, anxiety, and stress) (Abdi, 2012; Boisseau et al., 2010; Ellard et al., 2010; Farchione et al., 2012). Only the study by Mohammadi, Birashk, & Gharaie (2013) showed that the treatment model, in addition to decreasing emotional symptoms, is effective on the emotion regulation process. This is somehow consistent with the results of the present study.

In explaining the probable confirmation of the effect of the UP on emotional dysregulation, it can be elucidated that according to Barlow et al., 2009 (as cited in Farchione et al., 2012), the Unified treatment that holds emotional processes as the main objective of treatment, is applicable for anxiety and mood disorders and likely other disorders with strong emotional symptoms. On the other hand, the therapy components of the model (e.g., increasing emotional awareness, facilitating flexibility in appraisal, identification, and prevention of emotional and behavioral avoidance, and internal and situational encountering of emotional symptoms) are inconsistent with the factors involved in emotional dysregulation (Allen, McHugh, & Barlow, 2007). Thus, the UP can be effective in improvement of factors of emotional dysregulation, and accordingly, emotional dysregulation total.

Considering the research, the effectiveness of the treatment was mainly on the dimensions of non-acceptance of emotional responses and limited access to strategies. It has suggested that

the skill of acceptance or tolerating negative emotions, regardless of whether or not it facilitates emotions alteration, may be helpful in mental health (Berking et al., 2012). Campbell-Sills, Barlow, Brown, and Hofmann (2006) mentioned that judging emotions as unacceptable and suppressing emotions may be important aspects of the phenomenology of emotional disorders. The other therapy models based on emotion regulation, such as dialectical behavior therapy, emotion-focused therapy, acceptance and commitment therapy, and mindfulness, have also emphasized the role of acceptance in emotion regulation (Greenberg, 2002; Linehan, 1993; Roemer et al., 2009; Wicksell, Olsson, Hayes, 2010).

Besides understanding and accepting emotional experience, emotion regulation refers to a person's ability to engage in appropriate strategies to manage uncomfortable emotions and to engage in suitable behaviors when distressed (Salters-Pedneault, 2013). To dispose of negative emotions, individuals with emotional problems may utilize maladaptive emotion regulation strategies, and by rejecting their emotional experiences and avoiding them, they lose the opportunity to learn adaptive ways (Campbell-Sills & Barlow, 2009). An individual, who consciously uses the adaptive emotion regulation strategies in the face of problematic emotions, is capable of managing emotions and involving in targeted behaviors (Tull & Gratz, 2008). It appears that the severity of the effect of negative emotions on goal-directed behaviors may depend on the treasure of individual strategies for regulating emotion and flexibility in the use of these strategies (Orgeta, 2011). Thus, according to the findings, it seems that the dimensions of non-acceptance and strategies likely play a more important role in emotional regulation or dysregulation.

Other results of the study about strategies showed that although emotion regulation intervention could increase mean score of adaptive strategies, especially putting into

perspective, and reduce mean score of maladaptive strategies, especially blaming others and catastrophizing, this result was significant only for the strategy of catastrophizing. In this regard, the studies that have examined the cognitive emotion regulation strategies have mainly focused upon the relationship between the strategies and emotional problems (Aldao et al., 2010; Garnefski et al. 2001; Garnefski et al., 2004; Garnefski & Kraaij, 2006 a; Heij, 2010; Salehi, Baghban, Bahrami, & Ahmadi, 2011). We could not find information about the effect of therapeutic interventions on cognitive strategies. Hence, it is not possible to compare the results of this study with others. In explaining this result we can say that:

One of the main components of UP is facilitating flexibility in appraisals, and patients with emotional disorders tend to evaluate and interpret external events with cognitive biases such as extreme estimation of the probability of negative events and catastrophizing. Consequently, therapy originated from the UP can correct previous wrong cognitive appraisals in psychosomatic patients. The aim of cognitive therapy is the objective evaluation of wrong and negative appraisals, as well as using more realistic appraisals based on outcome evidence of a situation (Allen et al., 2007). In fact, the objective of cognitive emotion regulation is to change one's attention to or one's appraisals of a situation in order to change an emotion's duration, intensity, or both (Ochsner & Gross, 2005). Individuals, who use adaptive cognitive strategies when experiencing stress, changing their appraisals, will be able to manage negative emotions intensity effectively (Troy & Mauss, 2011). According to the present study, it appears that rumination and catastrophizing are the most important of maladaptive strategies in psychosomatic patients, but catastrophizing has more correlation with emotional dysregulation.

In summary, this study confirms the efficacy of emotion-focused cognitive behavioral therapy

(ECBT), originated from the Unified Protocol (UP), in emotional dysregulation treatment and in reducing maladaptive strategies of psychosomatic patients. From the point of view of studying the UP on emotional dysregulation and cognitive emotion regulation styles, the present study can be considered as a preliminary study. With regard to its promising results it can be performed in a larger scale in the future. In addition, the study, with extending the literature on interventions in psychosomatic patients, suggests that the main targets for interventions in those patients can be established based on the research on emotion regulation.

The limitations of this study, which may have considerable impact on the overall result of this study, are the small sample size, self-report questionnaires, not controlling other interfering factors in the treatment (e.g. drugs), having no follow-up phase in order to assess the effectiveness of the intervention in the long-term due to the absorption of some patients in other psychological therapies at the Subspecialty Center of Psychiatry, and having no comparison group for the same reason. It must be remembered that the studied group consisted of mainly digestive patients. Moreover, there was no similar study to compare the results. Considering the limited sample size, replication of this study with a larger sample size and comparison with a control group seems to be necessary.

Conflict of Interests

Authors have no conflict of interests.

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