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The effectiveness of the unified protocol on symptoms, quality of life, negative affect, and negative reactivity in irritable bowel syndrome patients in comorbidity with anxiety and depression

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ABSTRACT

Introduction: Irritable bowel syndrome (IBS) is a prevalent gastrointestinal dysfunction characterised by chronic abdominal pain and changes in bowel movement. Unified protocol is based on emotion regulations skills and can be used for a wide range of emotional disorders. The present study aimed to evaluate the effectiveness of unified protocol on Symptoms, Quality of Life, Negative Affect and Negative Reactivity in IBS patient's in comorbidity with anxiety and depression. *Method:* This study was a quasi-experimental study with a control group (n = 13) and an intervention group (n = 12) with random assignment and pre-test post-test with a three-month follow-up after treatment. In this study, the population included all of the patients with irritable bowel syndrome and the sample included the patients referring to Taleghani Hospital in 2020. Data were analyzed through repeated measures ANOVA. *Results:* The results of repeated measures ANOVA indicated that the symptoms of irritable bowel syndrome, anxiety, depression, negative affect, and fear of emotions, anxiety sensitivity, repetitive negative thinking, and the quality of life in the intervention group reduced over time compared to the control group and the difference between the means of two groups was statistically significant. *Discussion and conclusion:* In general, the results of this study showed that the unified protocol is effective on gastrointestinal symptoms and accompanying anxiety, depression symptoms and it can reduce both the symptoms of negative affect and the negative reactivity to emotions and also improve the quality of life of patients.

Keywords: Unified Protocol, IBS, anxiety and depression, quality of life, negative affect, negative reactivity.

1. INTRODUCTION

Irritable bowel syndrome (IBS) is a kind of bowel dysfunction without any structural or histological abnormalities. IBS is a chronic, common, and recurrent disease. Different studies have estimated its prevalence among adults at 10-25% of the general population around the world, although this rate is higher in women up to 67% (Canavan et al., 2014; Alanaz et al. 2021). The overall incidence of IBS is 1.1-25% in Iran (Jahangiri et al., 2012). More than 94% of patients with IBS suffer from different comorbidity psychiatric disorders of which depression, anxiety, and somatoform disorders are the most common (Whitehead et al., 2002). The existence of comorbidity psychiatric disorders leads to 10 times of increase in the cost of using care services, as well as a reduction in health status, job efficiency, and quality of life (Johansson et al., 2010; Spiegel et al., 2004; Vandvik et al., 2006). Studies have indicated that a variety of psychological therapies are effective in treating IBS patients as alternative orin combination with conventional therapies. Among a variety of psychotherapy, the therapies which have strong evidence for effectiveness are cognitive-behavioral therapy, hypnosis, and mindfulness-based therapies (Ballou et al., 2017; Sebastián Sánchez et al., 2017).

Meanwhile, the development of cognitive-behavioral therapy has resulted in the development of extensive treatment protocols to target a specific disorder, making it difficult for professionals to access and qualify (Farchione et al., 2012). This becomes problematic while facing the clinical reality of high rates of comorbidity in these patients, considering therapists in a position to select between single-disorder protocols. Thus, more comprehensive treatments are required to improve treatment (Farchione et al., 2012). Unified protocol is an emotion-focused transdiagnostic and cognitive-behavioral therapy which targets the factors which underlie all emotional disorders and are referred to as transdiagnostic factors rather than directly targeting the specific symptoms of disorder (Sauer-Zavala et al., 2012).

Previous studies indicated that targeting such common underlying factors decreases all symptoms of the disorder (Sauer-Zavala et al., 2012). The unified protocol aims to reduce negative reactivity to emotions by identifying maladaptive responses to emotions and teaching patients some skills for emotional management and regulation (Sauer-Zavala et al., 2012). Negative affect is one of the most significant transdiagnostic constructs in IBS disorders, anxiety and depression. Negative affect shows how much the mind engages in distressing and unpleasant activities and involves a variety of disturbing moods such as anger, humiliation, hatred, guilt, fear, and anxiety (Watson et al., 1988). Intrinsic tendency to experience negative affect is a common factor in etiology, clinical manifestations, and treatment of emotional disorders (Carl et al., 2014). In addition, it is a risk factor for IBS and intensifies symptoms, impaired performance, and poor quality of life (Muscatello et al., 2016; Yazici et al., 2015).

Several transdiagnostic variables which measure negative reactivity to emotional experience include the fear of emotions, anxiety sensitivity, and repetitive negative thinking. Fear of emotions means reacting negatively to the experience or expression of emotions which is associated with the belief that emotions are long-lasting and uncontrollable (Sauer-Zavala et al., 2012). The belief that emotions are bad or have devastating consequences in patients with IBS exacerbates symptoms, increases depression and anxiety, and reduces the quality of life of such patients directly and indirectly through increasing emotional repression (Ali et al., 2000; Bowers et al., 2017; Thakur, 2015). Anxiety sensitivity is another transdiagnostic construct which is also associated with fear of emotions. Anxiety sensitivity means the fear of the somatic symptoms of anxiety and believes that anxiety and its symptoms can have potentially damaging consequences for the body and mind (Sauer-Zavala et al., 2012). This transdiagnostic construct in IBS patients exacerbates abdominal pain and anxiety by increasing expected anxiety (Sugaya et al., 2013).

Repetitive negative thinking is another transdiagnostic construct, which means thinking repeatedly and negatively about problems or negative experiences and experiencing such thinking in a repetitive and uncontrollable way (Ehring et al., 2008). Previous studies reported that IBS is correlated with high worry (Hazlett-Stevens et al., 2003). In fact, worrying in these patients is a way of not experiencing the somatic and psychological responses associated with frightening stimuli (Drews et al., 2008).

Given the above-mentioned content, the present study aims to evaluate the effectiveness of the unified protocol for Transdiagnostic treatment on symptoms, quality of life, and negative emotion and negative reactivity (fear of emotions, anxiety sensitivity, and repetitive negative thinking) in IBS patients in comorbidity with anxiety and depression. Due to the high association of IBS with depression and anxiety and the presence of deficits in emotion regulation, it is assumed that this treatment is more cost-effective than therapies which specifically targets a disorder and leads to a reduction of wider symptoms in the short term by targeting common underlying variables.

2. METHOD

The present study was a quasi-experimental study with a control group with random assignment and pre-test post-test with three-month follow-up after treatment. In this study, the population included all patients with irritable bowel syndrome and the sample included the patients referring to Taleghani Hospital in 2020 and had inclusion and criteria. In this study, unified protocol was

regarded as an independent variable and its effectiveness on anxiety and depression, gastrointestinal symptoms, negative affect, fear of emotions, anxiety sensitivity, repetitive negative thinking and quality of life were evaluated as dependent variables. The members of the intervention group, who were randomly assigned in the transdiagnostic treatment course for 12 consecutive weeks. After the intervention and three months after treatment, the questionnaires were completed again by the group members.

The sample size was calculated based on the extraction of F test power and effect volume using the relevant studies (Johari-Fard et al., 2015; Mazaheri et al., 2014). Then, G* Power software was used to obtain the sample size as 12 subjects with F test power for alpha 0.05 and effect size 0.45 with two groups during three stages (Fig. 1 and 2).

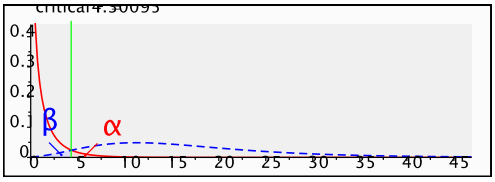


Figure 1 Alpha distribution and test power

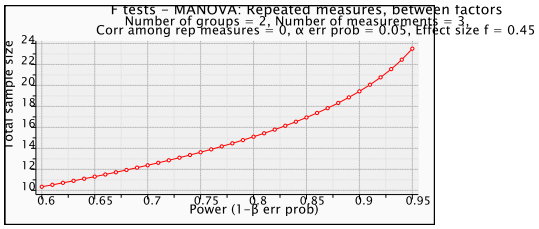


Figure 2 Sample size based on test power

In order to conduct this study, the general design of the study was first explained to the patients referring to Taleghani Hospital who were diagnosed with irritable bowel syndrome by a gastroenterologist. A number of 30 subjects who were interested in participating in the study and met the inclusion criteria were selected. Then, the objective, time, place and manner of conducting the research, confidentiality of information, how to provide the results, etc. were explained to the subjects and their informed consent was obtained. Considering the drop in each group, 30 subjects were selected by convenience sampling method and randomly divided into two groups receiving routine IBS treatments (medication and diet) and the group receiving psychological services in combination with medicine and diet. It should be noted that the content of sessions was designed based on the Unified Protocol treatment (Barlow et al., 2010) as shown in Table 1.

Table 1 Summary of Unified Protocol treatment

Sessions	Content
First	Motivational interview for patient participation and engagement during treatment Introducing treatment plan to patients and determining treatment goals
Second	Psycho-education for recognizing emotions and tracking emotional experiences Teaching three components of emotional experiences (thoughts, physical sensations and behaviors) and ARC model
Third and fourth	Emotional awareness training

Sessions	Content
	Learning to monitor emotional experiences using mindfulness techniques.
Fifth	Evaluation and Cognitive reassessment; Explaining the interrelationship between thoughts and emotions Introducing and identifying automated maladaptive evaluations and commonly used livelihoods of thought Helping the patient to increase flexibility in thinking
Sixth	Helping the patient to understanding different strategies for avoiding his/her emotions and understanding the contradictory effects of avoiding emotions
Seventh	Identifying behaviors caused by emotions and maladaptive EDBs and developing alternate actions through encountering behaviors
Eighth	Helping the patient to identify the feelings in emotional experiences and exercises on visceral exposure or visceral confinement in order to identifying physical sensations and increase the tolerance of these symptoms.
Ninth to eleventh	Helping the patient to cope with the internal and external triggers of emotions Teaching how to prepare a hierarchy of visual and real exposure and helping the patient to deal with them and prevent avoidance.
twelfth	A comprehensive overview of the concepts of treatment , Relapse prevention, and a discussion of the patient's therapeutic advances

During the study, three subjects from the intervention group and two subjects from the control group were taken out of the study because of exclusion criteria (Fig. 3). Inclusion criteria were the diagnosis of irritable bowel syndrome by gastroenterologist and IV ROME indicators, diagnosis of anxiety and depression based on the criteria of the Hospital Anxiety and Depression Questionnaire, an age of at least 18 years, fluency in Persian, minimum education of diploma, ability to attend treatment sessions weekly, lack of psychosis, bipolar disorder, and substance abuse. Exclusion criteria were entering other psychological therapies at the same time, the need to begin new medication or increased dose of medication during treatment of mental disorders after the intervention, emergence of suicidal thinking during treatment, consecutive absences of more than three sessions, unwillingness to continue treatment, impossibility to continue treatment due to severe somatic condition and very stressful events during the project.

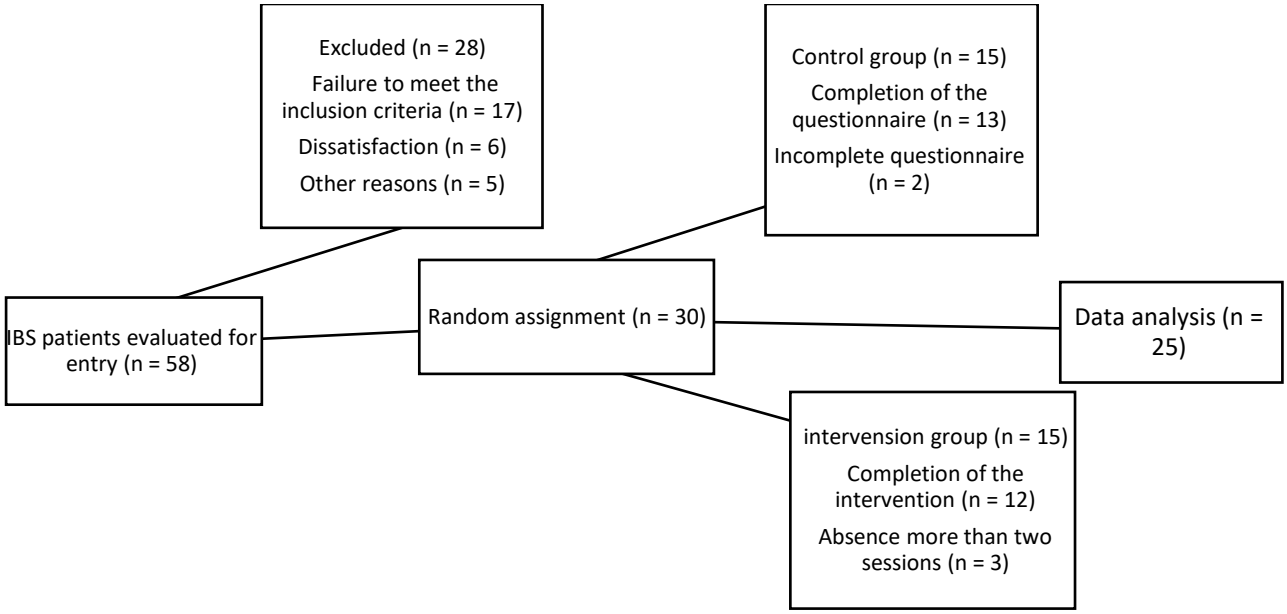


Figure 3 Flow diagram of the study

Measures

Demographic information questionnaire

It included gender, marital status, age, level of education, employment status, and length of disease.

Structured Clinical Interview for DSM-5 Disorders – Clinician Version

DSM-5 is the most common structured diagnostic instrument for evaluating disorders developed by First et al., (2013). To determine the validity and reliability of the clinical version of this instrument, one study indicated the percentage of positive relationship between the interview and clinical diagnosis as 0.73 -0.97 and its diagnostic sensitivity were 0.70. In a shared interview, the high positive agreement of more than 0.75 and kappa level of 0.70 were obtained for most diagnoses (Osório et al., 2019). The Persian version of SCID-5 has indicated an acceptable value for internal consistency, 0.95 - 0.99, test-re test reliability, 0.60 - 0.79, and Kappa reliability, 0.57 - 0.72 (Mohammadkhani et al., 2020).

IBS Symptom Severity Score

The IBS-SSS is a 5-item scale which measures the severity of IBS symptoms such as pain, constipation, bloating, the effect of disease on daily activities of life, and extra-intestinal symptoms. The mean score of each section is a maximum of 100 and the total score of the questionnaire is a maximum of 500. The score 75-175 shows mild IBS, 175-300 indicates moderate IBS, and above 300 shows severe IBS (Francis et al., 1997). The validity and reliability of the Persian version of this questionnaire was reported by Gholamrezaei (Gholamrezaei et al., 2011) (r=0.68).

Hospital Anxiety and Depression Scale (HADS)

HADS is a self-report 14-item screening scale and was developed by Zigmond and Snaith (et al., 1983). It is designed to demonstrate the possible presence of depression and anxiety symptoms. It consists of two 7-item scales, one for anxiety and other for depression. Anxiety (α = .83) and depression (α = .82) subscales have yielded good internal consistency. HADS has showed moderate to high correlations with other commonly questionnaires, .49 to .83 (Bjelland et al., 2002). The reliability and validity of this questionnaire in Iran was conducted by Kaviani et al., (2009). Cronbach's alpha for the depression subscale (0.70) and for the anxiety subscale (0.85) confirms good internal relationship for these subscales (Kaviani et al., 2009).

Positive and Negative Affect Scales (PANAS)

Neuroticism or the frequency of negative affect was measured by this scale. This scale measures the positive and negative affects of emotional structure and involves 20 words which describe both positive and negative affects. This instrument has been frequently used in various studies and has good internal consistency, as well as convergent and differential validity (Watson et al., 1988). Internal consistency coefficients (alpha coefficients) for P -PANAS and N-PANAS were 0.88 and 0.87, respectively. The reliability of the eight-week test-retest was 0.68 and 0.71 for P-PANAS and 0.71 for N-PANAS, respectively (Watson et al., 1988). This instrument has acceptable construct and audit validity in Iran based on a research by Bakhshipour and Dejkam (2006).

Affective Control Scale (ACS)

This scale is a 42-item questionnaire designed to evaluate the fear of losing control over emotions or behavioral reactions to emotions. The results of a study on the psychometric properties of ACS on the non-clinical population of students showed the acceptable validity and reliability of this instrument (Williams et al., 1997). In this study, the test-retest reliability of total scores was 0.78, total internal stability was obtained at 0.94, and the scores of anger, depression, anxiety and positive affect subscales were 0.72, 0.91, 0.89, and 0.84, respectively. The Persian version of this questionnaire was standardized by Tahmasebian et al., (2014) in Iran. The results indicated that this questionnaire has high internal consistency and reliability. Internal consistency of this scale among respondents using Cronbach's alpha test in different groups was higher than 0.75 (Tahmasebian et al., 2014).

Anxiety Sensitivity Index (Revise) (ASI-R)

This scale designed by Taylor and Cox (Taylor et al., 1998) is an expanded version of Anxiety Sensitivity Index by Reiss and Peterson in 1985. Taylor and Cox reported an internal consistency coefficient based on Cronbach's alpha for factors 1 to 4 at 0.91, 0.86, 0.88, and 0.89, respectively. In addition, a correlation coefficient between this index and anxiety sensitivity index of 0.94 was reported (Taylor et al., 1998). The Persian version of this questionnaire was standardized by Moradi Manesh et al., (1386) on the

non-clinical student population in Iran. The results indicated that the alpha coefficient for the whole scale was 0.94. Furthermore, the validity coefficient of the scale retest in four weeks for the whole scale was obtained at 0.95.

Repetitive Thinking Questionnaire (RTQ-10)

It is the short version of the 31-item Repetitive Thinking Questionnaire (RTQ) (Mahoney et al., 2012). The original version includes two subscales of repetitive negative thinking (27 items) and the lack of repetitive thinking (4 items). Evaluating the psychometric properties of this short transdiagnostic instrument in both clinical and non-clinical population indicated that this instrument with 31-item version has good divergent and convergent reliability and validity and supports its one-factor structure (Akbari, 2017). The internal reliability of this tool was 0.59 in the non-clinical population of students and 0.53 in the clinical population. The Persian version of the10-item repetitive thinking questionnaire was validated by Akbari in Iran (2017). The results of this study indicated that the reliability of this questionnaire was 0.76 by retest reliability and 0.91 by Cronbach's alpha. In addition, the simultaneous validity of this tool was obtained with the Ruminant Response Style Scale (0.72), the Pennsylvania State Anxiety Inventory (0.76), the Anxiety Inventory (0.79), and the Beck Depression Inventory (0.78).

Irritable bowel syndrome-quality of life (IBS-QOL-34)

The quality of life of IBS patients was obtained through this scale. This scale developed by Drossman and Patrick (Drossman et al., 2000). IBS-QOL-34 is one of the best scales available, which has been translated into several languages and its European and Asian versions have been validated (Bushnell et al., 2006; Park et al., 2007). In addition, the overall reliability of the Persian version of this test was obtained at 0.92. Further, the eight subscales of this questionnaire and the overall quality of life scale have relatively acceptable internal consistency coefficients (Masaeli et al., 2013).

The data were analyzed by repeated measures ANOVA in SPSS software version 25 Shapiro-Wilk tests was used to test the normality of data distribution. Data on anxiety and depression scale components, severity of gastrointestinal symptoms, negative affect, fear of emotions, anxiety sensitivity, repetitive negative thinking and quality of life were tested and reported using repeated measures ANOVA separately in three steps of pre-test, post-test, and three-month follow up after the treatment. It should be noted that the study protocol was approved by the ethics committee of Shahid Beheshti University of Medical Sciences with the code IR.SBMU.MSP.REC.1399.343.

3. RESULTS

Table 2 indicates the demographic information of the participants. The IBS patients in this study were 20-60 years old. Most of the participants were housewives or self-employed. In addition, 100% of the participants in the intervention group and 92.3% in the control group were female. Most of the IBS patients had bachelor's and master's degrees (48%) and 44% had a bachelor's or master's degree while 8% had a doctorate. Most of the participants in this study (76%) had average economic status. Furthermore, most of the participants (84%) had IBS for more than one year.

Table 2 Frequency distribution of demographic information of IBS patients in the study

(%) F											
Gender	Intervention	Control	age	Intervention	Control	Education	Intervention	Control	Duration of disease	Intervention	Control
Female	12 (0.100)	12 (92.3)	20- 30 years	2 (16.7)	3 (23.1)	Diploma	4 (0.33)	3 (1.23)	1-6 months	2 (16.7)	0
Male	0 (0.00)	1 (7.7)	30- 40 years	6 (0.50)	5 (38.5)	Associate degree	3 (0.25)	1 (7.7)	1-6 years	2 (16.7)	0
Total	12 (0.100)	13 (0.100)	40- 50 years	1 (8.3)	3 (23.1)	Master	2 (16.7)	4 (8.30)	More than one year	8 (66.7)	13(0.100)
			50 and over	3 (0.25)	2 (15.4)	Master	2 (16.7)	4 (8.30)	Total	12(0.100)	13(0.100)
			Total	12(0.100)	13(0.100)	Doctorate	1 (8.3)	1 (7.7)			

The effect of unified protocol treatment on variables was tested using repeated measures ANOVA. The descriptive parameters of research variables are shown in Table 3. In addition, the normality of data using Shapiro-Wilk test indicated that the research data are normal.

Table 3 Mean and standard deviation of variables in two groups of intervention and control

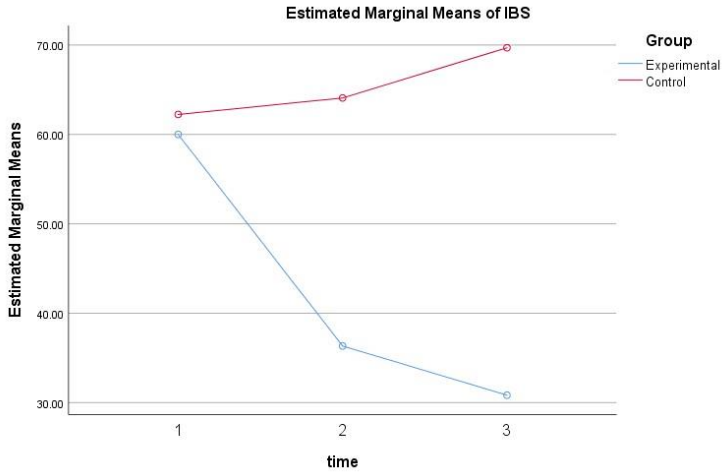
	Intervention						Control					
	pretest		Post-test		Follow up		pretest		Post-test		Follow up	
Variable	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
IBS symptoms	60/00	25/85	36/33	38/06	30/83	32/92	62/23	32/42	64/08	29/37	69/69	35/17
Symptoms of anxiety and depression	22/92	3/99	7/92	5/04	6/17	4/20	21/85	6/18	19/69	7/61	19/38	7/10
Negative affect and neuroticism	63/83	7/90	56/25	7/98	55/75	7/98	64/08	7/32	63/69	5/59	64/46	7/69
Fear of emotions	158/58	21/11	135/00	24/23	127/92	25/21	157/00	44/16	155/92	40/51	156/54	48/29
Anxiety sensitivity	51/67	20/25	23/92	17/48	20/08	20/54	55/00	31/42	51/85	26/11	53/23	34/62
Repetitive negative thinking	32/50	4/58	24/17	4/39	23/17	4/13	35/08	7/87	33/23	8/64	31/00	8/31
Quality of life	89/25	22/64	62/08	23/74	60/42	24/60	88/85	19/51	84/69	20/63	87/85	27/93

The results related to the variance test of homogeneity (Levene) indicated no significant difference between the two groups in the variables in three steps of measurement. In other words, the homogeneity of variance was established. In addition, the sphericity hypothesis was examined and the Greenhouse-Geisser statistics with adjusted degrees of freedom were used for the variables which did not confirm the sphericity hypothesis. The results obtained from the confrontations indicated that the interaction of group × time from pre-test to post-test on the symptoms of IBS, anxiety, depression components, negative affect, fear of emotions, anxiety sensitivity, repetitive negative thinking, and quality of life were significant. In other words, these variables in the intervention group have reduced more over time than the control group and there is a significant difference between the mean changes in the two groups (Table 4).

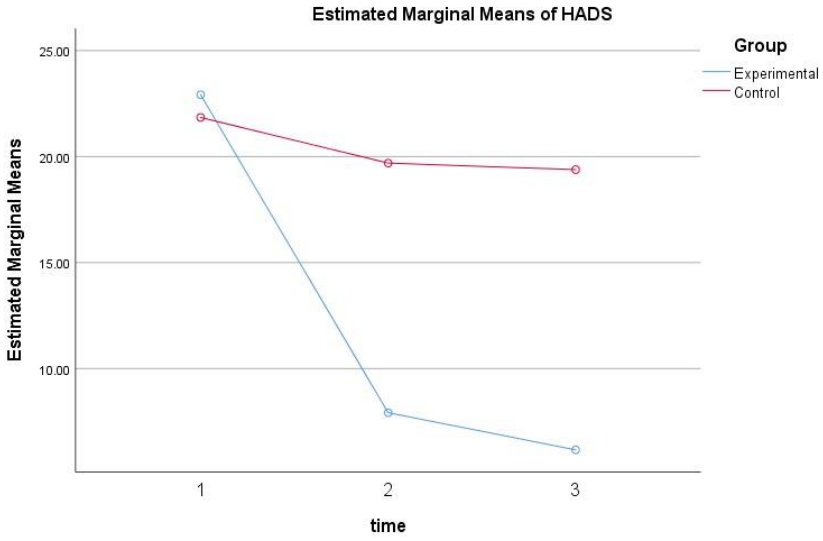
In addition, the amount of ETA for the interaction of group in time for the symptoms of IBS (0.17), anxiety and depression components (0.61), negative affect,(0.23), fear of emotions (0.25), anxiety sensitivity (0.33), repetitive negative thinking (0.35), and quality of life (0.25) indicated that unified protocol intervention can affect these variables at 17, 61, 23, 25, 33, 35, and 25%, respectively. The figures related to the mean variables in the three steps of measurement indicated a decrease in the mean of the intervention group (Fig. 4)

Table 4 Results of comparison test between three measurement steps in research variables

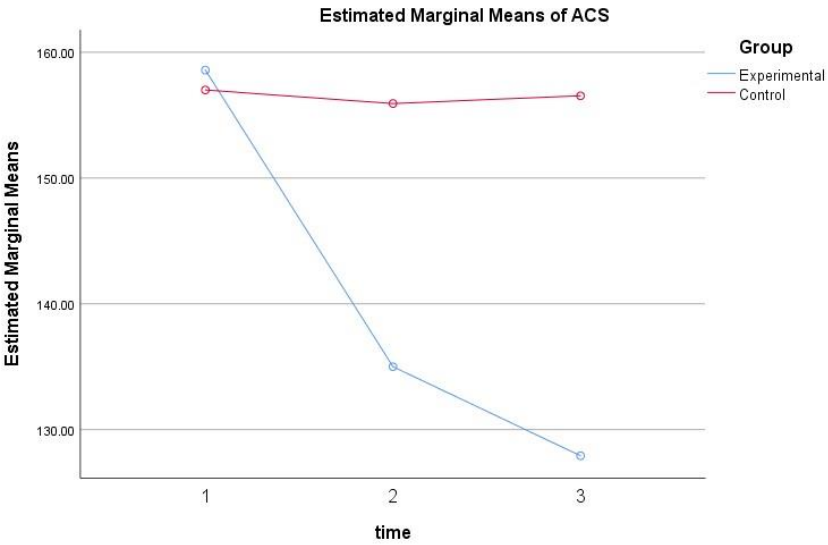
	Intra-subject effect						Interaction of group x time					
	Pre-test with post-test			Post-test with follow-up			Pre-test with post-test			Post-test with follow-up		
Variable	F	P	η^2	F	P	η^2	F	P	η^2	F	P	η^2
Symptoms of IBS	3/38	0/08	0/13	0/001	0/99	0/001	4/62	0/04	0/17	1/06	0/31	0/04
Symptoms of anxiety and depression	65/20	0/001	0/74	2/40	0/13	0/09	36/57	0/001	0/61	1/18	0/29	0/05
Negative affect	8/53	0/01	0/27	0/01	0/91	0/001	6/96	0/01	0/23	0/28	0/60	0/01
Fear of emotions	9/24	0/01	0/29	0/80	0/38	0/03	7/69	0/01	0/25	1/13	0/30	0/05
Anxiety sensitivity	17/94	0/001	0/44	0/14	0/72	0/01	11/36	0/001	0/33	0/62	0/44	0/03
Repetitive negative thinking	30/58	0/001	0/57	4/48	0/05	0/16	12/42	0/001	0/35	0/65	0/43	0/03
Quality of life	14/02	0/001	0/38	0/09	0/76	0/001	7/57	0/01	0/25	1/00	0/33	0/04



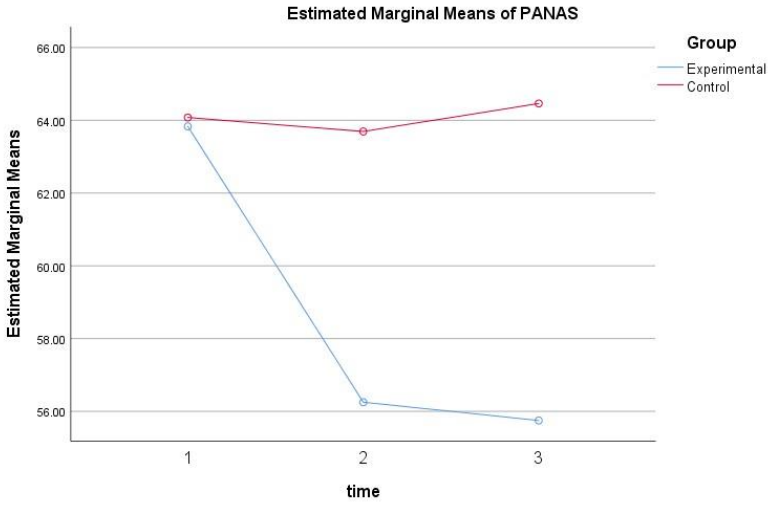
Symptoms of IBS



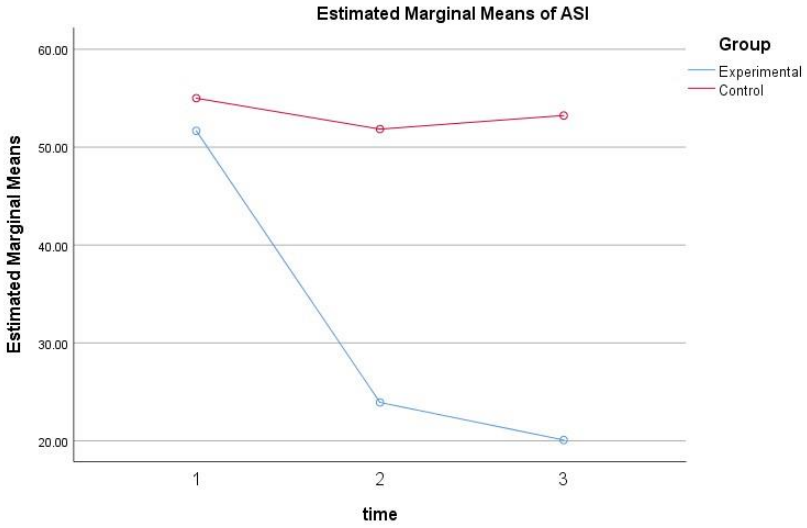
Symptoms of anxiety and depression



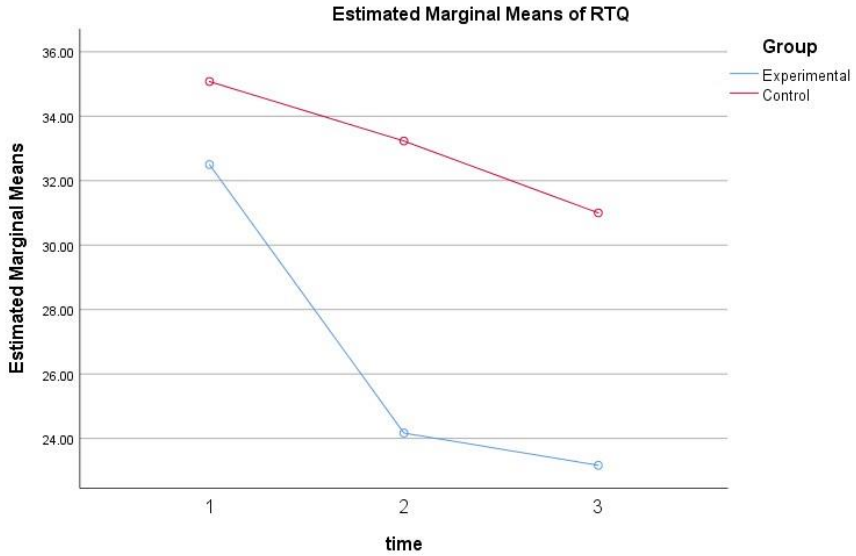
Fear of emotions



Negative affect



Anxiety sensitivity



Repetitive negative thinking

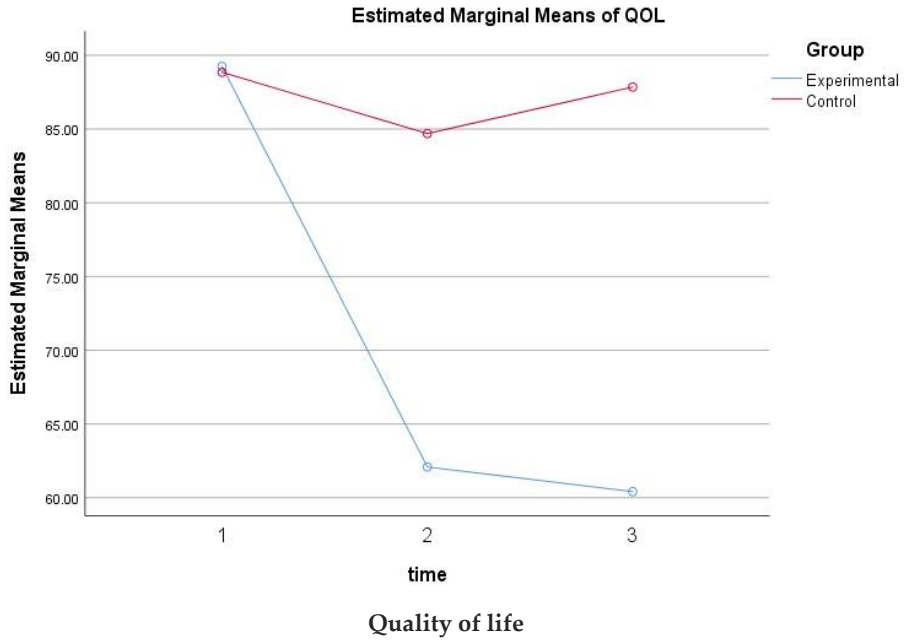


Figure 4 Mean of research variables in intervention and control groups in three steps of measurement

4. DISCUSSION

This study aimed to assess the effectiveness of unified protocol treatment on symptoms, quality of life, negative affect and negative reactivity such as fear of emotions, anxiety sensitivity and repetitive negative thinking in IBS patients in comorbidity with anxiety and depression. The results of this study indicated that unified protocol treatment effectively decreases the symptoms of IBS and the symptoms of anxiety and depression in IBS patient's in comorbidity with anxiety and depression. Although the studies on emotion-based therapies, especially those based on the unified protocol (UP) are limited, the findings of our study are consistent with the other studies which examined the effect of emotion-focused cognitive-behavioral transdiagnostic therapy on emotional disorders such as depression, anxiety and stress (Boisseau et al., 2010; Farchione et al., 2012; Suveg et al., 2006).

In explaining the effect of emotion regulation-based intervention on the symptoms of depression, anxiety, and stress, Barlow stated that unified protocol for transdiagnostic treatment is a cognitive-behavioral therapy focusing on emotion in which emotional processes are the main goal of treatment (Farchione et al., 2012). For example, the findings of this study are consistent with the results of previous studies on the effect of unified protocol therapy on emotional disorders in patients with gastrointestinal dysfunction and mental disorders (Mazaheri et al., 2014). In addition, the findings of our study indicated that unified protocol treatment can be effective in reducing the IBS symptoms. This result is consistent with Johari's study of reducing IBS symptoms through unified protocol therapy (Johari-Fard et al., 2015).

Studies have indicated that intervention on emotional regulation plays a role as the effect of unified protocol therapy on the changes in the symptoms related to emotional and gastrointestinal disorders in IBS patients (Mohsenabadi et al., 2018). Unified protocol therapy seems to help IBS patients identify and express their emotions that helps them to avoid more severe psychological and physical symptoms. Different studies have indicated that emotion regulation is a significant structure in psychopathology and IBS (Saigo et al., 2014; Sayar et al., 2000). In addition, emotion regulation problems are essential for the development and maintenance of psychopathology (Aldao et al., 2014; Gratz et al., 2015). Inconsistent strategies such as repression and avoidance for emotion regulation are associated with a wide range of emotional disorders and are directly related to anxiety and depression (Aldao et al., 2010). Thus, the lack of emotional regulation is a significant factor in developing mental disorders in IBS patients unified protocol therapy specifically targets defects in emotion regulation and results in the selection of more adaptive emotion regulation techniques through practice skills and dealing with emotions.

The goal of unified protocol therapy is to decrease emotional disorders while improving emotion regulation (Barlow et al., 2010). Emotional awareness as the first step in the emotion regulation process is related to a wide range of emotional disorders. The patients with psychosomatic disorders, especially IBS, have lower emotional awareness or suppress their emotions (Gross et al., 1998). Thus, it seems that unified protocol therapy can decrease the effects of emotional disorders and improve gastrointestinal symptoms through increasing emotional awareness and emotion regulation skills. In addition to emotional awareness, cognitive

reassessment is another component of unified protocol therapy. Cognitive reassessment is considered as a key emotion regulation strategy (Gross et al., 1998).

The significance of cognitive assessment and flexibility for the treatment of IBS patients were confirmed in the previous studies (Palgi, 2015). Among IBS patients, a positive relationship was observed between cognitive evaluation and abdominal pain and discomfort (Sugaya et al., 2008). Furthermore, anxiety is associated with cognitive assessment in these patients (Sugaya et al., 2008). Thus, unified protocol therapy is effective in cognitive assessment by improving emotion regulation skills and leads to decreased emotional symptoms in IBS patients. In short, emotion regulation mediated the improvement of emotional and gastrointestinal symptoms. This is important and indicates that targeting this common mechanism can be valuable for the patients with both physical and emotional symptoms. The results of this study indicated that unified protocol treatment can effectively increase the quality of life in IBS patients in comorbidity with anxiety and depression. Cognitive emotion regulation helps the person manage emotions after experiencing stressful events (Garnefski et al., 2007). The people who use adaptive cognitive strategies to regulate emotion when experiencing stress can effectively manage the intensity of their negative emotions by changing their assessments. The person's resilience probably increases when such negative emotions are regulated effectively and consistently (Troy et al., 2011).

Emotion regulation training has increased the emotional dimension of patients' quality of life leading to an improvement in the overall quality of life related to health in such people. Consistent with the findings of our study, Melin et al., (2010) reported a significant improvement in patients' quality of life. Other psychological interventions based on cognitive or behavioral therapy (Heymann-Mönnikes et al., 2000; Lackner et al., 2007; Tkachuk et al., 2003; Zargar et al., 2012) showed the effect of this treatment on the quality of life of patients with functional gastrointestinal disorders, especially IBS which is consistent with the findings of our study. As a result, unified protocol therapy based on emotion regulation which aims to increase emotional awareness, flexibility in assessment, prevention of emotional avoidance, and coping with emotional symptoms promotes emotion regulation and quality of life.

Furthermore, therapy helped them identify thinking, emotions, and behaviors which improve immunity, express emotions emphatically, learn skills to manage stress and anxiety, and rebuild their emotional state (Barlow et al., 2016; Barlow et al., 2020; Donker et al., 2009). The quality of life improves by improving the emotional state, reducing emotional disorders such as depression and anxiety, and reducing the IBS symptoms. The findings of our study reported that unified protocol therapy can reduce negative affect and negative reactivity including fear of emotions, anxiety sensitivity, and repetitive negative thinking in IBS patients in comorbidity with anxiety and depression. There may be several potential mechanisms by which unified protocol treatment can remove a wide range of symptoms. It is possible that the used strategies target the common and underlying processes which cause pain and emotional dysfunction. Another possibility is related to the teaching of a set of skills enables clients to apply such skills individually to each disorder (Allen et al., 2012).

In addition, what moves a person in the direction of anxiety depends on how to examine and manage the symptoms of anxiety (Fardaeni Sofla et al., 2015). The increased response of physiological emotions is one of the many characteristics of anxiety disorders which often lead to the use of maladaptive strategies to reduce such emotions. In unified protocol therapy, patients learn how to recognize thinking and behaviors as part of an emotional response and understand how physiological emotions can be involved in such emotions. In addition, the thinking and experience of physiological emotions may contribute to their emotional response. Increasing awareness and tolerance of physical emotions is one of the main skills in this treatment.

Further, the results of studies conducted by Bowell et al., (2013) indicated that coping with physiological stimuli is one of the main skills of unified protocol therapy and a useful treatment strategy for a wide range of anxiety disorders such as anxiety sensitivity. This study had its own limitations. The main limitation of this study was the small number of samples and future studies are suggested to focus on more samples. In addition, future studies are suggested to examine treatment mediators.

5. CONCLUSION

In general, the findings of our study showed that unified protocol therapy has significant effect on gastrointestinal symptoms, anxiety, depression symptoms, quality of life, negative affect and negative reactivity such as fear of emotions, anxiety sensitivity, and repetitive negative thinking in IBS patients in comorbidity with anxiety and depression. Given the high comorbidity of IBS with depression and anxiety and the presence of deficits in emotion regulation, this treatment seems to be more cost-effective than therapies which specifically target a disorder by targeting common underlying variables and lead to the reduction of wider symptoms in the short term.

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Ethical approval

The study was approved by the Medical Ethics Committee of Shahid Beheshti University of Medical Sciences (ethical code: IR.SBMU.MSP.REC.1399.343).

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Conflict of interests

The authors declare that there are no conflicts of interests.

Data and materials availability

All data associated with this study are present in the paper.

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