doi

**Original Paper** 

# The Effectiveness of the Unified Protocol for Emotional Problems of Women with Breast Cancer: A Randomized Clinical Trial

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**Submitted:** 19 September 2021 **Accepted:** 23 October 2021

Int J Behav Sci. 2021; 15(3): 168-174

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# **Abstract**

**Introduction:** The results of many studies have confirmed the existence of different emotional problems in women with breast cancer. So far, no study has been carried out on the effectiveness of the unified protocol. Therefore, the current research aimed at studying the effectiveness of this protocol on emotional problems of women who suffer from breast cancer.

**Method:** This study was a quasi-experimental study with a control group. The treatment lasted for 12 sessions (each session 60 min). The population included all women with breast cancer in Kermanshah. Sampling was done by convenience sampling. In this study, 40 women with breast cancer were divided into two control (20) and experimental (20) groups. The control group only received medication while the experimental group received a unified protocol along with medication. The participants were examined during pre-test, post-test and follow-up assessments. The assessments were done using the Depression, Anxiety and Stress Scale (DASS-21), The Emotion Regulation Questionnaire (ERQ), Acceptance & Action Questionnaire (AAQ-II), and Work and Social Adjustment Scale (WSAS). The data were analyzed via SPSS-24. Mean, standard deviation and repeated measures analysis were used to analyze the data.

**Results:** The results of repeated measures analysis indicated that the unified protocol leads to significant improvements in the variables of the study (P<0.01). The effect size of this treatment on the variables was medium and higher. The highest size effect belonged to reappraisal, suppression, acceptance and action, depression, stress, anxiety and socio-occupational adaptation.

**Conclusion:** The unified protocol led to a decrease in the emotional problems, an improvement in emotion regulation and acceptance towards this illness in women with breast cancer. The therapeutic implications have been discussed.

**Keywords:** Unified Protocol, Emotion Regulation, Socio-occupational Adaptation, Depression, Anxiety, Stress

#### Introduction

Breast cancer is the most prevalent type of cancer among women [1]. Presently, more than 7 million people are diagnosed with cancer, reaching to 28 million new cases in 2030 after a 50 percent rise [2]. In Iran, breast cancer is known as the most prevalent cancer diagnosis and also the second cancer-related death cause in women [3, 4]. Despite widespread advances in the biological treatment of breast cancer, some problems based on biopsychosocial aspects of this disease remain unsolved. The women who are diagnosed with breast cancer usually experience negative feelings, distorted perceptions of the body

image, inhibitions in sexual relationship, and decreased self-confidence [1]. The most important problems they deal with, include the changes in the sexual and physical functions. These changes could result in physical and psychological problems such as anxiety, fatigue, depression, and feeling an imminent death [5-7]. In addition, anxiety, stress, depression, and other mood disorders are expected to emerge right after being diagnosed with the illness. These symptoms could be affected by time, in response to the diagnosis, after experiencing relapses and making improvements in terms of health [8].

On the other hand, studies have shown that applying psychological interventions for patients with breast cancer, can decrease their fatigue, their fear of recurrent problems [9], the complaints about cognitive abilities [10], depression, stress and anxiety [11]. Different treatments such as pharmacotherapy, cognitive-behavioral therapy, and the third-wave treatments have been utilized for improving the mental-health problems of individuals with cancer. Effectiveness of Training Mindfulness on Psychological Well-being, Coping Strategy and Family Function among Women Suffering from Breast Cancer has studied [12]. Results of studies have shown that Cognitive-Behavioral Therapy (CBT) is the psychotherapy most commonly used in the medical setting, and has demonstrated suitable feasibility and efficacy [12]. However, CBT has some limitations such as not emphasizing comorbidities, diagnosis-based protocols and the underlying process [13]. Also, empirical evidence retrieved from meta-analyses demonstrated that psychological treatments (such as CBT) in cancer patients (especially breast cancer) generate very small to medium effects on mental health problems [14, 15].

In recent years, transdiagnostic protocols have been designed to target the underlying process involved in a wide range of psychological disorders, and recent Meta analyses have shown their effectiveness, including the Unified Protocol (UP) [16, 17]. The UP has been designed as a response to the limitations of CBT [18]. Unlike most of the other cognitive-behavioral treatments, this therapeutic method targets a specific disorder [19]. This emotion-based cognitive-behavioral consists of five main components which by emphasizing the mutual pathological bases [20-22]. target all the anxiety disorders, depressive disorders and other related mental problems [23]. Compared to other diagnostic approaches, this treatment has some advantages including the functionality of treatment for different disorders and different comorbid problems, the simplicity of the treatment in practice and the easiness of learning this treatment even for beginners [16, 22]. According to different investigations, this protocol is effective in treating emotional problems of different individuals [18, 19, 24]. In a study, Mohammadpour et al. examined the effectiveness of a transdiagnostic treatment UP on sleep comorbidity symptoms in patients with generalized anxiety disorder. The results showed that UP only affected some of the components of sleep quality in these patients [25]

Due to the increasing progress of trans-diagnostic therapies such as UP and its lack of study in the field of emotional problems of patients such as breast cancer so far, this study was conducted to examine trans-diagnostic treatment UP on depression, anxiety, stress, emotion regulation and overall performance in women with breast cancer. So the aims of the study were to investigate whether trans-diagnostic treatment UP improves depression, stress, anxiety in women with breast cancer, whether trans-diagnostic treatment UP improves emotion regulation in women with breast cancer and whether trans-diagnostic treatment UP improves overall performance in women with breast cancer.

#### Method

This quasi-experimental study was done with a control and an experimental group and included pre-test, post-test and follow-up assessments. The experimental group received the UP along with medications. For the control group however, only medication was applied. Each group consisted of 20 members. The study had a two-month follow-up. The statistical population included all women with breast cancer in Kermanshah. Sampling was done by convenience sampling. For this purpose, 40 women with breast cancer in Imam Reza Hospital in Kermanshah were selected and were randomly assigned to the experimental and control groups. This intervention was done in 2019-2020. Sample size was obtained either from previous studies or calculated using the following formula [26].

studies or calculated using the following formula [26]. 
$$\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2(s_1^2+s_2^2)}{(\mu_1-\mu_2)^2}$$

$$n = \frac{(10.49)(8.84^{2} + 13.47^{2})}{(32.40 - 15.20)^{2}} = 9.20$$

Considering probable losses from samples, this number was increased to 40. There was no significant difference between the two groups (P > 0.05). Demographic characteristics of the subjects have been presented in Table 1.

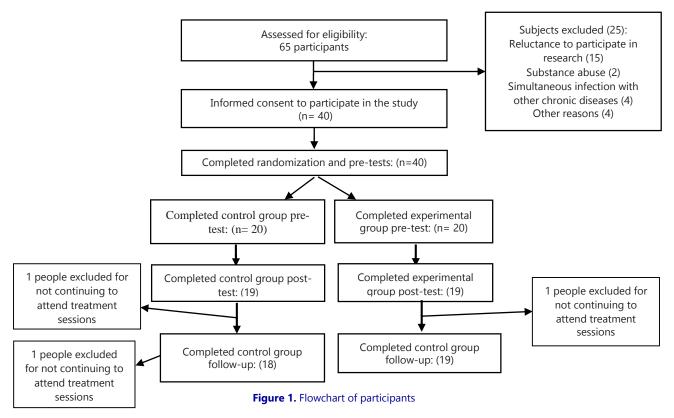
 Table 1. Demographic Characteristics of Subjects

Parameters	Experimental Group	Control Group
Grade		
Diploma	9 (0.45)	8 (0.40)
Bachelor	7 (0.35)	8 (0.40)
MSc	3 (0.15)	2 (0.10)
PhD	1 (0.5)	2 (0.10)
Marital status		
Single	3 (0.15)	2 (0.10)
Married	17 (0.85)	18 (0.90)

After considering the inclusion and exclusion criteria, 40 individuals were selected. The inclusion criteria included having a certain diagnosis for breast cancer and being ill for at least six months, not being diagnosed with any other serious conditions (chronic heart diseases, kidney or lung diseases in their severe stages) being at least 18 years old, having at least a secondary school diploma, being married, being interested to participate in the program,

having no history of substance abuse or addiction within one year before the program, and having emotional problems based on the score of the questionnaire. The exclusion criteria included being absent in more than two sessions, not doing the assignments, substance abuse, having suicidal ideations during the program, deterioration of symptoms during the program, participating in other psychological interventions simultaneously, and not being interested to take part in the sessions during the program. Before beginning the intervention, the participants completed an informed consent form. In addition, they could leave the program freely whenever they wanted to. The information about the participants was completely confidential. If any participant desired to know the results of the study, the information would be given to them. To observe the ethical principles, the control group was given a self-help trans-diagnostic book after the study. The allocation of the participants has been presented in Figure The patients were assessed in three stages: pre-test, post-test and follow-up. The experimental group received 12 sessions) 60 min) of the UP weekly . The assessments were done by a Master student of clinical psychology (other than the authors of this study) who did not have any information about the groups. The intervention was completely performed by a Master student of clinical psychology (the first author) who was trained for cognitive-behavioral therapy and also trans-diagnostic treatment. The sessions were supervised by a clinical psychology professor (the corresponding author). The intervention was performed individually.

The UP is a trans-diagnostic treatment with five core modules and three side modules. The five main modules include: (1) mindful emotion awareness, (2) cognitive flexibility, (3) identifying and preventing patterns of emotion avoidance, (4) increasing awareness and tolerance of emotion-related physical sensations, and (5) Interoceptive and situational emotion-focused exposures [27]. The UP is presented in Table 2.



**Table 2.** The Session Content of the Trans-diagnostic UP

The modules	Description	Number of Sessions	
1	Increasing the motivation and describing the intervention		
2	Psychoeducation and following the emotional experiences	2-3	
3	Providing education about present-focused emotional awareness	4	
4	Evaluation and cognitive reappraisal (increasing cognitive flexibility)	5	
5	Emotional avoidance and emotion-driven actions	6	
6	Awareness and tolerating the physical sensations related to emotions	7	
7	Interoceptive and situation-based emotional exposure	8-11	
8	Relapse prevention	12	

The tools used in this study are as follows:

The Depression, Anxiety and Stress Scale (DASS): This scale was developed by Lovibond and Lovibond (1995) and includes two long (42 items) and short (21 items) versions. In the 21-item version, each of the subscales including depression, anxiety and stress are examined via seven items. In order to measure the score for each subscale, the relevant items are added up. According to a study, the Cronbach's alpha was 0.95, 0.90, 0.93 and 0.97 for depression, anxiety, stress and the total scale respectively. In another study on the internal consistency of DASS-21, the Cronbach's alpha for depression was reported (0.77), anxiety (0.79), and stress (0.78) and according to calculations of criterion validity, the correlation of DASS-21 with Beck Depression Inventory, The Zung Self-Rating Anxiety Scale (SAS) and the Perceived Stress Scale (PSS) was reported to be 0.70, 0.67, and 0.49 respectively. All these correlations were significant [28]. In the Iranian version, the retest validity coefficient for stress, depression, and anxiety were 0.80, 0.81, and 0.78, respectively [29]

**The Emotion Regulation Questionnaire (ERQ):** This scale was designed by Gross and John (2003) and consists of 10 items. ERQ can measure two emotion regulation strategies; the constant tendency to regulate emotions by 1: cognitive reappraisal or 2: expressive suppression. The items are scored on a 7-point Likert scale from 1 (strongly disagree) to 7 (strongly agree) [30]. The scale has good internal consistency scores (0.79 for cognitive reappraisal and 0.73 for expressive suppression). The test-retest reliability of scale was 0.69 [30].

Acceptance and Action Questionnaire (AAQ-II): The first version of this scale was developed by Bond et al. (2004). This preliminary version was especially designed to be used in studies carried out on adults. It was a general scale including several ACT processes which indicated psychological flexibility. AAQ-II is a 10-item scale with suitable internal consistency (a=0.87) and test-retest reliability (r=0.80). The total scores for this scale range from 0 to 60. The AAQ-II includes positive and negative items. This scale is scored on a 7-point Likert scale. Higher scores indicate more flexibility and lower scores indicate less flexibility [31]. Cronbach's alpha coefficient in the Iranian version was 0.84. The test-retest reliability between three and 12 months was 0.81 and 0.79,

respectively [32].

Work and Social Adjustment Scale (WSAS): The WSAS has designed by Mundt et al (2002). The scale a 5-item measurement by which the individuals indicate the extent to which psychological symptoms have interfered with their occupational functions, home management, personal and social interests and family relationships. The rating varies from 0 (Not at all) to 8 (Very severely). According to Mundt et al. (2002), WSAS has proper psychometric properties. According to their report, the internal consistency and test-retest validity of WSAS are 0.75 and 0.73 respectively. They also calculated the correlation between this scale and the symptom severity of depressive disorders (0.76) and also Obsessive-Compulsive Disorder (OCD) (0.61) [33]. The reliability of the Persian version of this questionnaire is reported to be 0.70 [34].

In the descriptive statistics section, the mean and standard deviation were reported, and in the inferential statistics section, repeated measurement analysis was used.

#### Results

Table 3 presents the results of the mean and standard deviation of the dependent variables in pre-test, post-test and also follow-up.

Before applying the repeated measures ANOVA, the required pre-assumptions such as the results of the Box's M test, the Levene's test and Mauchly's test of sphericity were considered and confirmed. Since the Box's M test results were not significant for any of the variables (P> 0/05), the homogeneity of variance-covariance matrices was confirmed. Moreover, the insignificance of all the variables in the Levene's test indicates that the betweengroup variances are equal and that the error variance of the dependent variables is equal among both groups (P>0/05). However, the Mauchly's sphericity test results did not confirm the equality of the variance-covariance for any of the variables. Therefore, the Greenhouse–Geisser tests were applied for analyzing the obtained data.

According to Table 4, compared to the control group, performing the unified protocol in the experimental group has led to significant improvements in depression, stress, anxiety, reappraisal, suppression, acceptance and action and socio-occupational adaptation.

Table 3. Mean and Standard Deviation of Research Variables

Variable	Group	Pre-test	Post-test	Follow-up	
Depression	Experimental	13.05 (1.73)	7.49 (1.51)	8.87 (1.74)	
	Control	13.21 (1.76)	13.36 (0.50)	13.05 (1.95)	
Anxiety	Experimental	14.22 (1.47)	10.72 (1.10)	11.27 (1.36)	
	Control	13.31 (1.73)	15.10 (1.77)	15.21 (1.13)	
Stress	Experimental	19.61 (2.19)	15.11 (1.78)	15.83 (1.79)	
	Control	21.10 (2.42)	21.63 (2.40)	21.89 (2.33)	
Reappraisal	Experimental	19.11 (1.27)	24.38 (1.91)	24.05 (1.64)	
	Control	18.57 (1.34)	19.21 (1.68)	19.15 (1.70)	
Suppression	Experimental	21.38 (1.24)	16.83 (1.46)	17.38 (1.41)	
	Control	20.89 (1.32)	21.52 (1.42)	21.84 (1.38)	
AAQ	Experimental	30.05 (1.76)	22.50 (1.68)	22.11 (1.64)	
	Control	29.63 (1.46)	28.73 (2.90)	29.31 (2.51)	
WSAS	Experimental	28.05 (1.51)	23.38 (2.03)	23.55 (1.78)	
	Control	27.78 (1.61)	28.73 (1.58)	27.47 (1.69)	

**Table 4.** Mixed Analysis of Variance with Repeated Measures of Variables

Variable	Source	SS	Df	F	Р	Partial eta
Depression	Interaction (Time*Group)	74.27	1	49.36	0.01	0.50
	within-subjects (Time)	134.43	2	38.10	0.01	0.52
	Between subjects (Group)	292.45	1	49.03	0.01	0.58
Anxiety	Interaction (Time*Group)	44.99	1	312.80	0.01	0.62
	within-subjects (Time)	98.41	2	245.95	0.01	0.90
	Between subjects (Group)	12.77	1	25.84	0.01	0.50
Stress	Interaction (Time*Group)	108.28	1	72.33	0.01	0.67
	within-subjects (Time)	13.75	2	6.20	0.01	0.15
	Between subjects (Group)	169.14	1	47.80	0.01	0.57
Suppression	Interaction (Time*Group)	113.85	1	85.93	0.01	0.70
	within-subjects (Time)	78.49	2	39.54	0.01	0.53
	Between subjects (Group)	230.64	1	61.78	0.01	0.63
Reappraisal	Interaction (Time*Group)	85.89	1	47.54	0.01	0.57
	within-subjects (Time)	200.30	2	76.29	0.01	0.68
	Between subjects (Group)	343.10	1	66.53	0.01	0.65
AAQ	Interaction (Time*Group)	268.96	1	115.47	0.01	0.76
	within-subjects (Time)	430.35	2	103.59	0.01	0.74
	Between subjects (Group)	522.10	1	59.71	0.01	0.63
WSAS	Interaction (Time*Group)	80.94	1	73.93	0.01	0.67
	within-subjects (Time)	131.75	2	48.80	0.01	0.58
	Between subjects (Group)	213.06	1	34.84	0.01	0.49

#### Discussion

To our knowledge, there are no studies about the effectiveness of the UP on the emotional problems in women with breast cancer. The findings of this study are in line with the investigations that have shown the effectiveness of the UP on emotional problems [9, 12]. This finding is consistent with the underlying theories and therapeutic goals of the UP. Furthermore, the results of this research are in line with the study of González et al. in which they had assessed 52 individuals suffering from cancer. In their study, they compared two kinds of treatment (behavioral activation and acceptance and commitment therapy) in terms of their effectiveness on the emotional problems of the patients. According to their results, both treatments could effectively and significantly reduce the emotional problems. They concluded that activation and avoidance (which are both two of the main modules in the unified protocol) are the main required mechanisms for change [35]. In fact, by focusing on the mutual emotional factors (for example rumination, anxiety, avoidance, and emotional dysregulation) the UP leads to simultaneous improvements in emotional problems including depression, stress, and anxiety [36]. We could explain these findings by mentioning that since this treatment is emotion-based, its main solution for

change is emotion regulation [24]. Emotion regulation can reduce the main emotional problems by improving the individuals' problems and how they respond to their emotions. According to the effect sizes of the treatment on different variables, the treatment has clearly been more effective on this variable. Furthermore, the lack of enthusiasm for experiencing emotions like distress and anxiety generates different types of anxiety [37]. According to Rost et al., the underlying factor for reducing psychological distress in breast cancer patients, is reducing their cognitive and emotional avoidance [36]. In fact, this treatment decreases suppression and emotional problems by providing education on emotions, enhancing emotional skills, and preventing the individuals from avoiding their emotional experiences. Another problem that patients with chronic diseases deal with is the lack of motivation for receiving therapy or doing their daily tasks. According to Hayes et al., more than half of the changes in depression symptoms could be justified by the lack of acceptance and motivation [37]. The first module of the UP provokes motivation and consequently leads to better functioning in general.

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 [38]. Given that the UP seeks to improve the vulnerability of emotional disorders (and not the specific symptoms and signs of any disorder), emotion regulation can be considered as a potential change factor in this protocol [39]. Mazaheri et al. have shown that the integrated protocol is effective on some components of cognitive emotion regulation and difficulty in emotion regulation [38]. This is somehow consistent with the results of the present study.

Another variable which was assessed in this investigation was acceptance and action. This indicator can examine the level of psychological flexibility. In the unified protocol, the fourth module focuses specifically on psychological flexibility. Its target is for the patients to learn identifying their thought patterns and to increase their flexibility in different situations. The findings of this research are in line with a previous study [40]. In the mentioned study on patients in the final stages of ovarian cancer, they indicated that compared to the control group, the intervention group that had participated in acceptance and commitment therapy sessions (which aim at enhancing psychological flexibility) decreased the psychological distress and experiential avoidance more successfully. They also reported higher levels of quality of life at the end of the treatment [40].

This study faced limitations which require consideration when interpreting our findings. First, the small sample size may have made it difficult to generalize our findings. Secondly, the use of self-report questionnaires, not other tools such as MRI, FMRI, EEG. Thirdly, not controlling other interfering factors in the treatment (e.g. drugs). Finally, this study has been carried out on women and only one chronic illness. Given that the present study is one of the study to investigate the effectiveness of UP, it is suggested that more studies of different diagnostic groups with larger sample sizes could be conducted.

#### **Conclusion**

Although recent studies have made significant progress with regards to the development of evidence based interventions such as the UP, no study has been carried out on the effectiveness of this protocol in emotional disorders of chronic diseases such as breast cancer. The results of the present study indicated that UP significantly improved anxiety, stress, depression, and another components of emotional problems in women with breast cancer. This helps therapists to understand on which therapy components they should focus to produce better therapy outcomes and, consequently, enhance the efficacy of the treatment.

#### **Conflict of Interest**

The authors declare no conflicts of interest.

### **Ethical Approval**

Ethical principles were considered in this research. Before starting treatment, the participants completed an informed consent form. The participants were informed about the aims of the study. They were also assured about the confidentiality of their information. Also, they were allowed to leave the study whenever they wish, and if

desired, the results of the research would be available to them.

## **Acknowledgement**

The authors would like to thank all the participants who participated in this study. This article has been retrieved from Roya Farnoodimehr's thesis in partial fulfillment of the clinical psychology Master's degree from the Islamic Azad University of Kermanshah Branch.

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