

Applying the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP) on Emotional Regulation, Cognitive Flexibility, Mindful Emotional Awareness and Quality of Life in Breast Cancer: A Pilot Study

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Introduction: This study aimed to investigate the effectiveness of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP) for women with breast cancer.

Methods: It was a pilot randomized controlled trial in which women with breast cancer were allocated to a 9-week Unified Protocol for transdiagnostic treatment of emotional disorders (UP) (n=14) or a wait-list control group (n=15). Pre- and post-intervention, the Beck Depression Scale (BDI-II), Beck Anxiety Scale (BAI), Depression, Anxiety and Stress Scale (DASS-21), Cognitive Flexibility Inventory, Cognitive Emotion Regulation Strategies Scale (CERQ), Emotional Awareness Level Scale (LEAS), and The EORTC Breast Cancer-Specific Quality of Life (EORTC QLQ-BR23) were completed.

Results: Significant reductions in depressive, anxiety, and stress symptoms, as well as maladaptive emotional regulation strategies, were observed within the UP from baseline to post-treatment. Compared to the waitlist-control condition, participants in the UP condition showed increased adaptive strategies of emotional regulation, cognitive flexibility, mindful emotional awareness, and quality of life.

Conclusions: The findings provide preliminary evidence for the utility of the UP in the reduction of psychological dysfunctions and improving the quality of life in women with breast cancer.

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INTRODUCTION

Breast cancer is a common and progressive cancer with the death risk of women between 20 and 50 years old, accounting for about 30% of all female cancers. The study of breast cancer from 2006 to 2015 shows an annual increase of 0.3-0.4%, and Asians have increased (1.8%) more than the highest possible rate. Therefore, more attention has been paid to the psychological consequences of cancer,

cancer diagnosis, and treatment [1]. Patients and survivors showing limited understanding of their condition view their cancer as chronic and uncontrollable, with high consequences, more severe symptoms, and poorer physical/mental health outcomes, especially considering the condition's subjective effects [2]. One of the problems seen in patients with cancer is emotional disorder [3].

Psychological negative aspects of breast cancer include emotional reactions, anxiety and distress, and insomnia. These factors, along with physical disabilities, make treatment difficult and reduce the quality of life in women with breast cancer. Patients not following treatment instructions are less likely to have a good outcome. The results of 16 studies indicate that 16-65% of patients with breast cancer experience moderate or severe anxiety as one of the most critical psychological problems. In addition, the rate of depression in these patients is 45-80%. In general, studies show that about 32% of patients with breast cancer suffer from negative psychological consequences in the form of comorbidity [4]. Some patients with breast cancer do not have the proper ability to understand and express their emotions. They cannot manage emotions well and need correction and emotional regulation skills. Emotional regulation is a critical concept in understanding and continuing emotional disorders; those suffering from emotional problems may use incompatible ways of emotional regulation, such as suppression, or may follow the consequences of the problem [5, 6]. The function of the emotion regulation system is the regulation of any emotion that is effective in the emotional system and includes elements that create emotions and sensitivities, such as personal evaluation of the situation and reaction to emotions. Studies have shown that optimal strategies reduce limited emotional expression and increase adaptability and quality of life; proper regulation of emotions can positively affect the functioning of the body's immune system and endocrine glands. Therefore, those breast cancer patients using less efficient emotion regulation strategies reported more depression, anxiety, and emotional problems, as well as lower quality of life and physical health [7]. Cognitive changes are expected in cancer, and cognitive rehabilitation has the potential to address cognitive difficulties [8]. Few studies showed cognitive rehabilitation could affect cognitive dysfunction following adult-onset non-CNS tumors such as breast cancer [9]. In this regard, cognitive flexibility leads to psychological well-being, quality of life, functioning, and pain acceptance in breast cancer patients [10]. Appropriate cognitive flexibility provides better stress-coping skills [11, 12]. One of other factors in the field of psychological problems of breast cancer is mindful emotional awareness and its relation to emotional regulation and the quality

of life [13]. This awareness is a large part of what is known as emotional intelligence, including the ability to solve life's problems by understanding emotions, such as being able to regulate emotions and understand and empathize with the emotions of others [6, 14]. Accordingly, it seems that patients with breast cancer need appropriate clinical interventions to manage and improve their psychological symptoms and increase their quality of life. A fundamental model of individual differences is the self-regulatory model of illness perceptions, which is how individuals mentally represent illness/treatment [9]. Various psychological treatments have been used over the past years, including Cognitive-Behavioral Therapy (CBT), supportive treatments, etc. Specifically, cognitive behavioral techniques were valuable in relieving distress in cancer survivors, and several such treatments have been empirically validated. Research has shown that CBT is an effective intervention in improving breast cancer patients' and survivors' quality of life and psychological health. Results indicated that a range of techniques, including behavioral therapy, cognitive therapy, education, and relaxation, can be used by breast cancer patients to reduce depression, anxiety, and stress effectively [15, 16]. Moreover, the literature revealed 20 studies that examined CBT, Supportive-Expressive Group Therapy (SEGT), and a combination of these two treatments, which determined that CBT and SEGT have repeated experimental support for positively altering certain affective disturbances in this population [17]. Recently, another treatment approach in the psychological health field is the unified protocol for transdiagnostic treatment of emotional disorders (UP). This treatment targets awareness, coping, and emotion regulation strategies. Moreover, in a comparative trial, it has been found that this treatment is effective in reducing anxiety and depression [18]. Due to the high comorbid of psychological disorders in breast cancer patients, transdiagnostic treatments seeking to treat according to the needs of each person can be effective; they generally seek to identify common underlying mechanisms of comorbid disorders and therapeutic intervention based on these common mechanisms, which are at the opposite point of protocols based on the treatment of a psychiatric disorder [19]. One of the transdiagnostic treatments that directly targets emotional regulation is Barlow's unified protocol, which is designed to target common

transdiagnostic causative factors and is also presented for patients with anxiety and unipolar mood disorders with the ability to be used for other emotional disorders [20]. The UP is based on traditional cognitive-behavioral principles, focusing on 1) present-focused emotion awareness; 2) cognitive flexibility; 3) emotion avoidance and emotion-driven behaviors; 4) awareness and tolerance of physical sensations, and 5) interceptive and situation-based emotion. The ultimate goal of this treatment is to reduce the intensity and frequency of maladaptive emotional experiences and improve the emotional performance of patients [6]. Various studies have demonstrated that emotional regulation, emotional awareness, and cognitive flexibility are effective in the quality of life and improvement of emotional symptoms and disorders, such as depression, anxiety, and other mood disorders. It has also been effective in improving emotional problems and increasing the quality of life. For example, Sarzavala et al., (2016) investigated the effectiveness of the unified protocol on patients with borderline personality disorder and concurrent disorders. The results showed reductions in depression, anxiety, and clinical symptoms and improvements in emotion regulation skills among patients. Furthermore, the results of several studies indicate that patients receiving UP treatment experienced significant improvements in quality of life [21].

In a study conducted by Osma et al., (2021) on the effect of Unified protocol for transdiagnostic treatment (UP) on solving emotional problems of people, medical problems, such as obesity, cardiovascular diseases, etc., have been investigated until 2020. It has been determined that the UP is an effective treatment for emotional problems in the medical population [22]. The effectiveness of UP and neuropsychological therapy for cognitive disorders and emotional disorders among cancer survivors in Spain shows an increase in tolerance to extreme emotions and correction of emotion regulation inefficiencies in patients. At the end of treatment, a significant improvement in cognitive performance and emotional disorders in both intervention groups compared to the wait-list control group was observed. There were also improvements in anxiety, depression, and quality of life as secondary outcomes. These results were maintained at a 6-month follow-up [23]. In addition, in a research study conducted on a preventive

intervention to modify risk targets for depression after breast cancer diagnosis, 16 sessions were held based on the original UP. Unified Protocol for Prevention of Depression After Cancer (UP-PDAC) is a 5-hour intervention delivered to individual patients during four sessions over six weeks, with two weeks between sessions. Each module included psychoeducation, demonstration, practice, and feedback on the use of each targeted coping and emotion regulation strategy. Moreover, each session began with a review of the workbook. As a result, fifty-five percent of women screened within six months of diagnosis had reduced depression risk [18]. The current study results will probably affect the emotional regulation, cognitive flexibility, and mindful emotional awareness of patients with breast cancer and finally improve their quality of life. The present study is the first survey investigating this hypothesis using the scientific research process.

METHODS

Study setting and population: The participants of this study included all women with primary breast cancer referred to Mashhad hospitals between September and December 2021. Thirty participants were selected and randomly assigned into two groups: the intervention group and the wait-list control group. The intervention group received UP intervention once a week (generally, 9 group psychotherapy sessions of 90 minutes), but the wait-list control group did not receive any intervention. The inclusion criteria were as follows: 1) not receiving psychological treatments since the diagnosis of the disease; 2) obtaining average and low grades in the scales of emotion regulation; 3) cognitive flexibility, emotional awareness, and quality of life; 4) having minimum reading and writing literacy; and 5) being aged between 35 and 50 years. The exclusion criteria were: 1) simultaneously suffering from another chronic disease except breast cancer; 2) having a history of schizophrenia or bipolar disorder or cognitive disorders, substance abuse; 3) having suicidal symptoms or attempted suicide; and 4) increasing the consumption of psychiatric drugs during the research. Table 1 shows details of participants' demographic data.

The Ethics Committee of Ferdowsi University of Mashhad approved the study (IR. UM.RES.1400.304), and written informed consent was obtained from all participants.

Table 1: Demographic Characteristics of Participants

	Unified Protocol (UP) Group	Wait-list Control group
Age, mean±SD	46.5±4.09	44.26±4.01
Education, No.(%)		
High School	3(21.4)	3(20)
Diploma	4(28.5)	6(40)
Associate	0	1(6.6)
Bachelor	5(35.7)	3(20)
Masters	1(7.1)	2(13.3)
Ph.D.	1(7.1)	0
Marital Status, No.(%)		
Married	10(71.4)	12(80)
Singel	2(14.2)	1(6.6)
Divorced	2(14.2)	2(13.3)
Type of Treatment, No.(%)		
Surgery	4(28.5)	3(20)
Chemotherapy	3(21.4)	3(20)
Radiotherapy	0	1(6.6)
Two or More Items	7(50)	8(53.3)

Treatment goals and procedures were briefly explained to all study participants at the beginning of the treatment and each meeting. Moreover, the purpose of the meeting and related topics was explained in each meeting. In Each session, participants were allowed to proceed with the meeting actively. At the end of each session, the results were summarized, the feedback was taken from the participants, and an assignment was presented for the next session. In the first session, all people were asked to complete the pre-tests. The contents of each session are shown in Table 2. This protocol has been developed using the basic principles of UP treatment and tailored to the needs of breast cancer patients [6, 23].

Beck Depression Inventory-II

This 21-item instrument was developed by Beck, Steer and Brown (1996) to measure the physiological and psychological symptoms of depression in a self-report format. Each item is scored from 0 to 3. The values from 0 to 13 are regarded as normal, 14-19 as mild to moderate, 20- 28 as moderate to severe, and 29-63 as very severe. The one-week test-retest reliability of this measure was 0.93. Additionally, it had a high correlation coefficient

with the Hamilton scale ($r=0.71$) [24]. The internal consistency and Cronbach's alpha coefficients of the Beck Depression Inventory-II (BDI-II) indicate that this measure has high reliability among Iranian population. Cronbach's alpha for the Iranian version of BDI-II was 0.91 [25]. The BDI-II is a validate instrument used to diagnose and assess depression severity before and after the treatment.

Beck Anxiety Inventory

Beck Anxiety Inventory (BAI) consists of 21 items, each evaluating the presence of a symptom during the past week. Items can be answered on a 4-point scale from 0 to 3, with 0 indicating the respondent had no symptom, and 1, 2, and 3 indicating that the respondent has experienced mild, moderate, and severe symptoms. Total score is the sum of all and is calculated out of 63. Total scores of 0 to 9 are considered as normal, 10 to 18 mild to moderate, 19 to 29 moderates to severe, and 30 to 63 as severe anxiety [20]. BAI is translated to Persian by Kaviani et al. The Persian version of the BAI has good test-retest reliability ($r=0.83$, $P<0.001$) and adequate validity ($r=0.72$, $P<0.001$). The Persian version of BAI has excellent internal consistency with Cronbach's alpha of 0.92 [26].

The Depression, Anxiety, Stress Scales-21

Depression, Anxiety, Stress Scales-21 (DASS-21) is a suitable tool for measuring depression, anxiety, and stress for research and clinical purposes. The Persian version of this scale has satisfactory psychometric properties and can be used by the Iranian population. Researchers reported the Cronbach's alpha as 0.94 for the total scales, and 0.85, 0.85, and 0.87 for depression, anxiety, and stress scales, respectively. This tool has 3 scales, each containing 7 questions. The final score is also obtained through the sum of the scores. Each question varies from zero ("it doesn't apply to me at all") to 3 ("it applies to me completely"). Since this questionnaire is a shortened form of the main scale (42 questions), the final score of each subscale must be doubled. Each of the subscales is divided into four categories: normal, moderate, severe, and very severe [27].

Cognitive-Emotion Regulation Questionnaire

It is a multidimensional questionnaire established by Garnefski and Kraaij (2007) to recognize the

Table 2: Descriptions of the Unified Protocol (UP) Sessions

Session	Content
1	<ul style="list-style-type: none"> ● Familiarizing group members with each other and establishing a therapeutic relationship ● Familiarizing people with the subject of research and preliminary explanations ● Explaining the general plan of sessions and treatment ● Increasing the readiness and motivation of patients to change their behavior ● Psychological education about the nature of emotions and the main components of emotional experience ● Teaching more awareness of emotional responsiveness ● Pretest Capture
2	<ul style="list-style-type: none"> ● Teaching awareness of emotion ● Practicing conscious awareness of emotional experiences ● Receiving feedback ● Providing homework
3	<ul style="list-style-type: none"> ● Continuing the practice of conscious awareness of emotional experiences ● Teaching the role of inconsistent self-evaluations in creating emotional experiences ● Providing homework
4	<ul style="list-style-type: none"> ● Training to identify thinking patterns and correct inconsistent thinking ● Increasing flexibility in evaluating different situations ● Providing homework
5	<ul style="list-style-type: none"> ● Training to identify emotional avoidance patterns and emotional behaviors ● Maladaptive origins ● Changing current patterns of emotional response ● Providing homework
6	<ul style="list-style-type: none"> ● Increasing the patient's awareness of the role of physical feelings in emotional experiences ● Implementing exercises to face physical symptoms to invoke physical feelings similar to anxiety and distress ● Providing homework
7	<ul style="list-style-type: none"> ● Preparing a hierarchy of avoiding emotions ● Focusing encounters on emotional experience ● Providing homework
8	<ul style="list-style-type: none"> ● Working more in the field of practicing correct exposure to emotional experiences as well as exposure to physical emotional feelings ● Providing homework
9	<ul style="list-style-type: none"> ● Teaching vulnerability reduction skills ● Planning for relapse prevention ● Expressing the necessity of practicing the skills acquired during the sessions ● Assessing the progress of the work and acquired skills ● Taking the post-test

cognitive emotion regulation approaches (or cognitive coping policies) someone utilizes after experiencing negative events or conditions. The Cognitive-Emotion Regulation Questionnaire (CERQ) is a self-report questionnaire and has 36 items and including nine theoretical and empirical cognitive emotion regulation strategies: other-blame, self-blame, catastrophizing, rumination, positive refocusing, putting into perspective, positive reappraisal, refocus, and acceptance and planning. Scale scores range from 1 (almost never) to 5 (almost always). The score of each strategy is obtained through the sum of the scores given to each of the phrases making up that strategy, and it can be in the range of 4 to 20, and the sum of the total scores is in the range of 36 to 180. The psychometric properties of the Persian version of CERQ were investigated in a sample of 420, and Cronbach's

alpha coefficients ranged from 0.66 to 0.88, showing good reliability [28].

The Cognitive Flexibility Inventory (CFI)

The Cognitive Flexibility Inventory (CFI) is a brief 20-item self-report instrument designed to measure the aspects of cognitive flexibility that enables individuals to challenge and replace the maladaptive thoughts with more adaptive ones. It can be utilized in clinical and non-clinical areas and also be used to assess the individual's progress in developing flexible thinking in CBT for depression and other psychopathological diseases. The CFI was originally developed to measure three aspects of cognitive flexibility: a) the tendency to perceive difficult situations as controllable; b) the ability to perceive multiple alternative explanations for life occurrences and human behaviors; c) the ability to generate

multiple alternative solutions to difficult situations, but it ended in two factors and demonstrated adequate levels of validity, reliability and internal consistency. More specifically, the Cronbach's alphas for the CFI, Control and Alternatives subscales were 0.91, 0.84, and 0.91, respectively. The seven-week test-retest reliability coefficients for the CFI, Control and Alternatives subscales were 0.81, 0.77, and 0.75, respectively [29].

The Levels of Emotional Awareness Scale (LEAS)

The Levels of Emotional Awareness Scale (LEAS) was introduced by Lin et al., (1990) to measure the emotional awareness of the conscious mind. The LEAS scale includes 20 scenarios by which emotions such as sadness, anger, fear, happiness, and a combination of these feelings are measured. The characters in each scenario include themselves and another person. Twenty scenarios were scored independently by two evaluators, the inter-evaluator validity was high ($r=0.84$), and the internal homogeneity of the test was also measured by Cronbach's $\alpha=0.81$. In a study conducted in Iran, the reliability of this scale was reported between 0.79 and 0.87 [30].

The EORTC Breast Cancer-Specific Quality of Life Questionnaire

The EORTC Breast Cancer-Specific Quality of Life Questionnaire (EORTC QLQ-BR23) is a 23-item breast cancer-specific questionnaire measuring the quality of life in breast cancer patients, and the conceptual and methodological issues underlying the construction of the questionnaire are described by its pioneering authors in detail elsewhere. It incorporates two functional scales (body image, and sexual functioning) and three symptom scales (arm symptoms, breast symptoms, and systematic therapy side effects). The remaining items assess sexual enjoyment and shock due to hair loss. The reliability of the Persian version of this scale has been reported using Cronbach's α in the range of 0.71 to 0.95. Its reliability has been reported based on Cronbach's α for the functional dimension of 0.93 and for symptoms of 0.73 [30].

Data Analysis

Prior to the data analysis, missing data (i.e., dropout and missing item responses for outcomes) were examined. One of participants was lost in the

Unified Protocol (UP) group. Unified Protocol (UP) group and wait-list control group were compared on demographic factors. The normality of the variables was assessed using skewness and kurtosis indices and the Kolmogorov-Smirnov test. Multivariate analysis of covariance (MANCOVA) and analysis of covariance (ANCOVA) were used to determine differences between the groups. Data analysis was performed using IBM SPSS V.24 for Windows.

RESULTS

Means and standard deviations for the outcomes in the Unified Protocol (UP) condition and waitlist-control condition are reported in Table 3 and Table 4. As seen in Table 3, there was a significant effect after the UP application. We found large effect sizes of the UP on Anxiety Beck Inventory (BAI) ($F=182.97$, $P<0.001$, $\eta^2=0.87$) and Depression Beck Inventory (BDI-II) ($F=223.58$, $P<0.001$, $\eta^2=0.87$). Moreover, results of the MANCOVA showed a significant effect (Wilks Lambda=0.041, $F=172.97$, $P<0.001$) on symptoms of depression ($F=195.71$, $P<0.001$, $\eta^2=0.89$), anxiety ($F=131.89$, $P<0.001$, $\eta^2=0.85$), and stress ($F=267.92$, $P<0.001$, $\eta^2=0.92$) in the DASS-21. These findings indicated that treatment UP had a large, significant impact on reducing depression, anxiety, and stress over the treatment period. Analysis of the cognitive flexibility scores ($F=21.03$, $P<0.001$, $\eta^2=0.45$) and mindful emotional awareness scores ($F=79.27$, $P<0.001$, $\eta^2=0.75$) indicated significant differences between the treatment conditions at post-treatment. These findings indicated that treatment UP had a large, significant impact on improving cognitive flexibility and mindful emotional awareness over the treatment period. Regarding the quality of life of patients with breast cancer, results revealed that the increase in function ($F=465.31$, $P<0.001$, $\eta^2=0.95$) and decrease of symptoms ($F=454.56$, $P<0.001$, $\eta^2=0.95$) across the pre-test to post-test periods was higher in the UP group than the wait-list control group. The results are presented in Table 3.

Means, standard deviations, and MANCOVA and ANCOVA for the components of adaptive and maladaptive emotional regulation strategies are reported in Table 4. Results of the MANCOVA showed a significant effect (Wilks Lambda=0.037, $F=93.14$, $P<0.001$) for acceptance ($F=72.51$, $P<0.001$, $\eta^2=0.76$), positive refocusing ($F=54.94$, $P<0.001$, $\eta^2=0.71$), refocus on planning ($F=86.54$,

$P < 0.001$, $\eta^2 = 0.79$), positive re-appraisal ($F = 153.05$, $P < 0.001$, $\eta^2 = 0.87$), putting into perspective ($F = 116.45$, $P < 0.001$, $\eta^2 = 0.84$), and total adaptive CERQ ($F = 443.19$, $P < 0.001$, $\eta^2 = 0.94$). These findings indicated that treatment UP had a large, significant impact on improving emotional regulation strategies of patients with breast cancer. In addition, Emotional dysregulation strategies results of the MANCOVA showed a significant effect (Wilks Lambda=.054, $F = 88.09$, $P < 0.001$) for self-blame ($F = 92.03$, $P < 0.001$, $\eta^2 = 0.80$), rumination ($F = 180.16$, $P < 0.001$, $\eta^2 = 0.89$), catastrophizing ($F = 74.75$, $P < 0.001$, $\eta^2 = 0.76$),

other- blame ($F = 66.36$, $P < 0.001$, $\eta^2 = 0.74$), and total maladaptive CERQ ($F = 197.33$, $P < 0.001$, $\eta^2 = 0.88$).

DISCUSSION

This study examined the effectiveness of unified transdiagnostic for the treatment of emotional disorder (UP) on emotional regulation, cognitive flexibility, mindful emotional awareness, and quality of life in women with breast cancer. The results showed that UP has a significant effect on all these components. Patients with breast cancer, when facing stressful situations, use more maladaptive emotional

Table 3: Analysis of Covariance (ANCOVA) in Psychological Functioning, Cognitive Flexibility, Emotional Awareness and Quality of Life^a

	Unified Protocol (UP) Group, mean±SD (n=14)	Control Group, mean±SD (n=15)	Fb	Eta-squared (η^2)
Beck Anxiety Inventory (BAI)	32.78±2.45	38.6±3.33	182.97	0.87
Beck Depression Inventory (BDI-II)	22.21±1.96	28.33±2.69	223.58	0.87
Anxiety (DASS-21)	16.93±1.89	22±2.82	195.71	0.89
Depression (DASS-21)	12±1.41	17.33±1.95	131.89	0.85
Stress (DASS-21)	20.21±2.29	27.47±2.09	267.92	0.92
Cognitive Flexibility	63.43±9.46	59.4±10.07	21.03	0.45
Mindful Emotional Awareness	79.64±10.39	62.6±11.08	79.27	0.75
EORTC QLQ-BR23-Function of Breast Cancer	26.42±2.53	16.24±1.33	465.31	0.95
EORTC QLQ-BR23-Symptom of Breast Cancer	27.21±2.08	39.33±2.16	454.56	0.95

^a Abbreviations: BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory; DASS-21, Depression, Anxiety and Stress Scale; EORTC QLQ-BR23, EORTC Breast Cancer-Specific Quality of Life

^b $P < 0.001$

Table 4: Analysis of Covariance (ANCOVA) in Emotion Regulation Strategies^a

	Unified Protocol (UP) Group, mean±SD (n=14)	Control Group, mean±SD (n=15)	Fb	Eta-squared (η^2)
Adaptive CERQ				
Acceptance	10.70±2.23	7.60±1.96	72.51	0.76
Positive Refocusing	8.92±1.89	7.26±1.62	54.94	0.71
Refocus on Planning	9.28±1.43	7.13±1.72	86.54	0.79
Positive Re-appraisal	9.64±1.94	7.47±1.76	153.05	0.87
Putting Into Perspective	9.78±1.47	7.60±1.67	116.45	0.84
Total Adaptive CERQ	47.71±8.37	37.00±8.08	443.19	0.94
Maladaptive CERQ				
Self-Blame	12.50±1.82	16.13±2.09	92.03	0.80
Rumination	12.93±1.63	16.06±1.43	180.16	0.89
Catastrophizing	12.76±1.64	16.20±1.74	74.75	0.76
Other-Blame	11.21±1.36	14.87±1.84	66.36	0.74
Total Maladaptive CERQ	49.28±5.19	63.26±5.93	197.33	0.88

^a Abbreviations: Adaptive CERQ, Adaptive Cognitive Emotion Regulation Strategies; Maladaptive CERQ, Maladaptive Cognitive Emotion Regulation Strategies

^b $P < 0.001$

regulation strategies such as avoidance, blaming, rumination, etc., and less adaptive emotional regulation strategies such as acceptance, positive refocusing, reevaluation, etc. Moreover, they report more negative emotions, which causes high levels of anxiety and depression because strategies such as avoiding experiencing negative emotions have a contradictory effect on that emotion and increase the amount of conflict with that emotion. As a result, they experience higher negative emotions such as sadness, fear, etc. When the emotion rises, it is more difficult to control, leading to feelings of helplessness, high levels of anxiety, and depression [6]. The scores of cognitive flexibility and mindful emotional awareness in patients with breast cancer are at an average or low level. Since cognitive flexibility is the ability to change cognitive, those who are flexible to new situations can make different decisions, consider new issues in various choices, offer alternative options, and use stress-coping skills [11]. Spontaneous disturbing thoughts in people suffering from chronic diseases such as cancer are the stress response to a traumatic event. They experience mental pressure caused by physical pain and mental strain caused by psychologically endured issues. Non-flexibility to acceptance of what cannot be changed (internally or externally) disrupts living in the moment. Therefore, low cognitive flexibility may lead to rumination, stress, and ineffective coping strategies when facing chronic physical pain in breast cancer patients [31]. Emotional awareness is essential for establishing relationships with others [32]. As people get older, they can provide a more accurate reflection of their emotions and use more complex words to explain them. Part of this skill comes back to their language ability, and another aspect relates to a deeper understanding of their feelings and emotions [33]. In addition, Kranzler et al., found that low emotional awareness may predict anxiety and depression symptoms [4]. There is a close relationship between emotional and cognitive awareness and paying attention to one's feelings without judgment, which plays a significant role in a person's psychological well-being [14]. Due to the strong connection between emotional awareness and mindfulness, mindful emotional awareness is considered a transdiagnostic element that can help people to accept their thoughts, feelings, and behavior motivated by emotions and avoid critical judgment, change, or fear of experiencing [6]. Breast

cancer patients also need emotional awareness in order to be able to know their emotional mechanisms well and identify their inefficiency in different situations. According to a research study, there is a close relationship between emotional regulation and the quality of life of these patients with mindful emotional awareness [13].

In addition, breast cancer is a physical disease affecting a person's physical health. Based on these descriptions, it has been concluded that the quality of life in breast cancer patients depends on the long duration of involvement with the disease. For this reason, since 1940, examining the quality of life of oncology patients has been the focus of researchers [34]. Patients with breast cancer also experience many problems in different dimensions of quality of life, such as emotional and social functioning during the disease and even for some time after completion of treatment [4]. The findings of the research have revealed that social functioning and pain intensity are the strongest predictors of the quality of life of breast cancer patients [1]. Research also shows that several simple and effective interventions, such as emotional regulation of these patients, can significantly increase their quality of life [4]. According to what was said, it can be understood that patients with breast cancer need appropriate clinical interventions to improve their emotional problems and to increase their quality of life. In this regard, a recent meta-analysis reported a 36.6% prevalence of mental disorders in patients with a chronic medical condition. Some studies suggest that the relationship between mental health problems and medical conditions is bidirectional. Meta-analysis studies showed that treatments that follow the principles of CBT are more effective for treating disease and complications in patients with various medical conditions, such as cancer, diabetes disease, and Parkinson's disease, compared to other treatments. In recent years, CBT has proposed interventions with a transdiagnostic approach focusing on EDs' shared underlying mechanisms. This group of disorders presents problems in emotional regulation and shares etiological and maintenance mechanisms like high neuroticism. Several studies suggest that high neuroticism is directly associated with different medical conditions, meaning that it could play a vital role in the comorbidity between neuroticism and the group of EDs. In addition, high levels of

this personality dimension have been associated with increased treatment-seeking in health services for both medical and mental conditions and act as a predictor of individuals' quality of life and longevity. [EDs refer to mental disorders that have characteristics associated with medical conditions, mood, and illness. Related categories are grouped under this category] [22].

Transdiagnostic treatments are the opposite of treatments focused on a specific problem, which can focus on several emotional problems at the same time by considering the common mechanisms of emotional problems [35]. Among the transdiagnostic treatments, Barlow's unified transdiagnostic protocol can be mentioned, which has taken an imperative step in the treatment of patients' emotional problems by emphasizing the role of emotional regulation as the main cognitive-behavioral process in emotional disorders. This treatment focuses on 1) awareness of emotional experience; 2) cognitive flexibility and reevaluation of unpleasant emotions; 3) identification of patterns of avoiding the experience of unpleasant emotions and preventing their use; 4) recognition and awareness of the role of physical feelings in the emotional experience; and 5) A person's exposure to emotional situations [6]. Therefore, UP deals with emotional regulation and negative emotions to correct them, and emotional discipline is also a significant dimension of emotional regulation. Considering the fact that part of the mood problems of patients with breast cancer is due to their lack of proper ability to find emotional regulation and express their emotions properly, the unified protocol for transdiagnostic treatment teaches patients with breast cancer how to face their negative emotions and respond to these emotions more adaptively. Like the earlier study by, Clarck & Taylor, the findings of the current study indicated that UP has effects on increasing the use of adaptive emotional regulation strategies, positive refocusing, and reducing the frequency of using maladaptive emotional regulation strategies, especially rumination [32, 36]. In addition, previous studies have shown that modifications in the original UP cause an excellent versatility of this intervention that can be considered significant to adapt to the specific characteristics of each disease. For example, some research studies incorporate content related to the disease or related aspects (e.g., minority stress model) [6]. One of the

techniques in UP is cognitive reevaluation, through which a person becomes aware of the effect of the mutual relationship between thoughts and emotions. Moreover, using this technique helps to identify the individual's automatically inconsistent evaluations, increasing flexibility in thinking [36]. According to the study results, UP can facilitate flexibility that is adaptive to previous studies [37]. Like study that Brike et al., were written (2016), we found out that mindfulness practices are an important mechanism for enhancing people's awareness of their emotions. UP allows breast cancer patients to gain a more objective understanding of their emotional experiences by reviewing the interaction between thought, feeling, and behavior focused on the present and watching their emotions away from judgment. It causes them to become aware of their feelings in the moment and regulate them better; as a result, the knowledge of the patient expands. The expansion of the correct understanding is the basis for more adaptive behavior and emotion, which are the cause of awareness. The continuation of this cycle improves the mental health of the person.

This treatment had positive effects on patients with breast cancer. However, it was impossible to access more samples due to the restrictions caused by the special conditions of COVID-19. Moreover, as a new method in treating psychological problems of breast cancer patients, it would be better to compare the results of the present study with other treatment methods. It should be noted that it was impossible to compare the experimental group with the placebo group due to the limitations of the research conditions, and the experimental group was only compared with the waiting-list group that did not receive any services; therefore, research findings are not generalizable to other settings.

CONCLUSION

In conclusion, our findings supported evidence for the efficacy of the Barlow UP treatment in reducing anxiety and depression in breast cancer patients and improving emotional regulation, cognitive flexibility, mindful emotional awareness, and quality of life of patients.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

ETHICAL APPROVAL

The research protocol was approved by Ferdowsi University of Mashhad Research Ethics Committee (IR.UM.REC.1398.016).

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