Multidisciplinary Cancer Investigation **Original Article**

October 2024, Volume 8, e9

The Unified Protocol for Transdiagnostic Group Treatment of Emotional Disorders [UP] on Depression, Pain Perception, and Cognitive Emotion Regulation in Patients with Cancer

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Submitted: 15 September 2024

Revised: 18 September 2024

Accepted: 13 October 2024

e-Published: 24 October 2024

Keywords:
Unified Protocol
Depression
Pain Perception
Cognitive emotion regulation
Cancer

Introduction: The present study evaluates the efficacy of the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP) for cancer patients when delivered in a group format.

Materials and Methods: A clinical sample of 38 patients with a cancer diagnosis was enrolled in a randomized control trial (RCT) involving up to 7 sessions of treatment. Patients were randomly assigned to receive treatment with the UP (n=18) and the control group (n=20). The participants in the pre-test and post-test were examined by the Beck Depression Inventory Second Edition (BDI-II), McGill Pain Questionnaire (MPQ), and Cognitive Emotion Regulation Questionnaire (CERQ).

Results: The UP significantly reduced the rate of symptoms of Depression, Pain perception, and maladaptive strategies. Also, a significant increase was shown in adaptive strategies in comparison to participants in the control group.

Conclusions: Results from this RCT provide additional evidence for the efficacy of the UP in reducing symptoms of depression, pain perception, and maladaptive strategies in patients with cancer. Also, this therapy can increase adaptive strategies among these patients.

INTRODUCTION

Cancer represents a significant public health challenge globally, with a concerning rise in patient numbers over the last two decades [1, 2]. The number of new cancer cases in Iran will grow from 112.000 reported in 2016 to an estimated 160.000 by 2025, reflecting a 42.6 % increase [3].

Receiving a cancer diagnosis can lead to significant emotional, physical, and social distress for patients [4]. Many individuals experience depression as they confront the realities of their diagnosis, long-term treatment, and navigate the uncertainties surrounding cancer progression [5]. Previous research has indicated that the prevalence of depressive disorders in cancer patients is two to three times greater than that in the general population [6, 7]. Research indicates that 23.4% of cancer patients exhibit depressive symptoms [8]. Depression not only compounds the challenges of living with cancer but also increases the risk of adverse health outcomes, further complicating the patient's overall well-being [9, 10].

Cancer treatment can lead to a wide range of side effects, including pain, fatigue, and sleep disturbances [11]. One of cancer patients' most frequently reported symptoms is pain [12]. A systematic review found that over 50% of cancer patients undergoing anti-cancer treatment reported experiencing pain, with approximately 66% of those with advanced and metastatic cancer affected [13]. Cancer pain is a subjective and complex experience consisting of multiple dimensions [12]. Chronic pain can significantly affect various aspects of a patient's life. For instance, individuals experiencing chronic pain are more likely to suffer from mental health issues such as depression and anxiety [14, 15].

In the context of cancer, emotion regulation is another factor that has been linked with the patient's psychological health and well-being [16]. The experience of receiving a cancer diagnosis and undergoing the treatment is stressful, often triggering a range of negative emotions such as fear of death, anxiety, and depressive symptoms [17]. Emotion regulation is essential for initiating, assessing, and organizing adaptive behaviors while also helping to prevent negative emotions and maladaptive responses [10]. Emotion regulation strategies can be categorized into two adaptive and maladaptive categories. Research indicates that cancer patients who are not able to address the emotional responses to the stressful events and rely on maladaptive emotional strategies, such as suppression and inhibition, tend to experience greater emotional distress and psychological challenges [17, 18].

Given the circumstances, it is evident that cancer patients require psychological interventions to address cancer-related symptoms [19]. One increasingly utilized approach in mental health treatment is the Unified Protocol for Transdiagnostic Treatment [20]. Considering the high rates of mental disorders, particularly depression and anxiety, among cancer patients, a Transdiagnostic intervention like the Unified Protocol (UP) could be effective in alleviating these symptoms [21]. The Unified Protocol (UP) is an intervention based on Cognitive Behavioral Therapy [CBT] that emphasizes mutual pathological bases and trains adaptive emotional regulation strategies [21]. The UP consists of 5 core modules that address a specific emotional regulation strategy: 1. mindful emotion awareness, 2. cognitive flexibility, 3. identifying and preventing patterns of emotion avoidance, 4. increasing awareness and tolerance of emotion-related physical sensation, and 5. situational emotion-focused exposures [22].

Given the growing interest in transdiagnostic treatments like the Unified Protocol and the current lack of sufficient evidence regarding their impact on the emotional challenges faced by cancer patients, this study seeks to evaluate the effectiveness of Unified Protocol group therapy on depression, pain perception, and cognitive emotion regulation in individuals with cancer.

Materials and Methods

Study setting and population: The statistical population included all patients with non-metastatic cancer referred to Mashhad hospitals from September to December 2019. The sample size was determined using the G Power with an assumption of effect size (0.80 large), alpha: 0.05, and power: 0.85, with 2 groups and 1 covariate. A total of 37 participants were estimated to be included in the study to detect a large effect size (Cohen's d=0.80). Previous studies have reported a participant withdrawal rate of around 13% [23]. Therefore, assuming this withdrawal rate, the total sample would be 40 participants, 20 per group. The process for selecting subjects was conducted as follows: Initially, the records of 60 patients were reviewed. Among 60 patients, 40 cancer patients who met the inclusion criteria were selected through a voluntary sampling method, as they responded positively to the researcher's invitation to participate in the study. These patients were randomly assigned to either the intervention group or the control group through a drawing. The inclusion criteria were as follows: 1. the individual has not received any psychological treatments since being diagnosed with the disease;

- Acquiring average to high grades in the scales of depression, pain perception, and cognitive emotion regulation; 2. demonstrating basic reading and writing skills, and 3. patients with non-metastatic cancer. The exclusion criteria

included: 1. currently having another chronic illness in addition to cancer; 2. a history of schizophrenia, bipolar disorder, or substance abuse.

- Missing more than three sessions; and 3. an increase in psychiatric medication use. The Ethics Committee of Ferdowsi University of Mashhad approved the study [IR.UM.REC.1398.152], and written informed consent was obtained from all participants. Figure 1 provides a summary of participant enrollment in the study process.

Participants completed the Beck Depression Inventory (BDI-II), McGill Pain Questionnaire (MPQ), and Cognitive Emotion Regulation Questionnaire (CERQ) in both pre-test and post-test phases. The intervention group took the pre-test during the first session, while the control group completed theirs in a separate (Assessment meeting) on the same day. The intervention group underwent the UP therapy, consisting of seven weekly group psychotherapy sessions, each lasting 90 minutes. Each session began with an explanation of its purpose and relevant topics. Participants were encouraged to engage in discussion and activities, and at the end of each session, a summary was provided, feedback was collected, and assignments were given for the next session. Details of each session are outlined in Table 1. This protocol was designed based on UP treatment principles and tailored for cancer patients [22]. At the treatment's conclusion, the UP group completed the post-test in their final session, while the control group did so during an Assessment meeting on the same day. All patients in the UP group completed their therapy, except for two patients who were excluded from the study for missing more than three UP sessions. Thus, data from only eighteen patients were analyzed in the post-test phase.

Measures

Beck Depression Inventory-Second Edition (BDI-II)

The Beck Depression Inventory (BDI-II) is a 21-item

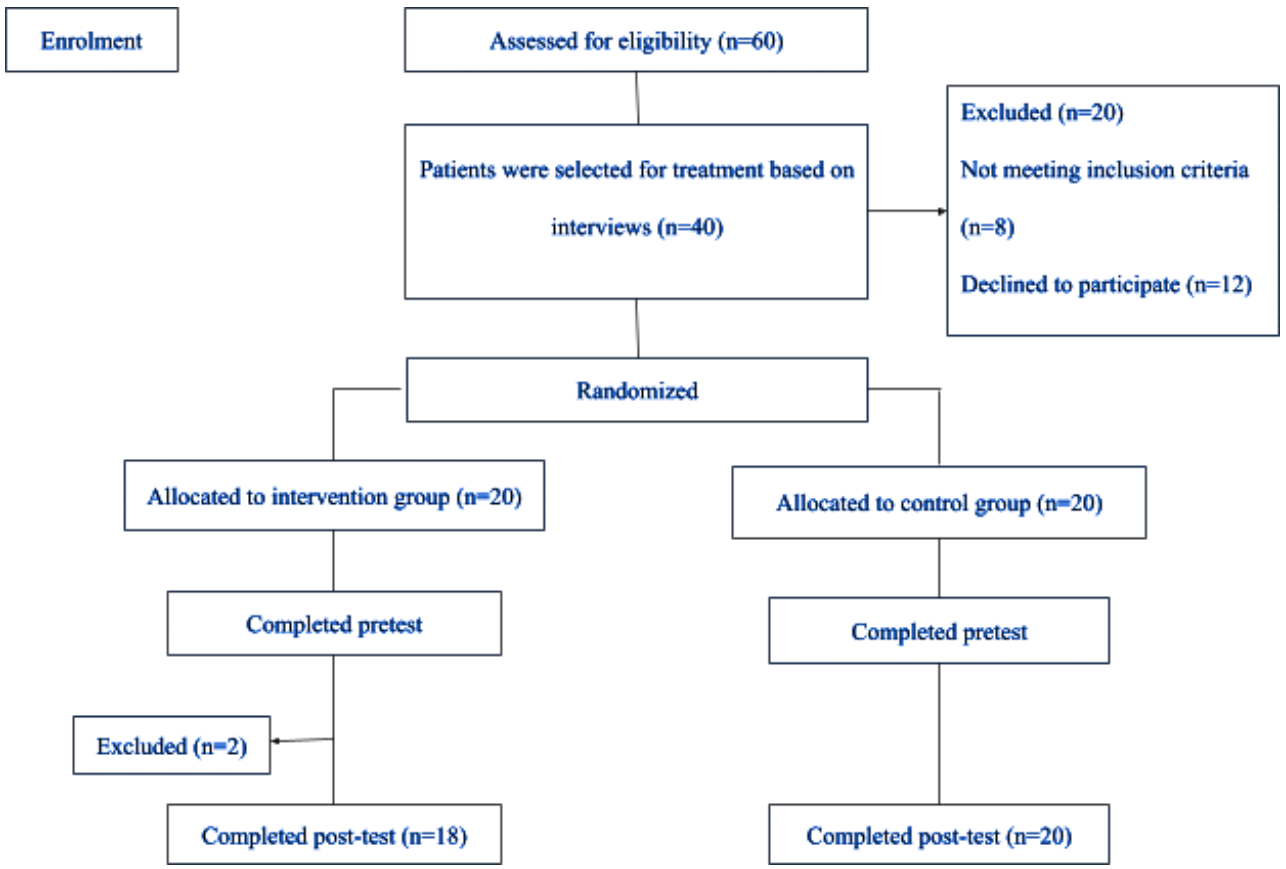

Figure 1. Flowchart of participants in study.

Table 1. Description of the United Protocol [UP] Sessions.

Session	Content
1	• Introducing group members to each other and building a therapeutic relationship. • Providing an overview of the research topic and offering initial explanations. • Explaining the overall plan for the sessions and treatment. • Enhancing a patient's readiness and motivation to make behavioral changes. • Providing psychological education on the nature of emotions. • Teaching techniques to increase awareness of emotional responsiveness. • Conducting a pre-test to assess the initial emotional state of participants.
2	• Teaching awareness of emotion. • Practice present-focused awareness using mindfulness exercises • Receiving feedback and providing homework assignments.
3	• Teaching the role of inconsistent self-evaluations in creating emotional experience. • Training to identify thinking patterns and correct inconsistent thinking. • Increasing flexibility in evaluating different situations. • Providing homework assignments.
4	• Training to identify emotional avoidance patterns and emotional behaviors. • Changing current patterns of emotional response. • Providing homework assignments
5	• Increasing the patient's awareness of the role of physical feelings and emotions. • Implementing exercises to face physical symptoms. • Providing homework assignments.
6	• Preparing a hierarchy of avoiding emotions. • Focusing encounters on emotional experience. • Providing homework assignments.
7	• Teaching vulnerability reduction skills • Developing strategies for prevention. • Reinforcing the importance of practicing acquired skills. • Evaluating progress and skill acquisition. • Conducting post-test.

self-administered inventory developed by Beck, Steer, and Brown to measure the intensity of psychological symptoms of depression in adults and adolescents [24]. Items are rated on a 4-point (0 to 3) scale, with total scores obtained by summing the ratings for all items. Scores ranging between 0 and 13 are regarded as minimal depression; scores that fall between 14 and 19 are indicated as a mild level of depression; scores of 20 to 28 are considered moderate; and scores of 29 to 63 are labeled severe [24]. 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 BDI-II indicate that this measure has high reliability and validity for the Iranian population. Cronbach's alpha for the Iranian version of BDI-II was 0.87 [25].

McGill Pain Questionnaire (MPQ)

The McGill Questionnaire is a 78-item description of pain quality that Melzack and Torgerson developed to measure the pain experience from multiple dimensions [26]. The MPQ categorizes pain characteristics in three dimensions: 1. Sensory qualities (word groups 1-10, 17-19); 2. Affective qualities (word groups 11-15, 20); and 3. Cognitive qualities or evaluative words (word groups 16, 20) [27]. The participants rate the intensity of their pain by selecting the one best word from a list of six words (0= none, 1=mild, 2= discomforting, 3= distressing, 4= horrible, and 5= excruciating) [27]. Finally, the Number of words Chosen (NWC; range 0-20) is the sum score of the total number of descriptors the participant chooses [27]. Moreover, it has good reliability and construct validity. The reliability of the MPQ was reported by the test-retest reliability of 70 [26]. Cronbach's alpha coefficients of the MPQ indicate that this questionnaire has adequate levels of reliability and validity for the Iranian population. Cronbach's alpha for the Iranian version of MPQ was 0.85 [28].

Cognitive-Emotion Regulation Questionnaire (CERQ)

The cognitive-Emotion Regulation Questionnaire

(CERQ) is a multidimensional questionnaire established by Garnefski to measure cognitive emotion regulation strategies that individuals utilize after experiencing negative events or conditions [29, 30]. This questionnaire consists of 36 items that contain nine conceptually distinct subscales: five adaptive strategies subscales (acceptance, positive refocusing, refocusing on planning, positive reappraisal, and putting into perspective) and four maladaptive strategies subscales (self-blame, rumination, catastrophizing, and blaming others) [30]. Scale scores range from 1 (rarely) to 5 (almost always). The score of each strategy is obtained through the sum of the scores given to each of the phrases (range, 4-20). A higher subscale score indicates greater use of specific cognitive strategies [30]. The CERQ has been demonstrated to have good reliability and validity [31]. In most research, alpha-reliabilities have been found to range between 0.72 and 0.85 [31]. The psychometric properties of the Farsi Version of CERQ were investigated in a sample of 420, and Cronbach's alpha coefficients ranged from 0.76 to 0.92 [31].

Statistical Analysis

We conducted an Analysis of Covariance (ANCOVA) to examine pre-test and post-test changes in Depression, Pain Perception, and Cognitive Emotion Regulation (CERQ) between the groups, with pre-test scores included as covariates to control for baseline differences. Additionally, we employed Multivariate Analysis of Covariance (MANCOVA) to analyze changes across all dimensions of adaptive and maladaptive CERQ between groups, again including pre-test scores as covariates. All analyses were conducted using SPSS (IBM SPSS Statistics version 22.0).

To test the hypotheses, ANCOVA and MANCOVA were applied. We first examined the assumptions of normality and homogeneity of the variance-covariance matrix. The Kolmogorov–Smirnov test and Box's M test were used to assess normality and homogeneity of variances, respectively. Results of the Kolmogorov–Smirnov test confirmed the data normality in the pretest and posttest (P>0.05). Furthermore, results of the Box's M test were not statistically significant (P>0.05), confirming the assumptions for these analyses.

RESULTS

First, the demographic characteristics of the participants are reported in Table 2. Table 2 presents the demographic information, showing that the average age and standard deviation in the unified protocol group were 45.55 years (SD=8.75), compared to 42.40 years (SD=6.64) in the control group. Notably, the majority of participants in both groups were married, with 83.3% in the UP group and 75% in the control group. Additionally, 88.9% of participants in the UP group had breast cancer compared to 80% in the control group. According to the results of Table 2, there were no significant differences between groups in all demographic characteristics. The means and standard deviations of the research variables, along with the results of the ANCOVA and MANCOVA analyses, are displayed in Table 3.

Table 2. Demographic characteristics of the participants.

Demographic	United Protocol Group [n=18]	Control Group [n= 20]	Chi-Square Test
Education			
High school	5	1	
Diploma	5	6	
Associate	2	6	6.11,
Bachelor	4	5	*p*= 0.29
Master's	1	2	
Ph. D	1	0	
Marital status			
Single	2	3	0.42,
Married	15	15	*p*= 0.80
Divorced	1	2	
Type of Cancer			
Breast	16	16	0.56,
Colorectal	2	4	*p*= 0.45
Therapy			
Surgery	4	4	
Chemotherapy	4	5	1.009,
Radiotherapy	0	1	*p*= 0.79
All therapy methods	10	10	

Table 3 presents the ANCOVA results, indicating significant differences in depression levels, pain perception, adaptive CERQ scores, and maladaptive CERQ scores between the Unified Protocol and control groups.

Table 3. Means and standard deviations of the research variables and the results of ANCOVA and MANCOVA.

Variables	United Protocol Group [n=18]		Control Group [n= 20]		F	*P*	*Cohen's d
	Pretest Mean±SD	Posttest Mean±SD	Pretest Mean±SD	Posttest Mean±SD			
Depression	28.44±4.28	22.27±5.48	29.80±4.79	33.40±5.54	45.41	0.001	2.25
Pain Perception	54.77±4.91	45±5.37	55.70±5.89	55.30±5.37	57.09	0.001	2.52
Adaptive CERQ							
Acceptance	7.16±2.09	9.94±2.12	7.85±1.63	7.40±2.01	26.32	0.001	1.71
Positive refocusing	6.88±2.02	10.16±2.43	7.20±2.01	7.20±1.85	27.49	0.001	1.75
Refocus on planning	6.72±2.02	8.44±2.30	7.60±2.06	7.35±2	5.03	0.03	0.75
Positive reappraisal	7.44±2.25	9±2.35	7.90±1.91	8.35±1.81	2.77	0.10	---
Putting into perspective	7.77±1.83	10.27±1.93	7.75±1.91	9.20±1.79	5.80	0.02	0.8
Total adaptive CERQ	36±5.36	47.83±4.98	38.30±5.04	39.50±4.45	49.97	0.001	2.36
Maladaptive CERQ							
Self-blame	15.27±1.93	11.38±2.27	15.15±2.08	13.45±1.98	14.91	0.001	1.29
Rumination	15.72±1.80	12.44±2.22	15.70±1.45	14.50±1.53	19.91	0.001	1.49
Catastrophizing	16.05±1.86	13.27±1.67	15.60±1.75	16.30±2.53	17.26	0.001	1.39
Other-Blame	14.61±1.46	11.55±1.82	14.45±1.63	13.10±2.17	11.32	0.002	1.12
Total maladaptive CERQ	61.66±3.23	48.66±3.64	60.90±2.61	57.35±4.27	56.37	0.001	2.51

* d=0.20 is small, d=0.50 is medium, and d>1.0 is large

Specifically, there were significant differences in all comparisons except for the Positive Reappraisal dimension of the adaptive CERQ (P>0.1). The ANCOVA results showed that participants in the Unified Protocol group had significantly lower depression scores (F=45.41, P<0.01, d=2.25), lower pain perception scores (F=57.09, P<0.01, d=2.52), and higher adaptive CERQ scores (F=49.97, P<0.01, d=2.36) compared to those in the control group, all indicating large effect sizes. Furthermore, participants in the Unified Protocol group scored significantly lower on maladaptive CERQ (F=56.37, P<0.01, d=2.51), suggesting that the Unified Protocol positively influences both adaptive and maladaptive coping strategies.

CONCLUSIONS AND DISCUSSION

This study aimed to evaluate the effectiveness of group-based UP in improving depression, pain perception, and cognitive emotion regulation among cancer patients. The UP significantly reduced the rate of symptoms of Depression, Pain perception, and maladaptive strategies. Also, a significant increase was shown in adaptive strategies in comparison to participants in the control group.

As expected, the UP group exhibited a significant reduction in depressive symptoms compared to the control group. Ito et al. found that the Unified Protocol is an effective treatment for depressive disorders, supporting the findings of our study [32]. Similarly, research by Sauer Zavala et al. demonstrated a significant reduction in depressive symptoms, which aligns with our results [33]. Additionally, a systematic review and meta-analysis by Longley et al. indicated that the Unified Protocol leads to substantial improvements in depressive symptoms, further corroborating our findings [34]. In patients with cancer, a tendency to excessively control emotional reactions and avoid emotions is correlated with depression [35]. UP is based on the emotional regulation strategies theory; therefore, this approach alleviates depression in patients with cancer via clarifying and accepting emotions, particularly through heightened emotional awareness and mindfulness exercises. Various studies have highlighted the importance of recognition and acceptance of emotions in alleviating depression symptoms. For instance, Sauer Zavala et al. noted that increased emotional awareness and acceptance correlate with lower anxiety and depression scores [33]. Furthermore, Boswell et al. demonstrated that mindfulness may serve as a key mechanism by which the UP effectively reduces depression [36]. Our findings further revealed that the group-based UP treatment significantly reduced pain perception in cancer patients. This aligns with the research

conducted by Allen et al, which demonstrated that UP can effectively alleviate pain in adolescents experiencing comorbid anxiety and depression [37]. Additionally, our results corroborate the study by Kamalinedjad and Talaei, which identified UP as an effective intervention for managing pain in cancer patients [38]. Furthermore, our findings are consistent with a systematic review by Osma, which found that the Unified Protocol is an effective treatment for alleviating medical symptomatology such as pain in patients [21]. It is suggested that UP improves pain perception by promoting present-focused awareness, encouraging individuals to observe their emotions mindfully as they arise rather than attempting to control or suppress them. Some studies have highlighted the significance of mindful observation of emotions in alleviating pain perception. For example, Garland and Howard found that directing attention to the sensation of breathing or other neutral present-moment experiences can diminish pain in adults experiencing chronic pain [39]. Furthermore, a systematic review by Chiesa and Serretti demonstrated that mindfulness exercises can improve pain acceptance and tolerance in patients with chronic pain [40]. Another key factor contributing to improvement in pain-related outcomes during UP treatment is the modification of maladaptive appraisals and the reduction of catastrophic thinking regarding pain. In fact, the UP reduces pain symptoms in cancer patients by adjusting and correcting misinterpretations, addressing negative self-talk, and modifying irrational and ineffective beliefs about pain.

Our investigation also revealed that group-based UP treatment reduces the mean score of maladaptive strategies and increases the mean score of adaptive strategies in post-tests. Our findings align with the research conducted by Mazaheri and Bameshgi, which demonstrated that the UP effectively enhances emotion regulation strategies in patients [41, 42]. Supporting this, Smith et al. also found that UP significantly improved a variety of adaptive emotion regulation strategies immediately after intervention [16]. In addition to reporting statistically significant differences, the magnitude of the intervention effects was examined using Cohen's d. Most effect sizes observed in our study were above 1.0, indicating very large effects according to conventional benchmarks. These large effect sizes suggest that the group-based UP not only produced statistically significant improvements in depression, pain perception, and emotion regulation strategies but also had a substantial and meaningful impact on the participants' outcomes. The particularly high Cohen's d values may be attributed to the combination of small sample size and notable pre-to-post intervention changes within the UP group, reinforcing the clinical significance of the intervention. Overall, these findings emphasize that the UP can produce strong and clinically meaningful improvements in both psychological and pain-related outcomes among cancer patients. Furthermore, Rahimi's study indicated that UP can enhance adaptive emotion regulation strategies while reducing maladaptive ones in breast cancer patients, reinforcing the validity of our results [43]. In explaining the potential confirmation of the effect of the UP on cognitive emotion regulation, it is important to note that according to Barlow et al., the UP treatment, which prioritizes emotional processes, is effective for depression and mood disorders and likely beneficial for other conditions characterized by significant emotional symptoms [41]. However, the components of the therapy model- such as enhancing emotional awareness, promoting flexibility in appraisal, and addressing emotional and behavioral avoidance- do not align with the factors that contribute to emotional dysregulation. Thus, UP can have an impact on factors of improving maladaptive strategies and fostering adaptive ones [41].

Several limitations of this study should be acknowledged. Firstly, it remains unclear whether the positive effects of this intervention will persist beyond the post-test period; therefore, adding follow-up duration is suggested to evaluate the ongoing effectiveness of the treatment. Additionally, this research examined the effectiveness of the UP in two kinds of cancer patients. It is recommended that future studies focus on specific types of cancer to ensure greater homogeneity within their samples. Lastly, as participants in this study were at various stages of cancer disease, further investigations are needed to

explore the influence of the disease phase as a significant variable.

In conclusion, our findings provide support for the effectiveness of the UP treatment in reducing depression levels and pain perception among cancer patients. Additionally, this treatment also contributes to improvement in emotional regulation for the patients.

CONFLICT OF INTEREST

The authors affirm that they have no competing interests to declare.

ETHICS APPROVAL

The research protocol was approved by the Ferdowsi University of Mashhad Research Ethics Committee [IR.UM.REC.1398.152].

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