

Emotion regulation as the mediator of reductions in anxiety and depression in the Unified Protocol (UP) for transdiagnostic treatment of emotional disorders: double-blind randomized clinical trial

Regulação emocional como mediadora de reduções em ansiedade e depressão no Protocolo Unificado para o tratamento transdiagnóstico de transtornos psicológicos: ensaio clínico randomizado duplo-cego

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Abstract

Objective: An important subject in evaluation of the efficacy of treatments is to examine how the intervention is effective and to identify the consequences of that treatment. In this regard, the current study investigates the role of emotion regulation as the mediator of the treatment outcomes of therapy using the Unified Protocol (UP) for transdiagnostic treatment of emotional disorders.

Method: This article describes a double-blind randomized clinical trial. A sample of 26 individuals was selected based on cut-off scores for the Beck Depression Inventory and Beck Anxiety Inventory and their final diagnoses were confirmed with the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV). The sample was randomly divided into two groups: control and treatment (13 patients each). The treatment group received 20 one-hour UP sessions. The Beck Depression Inventory, the Beck Anxiety Inventory, and the Difficulties in Emotion Regulation Scale were administered at two stages, pre-treatment and post-treatment.

Results: The UP reduced anxiety and depression in patients through improvement in emotion regulation. Furthermore, the results showed that the difficulty engaging in goal-directed behavior and non-acceptance of emotional response subscales were capable of predicting 62% of variance in anxiety scores. In turn, two subscales, difficulty engaging in goal-directed behavior and lack of emotional clarity, predicted 72% of variance in depression scores.

Conclusion: Emotion regulation can be considered as a potential mediating factor and as predictive of outcomes of transdiagnostic treatment based on the UP.

Clinical trial registration: Iranian Registry of Clinical Trials, IRCT2017072335245N1.

Keywords: Emotion regulation, mediator, treatment outcomes, unified protocol, randomized clinical trial.

Resumo

Objetivo: É importante, na avaliação da eficácia de tratamentos, examinar como a intervenção tem efeito e identificar suas consequências. O presente estudo investiga o papel da regulação emocional enquanto mediadora de desfechos do tratamento que emprega o Protocolo Unificado (PU) para o tratamento transdiagnóstico de transtornos psicológicos.

Método: Este artigo descreve um ensaio clínico randomizado duplo-cego. Uma amostra de 26 indivíduos foi selecionada com base em escores pré-estabelecidos para o Inventário de Depressão de Beck e o Inventário de Ansiedade de Beck, e seus diagnósticos finais foram confirmados utilizando o instrumento Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV). A amostra foi dividida aleatoriamente em dois grupos: controle e tratamento (13 pacientes em cada). O grupo tratamento recebeu 20 sessões de PU de 1 hora cada. O Inventário de Depressão de Beck, Inventário de Ansiedade de Beck e Escala de Dificuldades de Regulação Emocional foram administrados em duas etapas, antes e depois do tratamento.

Resultados: O PU reduziu a ansiedade e a depressão em pacientes, ao melhorar a regulação emocional. Além disso, os resultados mostraram que as subescalas dificuldade de se engajar em comportamentos orientados por objetivos e não aceitação de resposta emocional responderam por 62% da variância nos escores de ansiedade. Nos escores de depressão, duas subescalas, dificuldade de se engajar em comportamentos orientados por objetivos e falta de clareza emocional, explicaram 72% da variância.

Conclusão: A regulação emocional pode ser considerada o principal fator mediador e também preditora de desfechos do tratamento transdiagnóstico baseado no PU.

Registro do ensaio clínico: Iranian Registry of Clinical Trials, IRCT2017072335245N1.

Descritores: Regulação emocional, mediador, desfechos de tratamento, protocolo unificado, ensaio clínico randomizado.

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Introduction

Research shows that anxiety disorders, with one-year prevalence of 18%, and mood disorders, with a one-year prevalence of 9.5%, are among the most common psychological disorders.¹ Surveys in the field of “emotional disorders” (including anxiety disorders, mood disorders, and other related disorders) indicate that these disorders and psychological problems are related to people’s social status, economic status, education, health, and quality of life.^{2,3}

Significant advances have been made in treatment of emotional disorders over recent decades. These advances have largely been based on the specific attitude toward symptoms of disorders and an emphasis on differences, and have led to formation of many different and extensive explanations in various areas of the etiology, evaluation, maintenance, and treatment of a wide range of emotional disorders. Clinicians now have a variety of protocols for individual and group therapies and many clinical trials have confirmed their effectiveness.⁴ However, these evidence-based treatments are challenged by certain limitations, such as little attention to comorbidities, the existence of multiple protocols, the inability to address multiple problems using a single protocol, and restricted access to the most effective treatment for patients.

Many psychopathological theories have been proposed to overcome these challenges, exploring the causes of comorbidities and overlaps among emotional disorders. These theories state that the commonalities between disorders exceed the differences. It therefore seems that targeting common underlying factors can have important benefits compared to diagnosis-specific therapies.⁵ One of the main underlying factors among emotional disorders that has received special attention is emotion regulation. For example, Gross⁶ introduces this structure as a common underlying factor among emotional disorders in the Process Model of Emotion Regulation. Emotion regulation can be defined as the strategies that individuals use to express the vast range of the occurrence, experience, and intensity of emotions.^{6,7} In other words, emotion regulation implies how the emotions regulate themselves and not the other elements.

Many studies have studied the relationship between emotion regulation and the symptoms of emotional disorders.⁸ The results show that people who consider their emotional responses to be unacceptable may be more likely to be afflicted by emotional disorders.^{9,10} Berking & Wupperman¹¹ reviewed the role of emotion regulation in various disorders. Their results showed that emotion regulation is associated with a wide

range of psychological disorders and can be considered an important underlying factor in the etiology, maintenance, and treatment of emotional disorders. Aldao & Hoeksma¹² investigated the relationship between cognitive emotion regulation strategies and symptoms of eating disorder, anxiety disorders, and depression. According to their results, adaptive strategies of emotion regulation have negative correlations and maladaptive strategies have positive correlations with psychopathologies, and these associations were stronger with the maladaptive type.

On the other hand, findings from recent studies of treatment of emotional disorders suggested that treatments specifically targeting emotion regulation strategies can be used to treat a wide range of disorders.^{13,14} Additionally, Gratz et al.¹⁵ examined the role of emotion regulation in cognitive behavioral therapy and acceptance and commitment therapy. Their results indicated that, despite the fact that improvement of emotion regulation strategies is not the main goal of this group of treatments, these treatments can nevertheless affect emotion regulation strategies. In their opinion, changes in emotion regulation strategies are related to changes in patients’ clinical status and treatment outcomes.

One of the most efficacious, and cost-effective therapies for treatment of emotional disorders is the Unified Protocol (UP), a transdiagnostic treatment for emotional disorders.¹⁶ Many studies support the effectiveness of this therapeutic protocol in treatment of a wide range of emotional disorders.¹⁷⁻²⁰ This treatment unifies the underlying principles of specific cognitive behavioral therapies, with an emphasis on common transdiagnostic factors in etiology and treatment of emotional disorders, thereby addressing disorders and related issues.⁵

Despite evidence supporting the efficacy of the UP, our understanding of the mechanisms of change underlying this treatment is limited. In fact, a more fundamental issue is understanding how this treatment’s effects occur. The UP claims that changes in shared vulnerabilities lead to therapeutic gains and that improving these vulnerabilities can reduce the symptoms of related disorders. Trosper et al.,²¹ studied emotion regulation in adults with emotional disorders. Their results indicated that problems with emotional processing are one of the most influential factors in the high comorbidity of emotional disorders, and the UP is unique due to its emphasis on the way people with emotional disorders express and experience emotions.

Although many studies have investigated the role of emotion regulation in the psychopathology of

emotional disorders and have shown that treatments could effectively decrease emotion regulation, studies examining the mediating role of this construct during treatment are rare. To our knowledge only Sauer Zavala et al.²² have investigated the role of negative affectivity and negative reactivity to emotions in predicting outcomes in UP. Their results suggested that how people interact with negative emotions can better predict the treatment outcomes than the frequency of these emotions. It seems that recognizing the mechanism of change as well as identifying the role of common vulnerabilities such as emotion regulation, as a mediator of treatment outcomes, could be beneficial to developing this treatment. Although studies have shown that the UP is effective in improving emotion regulation strategies, few studies have considered this structure as a mediator of UP outcomes. In this regard, the present study seeks to examine the efficacy of the UP, in addition to investigating the role of emotion regulation as the mediator of the treatment outcomes.

Material and methods

This study is a double-blind randomized clinical trial and has been approved by the ethics committee at Zanzan University of Medical Sciences (reference number: ZUMS.REC.1396.143). All patients enrolled agreed to take part in the study and signed a free and informed consent form. The study is also registered on the Iranian Registry of Clinical Trials (registration number: IRCT2017072335245N1).

Participants

The statistical population for this research is all students at the Zanzan University of Medical Science. Figure 1 summarizes the sampling process. First, a sample of 315 people was recruited from the statistical population by convenience sampling and then the Beck Anxiety Inventory (BAI) and the Beck Depression Inventory (BDI) were administered. In the second step, individuals with depression scores between 20 and 28 and anxiety scores from 16 to 30 were selected (149

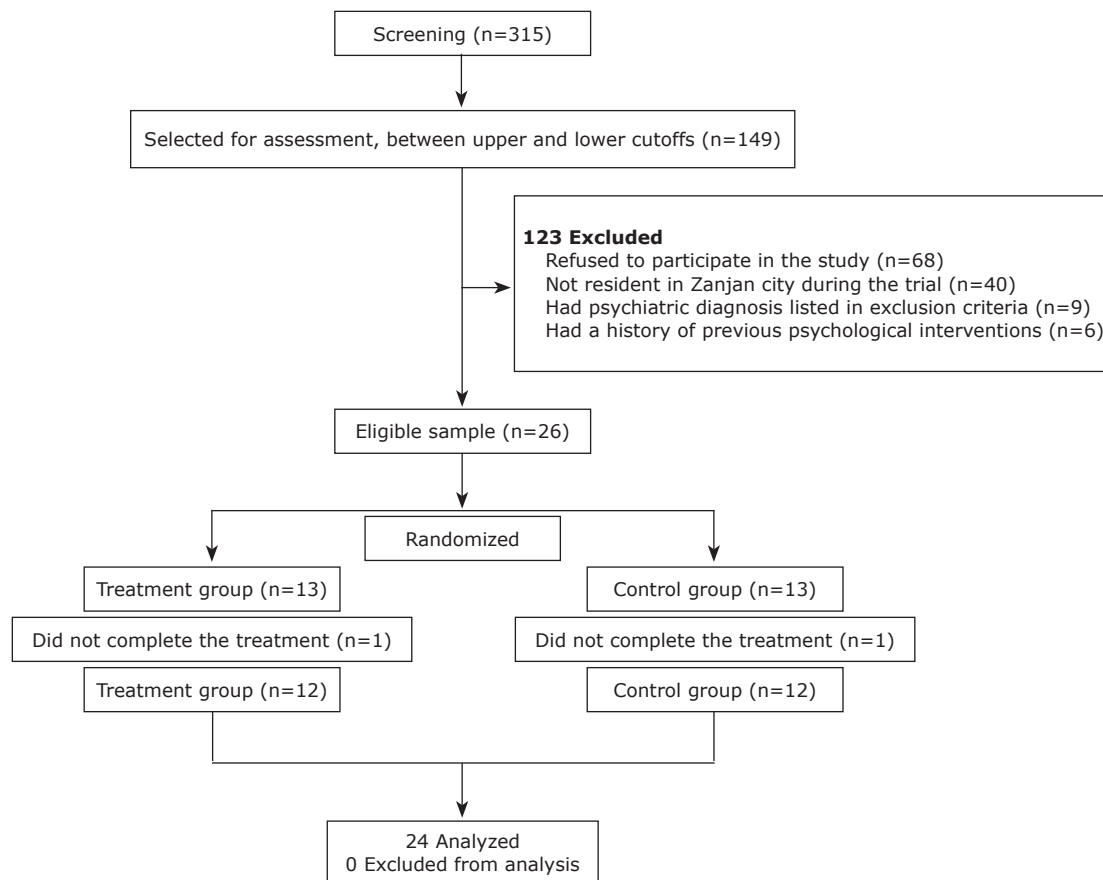


Figure 1 - CONSORT diagram illustrating participant flow during the study.

people). Finally, a sample of 26 individuals was selected from among these people by application of inclusion and exclusion criteria and Cohen table. Inclusion criteria included residence in Zanjan city during the research, willingness to participate in the research, and having a principal diagnosis of any anxiety or depressive disorder (assessed using the Anxiety Disorders Interview Schedule for DSM-IV-Lifetime Version [ADIS-IV-L]). Exclusion criteria included having a DSM-IV diagnosis of bipolar disorder, schizophrenia, or schizoaffective disorder; diagnostic history of psychiatric disorders; having a history of previous psychological interventions (particularly more than 5 sessions of cognitive behavioral therapy); absence from more than two sessions in a row; or not participating in the evaluation process.

Subsequently, these 26 individuals were randomly assigned to treatment or control groups of 13 patients each, selected by the second author of this study using Random Number Generator 3.1 software (the therapist was blind to randomized condition). All participants signed a written voluntary informed consent form. During the treatment, 1 member of the treatment group and 1 member of the control group failed to complete the treatment. The treatment group ($n = 12$) comprised 25% males and 75% females (mean age = 17.5, $SD = 4$ years) and the control group ($n = 12$) included 16.7% males and 83.3% females (mean age = 27.66, $SD = 5.23$ years). 25% of participants in the treatment group were undergraduate students, 33.3% were graduate students, and 41.7% were medical students. In the control group, 33.3% of participants were undergraduate students, 33.3% were graduate students, and 33.3% were medical students. According to chi-square test (χ^2) results, there were no significant differences between the two groups in terms of gender or education and, according to the independent t-test, the two groups did not differ in mean age ($p > 0.05$), which indicates that the treatment and control groups are homogeneous in demographic variables. Principal diagnoses included: obsessive-compulsive disorder (OCD, $n = 3$), generalized anxiety disorder (GAD, $n = 8$), social anxiety disorder (SOC, $n = 5$), panic disorder (PD, $n = 1$), and major depressive disorder (MDD, $n = 5$). Two participants had co-principal diagnoses (of equal severity): SOC with PD, and OCD with GAD. Comorbid disorders included MDD ($n = 5$) and OCD ($n = 1$). None of the participants used psychiatric drugs during the evaluation or treatment phases.

Measures

Anxiety Disorders Interview Schedule for DSM-IV-Lifetime Version (ADIS-IV-L)

This is a semi-structured diagnostic interview which is designed to assess existence and severity of anxiety,

mood, and somatoform disorders and previous mental health background. This scale also includes a short screening for psychotic symptoms and alcohol and substance use. Large-scale evaluations of this tool have been carried out and found strong support for using it on the basis of its diagnostic reliability. Each diagnosis is graded from 0 (no symptoms) to 8 (extremely severe symptoms) on a clinical severity rating (CSR) scale. A CSR score of 4 is the threshold for diagnosis based on DSM-IV. The schedule has a very good internal reliability for anxiety and mood disorders.²³

Beck Depression Inventory (BDI-II)

This 21-item inventory was designed by Beck et al. in 1996 to measure the severity of depression over the preceding two weeks. Items are scored from 0 to 3 on 4-point Likert scales. Total scores on the inventory are classified as follows: 10-13, minor depression; 14-19, mild depression; 20-28, moderate depression; and 29-63, severe depression.²⁴ Studies of the psychometric properties of the BDI-II conducted in various countries have shown that the inventory has acceptable reliability. Beck et al. reported high internal consistency for the inventory ($\alpha = 0.91$) and 1-week test-retest reliability of 0.93. A study conducted in Iran with non-clinical and clinical samples reported internal consistency coefficients of 0.90 and 0.89, respectively, while the test-retest coefficient for the non-clinical sample was 0.94.²⁵

Beck Anxiety Inventory (BAI)

The BAI is a 21-item inventory which was designed by Beck et al. in 1998 to measure the severity of anxiety in adults and adolescents. Total scores on the inventory are classified as follows: 0-7, minor anxiety; 8-15, mild anxiety; 16-25, moderate anxiety; and 26-63, severe anxiety. Beck et al.²⁶ obtained a Cronbach's alpha coefficient of 0.93 and the 5-week test-retest reliability coefficient for this inventory is 0.83. Adequate internal consistency and test-retest reliability have been reported for this inventory ($\alpha = 0.92$ and $r_{tt} = 0.83$).²⁷

Difficulties in Emotion Regulation Scale (DERS)

The DERS was developed by Gratz & Roemer in 2004, with 36 items and 6 subscales for measuring emotion dysregulation and emotional self-regulation strategies. The scale's subscales include lack of acceptance of emotional responses; difficulty in performing purposeful behavior; difficulty controlling impulse; lack of emotional awareness; limited access to emotion regulation strategies; and lack of clarity of emotion. The higher the score, the lower the emotion regulation ability. This scale has demonstrated high internal consistency ($\alpha =$

0.93) and adequate 2-week test-retest reliability ($r_{tt} = 0.85$).²⁸ Cronbach's alpha coefficients for the reliability of the Persian version of this scale vary in the range of 0.79 to 0.91 and its test-retest reliability is from 0.86 to 0.88 after 1 week.²⁹

Procedure

The treatment group received 20 one-hour individual treatment sessions. The UP was designed in 8 treatment modules (sessions and modules are described in Table 1). Diagnostic interviews and patient evaluations were conducted by a psychiatrist (the third author of this article) who was blind to randomized condition. The therapist for this study was a clinical psychology Masters student (the first author of this article) who was trained in cognitive behavioral therapy and transdiagnostic treatment. All treatment sessions were conducted under the supervision of a professor of clinical psychology (the second author of this article). In order to determine the appropriateness of the UP sessions, therapeutic sessions were recorded by the therapist and were randomly examined by a professor of clinical psychology (the second author). Additionally,

weekly meetings were also organized between the therapist and the professor of clinical psychology (the second author) to supervise the sessions.

Data analysis

Descriptive statistics (mean, standard deviation, frequency and tables) and inferential statistics were used to analyze data. The homogeneity of demographic variables between treatment and control groups was studied using χ^2 test and the independent t-test. Hedges' effect size, which is more appropriate for small samples, was calculated to determine the magnitude of change from pre-treatment to post-treatment in the treatment group. The prediction formula for Hedges' effect size is stated as follows.

$$hedges'g = \frac{M1 - M}{SD Pooled}$$

$$SD Pooled = \sqrt{\frac{(s1^2) + (s2^2)}{2}}$$

One-way analysis of covariance (ANCOVA) was used to compare the treatment and control groups by dependent variables and to examine the role of emotion

Table 1 - Transdiagnostic treatment protocol

Modules	Session	Intervention
Module 1. Motivational enhancement	1	This module helped patients to assess the advantages and disadvantages of changing their behavior or staying the same. Also, patients were asked to set more objective goals.
Module 2. Psychoeducation	2	In this module, the adaptive nature of the emotions and the main components of emotional experience were taught to patients.
Module 3. Present-focused, nonjudgmental awareness	3-5	During this module, patients were helped to understand how to observe and react to their emotions and practice present-focused awareness using mindfulness exercises.
Module 4. Increasing cognitive flexibility	6-8	In this module, patients are asked to identify their common thinking traps, learn how to modulate maladaptive thinking patterns, and increase their flexibility in assessing different situations.
Module 5. Identification and prevention of emotional and behavioral avoidance	9-11	This module generally focused on the behavioral components of emotional experience and helped patients to identify emotional avoidance and emotion-driven behaviors (EDBs) and work on current patterns of emotional responses.
Module 6. Increasing the awareness and tolerance of physical sensations	12-14	During this module, patients were encouraged to increase their tolerance to physical sensations. The therapist performed exercises to stimulate body sensations similar to those associated with anxiety and discomfort.
Module 7. Situational emotion exposures	15-19	During this module, the therapist helped patients to plan and then confront an emotional avoidance hierarchy. In these exposures, emphasis is on emotional experience.
Module 8. Relapse prevention	20	This module includes an overview of the treatment content and patient progress. The therapist helped patients to identify ways in which treatment advantages maintain and predict future difficulties.

regulation as a mediator of treatment outcomes, by controlling for initial differences between groups in the pre-test of dependent variables included as covariates. Stepwise regression analysis was used to study the mediating role of the difficulties in emotion regulation subscales in reducing anxiety and depression. Data were analyzed using SPSS-20 software.

Results

Table 2 lists means and standard deviations of pre-test, post-test, and change scores for anxiety, depression, and difficulty in emotion regulation in the treatment and control groups.

Hedges’ effect size was used to investigate the effect of the UP for reduction of anxiety and depression in the treatment group from pre-test to post-test. Hedges³⁰ reported effect sizes of 2.0, 5.0, and 8.0 as small, medium, and large, respectively. The results show that the UP produced strong reductions in anxiety (Hedges’ $g = 1.23$) and depression (Hedges’ $g = 0.87$) in the treatment group from pre-test to post-test.

Table 3 lists the results of ANCOVA, assessing the efficacy of the UP for anxiety and depression, controlling for the effects of pre-test anxiety, depression, and the role of emotional regulation. The main assumptions

for covariance analysis were observed, including the relative variability of the dependent variables, the normal distribution of variables, according to the Kolmogorov-Smirnov test, in both treatment and control groups ($p > 0.05$), the equality of covariance variables in both groups, according to Levene’s test ($p > 0.05$), conducting pre-test before treatment, linear correlation between dispersion (pre-test) and the independent variable ($p < 0.01$), and homogeneity of regression slopes in both anxiety and depression variables ($p > 0.05$).

The ANCOVA results in the first stage showed that after controlling for the effect of pre-test results, mean scores for anxiety and depression in the treatment group were significantly reduced compared to the control group ($p < 0.0001$), which suggests the efficacy of the UP for reducing anxiety and depression. Considering the research hypothesis that emotion regulation plays a mediating role in the efficacy of the UP for reducing anxiety and depression, in the second phase, in addition to controlling for the effect of pre-test results, difficulties in emotion regulation change scores were also controlled. These results showed that there was no significant difference between treatment and control groups after controlling for the effect of emotion regulation ($p > 0.05$), which suggests that emotion does play a mediating role in this treatment (Table 3).

Table 2 - Descriptive statistics for outcome variables

Variable	Treatment group (n = 12)			Control group (n = 12)		
	M ± SD Pre-test	M ± SD Post-test	M ± SD Change score	M ± SD Pre-test	M ± SD Post-test	M ± SD Change score
BAI	19.33±11.38	8.92±6.24	10.42±10.8	20±12.79	21.25±11.77	-1.25±5.26
BDI	18.5±11.16	8.33±12.21	10.17±5.67	19.67±10.13	21.92±11.28	-2.25±7.63
DERS	98.33±21.22	70.83±14.12	27.5±17.17	107.4±22.6	109±21.57	-1.58±15.55

BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; DERS = Difficulties in Emotion Regulation Scale; M = mean; SD = standard deviation.

Table 3 - Descriptive statistics and ANCOVAs for BDI and BAI

Dependent variable	Post-test adjusted means		df	MS	f	p	η ² or Eta
	Treatment M ± SD	Control M ± SD					
Pre-test							
BAI	9.1±1.95	21.06±1.95	1	857.85	18.89	0.0001	0.474
BDI	8.86±1.97	21.39±1.97	1	937.83	20.23	0.0001	0.491
Pre-test and DERS							
BAI	11.43±2.29	18.74±2.29	1	158.83	3.82	0.065	0.161
BDI	12.04±2.05	18.21±2.05	1	121.38	3.47	0.077	0.148

BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; DERS = Difficulties in Emotion Regulation Scale; M = mean; MS = mean sum of squares; η² = partial eta squared; SD = standard deviation.

Multivariate regression analysis was conducted to investigate the roles of the subscales of difficulties in emotion regulation as mediators of change in anxiety and depression (Table 5). First, the change score (change score = pretest - posttest) was calculated for each of the variables from the anxiety, depression, and difficulties in emotion regulation subscales. The main assumptions of the regression test, including normality, linearity, and homogeneity of variance, were observed, according to the standard residual chart method. Table 4 shows the correlation matrix for the variables.

The results of multivariate regression analysis suggest two models for prediction of anxiety and depression based on the difficulties in emotion regulation subscales. The first analysis examined change in difficulties in emotion regulation subscales

for predicting change in anxiety. These results indicate that the best predictor of anxiety is difficulty engaging in goal-directed behavior, which alone could explain 53.4% of the anxiety variances. This means that 53.4% of anxiety changes are explained by change in the difficulty engaging in goal-directed behavior score. In the second step, the non-acceptance of emotional responses subscale was added to the regression and, together with the difficulty engaging in goal-directed behavior, these two subscales had the power to explain 62% of the variance of anxiety.

The second multivariate regression analysis examined change in difficulties in emotion regulation subscales for predicting change in depression. These results indicate that the best predictor of depression is the difficulty engaging in goal-directed behavior

Table 4 - Correlations among anxiety, depression, and difficulties in emotion regulation

Variable	2	3	4	5	6	7	8	9
1. BAI	0.694*	0.726 [†]	0.731 [†]	0.689 [†]	0.167	0.590 [†]	0.514 [†]	0.732 [†]
2. BDI	1	0.519 [†]	0.813 [†]	0.645 [†]	0.284	0.733 [†]	0.539 [†]	0.764 [†]
DERS								
3. Nonaccept		1	0.813 [†]	0.540 [†]	0.340	0.508 [†]	0.478*	0.765 [†]
4. Goals			1	0.757 [†]	0.299	0.676 [†]	0.638 [†]	0.877 [†]
5. Impulse				1	0.151	0.682 [†]	0.481 [†]	0.676 [†]
6. Awareness					1	0.183	0.563 [†]	0.522 [†]
7. Strategies						1	0.529 [†]	0.824 [†]
8. Clarity							1	0.793 [†]
9. Total score								1

BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; DERS = Difficulties in Emotion Regulation Scale; Nonaccept= Nonacceptance of emotional responses; Goals = Difficulty engaging in goal-directed behavior; Impulse = Impulse control difficulties; Awareness = Lack of emotional awareness; Strategies = Limited access to emotion regulation strategies; Clarity = Lack of emotional clarity.

* $p < 0.05$, [†] $p < 0.01$.

Table 5 - Multivariate regression analysis for prediction of change in anxiety and depression

Dependent variable/model/ predictive variable	R	R ²	F	p of F	Beta	t	p
BAI							
Model 1							
Goals	0.731	0.531	24.03	0.0001	0.731	4.9	0.0001
Model 2							
Goals	0.787	0.620	16.028	0.0001	0.433	2.2	0.40
Nonaccept					0.418	2.13	0.046
BDI							
Model 1							
Goals	0.813	0.660	40.8	0.0001	0.813	6.39	0.0001
Model 2							
Goals	0.850	0.723	26.04	0.0001	0.584	3.65	0.002
Clarity					0.338	2.11	0.047

BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; Nonaccept = Nonacceptance of emotional responses; Goals = Difficulty engaging in goal-directed behavior; Clarity = Lack of emotional clarity.

subscale, which alone could explain 66% of the depression variance. In the second step, lack of emotional clarity was added to difficulty engaging in goal-directed behavior and together they were able to predict 72.3% of depression variance. The F test showed that prediction of anxiety and depression in both models is significant ($p < 0.05$). In the first anxiety prediction model, difficulty engaging in goal-directed behavior had a coefficient of $\beta = 0.731$ and $t = 4.19$ and, in the second model, non-acceptance of emotional responses had a coefficient of $\beta = 0.418$ and $t = 2.13$, and both were capable of predicting anxiety ($p < 0.05$). In the first depression prediction model, difficulty engaging in goal-directed behavior had a coefficient of $\beta = 0.813$ and a value of $t = 6.39$ and, in the second model, non-acceptance of emotional clarity had a coefficient of $\beta = 0.338$ and $t = 2.11$, and both were capable of predicting depression ($p < 0.05$).

Discussion

The first goal of this study was to examine the efficacy of the UP for improving anxiety and depression in people with emotional disorders. The initial results showed that the UP could significantly reduce anxiety and depression in the treatment group relative to the control group. This finding is consistent with the underlying theories and therapeutic goals of the UP. The improvement observed in this study is in line with the results of Pearl & Norton,¹⁹ Farchion et al.,³¹ and Elard et al.³⁰ and provides additional empirical evidence to support the efficacy of the UP in the treatment of emotional disorders.

The second goal of this study was to investigate the indirect effect of treatment through emotion regulation. The results showed that the UP reduces the anxiety and depression of people with emotional disorders through improvement of their emotion regulation strategies. The study findings indicate that there is a relationship between emotion regulation strategies and symptoms of anxiety and depression.³² 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. Previous research has reviewed the role of emotion regulation and indicates that few studies have focused on the mediating role of emotion regulation strategies as the mechanism of change during CBT.¹⁵ Only a study conducted by Sauer Zavala et al.²² has studied this structure as the mediator of the outcomes of the UP. Their results showed that

improvement in how one reacts to one's emotions, more than reduction of negative emotions, can predict the severity of symptoms after treatment.

The UP can improve emotion regulation strategies in different ways, thereby reducing the anxiety and depression of people with emotional disorders. People with emotional disorders experience more intense emotion in dealing with environmental stimuli and interpret their emotional experiences as threats.³³ Accordingly, the UP, by emphasizing how this group of patients experience and face emotions, teaches them to respond to their emotions in a more adaptive manner. For example, during the treatment, attempts are made to improve how individuals react to their emotions and to modify their assessments of their emotions, using present-focused, non-judgmental awareness (module 3), cognitive flexibility (module 4), and prevention of emotional and behavioral avoidance (module 5). Furthermore, during the UP, individuals have the opportunity to practice the emotion regulation strategies learned in previous modules by using situational emotion exposure (modules 6 and 7). These encounters help people to increase their tolerance to emotions and create new situational learning. The key to these encounters is to eliminate the maladaptive emotion regulation strategies (such as emotional avoidance or maladaptive situation modification) and stimulate authentic emotion.

On the other hand, a closer look revealed that difficulty engaging in goal-directed behavior can predict a large proportion of the change in anxiety (53%) and depression (66%) scores. As previously mentioned, the UP makes people face unpleasant emotions and situations and prevents them from escaping or avoiding these experiences. Under such conditions, and in the absence of catastrophic consequences, individuals form new learnings about their emotions and can pursue more goal-directed behaviors despite their disorders. In fact, the UP reduces the symptoms of emotional disorders by increasing goal-directed behavior and improving the overall performance of individuals when experiencing unpleasant emotions.

Additionally, the results revealed that the subscales lack of emotional response and lack of emotional clarity were the second-strongest predictors of change in anxiety and depression scores, respectively. Maladaptive attentional deployment (e.g. worry, rumination, distraction) is one of the maladaptive strategies of emotion regulation.⁶ Evidence suggested that emotion regulation strategies based on mindfulness, as well as recognizing and accepting internal experiences, without attempting to change or avoid them, are good alternatives to emotion dysregulation strategies.³⁴ In

this regard, the UP is also attempting to increase the clarity of emotions and their admission, in particular through mindfulness exercises (module 3), to address patients' anxiety and depression problems.

Various studies have identified the role of recognition and acceptance of emotions in reducing the symptoms of disorders. For example, Sauer Zavala et al.²² stated that increased awareness of emotions and their acceptance are accompanied by anxiety and depression scores. Additionally, Boswell et al.³⁵ also showed that mindfulness could be considered as one of the mechanisms of the UP effect in reducing depression.

This study has limitations which require consideration when interpreting our findings. First, the small sample size may have made it difficult to generalize our findings. Additionally, it should be noted that there are different definitions and measurements for assessing emotion regulation. Although we have tried to determine our vision of emotion regulation in this study, the various conceptualizations of this structure could affect the findings of this study. Given that the present study is one of the few studies to investigate the mediating role of emotion regulation in the efficacy of UP, it is suggested that more studies of different diagnostic groups with larger sample sizes could be conducted. Additionally, conducting studies to examine the individual effect of each of the UP modules could help to expand and improve this treatment protocol.

Conclusion

Although recent studies have made significant progress with regard to the development of evidence-based interventions such as the UP, relatively little is known about how the UP actually operates. The present study provides promising evidence showing, in addition to the efficacy of the UP for reducing anxiety and depressive symptoms, that emotion regulation plays an important role in the UP for emotional disorders. Our results are consistent with the theoretical framework of the UP that emphasizes commonalities across the emotional disorders and suggest a potential mediator of change in the UP. 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. Research should continue to investigate mediators of change such as emotion regulation in reduction of anxiety and depressive symptoms to continue improving treatment and understanding of emotional disorders and facilitating the implementation of treatments in clinical practice.

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