Investigating the Mechanisms of Change in the Unified Protocol Treatment: A Non-Randomized Trial on Transdiagnostic Factors

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Abstract
Objective: To investigate how emotion regulation mediates treatment outcomes using the Unified Protocol for transdiagnostic emotional disorder treatment.
Method: A non-randomized trial was conducted from December 2021 to May 2022 in Islamabad. A purposive sampling technique was employed, with 15 patients experiencing depression and anxiety completing a 14-week treatment program utilizing the Unified Protocol. The Beck depression inventory, the Beck anxiety inventory, and the difficulties in emotion regulation scale were administered during the baseline, mid-treatment, and post-treatment phases.
Results: The results indicated a significant reduction in the outcome measures for all the participants, as the treatment decreased anxiety, depression, and difficulties in emotion regulation. Additionally, the findings indicated that difficulties in controlling impulses and limited access to emotion regulation strategies were able to predict 72% and 33% variation in anxiety and depression scores, respectively.
Conclusion: Emotion regulation has the potential to act as a mediating factor and predict treatment outcomes in transdiagnostic therapy using the Unified Protocol.
Keywords: Emotion regulation, evidence-based treatment, mediator, transdiagnostic, unified protocol

Introduction

Mental health disorders, notably depression and anxiety, are a global issue, impacting over 280 million individuals worldwide[1]. Along with high prevalence rates, there is a high comorbidity between depression, anxiety, and related negative emotions such as irritability, guilt, and sadness[2]. Individuals with comorbid conditions are at a higher risk for chronicity, functional impairment, and poor response to treatment[3]. This cannot be fully accounted for by diagnosis-specific treatments[3].

Recent conceptualizations of emotional disorders have highlighted the importance of transdiagnostic factors in understanding and treating comorbidity[2]. Emotion regulation, the ability to recognize, understand, and manage emotions adaptively, has emerged as a key transdiagnostic factor in emotional disorders[4]. The research indicates a strong association between maladaptive emotional regulatory strategies and the onset of depression and anxiety[5]. Conversely, adaptive regulatory strategies, such as problem-solving and reappraisal, are inversely correlated with lower levels of psychopathological symptoms[5,6].

Negative affectivity, a broad construct encompassing various negative emotions, has been identified as playing a central role in emotion regulation[7]. When individuals with high negative affectivity struggle to regulate their emotions, maladaptive strategies like avoidance, uncertainty intolerance, and suppression often take hold, perpetuating and exacerbating emotional distress[8]. These difficulties, particularly prominent in internalizing disorders like depression and anxiety[9], highlight the potential of emotion regulation as a mediator for reducing such symptoms.

The Unified Protocol (UP) treatment is an evidence-based and transdiagnostic cognitive-behavioral therapy (CBT) that targets negative affectivity and emotion regulation as central mechanisms of change, recognizing that emotional disorders share common underlying factors and offering a comprehensive and integrated approach that differs from traditional disorder-specific treatments[8,10]. This treatment aims to equip individuals with adaptive strategies for managing and responding to emotions, leading to reductions in depression and anxiety symptoms[10]. It utilizes specific techniques like identifying and labelling emotions, challenging negative thoughts, and engaging in activities promoting long-term adaptive consequences[8]. A growing body of evidence found that individuals treated with UP exhibit significant improvements in their emotion regulation capacities and a decrease in their symptoms[8,11].

Considering the empirical evidence, the current research seeks to assess the effectiveness of the UP for treating emotional disorders and explore how emotion regulation mediates treatment outcomes. It is hypothesized that implementing the UP treatment will result in reduced symptoms of anxiety and depression, with improvements in emotion regulation playing a mediating role.

Patients and Methods

The study took place in Islamabad from December 2021 to May 2022 and was approved by the ethics committee of the School of Social Sciences and Humanities (0988/Ethic/01/S3H/083/DBS). Employing a purposive sampling technique, participants were recruited through study flyers on social media and screened using the Beck Depression Inventory (BDI-II)[12] and the Beck Anxiety Inventory (BAI)[13], followed by a semi-structured clinical interview to assess diagnoses based on DSM-5 TR criteria for depression and anxiety. Inclusion criteria: 18 years or older, with moderate to severe anxiety and/or depressive symptoms based on BDI-II and BAI scores. Exclusion criteria: suicidal risk, comorbidity with a pervasive developmental disorder, psychotic disorder, or severe physical illness; receiving concurrent psychotherapy or psychopharmacological treatments. Written informed consent was obtained from all participants in the study.

To estimate the sample size required for the single-group pre-post research design, the current study employed an a priori power analysis, considering an alpha level of 0.05, a desired power of 0.8, and a medium effect size (Cohen's d = 0.5). This sample size estimation was guided by previous studies demonstrating significant improvements in emotion regulation capacities and a decrease in symptoms following UP treatment[5,14,15].

The researchers used the adapted Unified Protocol treatment in the current study. It includes two complimentary modules for goal setting and psychoeducation, along with five core treatment modules: mindful emotion awareness, cognitive flexibility, countering emotional behaviors, awareness and tolerance of physical sensations, emotion exposures, and an optional module for relapse prevention. The participants attended 14 weekly individual sessions, each lasting 50-60 minutes. The therapist delivering the treatment is a certified-UP therapist with over 5 years of clinical experience. All research participants completed three assessment phases: baseline, mid-assessment (after 7 sessions), and post-treatment, utilizing the outcome measures in Urdu. They included the 21-item BDI-II and BAI for assessing depressive and anxiety symptoms, respectively, with both scales demonstrating high-reliability $\alpha = 0.90$ and $\alpha = 0.92$ in the present study. The study also used the Difficulties in Emotion Regulation Scale (DERS)[16], a 36-item tool measuring emotion regulation, containing 6 subscales. The subscales evaluate acceptance of emotional responses, purposeful behavior performance, impulse control, emotional awareness, emotion regulation strategies availability, and emotional clarity. The reliability of the overall scale and subscales ranged from $\alpha = 0.78$ to $\alpha = 0.92$ in this study.

Statistical analysis was performed using SPSS 25. Repeated measures analysis of variance (ANOVA) was used to estimate the effect size of mean differences in outcome measure scores across pre-, mid-, and post-assessment. Stepwise regression analysis was employed to study the

mediating role of the difficulties in emotion regulation subscales in reducing anxiety and depression.

Results

Out of the 22 people initially recruited, the final sample consisted of 15 participants aged between 21 and 45 years (M = 27.53 years, SD = 9.15) after excluding those at suicide risk and voluntary dropouts. The demographic breakdown was as follows: 11 (74%) were female, 4 (26%) males; 6 (40%) married, 9 (60%) unmarried; 13 (87%) had bachelor's degrees, 2 (13%) master's degree or above; 8 (53%) unemployed, 7 (47%) employed. The primary diagnosis based on DSM-5-TR was major depressive disorder 3 (20%), anxiety disorders 6 (40%), comorbidity of depression and anxiety 6 (40) %.

Table 1 lists repeated-measures ANOVA to evaluate the effect of UP on depression, anxiety, and difficulties in emotion regulation at pre-, mid-, and post-treatment phases. The results revealed a statistically significant difference between time points (BAI: F [1.43,20.05] = 8.79, η^2 = 0.38, P = 0.004; BDI: F [2,28] = 8.48, η^2 = 0.37, P = 0.001; DERS: F [2,28] = 14.21, η^2 = 0.50, P<0.001). The result of pairwise comparisons with the Bonferroni test indicated that the treatment group achieved a significantly greater magnitude of change from pre- to post-treatment for all variables (BAI: 15.00, P = 0.003; BDI: 17.80, P = .01; DERS: 40.73, P < 0.001.

Stepwise regression analysis investigated the mediating roles of difficulties in emotion regulation subscales in changes in anxiety and depression (Table 3). The basic assumptions of normality, linearity, and homoscedasticity were satisfied based on the results obtained from the Shapiro-Wilk test and standard residual chart method. Table 2 shows the correlation matrix for the variables.

Model 1: considering impulse control difficulties alone, the model accounted for a substantial 72% of the variance in BAI change, suggesting a strong influence of impulse control on anxiety trajectories. Individuals with higher Impulse scores (β = 0.84, p < .000) exhibited a significantly greater increase in anxiety symptoms, highlighting the detrimental impact of impulsivity on anxiety management. Model 2: focusing on limited access to emotion regulation strategies, the model explained 33% of the variance in BDI change, indicating a moderate yet significant association with depression severity. Limited access to emotion regulation strategies (β = 0.58, p = .003) predicted greater increases in depression symptoms, underscoring the importance of effective coping mechanisms for depression prevention.

Discussion

The findings from this study provide support for the efficacy of the UP in reducing symptoms of anxiety and depression, as well as improving difficulties in emotion regulation. The UP effectively reduced anxiety and depression, aligning with its theoretical foundations and treatment

objectives[8,11]. These findings add further empirical support for the effectiveness of UP in treating emotional disorders.

The mediating role of difficulties in emotion regulation in changes in anxiety and depression was also examined. The findings suggest a relationship between emotion regulation strategies and the symptoms of anxiety and depression. Emotion regulation is considered a potential factor for change in the UP, aiming to improve vulnerability to emotional disorders[5]. Research investigating this factor as a mediator of treatment outcomes demonstrated that an individual's ability to effectively manage and respond to their emotions serves as a predictor of symptom severity following treatment.

Upon examining the mediating role of specific difficulties in emotion regulation, it was observed that impulse control difficulties were a significant predictor of anxiety scores. People with anxiety disorders often encounter intense feelings of apprehension or fear in response to stressors. These negative emotions can feel overpowering and result in impulsive actions as a means of coping or seeking relief, prioritizing short-term emotional regulation over long-term self-regulatory objectives[17]. The UP strategies help individuals tolerate unpleasant emotions with a non-judgemental attitude and replace impulsive emotional reactions with more adaptive behaviors.

Secondly, limited access to emotional regulation strategies was found to be a strong predictor of depression scores. When individuals with inadequate coping mechanisms confront challenging emotions, they may find it difficult to effectively manage them. This can lead to the use of unhealthy strategies such as avoidance and rumination[6]. Additionally, inadequate emotional coping abilities can make individuals vulnerable to negative thought patterns that often contribute to feelings of helplessness, hopelessness, and worthlessness - key symptoms of depression[18]. The UP overcomes these challenges by increasing emotion regulation skills through cognitive flexibility, and prevention of emotional and behavioral avoidance.

The present research supports UP's focus on improving emotional regulation to reduce anxiety and depression in individuals with emotional disorders. The program emphasizes adaptive reactions to emotions through mindfulness, cognitive flexibility, and avoiding avoidance behaviors. It also teaches emotion regulation techniques and enhances tolerance for emotions by eliminating ineffective strategies[19].

The current study had some limitations. A larger sample size would provide more robust results. Additionally, the use of a comparison group rather than a single group design could enhance the study's validity. Consequently, future research should consider incorporating these design improvements to further validate the effectiveness of the UP in treating emotional disorders.

Conclusion

The Unified Protocol for the treatment of emotional disorders shows promise in reducing symptoms of anxiety and depression by targeting transdiagnostic

factors such as emotion regulation and negative affectivity. Further studies need to assess the role of other potential mediators in the treatment outcomes of the UP, such as cognitive flexibility and tolerance of uncertainty. Understanding the impact of these factors on the intervention's effectiveness can contribute to a more comprehensive understanding of the treatment's mechanisms and its potential benefits for individuals with emotional disorders.

Table 1: Descriptive statistics for outcome variables

Variable	Pre-treatment		Mid-treatment		Post-treatment	
	M	***SD***	***M***	***SD***	***M***	***SD***
BAI	36.66	2.61	32.65	3.99	21.66	2.47
BDI	38.20	4.01	28.20	1.49	20.40	2.60
DERS	120.53	7.75	118.06	3.54	79.80	5.61

M = Mean, SD = Standard Deviation; BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; DERS = Difficulty in Emotion Regulation Scale.

Table 2: Correlations among anxiety, depression, and difficulties in emotion regulation

Variable	2	3	4	5	6	7	8	9
1. BAI	.80***	.81**	.42	.81**	.88**	.74**	.74**	.45
2. BDI	1	.52**	.36	.56**	.52**	.42	.58*	.15
3.DERS		1	.73**	.89**	.89**	.91**	.82**	.65**
4.Non Accept			1	.42	.40	.73**	.45	.75**
5.Goals				1	.96**	.73**	.92**	.31
6.Impulse					1	.71**	.88**	.39
7.Awareness						1	.61**	,61**
8.Strategies							1	.20
9.Clarity								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 3: Stepwise regression analysis for prediction of change in anxiety and depression

Dependent variable/model/ predictive variable	R	R^2	F	p to F	Beta	t	p
BAI							
Model 1							
Impluse	.84	.72	33.28	.000	.84	5.76	.000
BDI							
Model 1							
Strategies	.58	.33	6.58	.003	.58	2.5	.003

BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; Strategies = Limited access to emotion regulation strategies; Impulse = Impulse control difficulties

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