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Investigating the mediational role of Intolerance of Uncertainty and its components in reducing symptoms of emotional disorders: A double-blind randomized clinical trial

Sahel Khakpoor, Jahangir Mohammadi Baytamar, Omid Saed

Summary

Background and Objectives: Intolerance of uncertainty (IU) is a transdiagnostic structure that plays an important role in developing and maintaining symptoms of emotional disorders. The current study was aimed to investigate the mediational role of IU and its components in reducing symptoms of emotional disorders.

Method: This was a double-blind randomized clinical trial. Based on the Beck anxiety inventory and Beck depression inventory 26 individuals were selected. They were randomly assigned into two groups of control and treatment (n=13) using random number generator 3.1.v software. The treatment group received 20 one-hour sessions of Unified Protocol (UP) for the transdiagnostic treatment of emotional disorders. Beck depression inventory, the Beck anxiety inventory, and Intolerance of uncertainty scale were performed in pre, post and three months follow-up. Data were analyzed by SPSS-20 software.

Results: After controlling the effect of IU, the results of one-way analysis of covariance (ANCOVA) showed a significant reduction in the difference between the two groups (P<0.05); which means that IU can be considered as a mediator of reductions in anxiety and depression in UP. The results of the stepwise regression analysis indicated that prospective IU and inhibitory IU could explain 61.4% and 8.2% of variances in anxiety scores, respectively. In predicting changes in depression score, only inhibitory IU could explain depression variance (43.3%).

Discussion: The best predictor of the changes in the anxiety and depression are, respectively, prospective IU and inhibitory IU. Conclusion. This study shows that UP may exert its effect by improving different components of IU.

Intolerance of uncertainty, prospective IU, inhibitory IU, Emotional disorders.

1. INTRODUCTION

Dimensional approach to the psychopathology of emotional disorders have become increasingly widespread in recent decades and transdiagnostic approach is one of them [1] the transdiagnostic conceptualization, an emotional disorder is characterized by the experience of fre-

Sahel Khakpoor[1], Jahangir Mohammadi Baytamar[1], Omid Saed[2]: [1]Education and Treatment Center of Beheshti Hospital, Zanjan University of Medical Sciences, Zanjan, Iran; [2]Department of Clinical Psychology, Faculty of Medicine, Zanjan University of Medical Sciences, Zanjan, Iran.
Correspondence address: o.saed@zums.ac

quent and intense negative emotions, negative reactivity to intense emotional states (which is associated with diminished sense of control), and efforts to withdraw, escape, or avoid emotional experience [2]. These mainly consist of anxiety and unipolar depressive disorders. Transdiagnostic approach, relying on common pathologic processes among emotional disorders, stated that the existence of biological vulnerabilities, such as neuroticism or negative affectivity as well as psychological vulnerabilities may predispose individuals to emotional disorders [3, 4]. Intolerance of Uncertainty (IU) is one of the cognitive vulnerabilities that has been recently propounding in the psychopathology of emotional disorders [5]. IU was originally established as a construct involved in worry associated with Generalized Anxiety Disorder (GAD) but, more recent evidence indicated that this construct is an important transdiagnostic maintaining factor for other anxiety and mood disorders [6-8] IU has been conceptualized as fear of unknowns and a desire to consider ambiguous experiences as unacceptable and threatening events, regardless of the probability of occurrence [6]. [9] propound IU as a kind of cognitive bias that affects how one receives, interprets, and responds to an uncertain situation in an emotional, cognitive and behavioral ways [9]. Interpreting ambiguous or unclear situations as stressful and upsetting events, evokes maladaptive behaviors, difficulty in problem-solving, and different cognitive avoidance ([8, 10]. It should be noted that uncertainty itself can be considered as a threat which perpetuates anxiety and depression symptoms, as well as exaggerates threat perceptions [11].

Factor analysis identified two general factors within IU: Prospective IU and Inhibitory IU [12]. Prospective IU represents aversive cognitive and emotional perception. In this case, people are actively trying to anticipate future experiences and achieve confidence. Individuals with a high level of prospective IU are afraid of future uncertainty and believe that worry will help them to effectively counteract or prevent the occurrence of terrible incidents. The second factor is inhibitory IU which represents inaction and perseveration. Individuals who reported a high level of inhibitory IU, form negative beliefs toward the problem which leads to distress and cognitive avoidance [13]. In fact, confronting uncertainty paralyze these individuals. Each of the IU dimensions has been associated with different anxiety disorder and depression symptoms [14, 15]. Studies suggest that prospective IU may be associated with worry and anxiety symptoms such as obsession [14], whereas inhibitory IU is more related to depression symptoms and phobias [16]. Anxious individuals who experience non-phobic anxiety symptom actively try to collect information as much as possible to make the future situation more predictable. Depressed individuals, on the other hand, more desire to avoid obscure situations and shows passive reactions.

Additionally, data from several studies indicated that various cognitive behavior therapies impact IU [8, 17]. Barlow developed a transdiagnostic treatment based on Unified Protocol (UP) which has been shown to effectively decrease IU and other symptoms [18]. This protocol is an evidence-based therapy which tries to modify an individual's perceptions of uncertainty and ambiguous situations and to replace more adaptive cognitive and behavioral strategies through various therapeutic techniques [17, 18] UP postulated can improve the shared mechanism, like IU, across diagnostic groups and so reduced emotional disorders symptoms. If this is the case, examining IU and its components that contribute to changes in anxiety and depression may offer better clues as to determine the potential mechanism of changes during UP. Studies showed that changes in the IU were associated with changes in emotional disorders symptoms [17, 19], however, it is unclear whether changes in IU predict changes in anxiety and depression symptoms differently. Given that each of the two components of IU differently related to the symptoms of emotional disorders, it seems that treatment also has different effects on these components and therefore decreases symptoms.

In this regard, the first goal of this study was to investigate the mediating role of IU in reducing students' anxiety and depression during UP. Based on prior research, it was hypothesized that IU can be considered as a mediator of the outcome during treatment with UP. In addition, the present study seeks to investigate the role of

the prospective IU and inhibitory IU in decreasing anxiety and depression in students during participating in UP treatment. In this regard, it was hypothesized that UP could reduce anxiety by improving prospective IU and reduce depression via improving inhibitory IU.

2. MATERIAL AND METHOD

2.1. Study design

A double-blind randomized clinical trial was conducted and has been approved by the Ethics Committee (reference number: ZUMS. REC.1396.143). It is also registered at Iranian Registry of Clinical Trials (registration number: IRCT2017072335245N1).

Participations were randomized to condition by the second author of this study based on Random Number Generator 3.1 software (the therapist was blind to randomized condition). Patients assigned to treatment and control groups were assessed before treatment, at the end of treatment, and after a 3-month follow-up period. All participants signed a written voluntary informed consent form.

2.2. Participants

Participants were recruited from the students of Zanjan University of Medical Sciences in 2017-2018 (statistical population = 3,500; Figure 1 summarizes the sampling process). Three hundred and fifteen individuals were assessed for eligibility. In order to eligible to participate in the study, patient had to meet the diagnostic criteria for at least one emotional disorder (assessed using the Anxiety Disorders Interview Schedule for DSM-IV–Lifetime Version (ADIS-IV-L)), be in the moderate range of BDI-II (between 20 and 28) and BAI (between 16 and 30), residence in Zanjan city during the study, and willing to participate in the study.

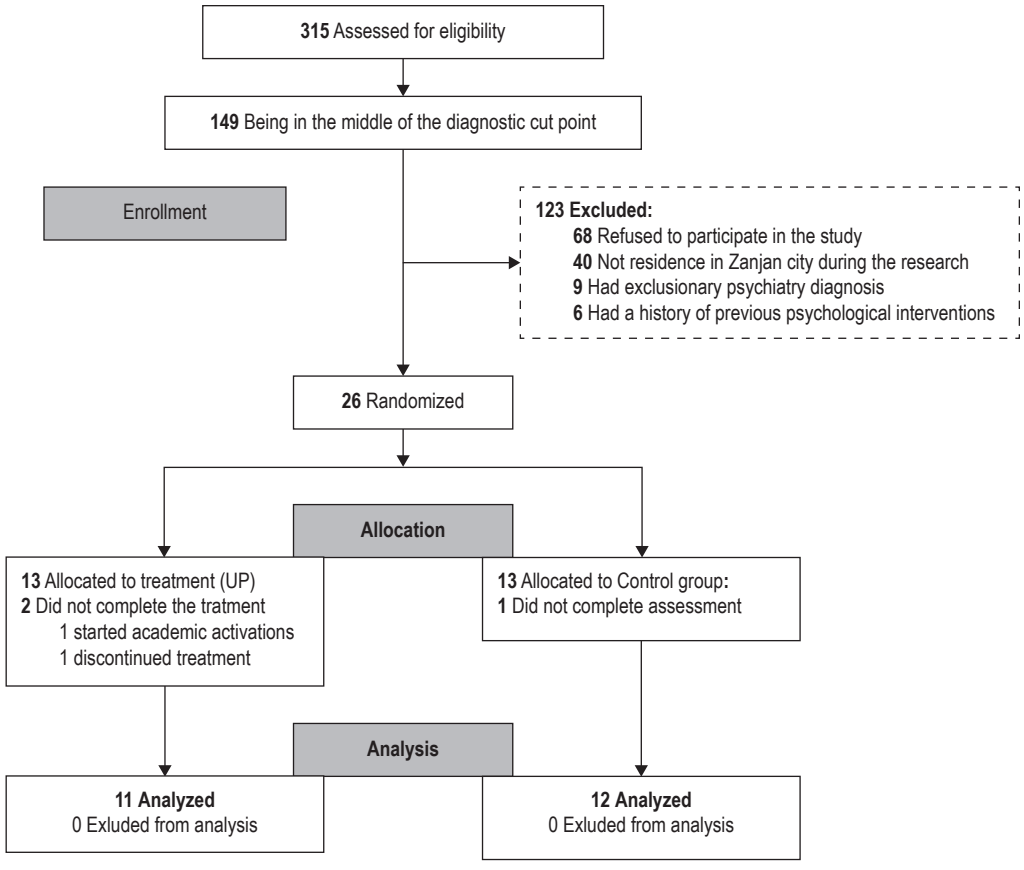

Figure 1. CONSORT diagram illustrating participant flow during the study

Exclusion criteria consisted primarily of those receiving a diagnosis of bipolar I and II disorders, schizophrenia and schizoaffective disorders, diagnostic history of psychiatric disorders, having a history of previous psychological interventions (particularly more than 5 sessions of cognitive behavior therapy which consist of principles such as cognitive restructuring and exposure), absence of more than two sessions in a row, or not participating in the evaluation process.

Finally, 26 patients were consented to the study and randomized to either treatment group (n= 13) and control group (n= 13). During the treatment, 2 in the treatment group and 1 in the control group were failed to complete the trial. The treatment group (n = 11) consisted of 27.3% male and 72.7% female with an average age of 24.27 years (SD = 2.65). In terms of educational status, 27.3% of the participants in the treatment group were undergraduate students, 27.3% were master students and 45.5 % were medical students. The control group consisted of (n = 12) 16.7% male and 83.3% female with an average age of 26.67 years (SD = 23.5), 33.3% were undergraduate students, 33.3% were master students and 33.3% were medical students. The two groups did not differ in mean age ($t = -1.36$, $P > 0.05$) or gender and education ($X2$, $P > 0.05$); which indicates the homogeneity of the treatment and control groups in demographic variables in the per-treatment. Principal diagnosis represented included: obsessive-compulsive disorder (OCD, n=3), generalized anxiety disorder (GAD, n=7), social anxiety disorder (SOC, n=5), panic disorder (PD, n=1), major depression disorder (MDD, n=5). Two participants had co-principal diagnoses (equal severity): SOC and PD, OCD and GAD. Comorbid disorders included MDD (n=5) and OCD (n=1). None of the participants were using psychiatric drugs during the evaluation and treatment phases.

2.3. Measures

2.3.1. Anxiety Disorders Interview Schedule for DSM-IV–Lifetime Version (ADIS-IV-L):

This program is a semi-structured diagnostic interview which was designed to assess the existence and severity of the anxiety, mood, and somatoform disorders and previous background of psychiatric disorders. This scale also includes a short screening for psychotic symptoms and alcohol and substance use. Each diagnosis is graded on a scale of clinical severity rating (CSR) from 0 (no symptoms) to 8 (extremely severe symptoms), the score of 4 in this scale is the clinical severity threshold for diagnosis based on DSM-IV [16] It has very good internal reliability for anxiety and mood disorders [8].

2.3.2. Beck Depression Inventory (BDI-II):

This 21-item inventory was designed by Beck, Steer, and Carbin in 1996 [20] to measure the severity of depression over the past two weeks. Items were scored on a 4-point Likert scale from 0-3 [20]. Studies about the psychometric properties of the BDI-II in various countries show acceptable reliability. Beck et al. reported a high internal consistency for this inventory (α=0.91) and retest reliability of 0.93 in a week. In a study done in Iran on non-clinical and clinical samples, internal consistency coefficients were reported to be 0.90 and 0.89, respectively, and the test-retest coefficients in the non-clinical sample were 0.94.

2.3.3. 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. Items were scored on a 4-point Likert scale from 0-3. Beck et al. [20] obtained Cronbach's alpha coefficient of 0.93 and five-week test-retest reliability coefficient for this inventory 0.83. Adequate internal consistency and test-retest reliability have been reported for this inventory (α= 0.92 and rtt =0.83) [21].

2.3.4. Intolerance of Uncertainty Scale (IUS-12):

This scale is a 12-item version of the original 27-item IUS designed in 2007 by [11]. It measures the ability to tolerate uncertainty in ambiguous situations, behavioral and cognitive re-

sponses to uncertainty, and effort to control future events. It has been shown that the IUS-12 has two subscales, Prospective IU and Inhibitory IU, both with identically high internal consistencies (α= 0.85). Items are rated on a 5-point Likert scale from not at all characteristic of me (1) to entirely characteristic of me (5). The internal stability of this scale has been reported high (α= 0.91). The correlation of the short form with the original version has been obtained from 0.94 to 0.96 [13]. Internal consistencies in the current study were high for the subscales (Prospective IU α = 0.74, Inhibitory IU α= 0.80), and the total score (α= 0.86).

2.4. Procedure

Treatment consisted of 20, one-hour weekly individual psychotherapy sessions. The UP consists of five core and three additional treatment modules. The modules are flexibly linked to sessions in that, depending on the needs of the individual, more or less time can be spent on a given module (sessions and modules are described in table 1).

Clinician for the study was a master of clinical psychology (the first author of this article) who received training for cognitive behavior therapy and transdiagnostic treatment. All treatment sessions were conducted under the supervision of a professor of clinical psychology (the third author of this article). To assure treatment fidelity, all sessions were audiotaped (with patients' permission) and randomly examined by the supervisor. In addition, to monitor treatment adherence, weekly supervision were organized. The examination of treatment sessions revealed that the therapist adhered to the treatment protocol, and delivered UP modules appropriately. In addition, patient elded the questions appropriately and elicited relevant examples. Finally, the assessments and analyses were conducted by an independent evaluator (the second author of this article) who was blind to treatment condition allocation.

Table 1. The unified protocol for the treatment of emotional disorders

	Number of sessions	Key concepts
Module 1. Motivational enhancement	1	Identify the pros and cons of changing and develop both specific and distant treatment goals.
Module 2. psychoeducation	2-3	Provide an overview of the adaptive nature of emotions, present three components of emotional experiences, and introduce the concept of emotion-driven behaviors (EDBs).
Module 3. present-focused, nonjudgmental awareness	2-3	Increasing mindfulness by enhancing and practice present-focused, objective, nonjudgmental awareness of emotional experiences.
Module 4. Increasing cognitive flexibility	2-3	Discussion of cognitive appraisals and reappraisals, evaluate these appraisals, and increase the flexibility of thinking.
Module 5. identification and prevention of emotional and behavioral avoidance	2-3	Introduce the concept of emotional avoidance and emotion-driven behaviors (EDBs) and identify and counter maladaptive EDBs.
Module 6. Increasing the awareness and tolerance of physical sensations	2-3	Identify internal physical sensations that can trigger intense emotions and exposure to physical sensations.
Module 7. Situational emotion exposures	4-5	Develop a fear and avoidance hierarchy and confront strong emotion through emotional exposure exercises.
Module 8. Relapse prevention	1	Overview of the treatment content, evaluate patient's progress and set goals for maintaining treatment advantages and predict future difficulties.

2.5. Data analysis

The raw data were analyzed using SPSS-20 software. Chi-square (X2) test and independent t-test were used to examine the homogeneities of demographic variables between treatment and control groups. One-way analysis of covariance (ANCOVA) was used to compare two treatment and control groups in BAI and BDI-II. To examine the mediational role of IU, ANCOVA was conducted including the initial groups' differences in the pretest of dependent variables as covariance. Stepwise regression analysis was used to investigate predictors of anxiety and depression change scores.

3. RESULT

Results from an ANCOVA analyze demonstrated a significant decrease in BAI and BDI-II scores during UP treatment (Table 2). Given that the women constituted the larger portion of the sample (72.7%), a t test was conducted to assess differences in the mean of BAI and BDI-II between two genders. The results indicated that there is no difference between men and women in both anxiety and depression at post-treatment (p>0/05).

To analyze the mediational role of IU in reducing anxiety and depression, two ANCOVAs were conducted. In the first step, initial groups' differences in pre-treatment of BAI and BDI-II were controlled. The results showed a significant difference between two groups in BAI and BDI-II mean scores (P <0.001). In the next step, the IU Change Score (Change Score = Pre-treatment – Post-treatment) was controlled in addition to controlling BAI and BDI-II pre-treatment scores (Table 2). The comparison of two ANCOVAs indicated that after controlling the IU change score, the significant difference between two groups was decreased (P <0.05). This finding suggests that the changes in IU across treatment are associated with changes in anxiety and depression.

Table 2. Descriptive statistics and ANCOVAs of dependent variables

Controlled variable	Source	Dependent Variable	Post-treatment adjusted means		df	MS	f	P.value	Eta
			Treatment group	Control group					
			M ±SD	M ±SD					
Pre-treatment	Group	BAI	7.96 ± 1.83	21.20 ± 1.75	1	1005.24	27.31	0.0001	0.577
	Group	BDI-II	6.76 ± 2.02	20.55 ± 1.93	1	1039.05	23.84	0.0001	0.544
Pre-treatment and IU	Group	BAI	11.58 ± 1.8	17.88 ±1.7	1	113.3	4.6	0.044	0.197
	Group	BDI-II	8.74 ± 2.3	18.74 ± 2.2	1	303.7	7.5	0.013	0.282

Notes. BAI= Beck Anxiety Inventory; BDI= Beck Depression Inventory; IU = Intolerance of Uncertainty.

To investigate the role of each IU component (prospective and inhibitory IU) in reducing anxiety and depression, two multivariate regression analyses were conducted (Table 3).

The first analysis examined changes in IU components in predicting changes in anxiety. Results indicated that the best predictor of anxiety changes is prospective IU which could explain 61.4% of anxiety variances. This means that 61.4% of the changes in anxiety are explained by a change in prospective IU. In the second step, the inhibitory IU has been added to the regression, which together they have been able to explain 69.2% of the anxiety variances. The F-ratio showed that the prediction of anxiety in both models is significant (P <0.001). In the first model, the reduction of the prospective IU with a coefficient of β = 784 and t=5.8, and in the second model, the reduction of the inhibitory IU with a coefficient of β = 377 and t=2.3 were able to predict anxiety reduction (P <0.05).

Table 3. Multivariate Regression Analysis for the Prediction of Changes in Anxiety and Depression

Collinearity statistics		P.value	t	Beta	P.value of F	F	R Square	R	Predictive variable	Model	Dependent Variable
VIF	tolerance										
1	1	0.0001	5.8	0.784	0.0001	33.4	0.614	0.784	prospective IU	1	BAI
1.8	0.551	0.005	3.2	0.531	0.0001	22.5	0.692	0.832	prospective IU	2	
1.8	0.551	0.035	2.3	0.377					inhibitory IU		
1	1	0.0001	3.9	0.656	0.0001	15.9	0.431	0.656	inhibitory IU	1	BDI-II

Notes. BAI= Beck Anxiety Inventory; BDI= Beck Depression Inventory; IU = Intolerance of Uncertainty.

The second multivariate regression analysis examined changes in IU components in predicting changes in depression. Results indicated that the best predictor of depression changes is inhibitory IU which could explain 43.3% of depression variance. This means that 43.3 % of the depression changes are explained by the inhibitory IU. The F-ratio showed that the prediction of depression in this model is significant ($P < 0.001$). The reduction of the inhibitory with a coefficient of $\beta = 0.665$ and $t=3.9$ was able to significantly predict depression reduction ($P < 0.001$).

4. DISCUSSION

The first aim of this study was to investigate the mediating role of IU in reducing anxiety and depression during UP. Results showed that UP could decrease anxiety and depression by improving IU in individuals with emotional disorders. Our finding is consistent with previous studies supporting the mediational role of IU during transdiagnostic treatment of emotional disorders [8, 18]

When an individual with emotional disorders faced with ambiguous situations, he/she perceives obscure events as threatening and becomes distressed [9]. They generally use two major strategies to reduce experiencing uncertainty. A group of individuals tries to collect as much information as possible to reduce the existing ambiguity and make the future situation more predictable. The second group, which has lower self-confidence in dealing with ambiguous situations, prefer to postpone decision making and start-up activities until sufficient information is obtained. In this regard, UP tries to modify individual's perceptions of ambiguity and replace previous maladaptive strategies with more adaptive cognitive and behavioral strategies, using various modules, including present-focused, nonjudgmental awareness (module 3), cognitive restructuring (module 4), and situational emotion exposures (module 5-7).

The second aim of this study was to investigate the role of the prospective and inhibitory IU in decreasing anxiety and depression. Results showed that in comparison with inhibitory IU, prospective IU predicts a greater degree of anxiety changes (61% versus 8%). [22] McEvoy and Hurn investigated the mediating role of IU components in predicting treatment outcomes across three different cognitive behavior therapy protocols. They indicated that the prospective IU could predict changes in anxiety symptoms strongly ([8]. In contrast, [17] showed that the inhibitory IU but not prospective IU could predict changes in anxiety symptoms following the transdiagnostic treatment [17]. This finding is not consonant with the current study. One potential explanation for the discrepancy between the two studies is that Talkovsky and Norton used the Anxiety Disorder Diagnostic Questionnaire (ADDQ) to measure anxiety symptoms while we used BAI. ADDQ measures the degree of fear and avoidance and it is sensitive to different types of anxiety symptoms. Given that the inhibitory IU is more closely linked to severe fears and avoidance [12] the connection between inhibitory IU and ADDQ seems logical. Moreover, they used a different transdiagnostic protocol which may affect the results. Talkovsky and Norton performed the treatment in a group format in 12 sessions, while the treatment in the current study was presented in 20 individual sessions.

Prospective IU is an active response to uncertainty and it represents the tendency of predicting probable conditions and consequences [12]. The research demonstrated that this component

is associated with non-phobic anxiety disorders (such as obsessive-compulsive disorder, generalized anxiety disorder) [11]. In an ambiguous situation, anxious individuals actively try to collect information as much as possible to make the future situation more predictable. They generally use some maladaptive cognitive or behavioral strategies (e.g., worry, obsession or compulsion) to reduce uncertainty which in turn serves to increase anxiety symptoms. In fact, maladaptive situation modification leads to an increase in negative emotion, decrease the chance of habituation, and poor treatment response [23]. In this regard, the UP attempts to first identify patients' maladaptive emotion-driven behaviors (module 5), and then encourage them to counter maladaptive these behaviors and confront with vague situations (module 7). UP also increases individuals' present-focused, nonjudgmental awareness which can reduce their maladaptive emotion-driven behaviors (module 3). Moreover, UP challenges individuals' appraisals about the situation ahead as well as their own abilities and modify their control perceptions, using cognitive reappraisals (module 4).

Finally, results showed that the best predictor of changes in depression is inhibitory IU (43%). Previous studies support the relationship between depression and inhibitory IU [14, 24]. The inhibitory IU represents avoidance or somehow perseveration [17]. Individuals with depression more desire to avoid obscure situations. They often have a negative attitude toward themselves, others, and the world which shows their preference for pessimistic certainty, rather than confronting the upcoming ambiguous situation. Their low self-confidence also makes them procrastinate making decisions in ambiguous situations until sufficient information is obtained. This passive reaction contradictorily leads to experience more depression symptoms. Under such circumstances, UP addresses their maladaptive strategies by increasing the awareness of avoidance patterns (module 5) and doing more adaptive behaviors (module 7). In fact, during treatment, depressed individuals face their own negative emotions, like uncertainty-related distress, and form a more adaptive and active reaction to the emotions they experienced.

In conclusion, results indicated that UP could exert its effects on reducing anxiety and depression, through different pathways. Changes in prospective IU have been found to largely account for changes in anxiety symptoms, whereas inhibitory IU is more related to changes in depression symptoms.

The main limitation of the present study was the small sample size, which makes it difficult to generalize the findings. Further research is needed to examine this relationship in different diagnostic groups with larger sample size. Moreover, the larger portion of the sample constituted the women. Future study could consider gender as a moderator or mediator of the relationship between IU and anxiety and depression. Another limitation was that IU is only one of the potential change process. Further research is warranted to investigate the interactive role of other mediators in reducing the symptoms of emotional disorders during treatment with UP. Moreover, each of the IU components might be linked to depression and anxiety symptoms differently. In this regard, further mediation analysis is needed to distinguish potential parallel and sequential effects of various mediators in the relationship between IU component and anxiety and depression symptoms.

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Conflict of Interest Statement
The authors declare that there are no conflicts of interest.

Author contributions
O.S and S.K carried out and design the experiment. S.K wrote the manuscript with support from O.S. J.M.B analyzed the data. All authors discussed the results and approved the final version of the manuscript.

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