Original Article

Effectiveness of Unified Protocols for Transdiagnostic Treatment in Emotion Regulation of Mothers and Anxiety of Children with Type I Diabetes

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Abstract

Background: Type I diabetes (T1DT1D) is recognized as one of the most prevalent chronic diseases in children. It is accompanied by potentially life-threatening complications which affect the mood, personality, and emotions of children and their families.

Objectives: The present study aimed to assess the effectiveness of the unified protocols for transdiagnostic treatment program in emotion regulation of mothers and anxiety of children with T1D.

Methods: The present experimental study was conducted using the pretest-posttest follow-up control group design. The statistical population included all children with T1D within the age range of 9-11 years T1Dand their mothers who were referred to Iran Diabetes Association in Tehran in 2019-2020. The statistical sample was selected via the convenience (purposive) sampling method from among children with T1D and their mothers, and the subjects were randomly assigned to two experimental and control groups. The Cognitive Emotion Regulation Questionnaire (CERQ) developed by Garnefski et al. and Spence Children's Anxiety Scale (SCAS) were completed in the pretest, posttest, and follow-up. Diabetic children and their mothers received 15 sessions of the unified protocols for transdiagnostic treatment, while no special training was provided to the control group.

Results: The results of the present study indicated that the three measurements performed in pretest, posttest, and follow-up significantly differed regarding children's anxiety and mothers' emotion regulation strategies (e.g., catastrophizing, coping and acceptance, positive thinking, and blaming others) pointing to the effectiveness of transdiagnostic treatment (P= 0.000).

Conclusion: The obtained results suggested the effectiveness of the unified protocols for transdiagnostic treatment program in reducing the anxiety of children with type 1 diabetes and improving the emotion regulation of their mothers.

Keywords: Anxiety, Diabetes, Emotion regulation, Transdiagnostic treatment

1. Background

Type I diabetes (T1D) is one of the most common endocrine diseases in childhood and adolescence and a major health problem in children across the globe (1). This chronic disease requires lifestyle changes to maintain and control blood glucose and avoid hypoglycemia. Moreover, it exerts a major impact on the psychological and psychosocial functioning of this age group and the resources of health systems (2). In 2015, the estimates from the International Diabetes Federation showed that approximately 86,000 children under the age of 15 are annually infected with this disease worldwide. Currently, in Iran, the rate of T1D patients has been reported to be between 5% and 10% to which one percent is added annually (3). The diagnosis of diabetes in children presents daunting challenges to parents (4) affecting both the child and the psychological burden of the disease perceived by the parents (5,6). Some symptoms, such as shock and grief, post-traumatic stress disorder, and increased levels of anxiety and depression, are common among parents of children diagnosed with T1D (7). In a systematic review study, Jones et al. (8) reported the prevalence of maternal psychological distress, followed by emotional dysregulation, to be

between 20%-30%. Numerous articles have indicated that emotional problems of mothers exert a negative impact on children's metabolic control (9-13). A previous study stated that daily insulin injections or fingertip blood sample collection to control blood glucose have different psychological effects on children and provoke anxiety, fear, and distress in children and families (14-17). One of the newest therapies for the treatment of psychological distress is trans-diagnostic treatment (18,19) which reduces the symptoms of anxiety and depression in children's parents. Several studies confirmed the effectiveness of this treatment for patients with a range of mood disorders and heterogeneous emotional anxiety disorders in the post-treatment and follow-up stages (20-25). The modification of threatening factors and emotion regulation by the provision of appropriate information and training can lead to the empowerment of mothers and their more effective involvement in taking care of their diabetic children. In general, emotion regulation can influence the physical and mental performance of children and their mothers in experiencing emotions (15). Nevertheless, just a few studies have investigated the correlations between T1D and emotion regulation, and little is known about the impact of Usual

Psychosocial Care (UPC) on mothers' emotion regulation and anxiety in children with T1D.

2. Objectives

The current study aimed to evaluate the effectiveness of the unified protocols for transdiagnostic treatment program in emotion regulation of mothers and reduced anxiety of children with T1D.

3. Methods

3.1. Study design, participants, as well as sample size and allocation

This experimental study was carried out on 16 children with diabetic type 1 (within the age range of 9-11 years old) and their mothers who were referred to Tehran Diabetes and Treatment Centers from 21 February-19 April 2020 (Tehran, Iran). The required sample size was estimated at 8 patients in each group based on the t-test formula (n1=n2) with an effect size of 2 and a dropout rate of 10% (α=5%, β=10%).

Therefore, 16 diabetic patients were selected via convenience sampling and randomly assigned to two groups (n=8) using block randomization methods.

3.2. Inclusion and exclusion criteria

The inclusion criteria were as follows: 1) the age range of 9-11 years, 2) diagnosis of T1D, 3) insulin injection at least once and at most three times a day, 4) being diabetic at least for 6 months after the diagnosis of diabetes, 5) non-use of psychiatric drugs at least for 1 month, 6) literacy, 7) lack of other diseases, 8) the ability to participate in regular training sessions, and 9) informed consent to participate in the research project. On the other hand, the exclusion criteria entailed: 1) absence for more than two sessions, 2) missing information in medical records, and 3) noncooperation of parents and children (Figure 1).

3.3. Intervention

The patients were randomly assigned to two groups of experiment and control. The experimental group received 15 unified transdiagnostic treatment
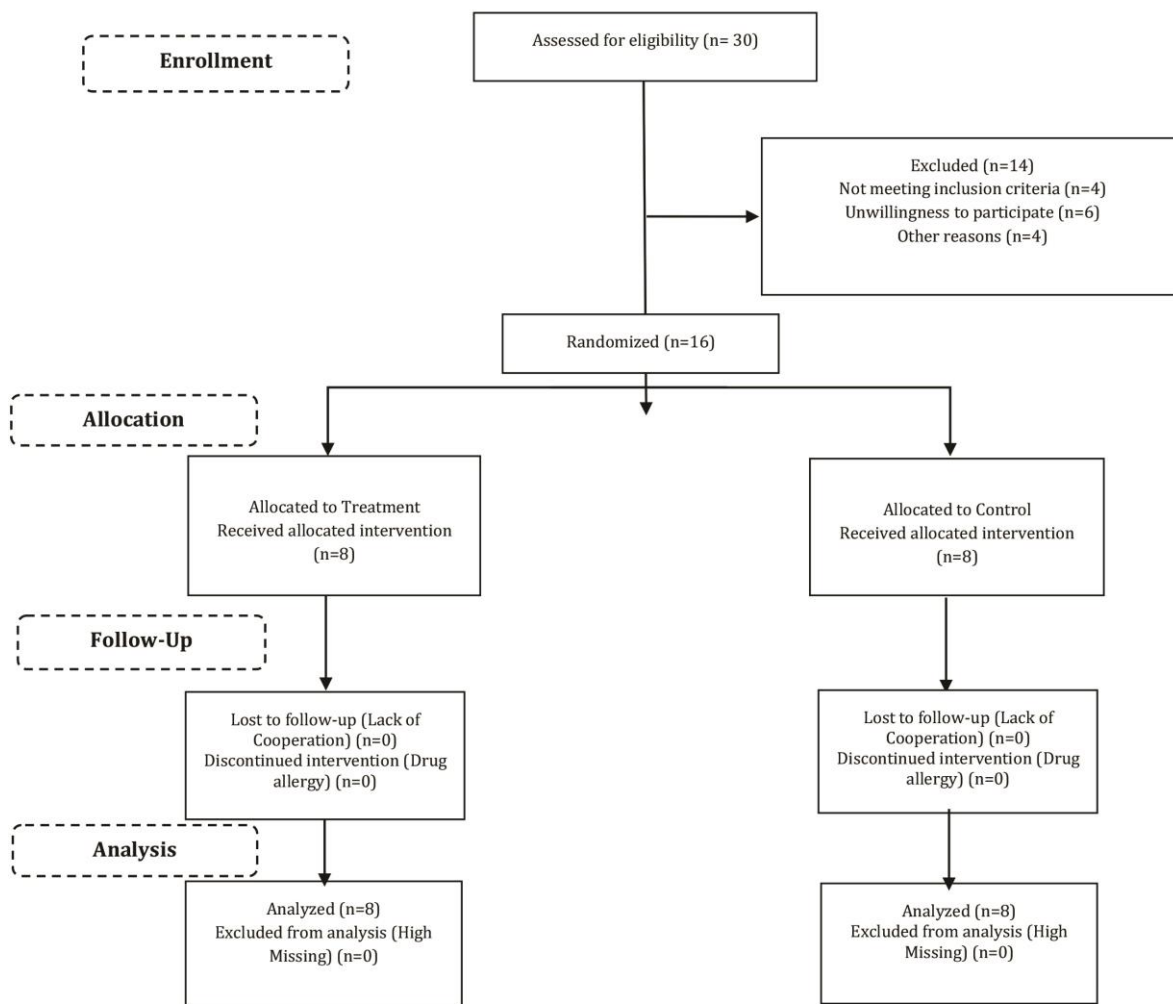

Figure 1. Study Follow up diagram

sessions therapy in the form of 60-minute weekly sessions, while the control group received no treatment. After the end of the treatments, the two groups were post-tested. Finally, after a 3-month follow-up, both treatment and control groups were again asked to answer the relevant questionnaire.

The Transdiagnostic treatment protocol is a guide for therapists and clients to analyze the treatment process consisting of five therapeutic components which are designed to address the central aspects of emotion processing and regulation of emotional experiences. These five main therapeutic components are: 1) providing psychological training about emotions and raising awareness about them, 2)

increasing cognitive flexibility, 3) identifying and preventing emotion avoidance models and emotion-induced maladaptive behaviors, 4) tolerating the physical sensations associated with the emotion and 5) situation-based and internal emotion-focused exposure. These components follow an introductory section focused on increasing motivation and readiness for change and involvement in the treatment process (20). This protocol was implemented for children in 15 60-minute sessions in parallel and simultaneously for parents in 16 60-minute sessions (18):

A summary of therapy protocols is provided in Table1.

Table 1. Content of the training sessions for children and parents

Session	Content of children's training sessions	Content of mothers' training sessions
First session	Introducing the structure of treatment to children, identifying the most important problems, establishing understanding and unity between group members and the therapist, increasing their emotional awareness	Introducing the five structures and skills to mothers, introducing the three-part model of emotions to parents, discussing the avoidance cycle and other emotional behaviors
Second session	Teaching the identification and grading of different emotions, normalizing emotional experiences, introducing the three components of emotional experience, helping children understand the avoidance cycle	Becoming familiar with the four emotional parenting behaviors and their opposite parenting behaviors, discussing the provision of positive reinforcement as a parenting behavior with criticism
Third session	Learning the concept of opposite action, using scientific experiments for emotional behaviors and opposite behavior, learning to track emotions and activities	Becoming familiar with scientific experiments for the behavior opposite to emotional behaviors, having a discussion with mothers about how to support children in scientific education focused on grief and sadness, providing mothers with 10 ways to strengthen the child
Fourth session	Describing the concept of body clues and their relationship with intense emotions, learning how to identify body clues related to different emotions, teaching the body scan skill to understand body clues	Teaching the concept of somatization, training how to perform a body scan, familiarizing parents with sensory exposure and practicing sensory exposure in the session, teaching how to empathize with children
Fifth session	Introducing the concept of flexible thinking, teaching how to identify mental traps	Becoming familiar with the concept of cognitive flexibility and four common cognitive traps, discussing emotional parenting behavior with a focus on instability and its opposite parenting behavior, strengthening stable discipline
Sixth session	Introducing the concept of emotions detective in a non-emotional way using a coding game, using the detective thinking skill	Introducing the concept of cognitive detective, practicing detective thinking, familiarizing mothers with maximum emotional parenting behavior/ maximum support and opposite parenting behavior, giving healthy independence
Seventh session	Introducing problem-solving using a non-emotional example or problem-solving game, practicing problem-solving using more personal and more specific scenarios	Introducing problem-solving steps, discussing the application of problem-solving for interpersonal conflicts, examining mothers' efforts for giving healthy independence
Eighth session	Learning the skill of "experiencing my emotions", teaching to the children by contact with the present moment playing the game of "using my five senses", introducing the idea of non-judgmental awareness	Discussing the importance of learning to experience emotions, becoming familiar with the concept of contact with the present moment , and non-judgmental awareness
Ninth session	Reviewing the emotion detective skill, reviewing the concepts of emotional behaviors and opposite action to prepare people for a new type of scientific experiment called exposure, performing exposure using a doll or other objects	Becoming familiar with the concept of situational emotion exposures as another type of scientific experiment, explaining the role of mothers in performing the exposure at home, becoming familiar with emotional parenting behavior and extreme modeling of intense emotions and avoiding its opposite parenting behavior, healthy emotional modeling
Tenth session	Reviewing the concept of using scientific experiments to deal with intense emotions, introducing the idea of safety behaviors and subtle avoidance behaviors (such as distraction), practicing a scientific experiment to deal with intense emotions	Reviewing the concept of exposure to emotion and discussing the application of exposure for different symptoms
Eleventh to fourteenth sessions	Planning and implementing situational exposure to emotion, planning and implementing exposure activities	Planning and implementing situational exposure to emotion, planning and implementing exposure activities
Fifteenth session	Reviewing the emotions detective skills learned in the UPC program, planning to deal with intense emotions in the future, appreciating the progress	Reviewing the emotions detective skills and opposite parenting behaviors, discussing and appreciating each child's progress, planning to maintain and enhance post-treatment progress, distinguishing between regression and relapse , and helping parents identify the warning signs of relapse

3.4. Research Tools

The Cognitive Emotion Regulation Questionnaire developed by Garnefski et al. and Spence Children's Anxiety Scale were employed in the current study.

The Cognitive Emotion Regulation Questionnaire (CERQ) was developed by Garnefski, Kraaij, and Spinhoven (26). This multidimensional questionnaire is a self-report tool consisting of 36 items rated on a five-point Likert scale ranging from always to never. The Persian version of this questionnaire was validated by Samani and Jokar (27). In this questionnaire, the respondents are asked to determine their reactions in the face of recently experienced threatening experiences and stressful life events by answering five questions that evaluate a strategy for emotion regulation. The main version of this questionnaire includes 9 subscales and 36 items. In this questionnaire, self-blame, blaming others, rumination, and catastrophizing indicate negative emotion regulation strategies, while acceptance, refocus on planning, positive refocusing, positive reappraisal, and putting into perspective signify positive emotion regulation strategies. The items in this questionnaire are rated on a five-point Likert scale (always, often, usually, sometimes, never). As reported by the designers of this questionnaire, the reliability of this questionnaire was confirmed rendering Cronbach's alpha coefficients of 0.91, 0.87, and 0.93 for positive strategies, negative strategies, and the whole questionnaire, respectively. In the current study, a 26-item questionnaire with four subscales was applied and Cronbach's alpha coefficients were obtained at 0.82, 0.79, 0.80, 0.74, 0.80, for self-blame and catastrophizing, coping and acceptance, positive thinking, blaming others, and the whole questionnaire, respectively.

Spence Children's Anxiety Scale (SCAS) developed by Spence et al. comprises 45 questions (28) and aims to measure and evaluate the anxiety of children aged 8-15 years based on the classification of the Diagnostic and Statistical Manual of Mental Disorders. This questionnaire which was translated into Persian by Mousavi, Moradi, Farzad, Mahdavi, and Spence(29) is available in two versions for children and parents, and both versions consist of six scales (separation anxiety, social anxiety, obsessive-compulsive disorder, market panic, generalized anxiety, and fear of bodily harm). The items are rated on a five-point scale (very low, low, partly, high, and very high). This questionnaire has high validity, its internal consistency coefficient (alpha coefficient) was calculated at 0.92, its reliability was obtained at 0.75 using the test-retest method (one-week interval), and the correlation of its items was reported as 0.30-0.76. Five types of content validity, concurrent validity, construct validity, diagnostic validity, and factor validity were assessed for this test, all of which confirmed the high efficiency of this tool in measuring the severity of anxiety.

3.5. Ethical considerations

All the participants in this research program were aware of the used methodology after a comprehensive explanation. The written informed consent was obtained from all participants after presenting enough explanations about the study objectives. The research procedure was in accordance with the Human Ethics Committee of the Tehran University of Medical Sciences (IR.UT.PSYEDU.REC.1399.024).

3.6. Statistical analysis

The data were analyzed in SPSS software (version 24) using descriptive statistical methods (frequency, percentage, mean, and standard deviation), Levene's test, Kolmogorov-Smirnov test, t-test. Moreover, the repeated-measures analysis of variance (ANOVA) was used to calculate within and between-group variability. The significance level in the present study was equal to 0.05.

4. Results

In terms of demographic variables, the mean age scores of the subjects were reported as 10.8±3.98 and 10.10±3.87 in the control and experimental groups, respectively. The baseline variables between the two groups are presented in Table 2. The result demonstrated that the two groups were the same according to the baseline variable.

Table 3 displays the descriptive information about anxiety and emotion regulation components in three stages of pretest, posttest, and follow-up in the experimental and control groups.

Repeated-measures ANOVA was used to evaluate the effect of the integrated transdiagnostic treatment program on anxiety and emotion regulation. The assumptions of repeated measures analysis of variance, including normality, were examined by the Kolmogorov-Smirnov test. The results of this test

Table 2. Baseline variables between the two groups

| Variables	Group				P-value
	Treatment		Control		
	Mean	Standard Deviation	Mean	Standard Deviation	
Anxiety	3.80	0.56	3.74	0.53	0.759
Catastrophizing	3.73	0.58	3.66	0.52	0.732
Acceptance	3.15	0.68	3.13	0.68	0.941
Positive thinking	3.14	0.68	3.11	0.67	0.902
Blaming others	3.70	0.57	3.67	0.52	0.878

Table 3. Mean and standard deviation of responses pre, post, and follow up variables in treatment and control groups

Variables	Time	Group				P-value
		Treatment		Control		
		Mean	Standard Deviation	Mean	Standard Deviation	
Anxiety	Pre	3.80	0.56	3.74	0.53	0.759
	Post	3.18	0.55	3.70	0.54	0.010
	Follow (3 Month Later)	3.09	0.51	3.79	0.56	0.001
	P-value	0.001		0.223		0.04
Catastrophizing	Pre	3.73	0.58	3.66	0.52	0.732
	Post	3.08	0.55	3.60	0.54	0.009
	Follow (3 Month Later)	2.99	0.58	3.71	0.55	0.001
	P-value	<0.001		0.197		0.041
Acceptance	Pre	3.15	0.68	3.13	0.68	0.941
	Post	3.82	0.55	3.14	0.67	0.003
	Follow (3 Month Later)	3.82	0.56	3.10	0.67	0.002
	P-value	0.001		0.368		0.037
Positive thinking	Pre	3.14	0.68	3.11	0.67	0.902
	Post	3.82	0.53	3.12	0.67	0.002
	Follow (3 Month Later)	3.82	0.55	3.10	0.66	0.002
	P-value	0.002		0.968		0.032
Blame others	Pre	3.70	0.57	3.67	0.52	0.878
	Post	3.07	0.56	3.60	0.53	0.007
	Follow (3 Month Later)	3.01	0.56	3.71	0.56	0.001
	P-value	0.001		0.093		0.033

demonstrated that the scores of anxiety and emotion regulation components were higher than 0.05 (P>0.05) in the experimental and control groups, pointing to the normality of data. Homogeneity of variances was also assessed using Levene's test. The results obtained from Levene's test for the variable of anxiety and emotion regulation components indicated the homogeneity of variances (P>0.05). Moreover, the results of Box's M test were not significant: Box's M=22.65 for the variable of anxiety and Box's M=13.79 for the component of catastrophizing, Box's M= 25.90 for coping and acceptance, Box's M= 19.71 for positive thinking, and Box's M=17.67 for blaming others (P>0.05). Therefore, the assumption of the equality of covariance matrices was confirmed. The sphericity assumption was assessed based on Mauchly's test and was confirmed in all variables. The results of this research disclosed that the variables of anxiety, catastrophizing, coping and acceptance, positive thinking, and blaming others were consistent at the commencement of the study in the two groups. Nonetheless, at the end of the study and follow-up, the changes were significant only in the intervention group, and the control group did not show any significant changes. This in turn indicated the significant effect of the intervention group, compared to the control group (Figure 2).

5. Discussion

The findings of the present study pointed to a significant increase in mothers' emotion regulation and a significant decrease in anxiety among children with T1D. This finding is in agreement with the results of previous studies (19-25,30,31). In fact, mothers' anxiety and stress are passed on to their children since they are considered the most important person in children's support system (22).
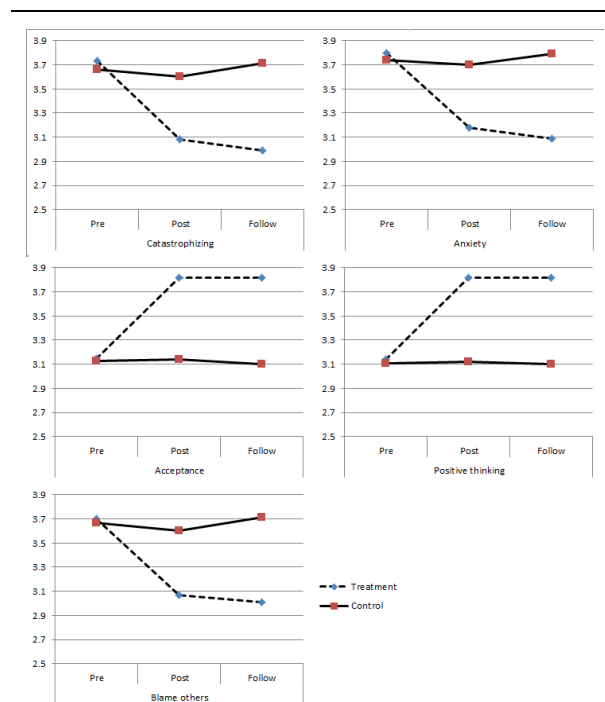
Figure 2. Study Follow up diagram

UPC provides people with positive cognitive emotion regulation strategies and helps them to deal with their problems by reducing negative emotions and improving cognitive and emotional functioning (19). Therefore, UPC can be regarded as an important factor in improving emotion regulation and reducing the psychological problems of mothers of children with T1D.

Moreover, it seems that the application of UPC in the context of stress and illness can help people to use efficient strategies by reducing negative emotions and enhancing positive emotions (20).

Furthermore, it can be stated that UPC, with targeted control of the stressor, decreases or eliminates the pressure arising therefrom. Obviously, the preferred treatment for diabetes is a multifaceted treatment, one of the main aspects of which is working on the ability to cope with stress and reduce anxiety, depression, and other psychiatric disorders, which in turn, affect the performance of individuals in other aspects of treatment (23). UPC emphasizes the adaptive and functional nature of emotions and primarily seeks to identify and modify maladaptive efforts to regulate experiences, thereby facilitating proportionate processing and silencing disproportionate emotional responses to internal and external cues (30). Given that people with T1D struggle with a negative and stressful experience in their lives, the adoption of these strategies can exert positive effects on the reduction of anxiety (13). New theories in the field of emotion place emphasis on the positive and adaptive role of emotion. The related studies have shown that individuals' ability for cognitive emotion regulation can play a crucial role in their adjustment to stressful life events (22). There is a clear connection between experience of negative events, emotion regulation strategies, and problems such as anxiety. Chronic anxiety in diabetic children puts them at the risk of isolation from peer groups and rejection (31). UPC provides individuals with positive cognitive emotion regulation strategies and helps them to deal with their problems by reducing negative emotions and improving cognitive and emotional functioning (24). Therefore, the integrated transdiagnostic treatment program can be regarded as an important factor in reducing the psychological problems of children with T1D. It also seems that the application of UPC in the context of stress and illness can facilitate the use of efficient strategies by decreasing negative emotions and enhancing positive emotions (23).

The notable limitations of the present study include the small sample size, non-participation of fathers in the UPC intervention program, and the restriction of participants to the patients of the Diabetes Association. It is recommended that in future studies, larger samples be considered for the generalization and effectiveness of the UPC program, along with the participation of both parents.

6. Conclusion

The obtained results indicated the effectiveness of unified protocols for transdiagnostic treatment program in the enhancement of mothers' emotion regulation and the reduction of anxiety among children with T1D.

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