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Original Article

The Effects of Cognitive Behavioral Therapy on Depression and Anxiety among Patients with Thalassemia: a Randomized Controlled Trial

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ABSTRACT

Introduction: Thalassemia is a chronic hereditary anemia which can be associated with different psychological, emotional, and behavioral problems such as depression and anxiety. This study aimed to evaluate the effects of cognitive behavioral therapy on depression and anxiety of patients with thalassemia.

Methods: This was a randomized controlled trial study. A total of 76 patients were randomly allocated to an experimental (n=38) and a control group (n=38). Patients in the experimental group were provided with cognitive behavioral therapy while their counterparts in the control group received routine care services. Depression and anxiety assessments were performed four weeks before the intervention as well as four and six weeks after that. Between-group and within-group comparisons were performed through the independent-sample t-tests and the paired sample t-test, respectively.

Results: The post-test mean score of anxiety in the experimental group was significantly lower than that for the control group, while there was no significant difference between the groups regarding the post-test mean score of depression. The mean score of depression in both study groups decreased significantly. The rate of decrease in the experimental group was significantly greater than that in the control group.

Conclusion: Cognitive behavioral therapy can be used to prevent or alleviate depression and anxiety among patients.

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Introduction

Thalassemia is a chronic hereditary anemia.[1] Each year, 330000 neonates are born with thalassemia worldwide.[2] In other words, its prevalence is two cases per 1000 births.[3] Thalassemia is particularly prevalent in the Mediterranean region, the Middle East, tropical areas, and Africa.[4-6] Iran, a Middle East country, is located on the Thalassemia belt. The prevalence of thalassemia in different regions of Iran ranges from 2.5% to 15 %.[1]

Thalassemia can cause different psychological, emotional, and behavioral problems on patients and their families. Its effects are stronger particularly during school age and adolescence, i.e. when people are seeking greater autonomy. Therefore, it can greatly affect the sense of autonomy and mental health.[3] Moreover, thalassemia treatments negatively affect general appearance (through causing bone deformities and short stature) and thereby, alter body image, bring about psychological problems, and reduce quality of life.[3,7] These problems can destroy a patients' interpersonal relationships, undermine self-confidence and self-esteem, and lead to depression and despair.[8]

Changes in self-esteem are associated with changes in the levels of depression, fear, and anxiety.[9] These psychological problems can significantly affect treatment adherence, self-management, and other patient outcomes.[10-12] On the other hand, improvements in the survival of thalassemia patients due to advances in thalassemia treatment in recent decades have resulted in patients' longer exposure to thalassemia-related problems and greater likelihood of developing psychological problems such as depression and anxiety.[13] Therefore, thalassemia patients need to be provided with adequate psychological therapies.

One of the psychological therapies is cognitive behavioral therapy (CBT). CBT is a deliberate attempt for maintaining the positive effects of behavioral therapies in a less doctrinaire context and coordinating patients' cognitive activities and emotional experiences with treatment courses.[14] It is supposed to improve emotions and functioning.[15] The aim of CBT is to identify and test maladaptive and dysfunctional imaginations and assumptions. CBT includes strategies such as supervision of negative thoughts, self-recognition, understanding cognition-emotion-behavior connections, assessment of the reasons behind thought distortion, realistic interpretation, and awareness and identification of dysfunctional beliefs.[16]

Previous studies showed the positive effects of CBT on patients with chronic conditions. For instance, a meta-manage depression and obsessive-compulsive disorder analysis by Hofmann et al., indicated that CBT helps. [17] Also two other studies reported the positive effects of CBT on coping abilities among patients with thalassemia.[18,19]

Studies in Iran also showed that CBT interventions alleviate helplessness and improve self-esteem among adolescents with thalassemia,[4] promote subjective well-being among patients with cardiovascular diseases,[20] and improve emotional state among patients with multiple sclerosis.[21] Moreover, different studies reported the effectiveness of CBT on alleviating anxiety and depression in different patient populations.[22]

Despite the wealth of studies in the area of CBT, the effects of this therapy on thalassemia-related psychological problems, particularly depression and anxiety, have not been extensively explored yet.

Moreover, to the best of our knowledge, no studies have yet assessed the effects of CBT on depression and anxiety among Iranian thalassemia patients. However, there have been a limited number of studies conducted to examine the effect of cognitive-behavioral therapy on the reduction of anxiety and depression in thalassemia patients. In addition, the majority of published research on thalassemia is predominantly for children and adolescents, and few studies have focused on the effect of cognitive behavioral therapy on the reduction of anxiety and depression in adult thalassemia patients. Therefore, the present study was designed and conducted in Iran to evaluate the effects of CBT on depression and anxiety among patients with thalassemia.

Materials and methods

This non-blind two-group pretest-posttest randomized clinical trial was conducted from October 2012 to June 2013. All participants were informed about the aim of the study, and assured about the confidentiality of the data, and then they signed a written informed consent prior to their enrollment. Participation in and withdrawal from the study were voluntary. In terms of ethical standards, after completing the study and the results obtained for the control group, a similar training course was also conducted. The protocol of this study was approved by the ethics committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran (AJUMS.REC.1392.180).

The population comprised thalassemia patients who referred to thalassemia care ward of Valiasr hospital, Khorramshahr, Iran, to receive outpatient medical and nursing services. An invitation announcement was posted in the unit to invite thalassemia patients to the study.

The eligibility criteria included a score of 11–40 for the Beck Depression Inventory or a score of greater than 22 for the Beck Anxiety Inventory, a definite diagnosis of depression or anxiety disorder made by a psychiatrist(The psychiatrist visited the patients and, if he detected depression or anxiety, they entered the study), no previous knowledge of CBT, no history of medical or psychological therapies for depression or anxiety, having at least primary education, and not being afflicted by serious illnesses (such as cancer, hepatic cirrhosis, AIDS, diabetes mellitus, epilepsy, and so on). Patients with three or more absences from the intervention sessions and those who developed serious physical or psychological problems during the study were excluded.

A pilot study was not used to determine the sample size. Sample size was calculated based on Hossein Komeili's[23] study with obtained $\mu_- \mu$=5 and S_1=S_2=7.27 in their work an estimation of the standard deviation of depression, a confidence level of 95%, a power of 80. Therefore, the sample size calculation formula showed that at least 34 patients were needed for each study group.

Yet, we recruited 38 patients for each group (76 in totals) in order to prevent probable withdrawals from affecting the study results.

Initially, 91 patients were recruited and asked to complete the Beck Anxiety and Depression Inventories twice with a two-week interval. The means of these two measurements were calculated and then, 76 patients with a mean depression score of 11–40 or a mean anxiety score of greater than 22 were included. Sampling was done conveniently. For randomization, we initially created a numbered list of patients' names and then, patients with odd and even numbers were respectively allocated to a control and an experimental group.

Three questionnaires were used for data collection. The first was a twelve-item demographic questionnaire, the content validity of which was approved by ten nursing faculty members. The second was the self-administered Beck Anxiety Inventory. This inventory was developed in 1990 by Beck et al., and specifically assesses the severity of anxiety symptoms. Each of the 21 items of the inventory deals with one of the symptoms of anxiety which are usually experienced by anxious people or those who are exposed to anxiety-inducing situations. The items are scored on a 4-point Likert scale from 0 to 3; thus, the total anxiety score would be 0–63. This inventory mainly focuses on the physiological aspects of anxiety and contains three main domains, namely anxious mood (3 items), panic disorder (3 items), and symptoms of autonomic hyperactivity and somatic tensions (15 items). The inventory was reported to discriminate between healthy and anxious people. Kaviani and Mousavi reported the Persian version of BAI to possess a good reliability (r=0.72), a very good validity (r=0.83), and an excellent internal consistency (Alpha=0.92).[24]

The third data collection questionnaire was the self-administered 21-item Beck Depression Inventory. The Beck Depression Inventory (BDI) is a 21-item, self-rated scale that evaluates key symptoms of depression, including mood, pessimism, sense of failure, self-dissatisfaction, guilt, punishment, self-dislike, self-accusation, suicidal ideas, crying, irritability, social withdrawal, indecisiveness, body image change, work difficulty, insomnia, fatigability, loss of appetite, weight

loss, somatic preoccupation, and loss of libido.[25] Items are scored in the same way as the Anxiety Inventory, resulting in a total score of 0–63. Scores 0–10, 11–20, 21–30, 31–40, and greater than 40 respectively indicate minimal, mild, moderate, and severe depression. The Cronbach's alpha of the Persian version of the inventory was reported to be 0.84.[26] The split-half correlation coefficient of the inventory was 0.70. All participants in both groups of the present study were asked to complete the Beck Depression and Anxiety Inventories four weeks before the intervention as well as four and six weeks after that. The mean of both post-test measurements was calculated and considered as the post-test score.

The intervention for the patients in the experimental group was an eight-session CBT educational program. Each patient held two 90 minute CBT sessions per week for four successive weeks, eight sessions in total. Initially, patients in the experimental group were divided into four small subgroups based on their ages and genders. The subgroups were as follows: eleven women who aged 15–22; eleven men who aged 15–22; ten women aged more than twenty; and six men aged more than twenty.

The aim of such grouping was to provide all patients in the subgroups with the opportunity to actively participate in group discussions and thereby, improve the quality and effectiveness of educations. In the first educational session, we familiarized the patients with the study, the intervention, cognitive therapy, and behavioral therapy, motivated them for regular attendance at the sessions, answered their questions, and provided them with an educational booklet about the study intervention.

The contents of the first session were about depression, anxiety, their symptoms, their prevention and treatments, cognitive therapy, behavioral therapy, and CBT. Other sessions were on the downward arrow, the cost-benefitanalysis, and relaxation techniques. In the downward arrow technique, we asked the participants to document their daily feelings and identify problematic feelings, thoughts, values, and beliefs which caused them anxiety and depression. This practice motivated them for change. Then, the following three steps were used for change. In the first step, the cost-benefit technique was used by the negative thoughts and feelings and their participants to analyze and rate the costs and the benefits of their irrational values and beliefs. In the second step, the participants initially used a 0–100 scale to predict their enjoyment and satisfaction with a given activity. Thereafter, they performed the activity and re-rated their real joyfulness and satisfaction. Then, they evaluated the differences between their predicted and real joyfulness and satisfaction. In the third step, they employed the forced fantasy technique to cope with their beliefs. Accordingly, they imagined the worst state or the most worrisome situation and then, attempted to rationally respond to it. This practice helped them gain greater self-confidence. Patients in the control group did not receive CBT.

The data were analyzed using the Statistical Package for the Social Sciences SPSS ver. 13. (SPSS Inc., Chicago, IL USA). Between-group comparisons with respect to nominal, ordinal, and numerical variables were performed through the Chi-square, the Mann-Whitney U, and the independent-sample t-tests, respectively. Moreover, within-group comparisons were done via the paired-sample t-test. Pvalues less than 0.05 were considered significant.

Result

In total, 76 thalassemia patients participated in this study. The total population of the research (number of patients referring to the thalassemia unit) was 98 patients, of which 7 were not included in the study due to their age being below 11 years and 15 patient did not enter the study due to their unwillingness for participation. 76 patients entered the study and were randomly divided into two groups: intervention and control. Three patients from the intervention group were excluded due to their absences from the sessions. Thus, 35 patients in the experimental and 38 in the control group completed the study (Figure 1).

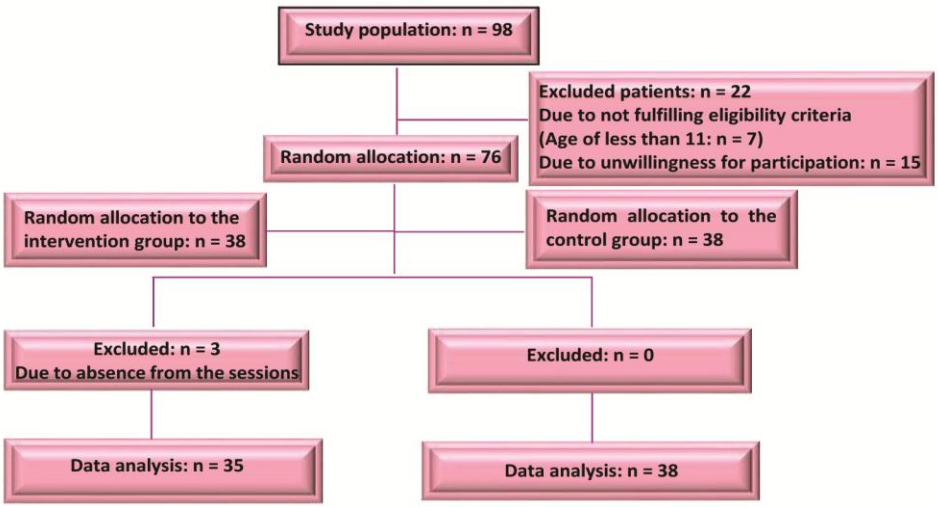

Figure 1. The flow chart of the study

The majority of the participants were female 54.8% and 39.7% of them had secondary high school diplomas or higher degrees. On average, they were aged 23.38 (9.00). Between-group comparisons, using the independent-sample t-test and the Chi-square tests revealed no significant differences regarding the participants' demographic characteristics (P< 0.05; Table 1).

Table 1. Participants' demographic characteristics

Variable	Experimental N (%)	Control N (%)	Total N (%)	P
Gender				0. 93*
Female	19 (54.3)	21 (55.3)	40 (54.8)	
Male	16 (45.7)	17 (44.7)	33 (45.2)	
Educational status				0.23*
Illiterate	0 (0.0)	1 (2.6)	1 (1.4)	
Primary	4 (11.4)	5 (13.2)	9 (12.3)	
Guidance school	6 (17.1)	10 (26.3)	16 (21.9)	
High school	10 (28.6)	8 (21.1)	18 (24.7)	
Diploma	14 (40.0	9 (23.7)	23 (31.5)	
Higher	1 (2.9)	5 (13.1)	6 (8.2)	
Age£	23.4 (6.58)	23.36 (11.43)	23.3 (9.00)	0.98^
Physical or psychological crisis in the past six months				0.36*
Yes	23 (65.7)	21 (55.3)	44 (60.3)	
No	12 (34.3)	17 (44.7)	29 (39.7)	
Type of residence				0.62*
Private	24 (68.6)	24 (63.2)	48 (65.8)	
Rented	11 (31.4)	14 (36.8)	25 (34.2)	
Living with parents				0.11*
Father	3 (8.6)	5 (13.2)	8 (11.00)	
Mother	10 (28.6)	3 (7.9)	13 (17.8)	
Both	18 (51.4)	22 (57.9)	40 (54.8)	
None	4 (11.4)	8 (21.1)	12 (16.4)	

£ Mean (SD), *The results of the Chi-square test, ^The results of the independent-sample t-test

The independent-sample t-test revealed that before the intervention, there was no significant difference between the groups with respect to the mean score of anxiety (P= 0.812), while after the intervention, the mean score of anxiety in the experimental group was significantly lower than that for the control group (P= 0.019; Table 2). Moreover, the results of the paired-sample t-test illustrated that the mean score of anxiety in experimental group decreased significantly after the intervention (P = 0.001), while it remained unchanged in the control group (P= 0.61; Table 2).

Table 2. Between- and within-group comparisons respecting depression and anxiety mean scores

Variables	N	Mean (SD)	P*
Anxiety			
Before			
Experimental	35	20.94(8.51)	0.81
Control	38	21.31(4.34)	
After			
Experimental	35	18.22(5.29)	0.01
Control	38	20.86(4.08)	
Depression			
Before			
Experimental	35	23.74(9.08)	0.20
Control	38	21.31(6.97)	
After			
Experimental	35	18.97(6.03)	0.29
Control	38	20.55(6.73)	

*The independent-sample t-test

The results of the independent-sample t-test also indicated no significant between-group differences regarding the mean score of depression at both pretest and posttest (P >0.05). However, the paired-sample t-test showed that the mean score of depression decreased significantly in both groups (P<0.05; Table 2). The independent-sample t-test revealed that the amount of decrease in the mean score of depression in the experimental group was significantly greater than that of the control group (P= 0.001; Table 3).

Table 3. Mean differences of depression in both groups in post-test and pre-test

Group	N	Mean difference (SD)	P*
Experimental	35	-4.77 (3.67)	0.001
Control	38	-0.76 (2.14)	

*The independent-sample t-test

Discussion

This study aimed to evaluate the effects of CBT on depression and anxiety among patients with thalassemia. The findings indicated the effectiveness of CBT in alleviating of anxiety and depression. CBT educational sessions help individuals learn necessary social skills, provide them with the opportunity to get familiar with others' problems, and thereby, gives them greater hope for life and higher levels of adaptation. It also shifts individuals' focus from superficial towards more valuable aspects of self and enables them to substitute negative thoughts about their illnesses and problems with more positive ones. Therefore, it

alleviates their anxiety and boosts their self-confidence and self-worth.

CBT holds that extreme thinking and data analysis distortion usually exacerbates depression and anxiety. Moreover, it states that people selectively pay attention to those data that are congruent with their own beliefs. The downward arrow technique challenges and changes irrational beliefs and thinking and thereby alleviates anxiety. Moreover, behavioral techniques, such as relaxation, help alleviate anxiety. In line with our findings, Kiani et al., reported that CBT significantly improves self-esteem and reduces helplessness among thalassemia patients.[4] Moreover, Aghaei et al., reported the effectiveness of CBT in alleviating anxiety among patients with coronary heart disease.[27] Daniels also reported the positive effects of CBT on the outcomes of chronic conditions such as thalassemia.[28] Conversely, Yaeghoobi-Nasrabadi et al., found that CBT had no significant effect on anxiety among patients with mood disorders.[29] The findings also showed that although mean score of depression significantly decreased in both groups, the amount of the decrease was significantly greater in the experimental group (4.77 vs. 0.76). These findings confirm the effectiveness of CBT in alleviating depression among thalassemia patients.

Previous studies also reported the positive effects of CBT on depression among different patient populations.[25,26,29-32] However, Bayazi et al., reported that CBT had no significant effect on depression among patients with chronic coronary heart disease.[33] Despite the more significant decrease in the mean score of depression in the experimental group, between-group differences at post-test were not statistically significant. An explanation for such insignificant between-group differences may be the relatively short course of the study.

Regarding the limitations of this study, we could refer to the differences among participants with respect to their reactions to depression, anxiety, and treatments. Moreover, states such as fatigue, anxiety, and sleeplessness might have affected the participants' responses to study questionnaires.

Investigating the effects of CBT on other patient outcomes (such as quality of life, adherence to treatment, anger, coping and adjustment) in future studies is recommended. The results should be interpreted with caution due to the small number of participants and at one- center administration. So we recommend this study be replicated with a larger sample size in multi-center.

Conclusion

This study indicates that CBT is effective in significantly alleviating anxiety and depression among patients with thalassemia. Therefore, CBT is recommended for alleviating psychological problems among patients with thalassemia. Together with firm social support, CBT can be an effective and comprehensive strategy for the rehabilitation of patients with chronic illnesses who suffer from psychological disorders. Educating nurses about anxiety and depression, their risk factors, their negative effects, and CBT techniques can enable them to use CBT techniques in their daily practice to alleviate their clients' anxiety and depression. Educational booklets and pamphlets can also be provided to different groups of healthcare professionals, particularly managers, counselors, psychologists, psychiatrists, nurses, and students in order to improve their CBT-related knowledge and practice.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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